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RURAL HEALTH CLINIC SERVICES  

§ 447.371  Services furnished by rural health clinics.  

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:  

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.  

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.  

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:  

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.  

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in § 405.2420 of this chapter.  

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.  

(d) For purposes of paragraph (c) (1) and (3) of this section, “visit” means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.  


Subparts G–H [Reserved]  

Subpart I—Payment for Drugs  

SOURCE: 72 FR 39239, July 17, 2007, unless otherwise noted.  

§ 447.500  Basis and purpose.  

(a) Basis. This subpart—  

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers’ calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.  

(2) Implements section 1903(l)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.  

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.  

(b) Purpose. This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.  

§ 447.502  Definitions.  

Bona fide service fees mean fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence
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of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

*Brand name drug* means a single source or innovator multiple source drug.

*Bundled sale* means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.

*Consumer Price Index—Urban (CPI–U)* means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

*Dispensing fee* means the fee which—

1. Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

2. Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

3. Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

*Estimated acquisition cost (EAC)* means the agency’s best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

*Innovator multiple source drug* means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA).

*Lagged price concession* means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

*Manufacturer* means any entity that possesses legal title to the NDC for a covered drug or biological product and—

1. Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

2. Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.
(3) With respect to authorized generic products, the term “manufacturer” will also include the original holder of the NDA.

(4) With respect to drugs subject to private labeling arrangements, the term “manufacturer” will also include the entity that does not possess legal title to the NDC.

National drug code (NDC) means the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in this part as being without respect to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means (1) a multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application, or (3) a drug that entered the market before 1962 that was not originally marketed under an original NDA.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application, PLA, ELA, or ADA.

States means the 50 States and the District of Columbia.

§ 447.504 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 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 impatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHS);

(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 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. (1) 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.
§ 447.518 State plan requirements, findings and assurances.

(a) State plan. The State plan must describe comprehensively the agency’s payment methodology for prescription drugs.

(b) Findings and assurances. Upon proposing significant State plan changes in payments for prescription drugs, and
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at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) **Findings.** The agency must make the following separate and distinct findings:

(i) **In the aggregate, its Medicaid expenditures for multiple source drugs are in accordance with the established upper limits.**

(ii) **In the aggregate, its Medicaid expenditures for all other drugs are in accordance with §447.512 of this subpart.**

(2) **Assurances.** The agency must make assurances satisfactory to CMS that the requirements set forth in §447.512 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) **Recordkeeping.** The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

[72 FR 39239, July 17, 2007, as amended at 75 FR 69597, Nov. 15, 2010]

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) **No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.**

(b) **As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.**

(c) **As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers in order to secure rebates.**

(b) **As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.**

(c) **A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.**

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