



Medicaid: Covered Outpatient Drugs Final Rule (CMS-2345-FC) Summary of Major Provisions

On January 21, 2016 the Centers for Medicare & Medicaid Services (CMS) released the Covered Outpatient Drugs final rule with comment that addresses key areas of Medicaid drug reimbursement and changes made to the Medicaid Drug Rebate Program by the Affordable Care Act. This final rule is intended to assist states and the federal government in managing drug costs, establish the long-term framework for implementation of the Medicaid drug rebate program, and create a fairer reimbursement system for Medicaid providers and pharmacies.

Effective date of the final rule: April 1, 2016 (with opportunity to comment on the definition and identification of line extension drugs until April 1, 2016). There should be no retroactive adjustments to rebates based upon the provisions finalized in this final rule.

Economic Analysis: CMS estimates that the Covered Outpatient Drugs Final Rule will save federal and state governments an estimated \$2.7 billion over five years. CMS estimates the savings from the implementation of the Federal upper [reimbursement] limit(s) (FULs) for multiple source noninnovator or generic drugs as revised in this final rule of \$2.735 billion over 5 years (2016 through 2020), \$1.61 billion to the federal government and \$1.125 billion to the states. They estimate costs to drug manufacturers and states of \$431.96 million for federal fiscal years 2016 through 2020.

DEFINITIONS

5i – Not Finalized -CMS decided not to finalize a formal definition of “5i” (inhalation, infusion, instilled, implanted or injectable drug not generally dispensed through a retail community pharmacy) because it was not necessary, but CMS will use the 5i designation for convenience.

However, CMS did finalize definition of AMP for 5i drugs (see discussion below).

Actual Acquisition Cost – CMS is replacing the term, “estimated acquisition cost” (EAC) with “actual acquisition cost” (AAC). AAC is defined as the agency’s determination of the actual price pharmacies and providers pay to acquire outpatient drugs covered by the drug rebate program [Covered Outpatient Drugs (COD)].

CMS believes the finalized definition of AAC allows states to retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks. AAC benchmarks can include:

- The NADAC (National average drug acquisition cost);¹
- Data survey of retail pharmacy providers;
- AMP data;
- WAC data, if that state can provide data to support model of reimbursement that is consistent with 447.512(b).²

CMS notes that several states (CO, ID, IA, LA) have already incorporated the use of acquisition costs based on survey data as reimbursement metric for COD.

Covered Outpatient Drugs (COD) – are drugs dispensed only on a prescription as needed and meet at least one criteria in Sec. 1927(k)(2):

- Had a National drug code (NDC);
- Not part of a bundled service
- In an outpatient setting;
- FDA approved application number [New Drug Application (NDA)].

CMS did not finalize the COD criterion that a drug be listed electronically with the FDA. CMS will use FDA information on Marketing Category and Drug Type to verify a drug but it is not required.

Manufacturers are required to report to CMS drugs that meet the COD definition via the Drug Data Reporting for Medicaid System.

Radiopharmaceuticals – CMS received a number of comments on the inclusion of radiopharmaceuticals as COD with many comments contending that they are diagnostic, not therapeutic. In the final rule, CMS disagreed and determined that radiopharmaceuticals are eligible for rebates.

Original NDA: CMS had proposed to use “original NDA” to define an NDA as equivalent to an NDA filed by the manufacturer for approval under section 505 of the FDCA for purposes of approval by FDA for safety and effectiveness. However, in light of the comments received and in accordance with the statutory definitions of innovator multiple source and single source drugs, CMS decided that the term “original NDA” is designed typically to mean an NDA (including an NDA filed under section 505(b)(1) or (2) of the FDCA), other than an ANDA, which is

¹ In regard to specialty pharmacies that have products primarily delivered through the mail, these pharmacies are not included in the NADAC survey at this time. However, specialty drug products purchased through retail community pharmacies are included in the NADAC files. If states choose to use the NADAC pricing files in their reimbursement methodologies, they will be responsible for determining AAC for specialty drugs dispensed through specialty pharmacies.

² 47.512(b) The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established must not exceed, in the aggregate, payments levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or
(2) Providers' usual and customary charges to the general public.

approved by the FDA for marketing. Manufacturers that believe that a drug should qualify for an exception to allow drugs to be reported as noninnovator, multiple source or generic have four quarters after the effective date of the final rule to apply for exception.

Line Extension Drug (New Formulation) – Not Finalized - CMS proposed to define line extension as a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug.

However, CMS did not finalize the regulatory definition of line extension drug and is requesting additional comments on the definition of line extension drug to consider addressing this in future rulemaking.

Under ACA, the additional rebate amount caused by the inflation adjuster is applied to line extension drugs although they are newly FDA approved and have a different NDA than their predecessor drug.

Multiple Source Drug – CMS finalized the definition of a multiple source drug as a COD for which there is at least one other drug product which is--

- Rated as therapeutically equivalent as reported in FDA's most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”;
- Pharmaceutically equivalent and bioequivalent, as determined by FDA; and
- Sold or marketed in the United States during the rebate period.

Noninnovator, Multiple Source (or Generic) Drug – CMS finalized the definition of a noninnovator multiple source drug to also include other drugs that have not gone through an FDA approval process but otherwise meet the definition of COD. CMS also clarified that 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 -- CMS finalized the definition of solid oral dosage form to mean capsules, tablets, or similar drug products intended for oral use, meaning any drug that is intended to be taken by mouth.

Pediatric Indication – The ACA established a minimum rebate percentage of 17.1 percent of AMP for single source and innovator multiple source (brand name or branded) drugs only to drug products whose FDA-approved labeling includes indications only for children from birth through 16 years of age³ or a subset of this group and only when this specific pediatric population age cohort appears in the “Indication and Usage.”

CMS clarified that if a drug’s labeling is changed resulting in that drug being exclusively pediatric for less than one rebate period, the 17.1 percent minimum rebate amount would continue to be applicable for that rebate period, which does not require that the minimum rebate

³ Meaning a patient has not reached 17th birthday.

percentage of 17.1 percent be applied to the drug more often than once a rebate period.

Professional Dispensing Fee – CMS finalized the proposal to change “dispensing fee” to “professional dispensing fee” to reinforce CMS’s position that the dispensing fee should reflect the pharmacist’s professional services and costs to dispense the drug product to a Medicaid beneficiary. States retain the flexibility to establish the professional dispensing fee that is representative of pharmacy costs associated with ensuring that possession of the appropriate COD is transferred to a Medicaid beneficiary, including establishing fees for specific pharmacy types overhead, and drugs dispense.

Single Source Drug – CMS finalized the definition of a single source drug to mean a COD that is produced or distributed under an NDA approved by FDA and has an approved NDA number issued by FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a COD approved under a Biologics License Application, Product License Application, Establishment License Application, or Antibiotic Drug Application.

States and United States Expands Rebates to Territories, but Delayed – Although many commenters opposed expanding the Medicaid rebate program to the territories, CMS finalized a definition of both “States” and “United States” to include the 50 states, the District of Columbia, and the territories (defined as the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa). Effectively, this extends the Medicaid Drug Rebate (MDR) to the territories.

However, CMS decided to delay including the territories in the definitions until 1 year after the final rule becomes effective to give the territories and manufacturers additional time to implement provisions necessary to include territories in all aspects of the MDR program. Additionally, CMS will consider allowing a territory to use existing waiver authority to elect not to participate in the MDR program consistent with the statutory waiver standards.

CMS expects to provide additional guidance to manufacturers regarding the inclusion of territory sales within their calculation of AMP and best price, including additional guidance regarding the treatment of sales to territories that have government imposed statutory caps.

Wholesaler – CMS finalized the definition of wholesaler to mean a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to, manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions. The definition does not require that a wholesaler be licensed by the state.

Determination of Average Manufacturer Price

In the final rule, CMS has clarified that manufacturers may continue to make reasonable assumptions, in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies in

their calculation of AMP, provided those assumptions are consistent with the requirements and intent of the law and federal regulations. Such assumptions should be documented by each manufacturer and as applicable, consistently applied to all CODs reported in MDR.

AMP Methodology – In the proposed rule, CMS asked for comments regarding two approaches manufacturers may take to determine which sales are included in the AMP when such sales are made to wholesalers for drugs distributed to retail community pharmacies. CMS is maintaining the “presumed inclusion” method under which the manufacturer presumes, in the absence of adequate documentation to the contrary, that certain prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, without data concerning that actual distribution. The presumed inclusion approach uses three data sources most manufacturers have available for the calculation of AMP: direct sales data, indirect sales data (identified by chargebacks submitted by the wholesaler to the manufacturer for contracted sales), and rebate payment data. Manufacturers must maintain actual and verifiable documentation that supports its AMP calculations.

AMP Definition (not including 5i) – CMS finalized the definition of AMP to mean “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 - CMS finalized the definition of Average Unit Price to mean “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.”

Net Sales - CMS finalized the definition of net sales to mean “quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates the Medicaid rebate program or other price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

When a sale to a retail community pharmacy is determined to be included in AMP, any rebate, discount, payment or other financial transaction associated with that sale should also be included in the determination of AMP, unless it is specifically excluded (see list of exclusions below).

Retail Community Pharmacies-- CMS decided not to automatically include home infusion, home health care, and specialty pharmacies in the definition of retail community pharmacies as they may or may not, depending on the business model adopted, qualify as retail community pharmacies to the extent that the pharmacy operates as an independent, chain, supermarket, 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. However, when these pharmacies do meet the definition of retail community pharmacy, sales to these pharmacies should be included in the manufacturer’s calculation of AMP.

The final definition 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.”

AMP Exclusions - 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.

AMPs for Inhalation, infusion, instilled, implanted, and injectable Drugs (5i Drugs)-- As discussed above, CMS did not finalize a formal definition of 5i drugs. However, manufacturers

must use reasonable assumptions to identify for CMS each COD that qualifies as a 5i drug.

Agreeing with commenters, CMS determined that a 90 percent threshold may not accurately reflect what it means to be not “generally dispensed” through retail community pharmacies. Instead, CMS is adopting a threshold of 70%. Therefore, to ensure sufficient sales to be included in AMP while at the same time appropriately restricting the inclusion of 5i drugs to those that are not generally dispensed through retail community pharmacies, at least 70 percent of a 5i drug’s sales must be to an entity other than a retail community pharmacy to allow for an AMP calculation based on a sufficient number of sales. “Generally dispensed” is based on units, not dollars and is calculated at the DC-9 level.

Additionally, CMS is allowing, but not mandating, a smoothing or averaging process to determine if the percent of sales were sufficient to meet the “not generally dispensed” threshold.

Determination of Best Price

Definitions of Best Price and Providers -- 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.

Best price exclusions – CMS outlines comments on the proposed language that would have required sales to 340B covered entities to be made “under the 340B program” in order to qualify for the best price exclusion for sales to 340B covered entities. As a result of comments, CMS clarified that any prices charged to a covered entity are excluded from best price. Additionally, manufacturers will not need to monitor 340B covered entity compliance or enforce Health Resources and Services Administration (HRSA) requirements as a condition of excluding 340B prices from best price.

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 above, excluding:

- 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). (CMS clarifies that manufacturers may exclude any prices offered at or below the 340B ceiling price (subceiling prices) paid for by covered entities, including prices paid for orphan drugs.)
- (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 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 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 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 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 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.

Authorized Generic Drugs

CMS defines the term "Primary manufacturer" to mean a manufacturer that holds the NDA of the authorized generic drug and "Secondary manufacturer of an authorized generic drug" to mean a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA.

Sales of an authorized generic should be included in the AMP and Best Price calculation of the

primary manufacturer holding title to the NDA when the drug is sold directly to a wholesaler, or to a secondary manufacturer when that secondary manufacturer is acting as a wholesaler. This would include transfer prices and fees paid by the secondary manufacturer to the primary manufacturer for the authorized generic product. However, the primary manufacturer should not include the price (be it a transfer price or a sale price) of the authorized generic drug in its AMP when the secondary manufacturer is relabeling the product with a different NDC.

The primary manufacturer has the responsibility to determine whether a secondary manufacturer is acting as a wholesaler (as defined above).

Exclusion from Best Price of Certain Sale at a Nominal Price

CMS added language to its regulations to include the two categories of entities (added by law in 2009) to the list of entities that are eligible for manufacturers to sell drugs at nominal prices and have those sales excluded from best price

- Non-profits (501(c)(3)) or state –owned or operated that provided the same services to the same type of populations as section 340B entities but not funded as such;
- Public or nonprofit entity, or an entity at an institution of higher learning whose primary purpose is to provide health care services to students of that institution that provides family planning services.

Medicaid Drug Rebates

In addition to answering questions about clotting factors, this section summarizes comments on new formulations. However, as mentioned above CMS is not finalizing the proposed definition of a line extension drug. Therefore, manufacturers are to rely on the statutory definition of line extension⁴, and where appropriate, are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug.

CMS did decide to limit the line extension provision to provide that a drug by one manufacturer will not be treated as a line extension of a drug by a different manufacturer, unless there is a corporate relationship between the manufacturers. This will limit the obligation of manufacturers to collect pricing information from unrelated parties. Therefore, the line extension obligations are limited to drugs that are manufactured by the initial brand name listed drug company and any other companies that have a corporate relationship with that manufacturer. CMS decided not to treat authorized generic drugs differently than other drugs when calculating additional rebates if those drugs qualify as line extensions. Manufacturers are responsible for calculating those additional rebates.

The URA for a line extension should be based on the greater of either (1) the standard URA or (2) the alternative URA, where the alternative URA is the product of the line extension AMP and the highest additional rebate for any strength of the original drug.

⁴ Section 1927(c)(2)(C) of the Act -- In this subparagraph, the term “line extension” means, with respect to a drug, a new formulation of the drug, such as an extended release formulation.

The final rule limits the rebate amount provides that, in no case, will the total rebate amount exceed 100 percent of the AMP of the drug.

Rebates for Drugs Dispensed Through Medicaid Managed Care Organizations

Because of data issues and flexibility, CMS did not finalize the provision requiring a Medicaid MCO that contractually provides CODs dispensed to Medicaid beneficiaries to submit a report containing specific data to the states for the state to access the rebates. Instead, states that have participating MCOs, which include CODs in their contracts, must report data pertaining to drugs dispensed through those MCOs separately from the data pertaining to drugs dispensed on a FFS basis in a way that works for the state. However, states will need to have detailed, prescription level information or other mutually agreeable data available for dispute resolution purposes.

340B - CMS noted that question of whether states have the authority to mandate that 340B covered entities carve out their Medicaid MCO drugs from their 340B purchases is beyond the scope of the final rule. It is, however, the states' responsibility to collect utilization data for purposes of the MDR program and to ensure that procedures are in place with their MCOs to exclude drugs subject to 340B discounts to avoid duplicate discounts.

FFS v. MCO - Utilization for MCO reporting should be reported based upon the date dispensed (date of service) within the quarter, as opposed to the claim paid date, since prospective capitation payment has been made to the MCO within that quarter. FFS utilization will continue to be reported based upon the date on which the state paid the claim.

Dispensing Fees - Medicaid MCOs are not required to adopt a pharmacy reimbursement methodology consistent with an AAC standard as provided in this final rule. Rather, as we previously stated in this section, Medicaid managed care organizations are permitted flexibility to reimburse for COD ingredients costs and professional dispensing fees at the levels necessary to achieve adequate access to a network of providers.

Requirements for Manufacturers

This section revises the manufacturer reporting requirements and clarifies that CMS will designate the electronic format in which the product and pricing data is submitted.

Because the OIG is responsible for decisions concerning the imposition of any civil monetary penalties (CMP), CMS did not finalize the language to report manufacturers to OIG and be impose CMPs on a manufacturer that fail to submit and certify a quarterly AMP or monthly AMP and AMP units to CMS for a product by the 30th day after the end of each month. CMS will continue to refer manufacturers to the OIG that do not report their monthly or quarterly AMP data and/or that report their monthly or quarterly AMP data untimely. Furthermore, OIG and CMS are working to identify and penalize noncompliant manufacturers through the CMP process.

A manufacturer can submit a request to revise its pricing data (AMP, best price, customary prompt pay discount, or nominal price) calculations outside of the 12-quarter filing deadline, if the revision request fell within one of the following categories:

1. Change is a result of a drug category change or a market date change;
2. Change is an initial submission for a product;
3. 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;
4. Change is due to a technical correction (such as a keying error), that is, not based on any changes in sales transactions or pricing adjustments from such transactions; or
5. Change is to address specific underpayments to states, or potential liability regarding those underpayments, as required by CMS, applicable law or regulations, or an OIG or Department of Justice investigation.

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. Change in pricing data outside of the 12-quarter rule would be considered if the change is to address specific rebate adjustments to states by manufacturers, as required by CMS or court order, under an internal investigation, or an OIG or DOJ investigation.

CMS received many comments in support of the CMS proposal to allow manufacturers to recalculate base date AMP on a product-by-product basis.

Requirements for States

Adequate Reimbursement to Pharmacies: States have a responsibility to ensure Medicaid pharmacy providers are adequately reimbursed. States are required to consider ingredient cost reimbursement and professional dispensing fee reimbursement when proposing changes to either of those components of the reimbursement for Medicaid covered drugs. States should consider pharmacy costs, including the 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 lists review activities, measurement or mixing of the COD, filling the container, beneficiary counseling, 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.

States must submit the State Plan amendment four quarters after the effective date of the final rule to revise its payment methodology for CODs under this final rule. This includes the incorporation of the 340B requirements described below.

States are required to submit utilization data in a standard reporting format to manufacturers within a 60-day timeframe. However, the statute does not absolve manufacturers of responsibility to provide rebates where states provide such information outside of that 60-day window. CMS did not propose any deadlines for states to submit prior quarter adjustments to manufacturers.

340B - The state shall provide a means for the covered entity to indicate that a drug is subject to the 340B program and not submit a claim for a rebate payment for such drug. States are encouraged to include such language in their MCO contracts so that 340B claims can be identified as to avoid including such claims in their rebate requests to manufacturers. CMS

disagreed with the suggestion to include a 340B identifier on invoices submitted to participating drug manufacturers. (More on 340B state requirements below.)

Drugs: Aggregate upper limits of payment

CMS has replaced “estimated acquisition cost” with “actual acquisition cost.” CMS believe that using AAC to determine the drug ingredient cost is more reflective of actual prices paid by retail pharmacies (or providers for 5i drugs), rather than EAC, which is often based on published compendia pricing, which does not reflect actual prices that pharmacies and providers pay for acquiring drugs.

States should calculate their professional dispensing fees to include those costs which are associated with ensuring that possession of the appropriate COD is transferred to a Medicaid beneficiary. The states retain the flexibility to establish, and if necessary, revise, their professional dispensing fee to ensure that the Medicaid pharmacies, including 340B pharmacies, adequately reimbursed (see above).

Upper limits for multiple source or generic drugs

Methodology -CMS will calculate a Federal upper [reimbursement] limit(s) (FUL) for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, using both innovator multiple source and noninnovator therapeutically and pharmaceutically equivalent multiple source drugs.

CMS will calculate the FUL as an aggregate upper limit at 175 percent of the weighted average of monthly AMPs for A-rated drugs, to use the most recently reported monthly AMPs and AMP units, and to eliminate single source drugs from the FUL calculation, with an exception. In response to comments, CMS conducted an analysis of the National Average Drug Acquisition Cost (NADAC) files, which found that about 40 percent of the individual FUL values calculated using the 175 percent multiplier are lower than the corresponding NADACs each month. FUL is calculated using AMPs which are based on prices paid to manufacturers by retail community pharmacies and wholesalers distributing drugs to retail community pharmacies. The NADAC file, in contrast, is based on a monthly nationwide survey of invoice prices for CODs purchased by retail community pharmacies.

This analysis led CMS to make an exception to FUL calculation at 175% of weighted monthly AMP, except where that amount is less than the average retail community pharmacies' acquisition cost for such drug products as determined by the most current national survey of such costs. In those cases, CMS will establish the FUL using a higher multiplier so that the FUL amount would equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. The higher multiplier will be determined using the most current monthly NADAC pricing file values.

However, states have the discretion to adjust reimbursement on a drug-by-drug basis using pricing benchmarks, such as the NADAC pricing file, or other reliable data, to adjust reimbursement, as long as such payments are consistent with the state plan. Additionally, where

a drug product does not have a FUL calculated for a given time period, the state would reimburse for that drug in accordance with the requirements⁵ and the approved state plan.

CMS plans to publish draft FULs calculated in accordance with this final regulation for two months beginning in January 2016 before finalizing the FULs.⁶ The final FULs will be published in late March 2016 and will be effective on April 1, 2016 to coincide with the effective date of this final rule. States will have up to 30 days from the April 1, 2016 effective date to implement the FULs. Thereafter, the FULs will be updated monthly on the [Medicaid.gov](http://www.Medicaid.gov) website, and will be effective on the first date of the month following the publication of the update. States will, likewise, have up to 30 days after the effective date to implement the FULs. CMS also plans to publish an updated Methodology and Data Elements Guide used to calculate these draft FULs.

5i generic drugs that are not generally dispensed through retail community pharmacies will not be included in the FUL calculations, nor will the FUL apply to 5i generic drugs that are not generally dispensed through retail community pharmacies.

Because drug manufacturers report and certify the same AMP calculated at the NDC-9 level for all package sizes (NDC-11) of that same drug product, CMS will base calculations of the FUL on AMPs at the NDC-9 level.

Calculation Requirements - Therapeutic Equivalent Criteria and Authorized Generic Pricing
Because a FUL must be calculated for each multiple source drug for which the FDA has rated three or more drug products therapeutically and pharmaceutically equivalent, an authorized generic drug, found by the FDA to be therapeutically and pharmaceutically equivalent to the reference listed drug, will also be used in the calculation of the FUL.

Terminated Drugs – To avoid issues with termination dates in the FDA’s Orange Book or manufacturers failing to terminate NDC numbers, CMS will use the data that manufacturers are required to report and certify data regarding the termination date of a product to the CMS MDR program via the DDR system to determine the termination date of the drug product. In the case where there are fewer than three therapeutically and pharmaceutically equivalent drug products for a monthly reporting period, a FUL would not be calculated for that multiple source drug product. Additionally, in the case where a drug product does not have any utilization prior to the drug product’s actual termination date, the drug manufacturer is responsible for reporting the drug product’s AMP, and that drug product’s AMP units would be correctly reported as zero. That drug product will not be considered in determining if three therapeutically equivalent multiple source drugs are available to calculate a FUL.

⁵ Section 1902(a)(30)(A) of the SSA Act - A State plan for medical assistance must ..provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section [1903\(i\)\(4\)](#)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

⁶ On 1/28/2016, CMS updated the [Federal Upper Limits page](#) to add first draft Affordable Care Act FULs calculated in accordance with this rule. <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/federal-upper-limits.html>.

National Availability – To address concerns about national availability and shortages, CMS plans to regularly monitor the availability of drugs by reviewing the FDA drug shortage list for drugs that have a FUL calculated, but are not likely to have enough supply in the market to meet current demand. CMS will not calculate a FUL for a given drug if CMS determines that there is a lack of availability of that drug to retail community pharmacies on a nationwide basis.

State Plan Requirements, Findings, And Assurances

States are required to implement pharmacy reimbursement limits, in the aggregate, as of the effective date of this final rule. However, when a state implements changes to its approved state plan prior to the CMS approval of those changes, and the SPA is subsequently disapproved, the state is responsible for any costs to the federal government of those changes. States may need to revise their Medicaid state plans to accommodate the FULs provisions of this final rule, and have four quarters from the effective date of this rule to submit a SPA to comply.

To the extent that a state is conducting a cost of dispensing study, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider's cost to dispense the drug product to a Medicaid beneficiary. States retain the flexibility to set professional dispensing fees, including creating a differential reimbursement per provider delivery type, using national or regional data from another state and CMS does not require that a state use a specific standard or methodology.

Noting that there may be unique circumstances for 340B covered entities that states should consider when establishing their professional dispensing fees for these providers, states must explain the rationale for the reimbursement methodologies proposed in their state plans. CMS will require states to substantiate how their dispensing fee reimbursement to pharmacy providers, including 340B providers, is consistent with section 1902(a)(30)(A) of the Act. States may decide to use different professional dispensing fee rates for different entities and providers. While CMS does not mandate any specific professional dispensing fee methodologies that states must use, states are required to provide data that indicate that the methodology is consistent with the regulation and ensures access to CODs by beneficiaries.

340B covered entities should be reimbursed for 340B drugs using methodologies consistent with the shift to AAC. CMS would consider a methodology that reimburses at the statutory 340B ceiling price for the ingredient cost component of reimbursement in addition to an adequate professional dispensing fee to be compliant with the AAC payment criteria. If states reimburse 340B providers for the ingredient cost at their actual purchase price, then those providers must be adequately reimbursed a professional dispensing fee that reflects the actual cost to dispense the drug. Specifically, the dispensing fee should not be earmarked as an offset for ingredient cost reimbursements set at AAC. States will be required to submit SPAs detailing how 340B covered entities are reimbursed for their 340B drugs, to the extent their approved state plans do not already include this information, by one year after the effective date of the final rule.

Federal Financial Participation (FFP): Conditions Relating To Physician-Administered Drugs

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