

“(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,

42 USC  
1395w-3a.