

**Tab 1-19**

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.

“(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.

“(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);

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(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:

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“(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;”;

(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