TITLE VI—MEDICAID AND SCHIP

Subtitle A—Medicaid

CHAPTER 1—PAYMENT FOR PRESCRIPTION DRUGS

SEC. 6001. FEDERAL UPPER PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS AND OTHER DRUG PAYMENT PROVISIONS.

(a) MODIFICATION OF FEDERAL UPPER PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS; DEFINITION OF MULTIPLE SOURCE DRUGS.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (e)(4)—

(A) by striking "The Secretary" and inserting "Subject to paragraph (5), the Secretary"; and

(B) by inserting "(or, effective January 1, 2007, two or more)" after "three or more";

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

"(5) USE OF AMP IN UPPER PAYMENT LIMITS.—Effective January 1, 2007, in applying the Federal upper reimbursement limit under paragraph (4) and section 447.332(b) of title 42 of the Code of Federal Regulations, the Secretary shall substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price.";

Effective date.

(3) in subsection (k)(7)(A)(i), in the matter preceding subclause (I), by striking "are 2 or more drug products" and inserting "at least 1 other drug product"; and

(4) in subclauses (I), (II), and (III) of subsection (k)(7)(A)(i), by striking "are" and inserting "is" each place it appears.

(b) DISCLOSURE OF PRICE INFORMATION TO STATES AND THE PUBLIC.—Subsection (b)(3) of such section is amended—

42 USC 1396r–8.

(1) in subparagraph (A)—

(A) in clause (i), by inserting "month of a" after "last day of each"; and

(B) by adding at the end the following: "Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).."; and

Effective date.

(2) in subparagraph (D)—

(A) by striking "and" at the end of clause (ii);

(B) by striking the period at the end of clause (iii) and inserting a comma; and

(C) by inserting after clause (iii) the following new clauses:

"(iv) to States to carry out this title, and

"(v) to the Secretary to disclose (through a website accessible to the public) average manufacturer prices.".

(c) DEFINITION OF AVERAGE MANUFACTURER PRICE.—

(1) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS EXTENDED TO WHOLESALERS.—Subsection (k)(1) of such section is amended—

(A) by striking "The term" and inserting the following:

"(A) IN GENERAL.—Subject to subparagraph (B), the term";

(B) by striking ", after deducting customary prompt pay discounts"; and

(C) by adding at the end the following:

"(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS EXTENDED TO WHOLESALERS.—The average manufacturer price for a covered outpatient drug shall be determined without regard to customary prompt pay discounts extended to wholesalers.".

(2) MANUFACTURER REPORTING OF PROMPT PAY DISCOUNTS.—Subsection (b)(3)(A)(i) of such section is amended by inserting ", customary prompt pay discounts extended to wholesalers," after "(k)(1))".

(3) REQUIREMENT TO PROMULGATE REGULATION.—

42 USC 1396r–8 note.

Deadline.

(A) INSPECTOR GENERAL RECOMMENDATIONS.—Not later than June 1, 2006, the Inspector General of the Department of Health and Human Services shall—

(i) review the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act, as amended by this section; and

(ii) shall submit to the Secretary of Health and Human Services and Congress such recommendations for changes in such requirements or manner as the Inspector General determines to be appropriate.

Regulations.

(B) DEADLINE FOR PROMULGATION.—Not later than July 1, 2007, the Secretary of Health and Human Services shall promulgate a regulation that clarifies the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act, taking into consideration the recommendations submitted to the Secretary in accordance with subparagraph (A)(ii).

(d) EXCLUSION OF SALES AT A NOMINAL PRICE FROM DETERMINATION OF BEST PRICE.—

42 USC 1396r–8.

(1) MANUFACTURER REPORTING OF SALES.—Subsection (b)(3)(A)(iii) of such section is amended by inserting before the period at the end the following: ", and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs".

(2) LIMITATION ON SALES AT A NOMINAL PRICE.—Subsection (c)(1) of such section is amended by adding at the end the following new subparagraph:

"(D) LIMITATION ON SALES AT A NOMINAL PRICE.—

"(i) IN GENERAL.—For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

"(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act.

"(II) An intermediate care facility for the mentally retarded.

"(III) A State-owned or operated nursing facility.

"(IV) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

"(ii) FACTORS.—The factors described in this clause with respect to a facility or entity are the following:

"(I) The type of facility or entity.

"(II) The services provided by the facility or entity.

"(III) The patient population served by the facility or entity.

"(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

"(iii) NONAPPLICATION.—Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code.".

(e) RETAIL SURVEY PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—Such section is further amended by inserting after subsection (e) the following new subsection:

"(f) SURVEY OF RETAIL PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—

"(1) SURVEY OF RETAIL PRICES.—

"(A) USE OF VENDOR.—The Secretary may contract services for—

"(i) the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

"(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

"(B) SECRETARY RESPONSE TO NOTIFICATION OF AVAILABILITY OF MULTIPLE SOURCE PRODUCTS.—If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4). Deadline.

"(C) USE OF COMPETITIVE BIDDING.—In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in— Contracts.

"(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

"(ii) working with retail pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

"(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(D) ADDITIONAL PROVISIONS.—A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

"(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

"(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

"(iii) The contract shall be effective for a term of 2 years.

"(E) AVAILABILITY OF INFORMATION TO STATES.—Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title of the retail survey price determined under this paragraph.

"(2) ANNUAL STATE REPORT.—Each State shall annually report to the Secretary information on—

"(A) the payment rates under the State plan under this title for covered outpatient drugs;

"(B) the dispensing fees paid under such plan for such drugs; and

"(C) utilization rates for noninnovator multiple source drugs under such plan.

"(3) ANNUAL STATE PERFORMANCE RANKINGS.—

"(A) COMPARATIVE ANALYSIS.—The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

"(B) AVAILABILITY OF INFORMATION.—The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

"(4) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.".

(f) MISCELLANEOUS AMENDMENTS.—

42 USC 1396r–8, 1395x.

(1) IN GENERAL.—Sections 1927(g)(1)(B)(i)(II) and 1861(t)(2)(B)(ii)(I) of such Act are each amended by inserting "(or its successor publications)" after "United States Pharmacopoeia-Drug Information".

(2) PAPERWORK REDUCTION.—The last sentence of section 1927(g)(2)(A)(ii) of such Act (42 U.S.C. 1396r–8(g)(2)(A)(ii)) is amended by inserting before the period at the end the following: ", or to require verification of the offer to provide consultation or a refusal of such offer".

42 USC 1396r–8 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of the enactment of this Act.

42 USC 1396r–8 note.

(g) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall take effect on January 1, 2007,

without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

SEC. 6002. COLLECTION AND SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.

(a) IN GENERAL.—Section 1927(a) of the Social Security Act (42 U.S.C. 1396r–8(a)) is amended by adding at the end the following new paragraph:

"(7) REQUIREMENT FOR SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.—

"(A) SINGLE SOURCE DRUGS.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title.

"(B) MULTIPLE SOURCE DRUGS.—

"(i) IDENTIFICATION OF MOST FREQUENTLY PHYSICIAN ADMINISTERED MULTIPLE SOURCE DRUGS.—Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this title. The Secretary may modify such list from year to year to reflect changes in such volume. Deadline. Publication.

"(ii) REQUIREMENT.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

"(C) USE OF NDC CODES.—Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used. Deadline.

"(D) HARDSHIP WAIVER.—The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.".

(b) LIMITATION ON PAYMENT.—Section 1903(i)(10) of such Act (42 U.S.C. 1396b(i)(10)), is amended—

(1) by striking "and" at the end of subparagraph (A);

(2) by striking "or" at the end of subparagraph (B) and inserting "and"; and

(3) by adding at the end the following new subparagraph:

"(C) with respect to covered outpatient drugs described in section 1927(a)(7), unless information respecting utilization data and coding on such drugs that is required to be submitted under such section is submitted in accordance with such section; or".

SEC. 6003. IMPROVED REGULATION OF DRUGS SOLD UNDER A NEW DRUG APPLICATION APPROVED UNDER SECTION 505(c) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) INCLUSION WITH OTHER REPORTED AVERAGE MANUFACTURER AND BEST PRICES.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)) is amended—

(1) by striking clause (i) and inserting the following:

Deadline.

"(i) not later than 30 days after the last day of each rebate period under the agreement—

"(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

"(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;"; and

(2) in clause (ii), by inserting "(including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act)" after "drugs".

(b) CONFORMING AMENDMENTS.—Section 1927 of such Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (c)(1)(C)—

(A) in clause (i), in the matter preceding subclause (I), by inserting after "or innovator multiple source drug of a manufacturer" the following: "(including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act)"; and

(B) in clause (ii)—

(i) in subclause (II), by striking "and" at the end;

(ii) in subclause (III), by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following:

"(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall

be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).''; and

(2) in subsection (k), as amended by section 6001(c)(1), by adding at the end the following:

''(C) INCLUSION OF SECTION 505(c) DRUGS.—In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.''.

(c) EFFECTIVE DATE.—The amendments made by this section take effect on January 1, 2007. 42 USC 1396r–8 note.