

NCPA Summary of CMS Medicaid Covered Outpatient Drugs “AMP”
Final Rule
Prepared January 2016

The Centers for Medicare & Medicaid Services (CMS) recently issued a 658-page, often-delayed, final rule on the use of Average Manufacturer Price (AMP) to calculate Federal Upper Limits (FULs) in determining reimbursement for generic drugs covered by fee-for-service Medicaid programs. FULs are calculated when there are at least three FDA-approved pharmaceutically and therapeutically equivalent multiple source drug products.

NCPA has been advocating on behalf of our members for over 10 years for a fair and equitable Medicaid pharmacy reimbursement system. We are pleased to offer this summary of the top-line issues in the final rule that will impact independent community pharmacy.

NCPA Advocacy at Work

"The final rule is designed to ensure that pharmacy reimbursement is aligned with the acquisition cost of drugs and that the states pay an appropriate professional dispensing fee," a CMS fact sheet states.

There are several positive provisions in the final rule that NCPA had strongly recommended. They include:

- **National Average Drug Acquisition Cost (NADAC) will serve as a reimbursement "floor"—or that in instances where the FUL is below acquisition cost—NADAC value will be used. CMS cited many of NCPA’s comments to the proposed rule when deciding to make this very significant change.**
- **CMS is requiring states to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes of the reimbursement for Medicaid covered drugs. NCPA has long advocated for a dispensing fee commensurate with a pharmacist’s time and expertise and other related costs.**
- **State Medicaid Agencies without an already established actual acquisition cost reimbursement must submit a SPA with an effective date no later than April 1, 2017, thereby providing a one-year timeframe for compliance. NCPA on multiple occasions requested a one-year implementation delay so states would have time to comply with the final rule.**

What's next for FUL's?

CMS on January 28, 2016, published draft FULs in accordance with the final rule. They will publish drafts for two months then the final FULs will be published in late March 2016 and will be effective on April 1, 2016. States will have up to 30 days to implement the FULs. Thereafter, the FULs will be updated monthly on the Medicaid.gov website, and will be effective on the first date of the month following the publication of the update. NCPA is currently analyzing the FULs.

Background:

Via the Deficit Reduction Act of 2005 (DRA), Congress passed legislation making changes to how FULs were calculated. This legislation drastically reduced the FULs by allowing sales outside the retail class of trade to be included in the definition of AMP. After CMS posted the rule to implement these changes, NCPA and NACDS filed a lawsuit and a federal court issued a temporary injunction to halt CMS' implementation of the drastic cuts, which allowed time for the community pharmacy industry to seek a solution. Fast forward to the Affordable Care Act (ACA), which changed the methodology used to calculate FULs to no less than 175% of the weighted average AMP.

After passage of the ACA in 2010, CMS began posting the newly calculated draft AMP-based FULs in 2011. NCPA submitted numerous comments to CMS outlining our concerns with the draft FULs, due to the fact that more than one third of all products with FULs were lower than independent pharmacy acquisition costs. In April 2012 NCPA submitted detailed comments in regards to the proposed rule CMS published implementing the ACA changes. After urging from NCPA and NACDS, CMS announced they would delay finalizing the draft FULs for state use. In addition, NCPA, NACDS and many Members of Congress on multiple occasions urged CMS to provide a one-year transition period for states to implement changes to be outlined in the final rule.

Determination of Average Manufacturer Price (AMP):

- AMP serves two purposes -- it is used by manufacturers to calculate Medicaid rebates and by CMS to calculate FULs.
- The definition of AMP and the sales included in or excluded from the calculation of AMP affects manufacturers, pharmacy groups, the federal and state governments, and Medicaid beneficiaries.
- Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies are excluded from AMP.
- Customary prompt pay discounts extended to wholesalers are excluded from the calculation of AMP. However, if a manufacturer extends a customary prompt pay discount to a retail community pharmacy that purchases drugs directly from the manufacturer, such discount is included in the determination of AMP.

- Payments received from, and rebates or discounts provided to PBMs are excluded from AMP. However, if a PBM owns an entity that meets the definition of a retail community pharmacy or wholesaler, manufacturer sales to the retail community pharmacy or wholesaler are included in AMP.
- Sales to specialty pharmacies, home health care providers and home infusion pharmacies, to the extent they meet the definition of a retail community pharmacy or the definition of wholesaler, should be included in AMP.
- Beginning with the April 2017 monthly AMP calculation, manufacturers will be required to include AMP-eligible sales in the United States Territories- the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa- in their AMP calculations.
- Sales for 5i drugs that are not generally dispensed through retail community pharmacies are to be used in determination of AMP. This will ensure that an AMP can be calculated and Medicaid rebates can be collected from manufacturers for 5i drugs that are not generally dispensed through retail community pharmacies. However, CMS will not include 5i drugs that are not generally dispensed through retail community pharmacies in the FUL calculations, nor apply the FUL to 5i drugs that are not generally dispensed through retail community pharmacies.
- When determining whether 5i drugs met the threshold for “not generally dispensed” through retail community pharmacies, manufacturers will need to apply the threshold test. That is if 70% or more of the monthly sales of units of a covered outpatient drug at the NDC-9 level are to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies, a manufacturer should use the 5i AMP Methodology to calculate AMP for the month.

Guidelines for Medicaid Reimbursement/Upper Limits of Payment for Drugs:

- Payment to Medicaid pharmacy providers must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access.
- CMS believes the total reimbursement should take into account the pharmacy’s cost to acquire the drug and the pharmacist’s professional services and costs to dispense the drug product to a Medicaid beneficiary.
- CMS believes that AAC will provide states with a more accurate reference price to base ingredient cost reimbursement, as it reflects prices actually paid by providers to acquire drugs.
- State Medicaid programs are required to implement AAC based pharmacy reimbursement methodologies for their fee-for-service Medicaid programs.
- State Medicaid programs must ensure that total pharmacy reimbursement for all multiple source drugs subject to a FUL is below the FUL in the aggregate.
- CMS has specified that pharmacy reimbursement by state Medicaid programs must be, in the aggregate, the lower of AAC coupled with a sufficient professional dispensing fee, or the pharmacy’s usual and customary charge to the general public.
- CMS agrees that states should have flexibility for establishing reimbursement rates, which could include a SMAC program.

- The FUL is designed as an aggregate upper limit. Therefore, states have the discretion to adjust reimbursement on a drug-by-drug basis to the extent that such an adjustment is consistent with the state plan, and may use their SMAC program as a benchmark to do so.
- A state's proposed AAC-based pharmacy reimbursement must consider and address the lower acquisition cost for a covered outpatient drug when a 340B Covered Entity or its contract pharmacy purchased the drug at the 340B price.
- CMS is not requiring that states create a differential reimbursement methodology based on pharmacy type; however, the states retain the option to adjust the reimbursement for provider type or services rendered such as special packaging or delivery.
- CMS will 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 also monitor weekly pricing changes available in the most current national survey of pricing to consider changes to the multiplier used to calculate the FULs, based on average retail community pharmacies' acquisition costs.
- CMS will not calculate a FUL for a given drug if CMS determines there is a lack of availability of that drug to retail community pharmacies on a nationwide basis.
- To the extent that an authorized generic drug or a repackaged drug is rated by the FDA as therapeutically and pharmaceutically equivalent, CMS will include those drugs in the calculation of the FUL.

State Requirements:

- States will have 1 year after the effective date of this final rule (April 1, 2016) to submit a state plan amendment (SPA) which would incorporate the requirements of the final rule.
- Medicaid MCOs are not required to adopt a pharmacy reimbursement methodology consistent with an AAC standard as provided in this final rule. Medicaid managed care organizations are permitted flexibility to reimburse for ingredients costs and professional dispensing fees at the levels necessary to achieve adequate access to a network of providers.
- States retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks, including, but not limited to, a national survey of AACs, a state survey of retail pharmacy providers, or AMP data.
- CMS has provided states with two reimbursement benchmarks that they can use in determining AAC; AMPs, which are reported and certified by drug manufacturers, and NADAC, which is based on a national survey.
- The state may use WAC to develop and support an AAC model of reimbursement.
- States must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either of these components of the reimbursement for Medicaid covered drugs. Further, states must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access.
- CMS is not requiring states to update their professional dispensing fees at specific intervals or frequencies, such as on an annual basis, but they will be required to evaluate each component when they propose changes.

- To the extent that entities have concerns with prices established under a state’s AAC methodology, those concerns should be raised to the state, especially given that states are responsible for setting payment rates and complying with a public notice process when setting those rates.

Definitions:

- **5i drug:** means an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy for purposes of determining AMP. CMS is not finalizing any formal definition of 5i drug but will use the “5i drug” acronym to refer to all inhalation, infusion, instilled, implanted, or injectable drugs when discussing the identification of such drugs.
- **Actual Acquisition Cost (AAC):** means CMS’ 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.
- **Average Manufacturer Price (AMP):** For any covered outpatient drug of a manufacturer, AMP means 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.
- **Best price:** means, for a single source drug or innovator multiple source 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. Any sale to a 340B Covered Entity is excluded from Best Price.
- **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 (including in almost all cases authorized generics).

- **Multiple source drug:** means, for a rebate period, a covered outpatient drug for which there is at least one other drug product which meets the following criteria: (1) Is rated as therapeutically equivalent as reported in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at <http://www.accessdata.fda.gov/scripts/cder/ob/>; (2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; (3) Is sold or marketed in the United States during the rebate period.
- **National Average Drug Acquisition Cost (NADAC):** means a monthly and weekly file of NADAC pricing values that CMS publishes. The NADAC file is based on a monthly voluntary nationwide survey of invoice prices, excluding rebates, for covered outpatient drugs (both brands and generics) purchased by retail community pharmacies.
- **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.
- **Retail Community Pharmacy:** 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. CMS does not believe that a retail community pharmacy must have a "brick and mortar" store front.
- **Wholesaler:** means 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.