§ 447.504 Determination of AMP.

(a) *AMP* means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

(b) *Average unit price* means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

(c) *Customary prompt pay discount* means any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

(d) *Net sales* means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

(e) *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

(g) *Sales, rebates, discounts, or other price concessions included in AMP.* Except with respect to those sales identified in paragraph (h) of this section, AMP for covered outpatient drugs shall include the following sales and associated rebates, discounts, or other price concessions—

(1) Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section;

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

(3) Direct and indirect sales to hospitals, where the drug is used in the outpatient pharmacy, except those sales that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use (for example hospital outpatient department, clinic, or affiliated entity);

(4) Sales at nominal prices to any entity except a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR) providing services as set forth in § 440.150 of this chapter, or a State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter;

(5) Sales to retail pharmacies including discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs to the retail pharmacy class of trade;

(6) Sales including discounts, rebates, or other price concessions provided to pharmacy benefit managers (PBMs) for their mail order pharmacy purchases;

(7) Sales directly to patients;

(8) Sales to outpatient facilities (for example, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers);

(9) Sales to mail order pharmacies;

(10) Sales to home infusion providers;

(11) Sales to specialty pharmacies;

(12) Sales to home health care providers;

(13) Sales to physicians;

(14) Rebates, discounts, or other price

concessions (other than rebates under section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade; and
(15) Sales of drugs reimbursed by third party payers including the Medicare Part D Program, a Medicare Advantage prescription drug plan (MA–PD), a Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), health maintenance organizations (HMOs) (including managed care organizations (MCOs)) that do not purchase or take possession of drugs, TRICARE Retail Pharmacy Program (TRRx), and Medicaid Programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under section 1927 of the Act or as otherwise specified in the statute or regulations).
(h) *Sales, rebates, discounts, or other price concessions excluded from AMP.* AMP excludes—
(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (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 Federal Supply Schedule (FSS) of the General Services Administration (GSA);
(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;
(4) Direct and indirect sales to hospitals, where the drug is used in the inpatient setting or in the outpatient pharmacy for outpatient use where the sales cannot be identified with adequate documentation;
(5) Sales to HMOs (including MCOs, and HMO/MCO-operated pharmacies) that purchase or take possession of drugs;
(6) Sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities;
(7) Sales to hospices (inpatient and outpatient);
(8) Sales to veterinarians;
(9) Sales to prisons;
(10) Sales outside the 50 States and the District of Columbia;
(11) Sales to State, county, and municipal entities;
(12) Sales to patient assistance programs;
(13) Sales to wholesalers where the drug is distributed to the non-retail pharmacy class of trade;
(14) Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number;
(15) 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;
(16) Manufacturer vouchers;
(17) Manufacturer-sponsored drug discount card programs;
(18) Free goods, not contingent upon any purchase requirement;
(19) Bona fide service fees;
(20) Customary prompt pay discounts extended to wholesalers;
(21) Returned or replaced goods when accepted or replaced in good faith;
(22) Discounts, rebates, or other price concessions to PBMs, except for their mail order pharmacy's purchases.
(23) Associated rebates, discounts, or other price concessions to third party payers including the Medicare Part D Program, an MA–PD, Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, SCHIP, SPAPs, HMOs (including MCOs that do not take possession of drugs) the TRICARE Retail Pharmacy Program, and Medicaid Programs; and
(24) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.
(i) *Further clarification of AMP calculation.* (1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume

discounts, chargebacks, incentives, administrative fees, service fees, distribution fees, (except bona fide service fees), and any other rebates, discounts or other price concessions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.
(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in the quarter.
(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

§ 447.505 Determination of best price.
(a) *Best price* means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.
(b) For purposes of this section, *provider* means a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.
(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section, best price for covered outpatient drugs includes the following prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly—
(1) Prices to wholesalers;
(2) Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs;
(3) Prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies);
(4) Prices available to non-profit entities;
(5) Prices available to governmental entities within the United States;
(6) Prices of authorized generic drugs, sold by the primary manufacturer in accordance with § 447.506(d) of this subpart;
(7) Prices of sales directly to patients;
(8) Prices available to mail order pharmacies;
(9) Prices available to outpatient clinics;
(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 nonexcluded 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, non-profit 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 § 447.504 of this subpart;
(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 § 447.504 of this subpart.
(ii) A manufacturer may choose to recalculate base date AMP on a productby-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 the methodology in section 447.504 of this subpart, except the period covered should be based on monthly, as opposed to quarterly, sales. The monthly AMP should be calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units sold, excluding goods or any other items given away unless contingent on any purchase requirements. Monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission. In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.
(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.
(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.
(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:
(1) The manufacturer's chief executive officer (CEO);
(2) The manufacturer's chief financial officer (CFO);
(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or
(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).
(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.
(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:
(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.