Medicaid Program: Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

(Final Rule – September 2024)

Note: *This document shows the final rule changes to 42 C.F.R. Parts 433.139; 438.3; 447.502; 504; 505; 509; 510; 518; and 520. Additions are in blue double-underlined text. Deletions are in red strike-through text.*

§ 433.139 Payment of claims.

(a) ***Basic provisions.***

(1) For claims involving third party liability that are processed on or after May 12, 1986, the agency must use the procedures specified in paragraphs (b) through (f) of this section.

(2) The agency must submit documentation of the methods (e.g., cost avoidance, pay and recover later) it uses for payment of claims involving third party liability to the CMS Regional Office.

(b) ***Probable liability is established at the time claim is filed.*** Except as provided in paragraph (e) of this section—

(1) If the agency has established the probable existence of third party liability at the time the claim is filed, the agency must reject the claim and return it to the provider for a determination of the amount of liability. The establishment of third party liability takes place when the agency receives confirmation from the provider or a third party resource indicating the extent of third party liability. When the amount of liability is determined, the agency must then pay the claim to the extent that payment allowed under the agency's payment schedule exceeds the amount of the third party's payment.

(2) [Reserved]

(3) The agency must pay the full amount allowed under the agency's payment schedule for the claim and seek reimbursement from any liable third party to the limit of legal liability (and for purposes of paragraph (b)(3)(ii) of this section, from a third party, if the third party liability is derived from an absent parent whose obligation to pay support is being enforced by the State title IV-D agency), consistent with paragraph (f) of this section if—

(i) The claim is for preventive pediatric services, including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B, of this chapter, that are covered under the State plan~~; or~~ that requires a State to make payments without regard to third party liability for pediatric preventive services except that the State may, if the State determines doing so is cost-effective and will not adversely affect access to care, only make such payment if a third party so liable has not made payment within 90 days after the date the provider of such services has initially submitted a claim to such third party for payment for such services; or

(ii) The claim is for service covered under the State plan that is provided to an individual on whose behalf child support enforcement is being carried out by the State title IV-D agency. The agency prior to making any payment under this section must assure that the following requirements are met:

(A) The State plan specifies whether or not providers are required to bill the third party.

(B) For child support enforcement services beginning February 9, 2018, the provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited up to 100 days ~~from~~after the date of the service and ~~has not received payment from the third party.~~provider of such services has initially submitted a claim to such third party for payment for such services, except that the State may make such payment within 30 days after such date if the State determines doing so is cost-effective and necessary to ensure access to care.

(C) The State plan specifies the method used in determining the provider's compliance with the billing requirements.

(c) ***Probable liability is not established or benefits are not available at the time claim is filed.*** If the probable existence of third party liability cannot be established or third party benefits are not available to pay the beneficiary's medical expenses at the time the claim is filed, the agency must pay the full amount allowed under the agency's payment schedule.

(d) ***Recovery of reimbursement.***

(1) If the agency has an approved waiver under paragraph (e) of this section to pay a claim in which the probable existence of third party liability has been established and then seek reimbursement, the agency must seek recovery of reimbursement from the third party to the limit of legal liability within 60 days after the end of the month in which payment is made unless the agency has a waiver of the 60-day requirement under paragraph (e) of this section.

(2) Except as provided in paragraph (e) of this section, if the agency learns of the existence of a liable third party after a claim is paid, or benefits become available from a third party after a claim is paid, the agency must seek recovery of reimbursement within 60 days after the end of the month it learns of the existence of the liable third party or benefits become available.

(3) Reimbursement must be sought unless the agency determines that recovery would not be cost effective in accordance with paragraph (f) of this section.

(e) ***Waiver of requirements.***

(1) The agency may request initial and continuing waiver of the requirements in paragraphs (b)(1), (d)(1), and (d)(2) of this section, if it determines that the requirement is not cost-effective. An activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the State.

(i) The agency must submit a request for waiver of the requirement in writing to the CMS regional office.

(ii) The request must contain adequate documentation to establish that to meet a requirement specified by the agency is not cost-effective. Examples of documentation are costs associated with billing, claims recovery data, and a State analysis documenting a cost-effective alternative that accomplishes the same task.

(iii) The agency must agree, if a waiver is granted, to notify CMS of any event that occurs that changes the conditions upon which the waiver was approved.

(2) CMS will review a State's request to have a requirement specified under paragraph (e)(1) of this section waived and will request additional information from the State, if necessary. CMS will notify the State of its approval or disapproval determination within 30 days of receipt of a properly documented request.

(3) CMS may rescind the waiver at any time that it determines that the State no longer meets the criteria for approving the waiver. If the waiver is rescinded, the agency has 6 months from the date of the rescission notice to meet the requirement that had been waived.

(4) An agency requesting a waiver of the requirements specifically concerning either the 60-day limit in paragraph (d)(1) or (d)(2) of this section must submit documentation of written agreement between the agency and the third party, including Medicare fiscal intermediaries and carriers, that extension of the billing requirement is agreeable to all parties.

(f) ***Suspension or termination of recovery of reimbursement.***

(1) An agency must seek reimbursement from a liable third party on all claims for which it determines that the amount it reasonably expects to recover will be greater than the cost of recovery. Recovery efforts may be suspended or terminated only if they are not cost effective.

(2) The State plan must specify the threshold amount or other guideline that the agency uses in determining whether to seek recovery of reimbursement from a liable third party, or describe the process by which the agency determines that seeking recovery of reimbursement would not be cost effective.

(3) The State plan must also specify the dollar amount or period of time for which it will accumulate billings with respect to a particular liable third party in making the decision whether to seek recovery of reimbursement.

§ 438.3 Standard contract requirements.

(a) ***CMS review.*** The CMS must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806. Proposed final contracts must be submitted in the form and manner established by CMS. For States seeking approval of contracts prior to a specific effective date, proposed final contracts must be submitted to CMS for review no later than 90 days prior to the effective date of the contract.

(b) ***Entities eligible for comprehensive risk contracts.*** A State may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) ***Payment.*** The following requirements apply to the final capitation rate and the receipt of capitation payments under the contract:

(1) The final capitation rate for each MCO, PIHP or PAHP must be:

(i) Specifically identified in the applicable contract submitted for CMS review and approval.

(ii) The final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

(2) Capitation payment may only be made by the State and retained by the MCO, PIHP or PAHP for Medicaid-eligible enrollees.

(d) ***Enrollment discrimination prohibited.*** Contracts with MCOs, PAHPs, PCCMs and PCCM entities must provide as follows:

(1) The MCO, PIHP, PAHP, PCCM or PCCM entity accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.

(e) ***Services that may be covered by an MCO, PIHP, or PAHP.***

(1) An MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the State plan as follows:

(i) Any services that the MCO, PIHP or PAHP voluntarily agree to provide, although the cost of these services cannot be included when determining the payment rates under paragraph (c) of this section.

(iii) Any services necessary for compliance by the MCO, PIHP, or PAHP with the requirements of subpart K of this part and only to the extent such services are necessary for the MCO, PIHP, or PAHP to comply with § 438.910.

(2) An MCO, PIHP, or PAHP may cover, for enrollees, services or settings that are in lieu of services or settings covered under the State plan as follows:

(i) The State determines that the alternative service or setting is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the alternative service or setting;

(iii) The approved in lieu of services are authorized and identified in the MCO, PIHP, or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP, or PAHP; and

(iv) The utilization and actual cost of in lieu of services is taken into account in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise.

(f) ***Compliance with applicable laws and conflict of interest safeguards.*** All contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must:

(1) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in § 438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(g) ***Provider-preventable condition requirements.*** All contracts with MCOs, PIHPs and PAHPs must comply with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this chapter. MCOs, PIHPs, and PAHPs, must report all identified provider-preventable conditions in a form and frequency as specified by the State.

(h) ***Inspection and audit of records and access to facilities.*** All contracts must provide that the State, CMS, the Office of the Inspector General, the Comptroller General, and their designees may, at any time, inspect and audit any records or documents of the MCO, PIHP, PAHP, PCCM or PCCM entity, or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(i) ***Physician incentive plans.***

(1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to “MA organization,” “CMS,” and “Medicare beneficiaries” must be read as references to “MCO, PIHP, or PAHP,” “State,” and “Medicaid beneficiaries,” respectively.

(j) ***Advance directives.***

(1) All MCO and PIHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives, as if such regulation applied directly to MCOs and PIHPs.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives as if such regulation applied directly to PAHPs if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to the requirements of this paragraph (j) must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(k) ***Subcontracts.*** All subcontracts must fulfill the requirements of this part for the service or activity delegated under the subcontract in accordance with § 438.230.

(l) ***Choice of network provider.*** The contract must allow each enrollee to choose his or her network provider to the extent possible and appropriate.

(m) ***Audited financial reports.*** The contract must require MCOs, PIHPs, and PAHPs to submit audited financial reports specific to the Medicaid contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(n) ***Parity in mental health and substance use disorder benefits.***

(1) All MCO contracts, and any PIHP and PAHP contracts providing services to MCO enrollees, must provide for services to be delivered in compliance with the requirements of subpart K of this part insofar as those requirements are applicable.

(2) Any State providing any services to MCO enrollees using a delivery system other than the MCO delivery system must provide documentation of how the requirements of subpart K of this part are met with the submission of the MCO contract for review and approval under paragraph (a) of this section.

(o) ***LTSS contract requirements.*** Any contract with an MCO, PIHP or PAHP that includes LTSS as a covered benefit must require that any services covered under the contract that could be authorized through a waiver under section 1915(c) of the Act or a State plan amendment authorized through sections 1915(i) or 1915(k) of the Act be delivered in settings consistent with § 441.301(c)(4) of this chapter.

(p) ***Special rules for certain HIOs.*** Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (b) of this section.

(q) ***Additional rules for contracts with PCCMs.*** A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to beneficiaries who reside sufficiently near one of the PCCM's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the beneficiary's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll in accordance with § 438.56(c).

(r) ***Additional rules for contracts with PCCM entities.*** In addition to the requirements in paragraph (q) of this section, States must submit PCCM entity contracts to CMS for review and approval to ensure compliance with the provisions of this paragraph (r); § 438.10; and § 438.310(c)(2).

(s) ***Requirements for MCOs, PCCMs, PIHPs, or PAHPs that provide covered outpatient drugs.*** Contracts that obligate MCOs, PCCMs, PIHPs, or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

(1) The MCO, PIHP or PAHP provides coverage of covered outpatient drugs as defined in section 1927(k)(2) of the Act, that meets the standards for such coverage imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP.

(2) The MCO, PIHP, or PAHP reports drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period. Such utilization information must include, at a minimum, information on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

(3) The MCO, PIHP or PAHP establishes procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section when states do not require submission of managed care drug claims data from covered entities directly.

(4) The MCO, PCCM, PIHP, or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and part 456, subpart K, of this chapter, as if such requirement applied to the MCO, PCCM, PIHP, or PAHP instead of the State.

(5) The MCO, PCCM, PIHP, or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

(6) The MCO, PIHP or PAHP must conduct a prior authorization program that complies with the requirements of section 1927(d)(5) of the Act, as if such requirements applied to the MCO, PIHP, or PAHP instead of the State.

(7) The MCO, PIHP, or PAHP must assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits.

(8) The MCO, PIHP, or PAHP that contracts with any subcontractor for the delivery or administration of the covered outpatient drug benefit must require the subcontractor to report separately to the MCO, PIHP, or PAHP the amounts related to:

(i) The incurred claims described in § 438.8(e)(2) such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug; and

(ii) Administrative costs, fees and expenses of the subcontractor.

(t) ***Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.*** In a State that enters into a Coordination of Benefits Agreement (COBA) with Medicare for Medicaid, an MCO, PIHP, or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must specify the methodology by which the State ensures that the appropriate MCO, PIHP, or PAHP receives all applicable crossover claims for which the MCO, PIHP, or PAHP is responsible. If the State elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the State's remittance advice that the State has not denied payment and that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

(u) ***Recordkeeping requirements.*** MCOs, PIHPs, and PAHPs must retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in § 438.416, base data in § 438.5(c), MLR reports in § 438.8(k), and the data, information, and documentation specified in §§ 438.604, 438.606, 438.608, and 438.610 for a period of no less than 10 years.

(v) ***Applicability date.*** Sections 438.3(h) and (q) apply to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.6(g) and (k) contained in the 42 CFR, parts 430 to 481, edition revised as of October 1, 2015.

(w) ***Applicability date.*** Paragraphs (s)(7) and (8) of this section apply to the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2023.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is 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 name drug.

Bona fide service fee means a fee paid by a manufacturer to an entity that represents 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 of the service arrangement, and that is 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. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

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

Bundled sale means any 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.

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

(3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale.

Clotting factor means a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by CMS and posted on the CMS Web site.

CMS-authorized supplemental rebate agreement means an agreement that is approved through a state plan amendment (SPA) by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal Government.

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.

Covered outpatient drug (COD) means, of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;

(ii) Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

(iv) Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the ~~following~~ services in paragraphs (2)(i) through (viii) of this definition (and for which payment may be made as part of payment for that service ~~instead of~~and not as ~~a~~ direct reimbursement for the drug~~):~~, as described in paragraph (4) of this definition).

(i) Inpatient Services;

(ii) Hospice Services;

(iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;

(iv) Physician services;

(v) Outpatient hospital services;

(vi) Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;

(vii) Other laboratory and x-ray services; or

(viii) Renal dialysis.

(3) A covered outpatient drug does not include:

(i) Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;

(ii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;

(iii) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(iv) Over-the-counter products that are not drugs.

(4) Direct reimbursement for a drug may include both:

(i) Reimbursement for a drug alone, or

(ii) Reimbursement for a drug plus the service, in a single inclusive payment if:

(A) The drug, charge for the drug, and number of units of the drug are separately identified on the claim, and;

(B) The inclusive payment includes an amount directly attributable to the drug, and,

(C) The amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

Customary prompt pay discount means any discount off of 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.

Drug product information means National Drug Code (NDC), drug name, units per package size (UPPS), drug category ("S", "I", "N"), unit type (for example, TAB, CAP, ML, EA), drug type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension indicator, 5i indicator, 5i route of administration (if applicable), FDA approval date, FDA application number or OTC monograph citation (if applicable), market date, and COD status.

Innovator multiple source drug means a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section). It also 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 biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

Internal investigation means a manufacturer's investigation of its AMP, best price, customary prompt pay discounts, or nominal prices that have been previously certified in the Medicaid Drug Rebate Program (MDRP) that results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding.

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.

Line extension means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

(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) For authorized generic products, the term "manufacturer" will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term "manufacturer" will also include the entity under whose own label or trade name the product will be distributed.

Market date, for the purpose of establishing the base date AMP quarter, means the date on which the covered outpatient drug was first sold by any manufacturer.

Multiple source drug means, for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all of the following criteria:

(1) Is rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/*).

(2) Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by FDA.

(3) Is sold or marketed in the United States during the period.

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard 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 or her designee and a manufacturer to implement section 1927 of the Act.

New formulation means, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

Nominal price means a price that is less than 10 percent of the average manufacturer price (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 ANDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that ~~was~~is not ~~originally~~ marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug; or

(5) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product's drug category changes to correlate with the new product application type.

Oral solid dosage form means, an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.

Over-the-counter (OTC) drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group meaning from birth through 16 years of age, or a subset of this group as specified in the “Indication and Usage” section of the FDA approved labeling, or in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in a pediatric age group, or a subset of this group.

Professional dispensing fee means the professional 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 beneficiary. 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.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in this section), and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

United States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:

(1) Evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or

(2) Outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

§ 447.504 Determination of average manufacturer price.

(a) ***Definitions.*** For the purpose of this section, the following definitions apply:

Average manufacturer price (AMP) means, for 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), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs

distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Average unit price means a manufacturer's sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter. Charitable and not-for profit pharmacies means organizations exempt from taxation as defined by section 501(c)(3) of the Internal Revenue Code of 1986.

Insurers means entities that are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies.

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.

Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(b) ***Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP.*** Except for those sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions identified in paragraph (c) of this section, AMP for covered outpatient drugs includes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to wholesalers for drugs distributed to retail community pharmacies.

(2) Sales to retail community pharmacies (including those sales, nominal price sales, and associated discounts, rebates (other than rebates under section 1927 of the Act or as specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies).

(c) ***Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions excluded from AMP.*** AMP excludes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(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) Sales outside the United States.

(5) Sales to hospitals.

(6) Sales to health maintenance organizations (HMOs) (including managed care organizations (MCOs)), including HMO or MCO operated pharmacies.

(7) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, 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.

(8) Sales to mail order pharmacies.

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

(10) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(11) Sales to charitable pharmacies.

(12) Sales to not-for-profit pharmacies.

(13) Sales, associated rebates, discounts, or other price concessions paid directly to insurers.

(14) Bona fide service fees, as defined in § 447.502, paid by manufacturers to wholesalers or retail community pharmacies.

(15) Customary prompt pay discounts extended to wholesalers.

(16) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only those costs.

(17) Associated discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program under section 1860D–14A of the Act.

(18) Payments received from and rebates and discounts provided to pharmacy benefit manufacturers (PBMs).

(19) 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.

(20) Sales to hospices (inpatient and outpatient).

(21) Sales to prisons.

(22) Sales to physicians.

(23) Direct sales to patients.

(24) Free goods, not contingent upon any purchase requirement.

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

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that~~ the manufacturer ensures: the~~: The voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other ~~AMP-eligible~~AMP eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the ~~manufacturer ensures the~~ full value of the discount is passed on to the consumer and the pharmacy, agent, or ~~the~~ other ~~AMP-eligible~~AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent ~~that the manufacturer ensures~~ that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other ~~AMP-eligible~~AMP eligible entity does not receive any price ~~concession~~concessions.

(29) Manufacturer copayment assistance programs, to the extent that the ~~manufacturer ensures the~~ program benefits are provided entirely to the patient and the pharmacy, agent, or other ~~AMP-eligible~~AMP eligible entity does not receive any price concession.

(30) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(d) ***Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP for 5i drugs that are not generally dispensed through retail community pharmacies.*** Except for those sales, nominal price sales, and associated discounts, rebates, payments, and other financial transactions identified in paragraph (e) of this section, AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i) covered outpatient drugs identified in accordance with § 447.507 shall include sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions to all entities specified in paragraph (b) of this section, as well as the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales to insurers (except for rebates under section 1927 of the Act and this subpart).

(5) Sales to hospitals.

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

(7) Sales to mail order pharmacies.

(8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, 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.

(9) Sales to hospices (inpatient and outpatient).

(10) Sales to manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy.

(e) ***Sales, nominal price sales, and associated discounts, rebates, payments, or other transactions excluded from AMP for 5i drugs that are not generally dispensed through retail community pharmacies.*** AMP for 5i covered outpatient drugs identified in accordance with § 447.507 excludes the following sales, nominal price sales, and associated discounts, rebates, or other financial transactions:

(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) Sales outside the United States.

(5) Bona fide service fees as defined in § 447.502 paid by manufacturers to wholesalers or retail community pharmacies.

(6) Customary prompt pay discounts extended to wholesalers.

(7) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only these costs.

(8) 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 for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by

manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

(9) 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.

(10) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(11) Sales to patients.

(12) Free goods, not contingent upon any purchase requirement.

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

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the ~~manufacturer ensures: the~~ voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other ~~AMP-eligible~~AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the ~~manufacturer ensures the~~ full value of the discount is passed on to the consumer and the pharmacy, agent, or ~~the~~ other ~~AMP-eligible~~AMP eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer ~~ensures the manufacturer provided~~provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other ~~AMP-eligible~~AMP eligible entity does not receive any price ~~concession~~concessions.

(17) Manufacturer copayment assistance programs, to the extent that the ~~manufacturer ensures the~~ program benefits are provided entirely to the patient and the pharmacy, agent, or other ~~AMP-eligible~~AMP eligible entity does not receive any price concession.

(18) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(19) Sales to charitable pharmacies.

(20) Sales to not-for-profit pharmacies.

(f) ***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 that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees

(other than bona fide service fees), and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in that 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, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation.

§ 447.505 Determination of best price.

(a) ***Definitions.*** For the purpose of this section, the following definitions apply:

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement.

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.

(b) ***Prices included in best price.*** Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in paragraph (a) of this section.

(c) ***Prices excluded from best price.*** Best price excludes the following:

(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, or the PHS.

(2) Any prices charged to 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).

(3) Any prices charged under the FSS of the GSA.

(4) Any prices, rebates, or discounts provided to a designated State Pharmacy Assistance Program (SPAP).

(5) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(6) 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 for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

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

(8) Manufacturer-sponsored drug discount card programs, but only to the extent ~~the manufacturer ensures~~ that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent ~~the manufacturer ensures~~ 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.

(10) Manufacturer copayment assistance programs, to the extent that the ~~manufacturer ensures the~~ program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that ~~the manufacturer ensures~~ the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the ~~manufacturer ensures the~~ voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

(13) Free goods, not contingent upon any purchase requirement.

(14) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including, but not limited to, reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only these costs.

(15) Nominal prices to certain entities as set forth in § 447.508.

(16) Bona fide service fees as defined in § 447.502.

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

(18) Sales outside the United States.

(19) Direct sales to patients.

(d) ***Further clarification of best price.***

(1) Best price is net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, 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.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of best price by statute or regulation.

§ 447.509 Medicaid drug rebates (MDR).

(a) ***Determination of rebate amount*** —

(1) ***Basic rebate for single source drugs and innovator multiple source drugs.*** The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug is equal to the product of:

(i) The total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) The greater of:

(A) The difference between the AMP and the best price for the dosage form and strength of the drug; or

(B) The AMP for the dosage form and strength of the drug multiplied by one of the following percentages:

(*1*) For a clotting factor, 17.1 percent;

(*2*) For a drug approved by FDA exclusively for pediatric indications, 17.1 percent; or

(*3*) For all other single source drugs and innovator multiple source drugs, 23.1 percent.

(2) ***Additional rebate for single source and innovator multiple source drugs.*** In addition to the basic rebate described in paragraph (a)(1) of this section, for each dosage form and strength of a single source drug or an innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds:

(B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(3) ***Total rebate.*** The total rebate amount for single source drugs and innovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(4) ***Treatment of new formulations.***

(i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for the rebate periods beginning January 1, 2010 through September 30, 2018 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(ii) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for the rebate periods beginning on October 1, 2018 through December 31, 2021 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(iii) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug, provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form, the rebate obligation for the rebate periods beginning on and after January 1, 2022 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(iv) The alternative rebate is required to be calculated if the manufacturer of the line extension drug also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

(5) ***Limit on rebate.*** ~~In~~For a rebate period beginning after December 31, 2009, and before January 1, 2024, in no case will the total rebate amount exceed 100 percent of the AMP of the single source or innovator multiple source ~~innovator~~ drug.

(6) ***Rebate for ~~noninnovator~~drugs other than a single source drug or innovator multiple source ~~drugs~~drug***. The amount of the basic rebate for each dosage form and strength of a ~~noninnovator~~drug other than a single source drug or innovator multiple source drug will be equal to the product of:

(i) The total number of units of such dosage form and strength for which payment was made under the State plan for the rebate period; and

(ii) The AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

(7) ***Additional rebate for ~~noninnovator~~drugs other than a single source drug or innovator multiple source ~~drugs~~drug.*** In addition to the basic rebate described in paragraph (a)(6) of this section, for each dosage form and strength of a ~~noninnovator~~drug other than a single source drug or innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(B) The base date AMP has the meaning of AMP set forth in sections 1927(c)(2)(A)(ii)(II), 1927(c)(2)(B) and 1927(c)(3)(C) of the Act.

(8) ***Total rebate.*** The total rebate amount for ~~noninnovator~~a drug other than a single source drug or innovator multiple source ~~drugs~~drug is equal to the basic rebate amount plus the additional rebate amount, if any.

(9) ***Limit on rebate.*** ~~In~~For a rebate period beginning after December 31, 2014, and before January 1, 2024, in no case will the total rebate amount exceed 100 percent of the AMP for ~~the noninnovator~~a drug other than a single source drug or innovator multiple source drug.

(b) ***Rebates for drugs dispensed through Medicaid managed care organizations (MCOs).***

(1) Manufacturers participating in the Medicaid drug rebate program will provide a rebate for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs.

(2) Manufacturers are exempt from the requirement in paragraph (b)(1) of this section if such drugs are the following:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act; and

(ii) Discounted under section 340B of the PHSA.

(c) ***Federal offset of rebates.*** States must remit to the Federal government the amount of the savings resulting from the following increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by FDA exclusively for pediatric indications:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 8.0 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 23.1 percent, then the offset amount is the difference between AMP times 23.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 23.1 percent, then there is no offset amount.

(2) For single source or innovator multiple source drugs that are clotting factors and drugs approved by FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 2.0 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 17.1 percent, then the offset amount is the difference between AMP times 17.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 17.1 percent, then there is no offset amount.

(3) For a drug that is a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, the offset amount is the difference between the unit rebate amount (URA) calculation for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act.

(4) For ~~noninnovator~~a drug other than a single source drug or innovator multiple source ~~drugs~~drug, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

(d) ***Manufacturer misclassification of a covered outpatient drug and recovery of unpaid rebate amounts due to the misclassification and other penalties—***

(1) *Definition of misclassification*. A misclassification in the MDRP has occurred when a manufacturer has:

(i) Reported and certified to the agency its drug category or drug product information related to a covered outpatient drug that is not supported by the statute and applicable regulations; or,

(ii) Reported and certified to the agency its drug category or drug product information that is supported by the statute and applicable regulations, but pays rebates to States at a level other than that associated with that classification.

(2) ***Manufacturer notification by the agency of drug misclassification***. If the agency determines that a misclassification has occurred as described in paragraph (d)(1) of this section, the agency will send written and electronic notification of this misclassification to the manufacturer of the covered outpatient drug, which may include a notification that past rebates are due. The manufacturer has 30 calendar days from the date of notification to:

(i) Provide the agency such drug product and drug pricing information needed to correct the misclassification of the covered outpatient drug and calculate rebate obligations due, if any, pursuant to paragraph (d)(3) of this section. The required pricing data submitted by the manufacturer to the agency shall include the best price information for the covered outpatient drug, if applicable, for the rebate periods for which the manufacturer misclassified the covered outpatient drug; and,

(ii) Certify applicable price and drug product data after entered into the system by the agency.

(3) ***Manufacturer payment of unpaid rebates due to misclassification determined by agency.***

(i) When the agency has determined that a manufacturer has misclassified a covered outpatient drug as described in paragraph (d)(1) of this section, such that rebates are owed to the States, and notification has been provided to the manufacturer as provided under paragraph (d)(2) of this section, a manufacturer must pay to each State an amount equal to the sum of the products of:

(A) The difference between:

(*1*) The per URA paid by the manufacturer for the covered outpatient drug to the State for a period during which the drug was misclassified; and

(*2*) The per URA that the manufacturer would have paid to the State for the covered outpatient drug for each period, as determined by the agency based on the data provided and certified by the manufacturer under paragraph (d)(2) of this section, if the drug had been correctly classified by the manufacturer; and,

(B) The total units of the drug paid for under the State plan in each period.

(ii) Manufacturers must pay such rebates to the States for the period or periods of time that such covered outpatient drug was misclassified, based on the formula described in this section, within 60 calendar days of notification by the agency to the manufacturer of the misclassification, and provide documentation to the agency that the States were contacted by the manufacturer, and that such payments were made to the States within the 60 calendar days.

(4) ***Agency authority to correct misclassifications and additional penalties for drug misclassification.*** The agency will review the information submitted by the manufacturer based on the notice sent under paragraph (d)(2) of this section. If a manufacturer fails to comply with paragraph (d)(2) of this section within 30 calendar days from the date of the notification by the agency of the misclassification to the manufacturer under paragraph (d)(1) of this section, fails to pay the rebates that are due to the States as a result of the misclassification within 60 calendar days from the date of the notification, if applicable, and/or fails to provide to the agency such documentation that such rebates have been paid, as described in paragraph (d)(3) of this section, the agency may do any or all of the following:

(i) Correct the misclassification of the drug in the system on behalf of the manufacturer, using any pricing and drug product information that may have been provided by the manufacturer. In such case, the manufacturer must certify the applicable correction within 30 calendar days.

(ii) Suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's rebate agreement from the MDRP, and exclude the misclassified drug from FFP in accordance with section 1903(i)(10)(E) of the Act.

(iii) Impose a civil monetary penalty (CMP) for each rebate period during which the drug is misclassified, not to exceed an amount equal to the product of:

(A) The total number of units of each dosage form and strength of such misclassified drug paid for under any State plan during such a rebate period; and

(B) 23.1 percent of the AMP for the dosage form and strength of such misclassified drug for that period.

(iv) Other actions and penalties available under section 1927 of the Act (or any other provision of law), including referral to the HHS Office of the Inspector General and termination from the MDRP.

(5) ***Transparency of manufacturers' drug misclassifications.*** The agency will make available on a public website an annual report as required under section 1927(c)(4)(C)(ii) of the Act on the covered outpatient drug(s) that were identified as misclassified during the previous year, any steps taken by the agency with respect to the manufacturer to reclassify the drugs and ensure the payment by the manufacturer of unpaid rebate amounts resulting from the misclassifications, and a disclosure of the expenditures from the fund created in section 1927(b)(3)(C)(iv) of the Act.

§ 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 the following:

(1) AMP, calculated in accordance with § 447.504.

(2) Best price, calculated in accordance with § 447.505.

(3) Customary prompt pay discounts, which are 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.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) 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 any revision 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. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction; that is, not based on any changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation as defined at § 447.502, or an Office of Inspector General (OIG) or Department of Justice ~~(DOJ)~~ investigation.

(vi) The change is a result of a VBP arrangement, as defined in § 447.502, requiring the manufacturer to make changes outside of the 12-quarter rule in this paragraph (b), when the outcome must be evaluated outside of the 12-quarter period.

(2) A manufacturer must report revised AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) ***Base date AMP report*** —

(1) ***Reporting period.*** A manufacturer may report a revised Deficit Reduction Act (DRA) base date AMP to CMS within the first 4 full calendar quarters following July 17, 2007.

(2) ***Recalculation of the DRA base date AMP.***

(i) A manufacturer's recalculation of the DRA base date AMP must only reflect the revisions to AMP as provided for in § 447.504 in effect from October 1, 2007 to December 14, 2010.

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

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

(3) ***Reporting a revised Affordable Care Act base date AMP.*** A manufacturer may report a revised Affordable Care Act base date AMP to CMS within the first 4 full calendar quarters following April 1, 2016.

(4) ***Recalculation of the Affordable Care Act base date AMP.***

(i) A manufacturer's recalculation of the Affordable Care Act base date AMP must only reflect the revisions to AMP as provided for in § 447.504.

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

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

(d) ***Monthly AMP*** —

(1) ***Definition.*** 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 is calculated based on § 447.504, except the period covered is based on monthly, as opposed to quarterly, sales.

(i) The monthly AMP is 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.

(ii) It is calculated as net sales divided by number of units sold, excluding goods or any other items specifically excluded in the statute or regulations. Monthly AMP is calculated based on the best data available to the manufacturer at the time of submission.

(iii) In calculating monthly AMP, a manufacturer must estimate the impact of its lagged AMP-eligible price concessions using a 12-month rolling percentage in accordance with the methodology described in this paragraph (d)(2).

(A) For each NDC–9 with at least 12 months of AMP-eligible sales, after adjusting for sales excluded from AMP, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period (inclusive of the current reporting period) available associated with sales subject to the AMP reporting requirement divided by the total in dollars for the sales subject to the AMP reporting requirement for the same 12-month period.

(B) For each NDC–9 with less than 12 months of AMP-eligible sales, the calculation described in paragraph (d)(2)(iii)(A) of this section is performed for the time period equaling the total number of months of AMP-eligible sales.

(iv) The manufacturer multiplies the applicable percentage described in paragraph (d)(2)(iii)(A) or (B) of this section by the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted. The result of this multiplication is then subtracted from the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted.

(v) The manufacturer uses the result of the calculation described in paragraph (d)(2)(iv) of this section as the numerator and the number of units sold in the month (after adjusting for sales excluded from AMP) as the denominator to calculate the manufacturer's AMP for the NDC for the month being submitted.

(vi) ***Example.*** After adjusting for sales excluded from AMP, the total lagged price concessions over the most recent 12-month period available associated with sales for NDC 12345–6789 subject to the AMP reporting requirement equal $200,000, and the total in dollars for the sales subject to the AMP reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the AMP reporting requirement for the month being reported equals $50,000 for 10,000 units sold. The manufacturer's AMP calculation for this NDC for this month is: $50,000−(0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33340 (AMP).

(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, except as allowed in paragraph (b)(1) of this section.

(4) ***Exception.*** A manufacturer must report revisions to monthly AMP within the 36-month time period, 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.

(6) ***Monthly AMP units.*** A manufacturer must report the total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP to CMS not later than 30 days after the last day of each month.

(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 paragraphs (e)(1) through (3) of this section.

(f) ***Recordkeeping requirements.***

(1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period.

(i) 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.

(ii) The 10-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 10-year period if all 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 designated by CMS.

(h) ***Suspension of manufacturer's NDRA for late reporting of drug pricing and drug product information***.

(1) If a manufacturer fails to timely provide information required to be reported to the agency under section 1927(b)(3)(A) of the Act, and paragraphs (a) and (d) of this section, the agency will provide written notice to the manufacturer of failure to provide timely information. If such information is not reported within 90 calendar days of the date of the notice communicated to the manufacturer electronically and in writing by the agency, such failure by the manufacturer to report such information in a timely manner shall result in suspension of the manufacturer's rebate agreement for all covered outpatient drugs furnished after the end of the 90-day calendar period. The rebate agreement will remain suspended until the date the information is reported to the agency in full and certified, and the agency reviews for completeness, but not for a period of fewer than 30 calendar days. Continued suspension of the rebate agreement could result in termination for cause. Suspension of a manufacturer's rebate agreement under this section applies for Medicaid purposes only and does not affect manufacturer obligations and responsibilities under the 340B Program or reimbursement under Medicare Part B during the period of the suspension.

(2) During the period of the suspension, the covered outpatient drugs of the manufacturer are not eligible for FFP. The agency will notify the States 30 calendar days before the beginning of the suspension period for the manufacturer's rebate agreement and any applicable associated labeler rebate agreements.

(i) ***Manufacturer audits of State-provided information.*** A manufacturer may only initiate a dispute, request a hearing, or seek an audit of a State regarding State drug utilization data, during a period not to exceed 12 quarters from the last day of the quarter from the State invoice postmark date.

§ 447.518 State plan requirements, findings, and assurances.

(a) ***State plan.***

(1) The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:

(i) A covered entity described in section 1927(a)(5)(B) of the Act.

(ii) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(iii) An Indian Health Service, tribal and urban Indian pharmacy.

(2) The agency's payment methodology in paragraph (a)(1) of this section must be in accordance with the definition of AAC in § 447.502.

(b) ***Findings and assurances.*** Upon proposing significant State plan changes in payments for prescription drugs, and 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, identified and listed in accordance with § 447.514(a), are in accordance with the upper limits specified in § 447.514(b).

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

(2) ***Assurances.*** The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 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.

(d)

~~(1)~~ ***Data requirements***. (1) When proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to evaluate their proposed changes in accordance with the requirements of this subpart, and States must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide adequate cost-based data, such as a State or national survey of retail pharmacy providers or other reliable cost-based data other than a survey, to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment ~~through the~~ formal review process. Research and data must be based on pharmacy costs and be sufficient to establish the adequacy of both current ingredient cost reimbursement and professional dispensing fee reimbursement. Submission by the State of data that are not based on pharmacy costs, such as market-based research (for example, third party payments accepted by pharmacies), to support the professional dispensing fee would not qualify as supporting data.

(2) A State participating in VBP arrangements approved under a CMS-authorized supplemental rebate agreement (SRA) must report data described in paragraph (d)(3) of this section on an annual basis.

(3) Within 60 days of the end of each year, the State must submit all of the following data, including cumulative data to date:

(i) State.

(ii) National drug code(s) (for drugs covered under the CMS-authorized VBP SRA).

(iii) Product's FDA list name.

(iv) Number of prescriptions.

(v) Cost to the State to administer the CMS-authorized VBP SRA (for example, systems changes, tracking outcomes, etc.).

(vi) Total savings generated by the supplemental rebate due to the CMS-authorized VBP SRA.

§ 447.520 Federal Financial Participation (FFP): Conditions relating to physician-administered drugs.

(a) ***Availability of FFP.*** No FFP is available for physician-administered single source drugs or the multiple source drugs identified under paragraph (c) of this section that are covered outpatient drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to ~~bill~~invoice a manufacturer for rebates in a manner consistent with the requirements of this section. In the case of multiple source drugs not identified under paragraph (c), a failure to comply with the requirements of this section may result in FFP being withheld as provided under 42 CFR 430.35. [1]

(1) ~~As of~~***Single source drugs.*** For a covered outpatient drug that is a single source, physician-administered drug, administered on or after 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~~ using National Drug Code (NDC) numbers to secure rebates~~.~~ and receive FFP.

(2) ~~As of~~*Multiple source drugs*. For a covered outpatient drug that is a multiple source, physician-administered drug on the list published by CMS described in paragraph (c) of this section, administered on or after January 1, ~~2007~~2008, 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 to secure rebates and receive FFP.

(3) States are required to invoice for rebates consistent with this section for multiple source physician-administered drugs that are CODs and that are not on the top 20 multiple source physician-administered drug list published under paragraph (c) of this section, or may be subject to a withhold of FFP as provided under 42 CFR 430.35.[2]

(b) ***Required coding.*** As of January 1, ~~2008~~2007, a State must require providers to submit claims for ~~the~~ a covered outpatient drug that is described in paragraph (a)(1) or (2) of this section that is a physician-administered drug using NDC numbers. As of November 19, 2024, a State must also comply with this

[1] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-430.*
[2] Ibid.

requirement for a covered outpatient drug that is a physician-administered drug described in paragraph (a)(3) of this section.

(c) ***Top 20 multiple source physician-administered*** ~~**drugs**~~***drug list***. The top 20 multiple source physician-administered drug list, identified by the Secretary as having the highest dollar ~~value~~volume of physician-administered drugs dispensed under the Medicaid ~~Program using NDC numbers to secure rebates~~program, will be published and may be modified from year to year to reflect changes in such volume.

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