H.R.1

Medicare Prescription Drug, Improvement, and Modernization Act of 2003
(Enrolled as Agreed to or Passed by Both House and Senate)

SEC. 303. PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE-
(1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE VALUE UNITS- Section 1848(c)(2) (42 U.S.C. 1395w-4(c)(2)) is amended--
(A) in subparagraph (B)--
(i) in clause (ii)(II), by striking `The adjustments' and inserting `Subject to clause (iv), the adjustments'; and
(ii) by adding at the end of subparagraph (B), the following new clause:
`(iv) EXEMPTION FROM BUDGET NEUTRALITY- The additional expenditures attributable to--
`(I) subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004;
`(II) subparagraph (I) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year for a specialty described in subparagraph (I)(ii)(II); and
`(III) subparagraph (J) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year.'; and
(B) by adding at the end the following new subparagraphs:
`(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING IN 2004-
`(i) USE OF SURVEY DATA- In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 if the survey--

`(I) covers practice expenses for oncology drug administration services; and

`(II) meets criteria established by the Secretary for acceptance of such surveys.

`(ii) PRICING OF CLINICAL ONCOLOGY NURSES IN PRACTICE EXPENSE METHODOLOGY- If the survey described in clause (i) includes data on wages, salaries, and compensation of clinical oncology nurses, the Secretary shall utilize such data in the methodology for determining practice expense relative value units under subsection (c).

`(iii) WORK RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES- In establishing the relative value units under this paragraph for drug administration services described in clause (iv) furnished on or after January 1, 2004, the Secretary shall establish work relative value units equal to the work relative value units for a level 1 office medical visit for an established patient.

`(iv) DRUG ADMINISTRATION SERVICES DESCRIBED- The drug administration services described in this clause are physicians' services--

`(I) which are classified as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy); chemotherapy administration services; and therapeutic, prophylactic, or diagnostic injections;

`(II) for which there are no work relative value units assigned under this subsection as of such date; and

`(III) for which national relative value units have been assigned under this subsection as of such date.

`(I) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING WITH 2005-

`(i) IN GENERAL- In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2005 or 2006, the Secretary shall adjust the practice expense relative value units for such year consistent with clause (ii).

`(ii) USE OF SUPPLEMENTAL SURVEY DATA-

`(I) IN GENERAL- Subject to subclause (II), if a specialty submits to the Secretary by not later than March 1, 2004, for 2005, or March 1, 2005, for 2006, data that includes expenses for the administration of drugs and biologicals for which the payment amount is determined pursuant to

section 1842(o), the Secretary shall use such supplemental survey data in carrying out this subparagraph for the years involved insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

`(II) LIMITATION ON SPECIALTY- Subclause (I) shall apply to a specialty only insofar as not less than 40 percent of payments for the specialty under this title in 2002 are attributable to the administration of drugs and biologicals, as determined by the Secretary.

`(III) APPLICATION- This clause shall not apply with respect to a survey to which subparagraph (H)(i) applies.

`(J) PROVISIONS FOR APPROPRIATE REPORTING AND BILLING FOR PHYSICIANS' SERVICES ASSOCIATED WITH THE ADMINISTRATION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS-

`(i) EVALUATION OF CODES- The Secretary shall promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption.

`(ii) USE OF EXISTING PROCESSES- In carrying out clause (i), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

`(iii) IMPLEMENTATION- In carrying out clause (i), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1847A or section 1847B, and shall take such steps within the Secretary's authority to expedite such considerations under clause (ii).

`(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED- Nothing in subparagraph (H) or (I) or this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively.'.

(2) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL- The Secretary shall make adjustments

to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the Federal Register on December 31, 2002 (67 Fed. Reg. 251)), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of services not determined under such methodology, as a result of the amendments made by paragraph (1).

(3) PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECHNIQUE-

(A) REVIEW OF POLICY- The Secretary shall review the policy, as in effect on October 1, 2003, with respect to payment under section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for the administration of more than 1 drug or biological to an individual on a single day through the push technique.

(B) MODIFICATION OF POLICY- After conducting the review under subparagraph (A), the Secretary shall modify such payment policy as the Secretary determines to be appropriate.

(C) EXEMPTION FROM BUDGET NEUTRALITY UNDER PHYSICIAN FEE SCHEDULE- If the Secretary modifies such payment policy pursuant to subparagraph (B), any increased expenditures under title XVIII of the Social Security Act resulting from such modification shall be treated as additional expenditures attributable to subparagraph (H) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)), as added by paragraph (1)(B), for purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).

(4) TRANSITIONAL ADJUSTMENT-

(A) IN GENERAL- In order to provide for a transition during 2004 and 2005 to the payment system established under the amendments made by this section, in the case of physicians' services consisting of drug administration services described in subparagraph (H)(iv) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)), as added by paragraph (1)(B), furnished on or after January 1, 2004, and before January 1, 2006, in addition to the amount determined under the fee schedule under section 1848(b) of such Act (42 U.S.C. 1395w-4(b)) there also shall be paid to the physician from the Federal Supplementary Medical Insurance Trust Fund an amount equal to the applicable percentage specified in subparagraph (B) of such fee schedule amount for the services so determined.

(B) APPLICABLE PERCENTAGE- The applicable percentage specified in this subparagraph for services furnished--

(i) during 2004, is 32 percent; and
(ii) during 2005, is 3 percent.

(5) MEDPAC REVIEW AND REPORTS; SECRETARIAL RESPONSE-

(A) REVIEW- The Medicare Payment Advisory Commission shall review the payment changes made under this section insofar as they affect payment under part B of title XVIII of the Social Security Act--

(i) for items and services furnished by oncologists; and
(ii) for drug administration services furnished by other specialists.

(B) OTHER MATTERS STUDIED- In conducting the review under subparagraph (A), the Commission shall also review such changes as they affect--

(i) the quality of care furnished to individuals enrolled under part B and the satisfaction of such individuals with that care;
(ii) the adequacy of reimbursement as applied in, and the availability in, different geographic areas and to different physician practice sizes; and
(iii) the impact on physician practices.

(C) REPORTS- The Commission shall submit to the Secretary and Congress--

(i) not later than January 1, 2006, a report on the review conducted under subparagraph (A)(i); and
(ii) not later than January 1, 2007, a report on the review conducted under subparagraph (A)(ii).

Each such report may include such recommendations regarding further adjustments in such payments as the Commission deems appropriate.

(D) SECRETARIAL RESPONSE- As part of the rulemaking with respect to payment for physicians services under section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for 2007, the Secretary may make appropriate adjustments to payment for items and services described in subparagraph (A)(i), taking into account the report submitted under such subparagraph (C)(i).

(b) APPLICATION OF MARKET-BASED PAYMENT SYSTEMS- Section 1842(o) (42 U.S.C. 1395u(o)) is amended--

(1) in paragraph (1), by striking `equal to 95 percent of the average wholesale price.' and inserting `equal to the following:

`(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

`(i) A drug or biological furnished before January 1, 2004.
`(ii) Blood clotting factors furnished during 2004.
`(iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.

`(iv) A vaccine described in subparagraph (A) or (B) of section 1861(s)(10) furnished on or after January 1, 2004.

`(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

`(B) In the case of a drug or biological furnished during 2004 that is not described in--

`(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

`(ii) subparagraph (D)(i), or

`(iii) subparagraph (F),

the amount determined under paragraph (4).

`(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005, the amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13), as the case may be for the drug or biological.

`(D)(i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

`(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1847 on or after January 1, 2007, the amount provided under section 1847.

`(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished--

`(i) in 2004, the amount of payment provided under paragraph (4); and

`(ii) in 2005 and subsequent years, the amount of payment provided under section 1847A.

`(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

`(G) The provisions of subparagraphs (A) through (F) of this paragraph shall not apply to an inhalation drug or biological furnished through durable medical equipment covered under section 1861(n).'; and

(2) by adding at the end the following new paragraph:

`(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

`(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled `Average of GAO and OIG data (percent)' in the table entitled `Table 3- Medicare Part B Drugs in the Most Recent GAO and OIG Studies' published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

`(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.
`(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.
`(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.'.
(c) APPLICATION OF AVERAGE SALES PRICE METHODS BEGINNING IN 2005-

(1) IN GENERAL- Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w-3), as amended by section 302(b), the following new section:

`USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

`SEC. 1847A. (a) APPLICATION-

`(1) IN GENERAL- Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1842(o)(1)(C) and that are furnished on or after January 1, 2005.

`(2) ELECTION- This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B for that section to apply instead of this section for the payment for drugs and biologicals.

`(b) PAYMENT AMOUNT-

`(1) IN GENERAL- Subject to subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance--

`(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3); or

`(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4).

`(2) SPECIFICATION OF UNIT-

`(A) SPECIFICATION BY MANUFACTURER- The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1927(b)(3)(A)(iii).

`(B) UNIT DEFINED- In this section, the term `unit' means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or

grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

`(3) MULTIPLE SOURCE DRUG- For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) determined by--

`(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of--

`(i) the manufacturer's average sales price (as defined in subsection (c)); and

`(ii) the total number of units specified under paragraph (2) sold; and

`(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

`(4) SINGLE SOURCE DRUG OR BIOLOGICAL- The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

`(A) AVERAGE SALES PRICE- The average sales price as determined using the methodology applied under paragraph (3) for all National Drug Codes assigned to such drug or biological product.

`(B) WHOLESALE ACQUISITION COST (WAC)- The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for all National Drug Codes assigned to such drug or biological product.

`(5) BASIS FOR PAYMENT AMOUNT- The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

`(c) MANUFACTURER'S AVERAGE SALES PRICE-

`(1) IN GENERAL- For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's `average sales price' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit--

`(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

`(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

`(2) CERTAIN SALES EXEMPTED FROM COMPUTATION- In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

`(A) SALES EXEMPT FROM BEST PRICE- Sales exempt from the inclusion in the determination of `best price' under section 1927(c)(1)(C)(i).

`(B) SALES AT NOMINAL CHARGE- Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1927(c)(1)(C)(ii)(III), except as the Secretary may otherwise provide).

`(3) SALE PRICE NET OF DISCOUNTS- In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

`(4) PAYMENT METHODOLOGY IN CASES WHERE AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS UNAVAILABLE- In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on--

`(A) the wholesale acquisition cost; or

`(B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

`(5) FREQUENCY OF DETERMINATIONS-

`(A) IN GENERAL ON A QUARTERLY BASIS- The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

`(B) UPDATES IN PAYMENT AMOUNTS- The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

`(C) USE OF CONTRACTORS; IMPLEMENTATION- The Secretary may contract with appropriate entities to calculate the

payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

`(6) DEFINITIONS AND OTHER RULES- In this section:

`(A) MANUFACTURER- The term `manufacturer' means, with respect to a drug or biological, the manufacturer (as defined in section 1927(k)(5)).

`(B) WHOLESALE ACQUISITION COST- The term `wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

`(C) MULTIPLE SOURCE DRUG-

`(i) IN GENERAL- The term `multiple source drug' means, for a calendar quarter, a drug for which there are 2 or more drug products which--

`(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of `Approved Drug Products with Therapeutic Equivalence Evaluations'),

`(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

`(III) are sold or marketed in the United States during the quarter.

`(ii) EXCEPTION- With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

`(D) SINGLE SOURCE DRUG OR BIOLOGICAL- The term `single source drug or biological' means--

`(i) a biological; or

`(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

`(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT- Subparagraph (C)(ii) shall not apply if the Food and Drug

Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

`(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE- For purposes of this paragraph--

`(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

`(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

`(G) INCLUSION OF VACCINES- In applying provisions of section 1927 under this section, `other than a vaccine' is deemed deleted from section 1927(k)(2)(B).

`(d) MONITORING OF MARKET PRICES-

`(1) IN GENERAL- The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

`(2) COMPARISON OF PRICES- Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with--

`(A) the widely available market price for such drugs and biologicals (if any); and

`(B) the average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.

`(3) LIMITATION ON AVERAGE SALES PRICE-

`(A) IN GENERAL- The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

`(B) APPLICABLE THRESHOLD PERCENTAGE DEFINED- In this paragraph, the term `applicable threshold percentage' means--

`(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

`(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the

Secretary may specify for the widely available market price or the average manufacturer price, or both.

`(C) AUTHORITY TO ADJUST AVERAGE SALES PRICE- If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of--

`(i) the widely available market price for the drug or biological (if any); or

`(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.

`(4) CIVIL MONEY PENALTY-

`(A) IN GENERAL- If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

`(B) PROCEDURES- The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (B) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

`(5) WIDELY AVAILABLE MARKET PRICE-

`(A) IN GENERAL- In this subsection, the term `widely available market price' means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

`(B) CONSIDERATIONS- In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

`(i) Manufacturers.

`(ii) Wholesalers.

`(iii) Distributors.

`(iv) Physician supply houses.

`(v) Specialty pharmacies.

`(vi) Group purchasing arrangements.

`(vii) Surveys of physicians.

`(viii) Surveys of suppliers.

`(ix) Information on such market prices from insurers.
`(x) Information on such market prices from private health plans.

`(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY- In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

`(f) QUARTERLY REPORT ON AVERAGE SALES PRICE- For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1927(b)(3).

`(g) JUDICIAL REVIEW- There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of--

`(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;
`(2) the identification of units (and package size) under subsection (b)(2);
`(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;
`(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and
`(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).'.

(2) REPORT ON SALES TO PHARMACY BENEFIT MANAGERS-

(A) STUDY- The Secretary shall conduct a study on sales of drugs and biologicals to large volume purchasers, such as pharmacy benefit managers and health maintenance organizations, for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent physicians.

(B) REPORT- Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations on whether such sales to large volume purchasers should be excluded from the computation of a manufacturer's average sales price under section 1847A of the Social Security Act, as added by paragraph (1).

(3) INSPECTOR GENERAL REPORT ON ADEQUACY OF REIMBURSEMENT RATE UNDER AVERAGE SALES PRICE METHODOLOGY-

(A) STUDY- The Inspector General of the Department of Health and Human Services shall conduct a study on the ability of physician practices in the specialties of hematology, hematology/oncology, and medical oncology of different sizes, especially particularly large practices, to obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the average sales price for the drugs and biologicals. In conducting the study, the Inspector General shall conduct an audit of a representative sample of such practices to determine the adequacy of reimbursement under section 1847A of the Social Security Act, as added by paragraph (1).

(B) REPORT- Not later October 1, 2005, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A), and shall include recommendations on the adequacy of reimbursement for such drugs and biologicals under such section 1847A.

(d) PAYMENT BASED ON COMPETITION-

(1) IN GENERAL- Title XVIII is amended by inserting after section 1847A, as added by subsection (c), the following new section:

`COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS

`SEC. 1847B. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION-

`(1) IMPLEMENTATION OF PROGRAM-

`(A) IN GENERAL- The Secretary shall establish and implement a competitive acquisition program under which--

`(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

`(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1847A; and

`(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

This section shall not apply in the case of a physician who elects section 1847A to apply.

`(B) IMPLEMENTATION- For purposes of implementing the program, the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the

program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

`(C) WAIVER OF CERTAIN PROVISIONS- In order to promote competition, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

`(D) EXCLUSION AUTHORITY- The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals--

`(i) is not likely to result in significant savings; or

`(ii) is likely to have an adverse impact on access to such drugs or biologicals.

`(2) COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS AND PROGRAM DEFINED- For purposes of this section--

`(A) COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS DEFINED- The term `competitively biddable drugs and biologicals' means a drug or biological described in section 1842(o)(1)(C) and furnished on or after January 1, 2006.

`(B) PROGRAM- The term `program' means the competitive acquisition program under this section.

`(C) COMPETITIVE ACQUISITION AREA; AREA- The terms `competitive acquisition area' and `area' mean an appropriate geographic region established by the Secretary under the program.

`(D) CONTRACTOR- The term `contractor' means an entity that has entered into a contract with the Secretary under this section.

`(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY-

`(A) IN GENERAL- With respect to competitively biddable drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has elected this section to apply--

`(i) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

`(ii) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved; and

`(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals--

`(I) shall be made only to such contractor; and

`(II) shall be conditioned upon the administration of such drugs and biologicals.

`(B) PROCESS FOR ADJUSTMENTS- The Secretary shall provide a process for adjustments to payments in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

`(C) INFORMATION FOR PURPOSES OF COST-SHARING- The Secretary shall provide a process by which physicians submit information to contractors for purposes of the collection of any applicable deductible or coinsurance amounts under subparagraph (A)(ii).

`(4) CONTRACT REQUIRED- Payment may not be made under this part for competitively biddable drugs and biologicals prescribed by a physician who has elected this section to apply within a category and a competitive acquisition area with respect to which the program applies unless--

`(A) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

`(B) the physician has elected such contractor under paragraph (5) for such category and area.

`(5) CONTRACTOR SELECTION PROCESS-

`(A) ANNUAL SELECTION-

`(i) IN GENERAL- The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of competitively biddable drugs and biologicals for an area by selecting physicians.

`(ii) TIMING OF SELECTION- The selection of a contractor under clause (i) shall be made at the time of the election described in section 1847A(a) for this section to apply and shall be coordinated with agreements entered into under section 1842(h).

`(B) INFORMATION ON CONTRACTORS- The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

`(C) SELECTING PHYSICIAN DEFINED- For purposes of this section, the term `selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area.

`(b) PROGRAM REQUIREMENTS-

`(1) CONTRACT FOR COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS- The Secretary shall conduct a competition among

entities for the acquisition of competitively biddable drugs and biologicals. Notwithstanding any other provision of this title, in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.

`(2) CONDITIONS FOR AWARDING CONTRACT-

`(A) IN GENERAL- The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of competitively biddable drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

`(i) CAPACITY TO SUPPLY COMPETITIVELY BIDDABLE DRUG OR BIOLOGICAL WITHIN CATEGORY-

`(I) IN GENERAL- The entity has sufficient arrangements to acquire and to deliver competitively biddable drugs and biologicals within such category in the area specified in the contract.

`(II) SHIPMENT METHODOLOGY- The entity has arrangements in effect for the shipment at least 5 days each week of competitively biddable drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

`(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS- The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including--

`(I) the establishment of procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

`(II) a grievance and appeals process for the resolution of disputes.

`(B) ADDITIONAL CONSIDERATIONS- The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon--

`(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

`(ii) the exclusion of the entity under section 1128 from participation under this title.

`(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN- For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1868(b), as added by section 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

`(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA- The Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

`(A) The bid prices for competitively biddable drugs and biologicals within the category and area.

`(B) Bid price for distribution of such drugs and biologicals.

`(C) Ability to ensure product integrity.

`(D) Customer service.

`(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

`(F) Such other factors as the Secretary may specify.

`(4) TERMS OF CONTRACTS-

`(A) IN GENERAL- A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

`(B) PERIOD OF CONTRACTS- A contract under this section shall be for a term of 3 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

`(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM- A contractor (as defined in subsection (a)(2)(D)) shall--

`(i) acquire all drug and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

`(ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.

Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs or biologicals.

`(D) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES- Under the contract--

`(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

`(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

`(E) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS- Under the contract the contractor shall only supply competitively biddable drugs and biologicals directly to the selecting physicians and not directly to individuals, except under circumstances and settings where an individual currently receives a drug or biological in the individual's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not--

`(i) require a physician to submit a prescription for each individual treatment; or

`(ii) change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.

`(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS- The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

`(A) The drugs or biologicals are required immediately.

`(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

`(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

`(D) The drugs or biologicals were administered in an emergency situation.

`(6) CONSTRUCTION- Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

`(c) BIDDING PROCESS-

`(1) IN GENERAL- In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the bid price and the other factors referred to in subsection (b)(3).

`(2) BID DEFINED- In this section, the term `bid' means an offer to furnish a competitively biddable drug or biological for a particular price and time period.

`(3) BIDDING ON A NATIONAL OR REGIONAL BASIS- Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

`(4) UNIFORMITY OF BIDS WITHIN AREA- The amount of the bid submitted under a contract offer for any competitively biddable drug or biological for an area shall be the same for that drug or biological for all portions of that area.

`(5) CONFIDENTIALITY OF BIDS- The provisions of subparagraph (D) of section 1927(b)(3) shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference--

`(A) in that subparagraph to a `manufacturer or wholesaler' is deemed a reference to a `bidder' under this section;

`(B) in that section to `prices charged for drugs' is deemed a reference to a `bid' submitted under this section; and

`(C) in clause (i) of that section to `this section', is deemed a reference to `part B of title XVIII'.

`(6) INCLUSION OF COSTS- The bid price submitted in a contract offer for a competitively biddable drug or biological shall--

`(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

`(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

`(7) PRICE ADJUSTMENTS DURING CONTRACT PERIOD; DISCLOSURE OF COSTS- Each contract awarded shall provide for--

`(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

`(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

`(d) COMPUTATION OF PAYMENT AMOUNTS-

`(1) IN GENERAL- Payment under this section for competitively biddable drugs or biologicals shall be based on bids submitted and accepted under this section for such drugs or biologicals in an area. Based on such bids the Secretary shall determine a single payment amount for each competitively biddable drug or biological in the area.

`(2) SPECIAL RULES- The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1847A to the use of a price for specific competitively biddable drugs and biologicals in the following cases:

`(A) NEW DRUGS AND BIOLOGICALS- A competitively biddable drug or biological for which a payment and billing code has not been established.

`(B) OTHER CASES- Such other exceptional cases as the Secretary may specify in regulations.

`(e) COST-SHARING-

`(1) APPLICATION OF COINSURANCE- Payment under this section for competitively biddable drugs and biologicals shall be in an amount equal to 80 percent of the payment basis described in subsection (d)(1).

`(2) DEDUCTIBLE- Before applying paragraph (1), the individual shall be required to meet the deductible described in section 1833(b).

`(3) COLLECTION- Such coinsurance and deductible shall be collected by the contractor that supplies the drug or biological involved. Subject to subsection (a)(3)(B), such coinsurance and deductible may be collected in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part.

`(f) SPECIAL PAYMENT RULES-

`(1) USE IN EXCLUSION CASES- If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for payment to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847A.

`(2) APPLICATION OF REQUIREMENT FOR ASSIGNMENT- For provision requiring assignment of claims for competitively biddable drugs and biologicals, see section 1842(o)(3).

`(3) PROTECTION FOR BENEFICIARY IN CASE OF MEDICAL NECESSITY DENIAL- For protection of individuals against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

`(g) JUDICIAL REVIEW- There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of--

`(1) the establishment of payment amounts under subsection (d)(1);

`(2) the awarding of contracts under this section;

`(3) the establishment of competitive acquisition areas under subsection (a)(2)(C);

`(4) the phased-in implementation under subsection (a)(1)(B);

`(5) the selection of categories of competitively biddable drugs and biologicals for competitive acquisition under such subsection or the selection of a drug in the case of multiple source drugs; or

`(6) the bidding structure and number of contractors selected under this section.'.

(2) REPORT- Not later than July 1, 2008, the Secretary shall submit to Congress a report on the program conducted under section 1847B of the Social Security Act, as added by paragraph (1). Such report shall include information on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors

available to physicians, the satisfaction of physicians and of individuals enrolled under this part, and information comparing prices for drugs and biologicals under such section and section 1847A of such Act, as added by subsection (c).

(e) ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINISTRATION OF DRUGS AND BIOLOGICALS-

(1) ITEMS AND SERVICES RELATING TO FURNISHING OF BLOOD CLOTTING FACTORS- Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (b)(2), is amended by adding at the end the following new paragraph:

`(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled `Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost', provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

`(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

`(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

`(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

`(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.'.

(2) PHARMACY SUPPLYING FEE FOR CERTAIN DRUGS AND BIOLOGICALS- Section 1842(o) (42 U.S.C. 1395u(o)), as previously amended, is amended by adding at the end the following new paragraph:

`(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1861(s)(2) and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).'.

(f) LINKAGE OF REVISED DRUG PAYMENTS AND INCREASES FOR DRUG ADMINISTRATION- The Secretary shall not implement the revisions in payment amounts for drugs and biologicals administered by physicians as a result of the amendments made by subsection (b) with respect to 2004 unless the Secretary concurrently makes adjustments to the practice expense payment adjustment under the amendments made by subsection (a).

(g) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW-

(1) DRUGS- Section 1842(o) (42 U.S.C. 1395u(o)), as previously amended, is amended by adding at the end the following new paragraph: `(7) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).'.

(2) PHYSICIAN FEE SCHEDULE- Section 1848(i)(1)(B) (42 U.S.C. 1395w-4(i)(1)(B)) is amended by striking `subsection (c)(2)(F)' and inserting `subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I)'.

(3) MULTIPLE CHEMOTHERAPY AGENTS, OTHER SERVICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL, AND TRANSITIONAL ADJUSTMENT- There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (2) through (4) of subsection (a).

(h) CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS- Nothing in the amendments made by this section shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.

(i) CONFORMING AMENDMENTS-

(1) APPLICATION OF ASP AND COMPETITIVE BIDDING- Section 1842(o)(2) (42 U.S.C. 1395u(o)(2)) is amended by adding at the end the following: `This paragraph shall not apply in the case of payment under paragraph (1)(C).'.

(2) NO CHANGE IN COVERAGE BASIS- Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting `(or would have been so included but for the application of section 1847B)' after `included in the physicians' bills'.

(3) PAYMENT- (A) Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting `(or, if applicable, under section 1847, 1847A, or 1847B)' after `1842(o)'.

(B) Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is amended--

(i) by striking `and' at the end of subparagraph (H);

(ii) by striking the semicolon at the end of subparagraph (I) and inserting `, and'; and

(iii) by adding at the end the following new subparagraph: `(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive

area under section 1847B, that is not furnished by an entity under a contract under such section;'.

(4) CONSOLIDATED REPORTING OF PRICING INFORMATION- Section 1927 (42 U.S.C. 1396r-8) is amended--

(A) in subsection (a)(1), by inserting `or under part B of title XVIII' after `section 1903(a)';

(B) in subsection (b)(3)(A)--

(i) in clause (i), by striking `and' at the end and inserting a semicolon;

(ii) in clause (ii), by striking the period and inserting `; and'; and

(iii) by adding at the end the following:

`(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)--

`(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

`(II) if required to make payment under section 1847A, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

`(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii).

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services.';

(C) in subsection (b)(3)(B)--

(i) in the heading, by inserting `AND MANUFACTURER'S AVERAGE SALES PRICE' after `PRICE'; and

(ii) by inserting `and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment' after `manufacturer prices'; and

(D) in subsection (b)(3)(D)--

(i) in the matter preceding clause (i), by inserting `(other than the wholesale acquisition cost for purposes of carrying out section 1847A)' after `subsection (a)(6)(A)(ii)'; and

(ii) in clause (i), by inserting `, to carry out section 1847A (including the determination and implementation of the payment amount), or to carry out section 1847B' after `this section'.

(5) IMPLEMENTATION- The provisions of chapter 8 of title 5, United States Code, shall not apply with respect to regulations implementing the amendments made by subsections (a), (b), and (e)(3), to regulations implementing section 304, and to regulations implementing the amendment made by section 305(a), insofar as such regulations apply in 2004.

(6) REPEAL OF STUDY- Section 4556 of the Balanced Budget Act of 1997 (42 U.S.C. 1395u note) is amended by striking subsection (c).

(j) APPLICATION TO CERTAIN PHYSICIAN SPECIALTIES- Insofar as the amendments made by this section apply to payments for drugs or biologicals and drug administration services furnished by physicians, such amendments shall only apply to physicians in the specialties of hematology, hematology/oncology, and medical oncology under title XVIII of the Social Security Act.