(10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements; and

(11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity.

(d) *Prices excluded from best price.* Best price excludes:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the FSS of the GSA;

(3) Any prices provided to a designated SPAP;

(4) Any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(5) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA–PD plan under Part C of such title with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare;

(6) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer-sponsored drug discount card program;

(8) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(9) Goods provided free of charge under a manufacturer's patient assistance programs;

(10) Free goods, not contingent upon any purchase requirement;

(11) Nominal prices to certain entities as set forth in § 447.508 of this subpart;

(12) Bona fide service fees; and

(13) PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level.

(e) *Further clarification of best price.* (1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount as described in § 447.508 of this subpart.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Authorized generic drug defined.* For the purposes of this subpart, an authorized generic drug means any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug.

(b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when

such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity described in section 340B(a)(4) of the PHSA;

(2) An ICF/MR providing services as set forth in § 440.150 of this chapter; or

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(b) *Nonapplication.* This restriction shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38, U.S.C. 8126.

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with section 1927(k)(1) of the Social Security Act.

(2) Best price, calculated in accordance with § 447.505 of this subpart;

(3) Customary prompt pay discounts, which shall be reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period; and

(4) Prices that fall within the nominal price exclusion, which shall be reported as an aggregate dollar amount and shall include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.

(2) A manufacturer must report revisions to AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.* (1) A manufacturer may report a revised base date AMP to CMS within the first four full calendar quarters following [OFR: insert publication date of the final rule].

(2) *Recalculation of base date AMP.* (i) A manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in section 1927(k)(1) of the Social Security Act.

(ii) A manufacturer may choose to recalculate base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating base date AMP.

(d) *Monthly AMP*—(1) *Definition of Monthly AMP.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP should be calculated based on section 1927(k)(1) of the Social Security Act, except the period covered should be based on monthly, as opposed to quarterly AMP sales.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due.

(4) *Exception.* A manufacturer must report revisions to monthly AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.