Medicaid Covered Outpatient Drugs Final Rule Summary

On January 21, the Federal Register posted the Centers for Medicare & Medicaid Services (CMS) Covered Outpatient Drugs Final Rule (Final Rule), implementing significant changes to pharmacy reimbursement for both brand and generic drugs dispensed to the Medicaid Population.

The purpose of the Final Rule is to implement the changes to the Medicaid Drugs Rebate Program and prescription drug reimbursement system as enacted by the Affordable Care Act (ACA). Below is a summary of the provisions included in the Final Rule that are specific to retail community pharmacies and the reimbursement for prescription drugs dispensed to Medicaid beneficiaries. CMS estimates that the final rule will cut $2.7 billion over 5 years. After the ACA passed Congress, CMS estimated $1.7 billion in reduced government savings over 5 years.

**Highlights:**

- For Medicaid FFS brand product reimbursement, states not paying already on the basis of acquisition costs have 4 calendar quarters for compliance with acquisition payment, filing a SPA no later than June 30, 2017, effective back to April 1, 2017.

- For states paying under Medicaid FFS reimbursement for generic drugs, the FULs apply April 1, 2016 in the aggregate. If states have to change reimbursement to an acquisition basis for generic drugs, they must do so within four calendar quarters and must file SPAs by June 30, 2017 effective back to April 1, 2017.

- CMS will be publishing two draft versions of the AMP-based FULs for stakeholder review and comment. NACDS will be reviewing and analyzing those draft publications and will provide impact analysis at that time.

- The Final Rule creates an exception to the FUL calculation, which allows for the use of a higher multiplier than 175% if the FUL amount established by CMS is lower than the average retail community pharmacies' acquisition cost for such drug product.

- The Final Rule requires states to evaluate all portions of reimbursement, both the ingredient cost reimbursement and the professional dispensing fee reimbursement, when proposing changes to either of these components to ensure that total reimbursement to pharmacy providers is adequate to preserve patient access.

- Lastly, CMS will be accepting comments on the Final Rule. However, that comment period is specific to the definition and identification of line extension drugs.
Below is a detailed summary of the provisions in the Final Rule that impact Medicaid reimbursement to retail community pharmacy. Please note that this summary is presented in the order in which these issues were addressed in the NACDS comments to the 2012 Proposed Rule.

**Replacement of Estimated Acquisition Cost (EAC) with Actual Acquisition Cost (AAC):**

In the Final Rule, CMS finalizes the replacement of EAC as a basis of reimbursement for brand name drugs and some generic drugs. The Final Rule will base reimbursement on AAC, which is defined as the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. The AAC definition in the Final Rule does not mandate that states use a specified formula or methodology to establish their AAC reimbursement.

CMS had not proposed specific requirements regarding state surveys to determine an AAC model of reimbursement. However, CMS agrees with commenters that when states are conducting surveys to establish an AAC model of reimbursement, the process should be transparent, comprehensive, and one that will allow the state to provide adequate reimbursement to Medicaid pharmacy providers. CMS allows states to retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks. These benchmarks include, but are not limited to, National Average Drugs Acquisition Cost (NADAC) files, Average Manufacturer Price (AMP), or surveys such as a state survey of retail pharmacy providers, as they believe that all of these measures are based on actual market prices of drugs. CMS does note that with the use of AMP as a benchmark, states would have to demonstrate that by adjusting AMP, pharmacies would be reimbursed at a price that reflects AAC. In addition, states may also use Wholesale Acquisition Cost (WAC) to develop and support an AAC model of reimbursement if the state can provide data to support a model of reimbursement using the WAC prices consistent with the provisions of the Final Rule.

Although states are allowed to use AAC-based reimbursement for specialty and physician administered drugs, the Final Rule does not require states to do so. Instead, the Final Rule allows states the flexibility to determine a separate reimbursement rate (ingredient cost and dispensing fee) for specialty and physician administered drugs. Lastly, CMS rejects the use of a multiplier or percentage markup to AAC.

CMS acknowledges that the move to AAC is not required by the ACA, however CMS maintains the position that it has the authority to make these changes under section 1902(a)(30)(A) of the Social Security Act. Furthermore, CMS believes that AAC will be more reflective of actual prices paid, as opposed to unreliable published compendia pricing, while continuing to provide sufficient payment to assure beneficiary access.

**Professional Dispensing Fee:**

As states move to cost based reimbursement methodologies, the Final Rule requires states to consider both the ingredient cost reimbursement and the professional dispensing fee when proposing changes to either of these components to ensure that total reimbursement to the pharmacy provider is in accordance with access requirements in the Social Security Act. While
states are not required to conduct their own cost studies, they are required to provide adequate data such as regional data from another state or national survey of retail pharmacy providers, or other reliable data, to support any proposed changes to either or both of the components of the reimbursement methodology.

In the Final Rule, CMS finalizes the renaming of the term “dispensing fee” with “professional dispensing fee.” States are required to calculate their professional dispensing fees to include those costs that are associated with ensuring the appropriate covered outpatient drugs are provided to Medicaid beneficiaries. CMS does not mandate a specific formula or methodology that the state must use when calculating their professional dispensing fees. It allows states to maintain the flexibility to establish and, if necessary, revise the professional dispensing fee to ensure that the Medicaid pharmacy providers are adequately reimbursed.

Finally, with regard to the professional dispensing fee, CMS addressed tiered reimbursement rates and dispensing fees varying by setting. As to the former issue, CMS rejects all suggestions to disapprove SPAs that propose to tier dispensing fees based on pharmacy types. States retain the authority to assess adequate fees for their pharmacies and to decide if tiered fees are appropriate. With respect to the latter issue, CMS does not require states to create a differential reimbursement methodology based upon pharmacy type, but allows the states to adjust dispensing fees based upon provider type or services rendered.

**Definition of Average Manufacturer Price, Retail Community Pharmacy, and Wholesaler:**

**Average Manufacturer Price:** In the Final Rule, CMS finalizes the definition of AMP. Pursuant to the ACA, AMP is defined as 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.

**Retail Community Pharmacy:** In the Proposed Rule, CMS had suggested including in AMP calculations sales to entities such as specialty pharmacies, home infusion pharmacies, and home health care providers. In the Final Rule, CMS does not finalize the proposed provision specifically including sales to include specialty pharmacies, home infusion pharmacies, and home health care providers. However, CMS creates an exceptions qualifier as to when these sales could be included in the manufacturer’s calculation of AMP. In the Final Rule, CMS states that sales to specialty, home health care, or home infusion pharmacies could be included in AMP calculations if the entity does not dispense medications primarily through the mail, and otherwise satisfies the definition of a retail community pharmacy (i.e., the entity 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). Accordingly, in some cases, where a specialty, home health, or infusion pharmacy meets this standard, sales of drugs to them would be included in the AMP calculation.

**Non-Retail Sales Included in AMP for 5i Drugs Not Generally Dispensed via Retail Community Pharmacy:** CMS had proposed to allow manufacturers to include non-retail sales in AMP calculations as limited to inhalation, infusion, instilled, implanted, or injectable (5i) drugs only
when they are not generally dispensed through retail community pharmacies. Under the Proposed Rule, a drug would have been considered as not generally dispensed through a retail community pharmacy when 90 percent or more of unit sales are to entities other than retail community pharmacies. In other words, if 10 percent or more of a manufacturer’s unit sales were to retail community pharmacies, then that drug would be considered generally dispensed through a retail community pharmacy. The Final Rule revises the 90/10 standard to a 70/30 standard. CMS believes that the 70/30 rule will provide for more flexibility, reduce the volatility of AMP, and ensure sufficient sales to be included in AMP while appropriately restricting the inclusion of 5i drugs to those that are not generally dispensed through retail community pharmacies.

CMS also permits manufacturers to make reasonable assumptions and include a smoothing process for monthly sales from the preceding 12-month period to determine if the percent of sales were sufficient to meet the “not generally dispensed” threshold. However, the manufacturer must document those reasonable assumptions and consistently apply them across all products included in the AMP calculation for such 5i drugs.

As for AMPs for 5i drugs being used to calculate FULs, CMS has accepted stakeholder comments and 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.

Excluded Discounts and Fees from AMP Calculations: The Final Rule maintains all of the following exclusions from the calculation of AMP.

- Bona fide service fees, including but not limited to:
  - Distribution service fees,
  - Inventory management fees,
  - Product stocking allowances,
  - Fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs),
- Reimbursement for returned goods and associated costs,
- Transactions with PBMs, MCOs, HMOs, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy, and
- Manufacturer discounts provided in the Medicare Coverage Gap Discount program (section 1860D-14A of the Social Security Act).

Prompt Pay Discounts: CMS rejects stakeholder requests to exclude from AMP customary prompt pay discounts provided to AMP-eligible customers other than wholesalers. While customary prompt pay discounts paid to wholesalers are excluded from standard AMP, they are to be included when paid to retail community pharmacies. In the Final Rule, CMS explains that the statutory exclusion is limited to wholesalers and that the regulatory exclusion must be limited in the same manner. However, the definition of “wholesaler” includes “chain drug warehouses,”
which suggests that prompt pay discounts to chain drug warehouses should be excluded from AMP.

**Definition of Wholesaler:** In the Final Rule, CMS rejects suggestions to require entities to be licensed as wholesalers in order to meet the proposed definition. CMS finalizes the proposed definition of wholesaler, which is defined as “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.”

**Presumed Inclusion:** In the Proposed Rule, CMS had solicited stakeholder comments on the proposed “buildup methodology” in which a manufacturer would only include in its AMP calculation those prices where there is adequate, verifiable documentation showing that the drug was actually distributed to a retail community pharmacy, either directly or indirectly through the wholesaler. In the Final Rule, CMS states that the presumed inclusion approach is “reasonable” and consistent with pharmaceutical practices, and it will not require manufacturers to use a “buildup methodology” to calculate AMP. Rather, manufacturers can rely upon reasonable assumptions consistent with the AMP provisions, and presume in the absence of guidance and documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies.

**When to Calculate a Federal Upper Limit:**

In the Final Rule, CMS finalizes provisions as to when Federal Upper Limits will be calculated. FULs will be calculated for multiple source drugs when there are at least three drug products that are therapeutically and pharmaceutically equivalent and available for purchase by retail community pharmacies on a nationwide basis. The Final Rule also establishes that only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and the limit will only be applied to those equivalent drug products. Relatedly, CMS also agrees with stakeholder comments and concerns that B-rated drug products should not be included in the calculation and application of the FUL.

Based on several stakeholder comments, CMS also addresses concerns regarding the inclusion of single source drugs, authorized generics, terminated products, and nationwide availability and if such products will be included in the calculation of FULs.

**Single Source Drugs:** CMS states that in accordance with 1927(k)(7) of the Social Security Act, single source drugs do not meet the established definition of multiple source drugs and thus will not be included in the FUL calculation.

**Authorized Generics:** CMS finalizes its proposal to maintain the same definition of “authorized generic drug” and to define “primary manufacturer” to mean a manufacturer that holds the New Drug Application (NDA) of the authorized generic drug. The Final Rule also finalizes the
proposal to define “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. Lastly, CMS finalizes its proposal to specify that sales of an authorized generic drug must be included in the primary manufacturer’s computation of AMP under specified circumstances:

- Such drug is sold directly to a wholesaler for drugs distributed to retail community pharmacy; or
- Such drug is sold or licensed to a secondary manufacturer, if the secondary manufacturer is acting as a wholesaler. However, CMS states that sales to secondary manufacturers that relabel or repackage the drug and sell the drug to wholesalers should not be included in the primary manufacturer’s AMP.

Regarding FULs, CMS states that when an authorized generic drug product is found by FDA to be therapeutically and pharmaceutically equivalent to the reference-listed drug product, the authorized generic will be used in the calculation of the FUL.

**Terminated Products:** The Final Rule states that FULs will be calculated using the weighted average of the most recently reported AMPs for A-rated multiple source drugs that are available for purchase by retail community pharmacies on a nationwide basis. The AMP of a terminated drug will not be used to calculate the FUL, beginning with the first day of the month after the termination date reported by the manufacturer. 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. In the case where a drug product does not have any utilization prior to the 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.

**Nationwide Availability:** The ACA was clear in regards that CMS can only calculate a FUL if there are at least three drug products that are therapeutically and pharmaceutically equivalent and available for purchase by retail community pharmacies on a nationwide basis. However, in the Proposed Rule CMS did not address plans or processes to properly define or assess nationwide availability, instead the Proposed Rule assumed that all products are available nationwide and that all retail community pharmacies would be able to purchase at least one of the drug products through a pharmaceutical market channel of distribution. To address stakeholder concerns regarding nationwide availability, in the Final Rule CMS states that for any given month, when there are at least three FDA-approved, therapeutically and pharmaceutically equivalent multiple source drug products reported by their manufacturers with a monthly AMP, and AMP units greater than zero for that given month, that drug would be considered as being available for purchase by retail community pharmacies on a nationwide basis. CMS also stated that it will monitor the FDA shortage list for drugs.
Amount of the Federal Upper Limit

The ACA gives CMS the authority to calculate the FULs at “no less than” 175 percent. Despite this authority to use a higher multiplier, in the Proposed Rule, CMS had not included a process for determining when a higher multiplier would be used when calculating the FULs. In response to stakeholder comments and concerns, the Final Rule creates an exception to the FUL calculation, which allows for the use of a higher multiplier than 175 percent if the established FUL amount is lower than the average retail community pharmacies’ acquisition cost for such drug product. CMS also states that they believe that this process will address any concerns in fluctuations in FUL amounts as a result of situations like shortages or drug termination issues.

Smoothing: CMS had proposed for manufacturers to use a 12-month rolling percentage to estimate the lagged price concessions in their calculations of AMPs. While CMS had not proposed any additional smoothing methodologies, the agency solicited stakeholder comments on smoothing. In response, NACDS urged CMS to also adopt a 12-month rolling average to determine the FULs as a mechanism to reduce the variability in the FULs from month-to-month and provide greater predictability for pharmacy providers. In addition, NACDS urged CMS to develop additional processes to protect against disruptions in the supply chain, such as drug shortages, that could affect FUL calculations. In response to these requests, CMS states that smoothing pricing data may prevent some month-to-month fluctuations in the FULs, but implementing any smoothing methods would have limitations. Therefore CMS will not be applying a specific methodology to smooth the FULs at the time of the Final Rule.

Rule Effective Date and State Compliance Date:

The Final Rule is effective April 1, 2016. However, CMS acknowledges that states must take several time consuming steps, including legislative and regulatory changes, and are required to submit state plan amendments to fully implement the requirements included in the Final Rule.

For Medicaid FFS brand product reimbursement, states not paying already on the basis of acquisition costs have 4 calendar quarters for compliance with acquisition payment, filing a SPA no later than June 30, 2017, effective back to April 1, 2017.

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