ML STRATEGIES

Deciphering the Final AMP Rule – Key Provisions Impacting Pharmacies, PBMs, and Manufacturers

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In late January, the Centers for Medicare & Medicaid Services ("CMS") released the much anticipated Covered Outpatient Drugs Final Rule with Comment (the "**AMP Final Rule**"). The rule creates the regulatory definition for Average Manufacturer Price ("AMP") and further refines how pharmaceutical manufacturers must calculate Medicaid drug rebates in the wake of the Affordable Care Act ("ACA") and recent health care reform measures. The AMP Final Rule is effective April 1, 2016 and requires prospective compliance, although a limited number of provisions have been delayed until April 2017. Given this compliance date, manufacturers, states, and pharmacies have a limited amount of time to fully analyze and implement the provisions of the rule.

This advisory focuses on four key provisions of the AMP Final Rule that are likely to significantly impact pharmacies, pharmacy benefit managers, and manufacturers: (i) the definition of bona fide service fees; (ii) the definition of bundled sales; (iii) the definition of retail community pharmacy; and (iv) the change in Medicaid reimbursement to reimbursement based on Actual Acquisition Cost ("AAC").

The Long Road to the Final AMP Rule

AMP is used to calculate a manufacturer's Medicaid rebate. AMP was first passed into law as part of the Deficit Reduction Act of 2005. CMS's first effort to create implementing regulations for the law was immediately challenged in court by the National Community Pharmacists Association ("NCPA") and enjoined. The statute was then further refined in reaction to the court ruling and NCPA pressure in the Affordable Care Act. Now, almost 11 years after Congress sought to move Medicaid away from the average wholesale price regime, CMS has once again issued implementing regulations.

Bona Fide Service Fees

One question that arises in calculating AMP and a drug's best price is how to account for fees that manufacturers pay to wholesalers and other purchasers. The ACA provides that a drug's AMP calculation should not take into account certain types of fees, including "bona fide service fees," as well as other payments made by manufacturers to purchasers (e.g., reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods). Examples of bona fide service fees include 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.)

There has been significant controversy and inconsistent price reporting treatment of service fees by manufacturers. Some manufacturers historically accounted for administrative service fees as "bona fide service fees" excluded from AMP, while others accounted for these fees as "discounts" included in AMP. The controversy erupted into the **Streck litigation** that remains pending in Philadelphia federal court. While a lower AMP may reduce a manufacturer's Medicaid rebate, it also often reduces the reported Average Sales Price and other reported price metrics, creating a mixed bag of conflicting financial incentives. It is likely the case that higher reported AMP prices increase a manufacturer's rebate, so CMS was inclined to favor a definition that required manufacturers to treat these price concessions as fees, not discounts.

CMS's definition of bona fide services has a long and tortured history **which we discussed here** in the context of the 2012 Proposed Rule. One recurring issue has been the scope of the definition – specifically, whether bona fide service fees include fees paid to any type of entity or whether they apply only to a narrow subset of entities. In its 2012 Proposed Rule, CMS took the latter approach by defining bona fide services as only fees paid "by a manufacturer to a wholesaler or retail community pharmacy." CMS received numerous comments on this limited definition. In the AMP Final Rule, CMS reverses course and broadens the definition to include fees paid to "an entity." In making this change, CMS notes that it does not believe Congress intended to limit the definition of bona fide services fees to only wholesalers and retail community pharmacies.

The AMP Final Rule also addresses the four-part test used to determine if a fee is a bona fide service fee. CMS first introduced this four-part test in a 2007 **final rule** promulgated in response to the Deficit Reduction Act of 2005. Under the four-part test, a fee is a bona fide service if the fee:

1. represents fair market value;
2. for a bona fide, itemized service actually performed on behalf of the manufacturer;
3. that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and
4. that is not passed on in whole or in part to a client or customer of an entity.

In the AMP Final Rule, CMS changes its policy regarding how manufacturers should determine whether a fee is "passed on" under the fourth prong of the test. This policy change is accomplished by CMS's adoption of an existing policy that applies to the calculation of Average Sales Price ("ASP"). When calculating ASP, manufacturers are allowed to presume, in the absence of evidence or notice to the contrary, that the fee paid is not passed on. CMS has now adopted this approach in the AMP context. Therefore, if a manufacturer has determined that a fee paid meets the other elements of the definition of bona fide service fee, then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.

The AMP Final Rule does not, however, provide any further guidance about which specific services are considered bona fide service fees. CMS also declined to provide substantive guidance on how to calculate the fair market value of a bona fide service fee. CMS did, however, state that any documentation can be used to demonstrate fair market value as long as the documentation clarifies the methodologies or factors the manufacturer used in making its fair market value determination and the manufacturer maintains adequate documentation supporting its determination.

The net result of the lack of CMS guidance may be yet another windfall to the consulting industry as manufacturers retain experts to advise them concerning the 'fair market value' of various wholesaler services that historically were performed at no charge. This calculation of fair market value is an artificial exercise that is the product of a regulatory system, not an actual matter of economics or financial accounting, as wholesalers historically treated the administrative service fees received from manufacturers as discounts, not fees.

Bundled Services

When calculating AMP, manufacturers must take into account the discounts they provide in a "bundled sale." Bundled sales are sales where the rebate, discount or price concession is "conditioned" upon additional purchase requirements. In its proposed rule, CMS sought to revise the bundled sale definition by adding the following underlined text:

> **The discounts in a bundled sale, <u>including but not limited to those discounts resulting from a contingent arrangement,</u> are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement.**

CMS decided against finalizing the proposed language. The decision came in response to numerous commenters who expressed concern that the proposed language would require manufacturers to allocate non-contingent discounts provided on drugs included in the bundle sale (as well as any contingent discounts on those drugs) across all products in the bundled sale. CMS explains in the commentary to the Final AMP Rule that its proposed language was not intended to revise its policy of allocating the value of the discounts across only the products within the bundled arrangement. CMS further clarifies this issue by providing that when a manufacturer offers discounts on multiple products under a single contract (for example, to minimize the administrative burden of developing several single contracts which offer separate discounts on the multiple products) no bundled sale exists if the following conditions are satisfied:

1. a discount or price concession is established independently for each product within the contract;
2. the purchase price under the contract is not contingent upon any other product in the contract or upon some other performance requirement (such as the achievement of market share or inclusion or tier placement on a formulary); and
3. the discount provided for any product under the contract is no greater than if the product was purchased outside of the contract.

The AMP Final Rule also revises the definition of "bundled sale" by substituting the word "product" instead of "drugs." CMS explains that bundled arrangements can include covered-outpatient drugs (CODs) as well as other product purchases as part of the bundled sale requirement. The substitution therefore clarifies that a discount on drug purchases that is contingent upon sales of non-drug products is considered a bundled sale.

Retail Community Pharmacy

The definition of retail community pharmacy is critical in determining how to calculate AMP, as AMP is defined as the average price paid by (i) wholesalers for drugs distributed to *retail community pharmacies*; and (ii) *retail community pharmacies* for drugs purchased directly from the manufacturer. A key issue with this definition is the extent to which specialty pharmacies, home infusion pharmacies, and home health care providers are considered retail community pharmacies.

CMS finalizes its definition of a retail community pharmacy to mean 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. It excludes from this definition: pharmacies that dispense 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.

In the proposed rule, however, CMS sought comments on a proposal that would include "entities that conduct business as a wholesaler or retail community pharmacy," in the definition of retail community pharmacy. CMS's intent was to specifically capture specialty and home infusion pharmacies and home healthcare providers, and it indicated in the proposed rule that this proposed addition is consistent with the statutory language.

CMS did not finalize this proposal, stating that these entities fall within the existing definition so the expansion is not required. CMS's decision not to expand the definition could be seen as backing away from the requirement that all specialty pharmacies, home infusion pharmacies, and home health care providers be included in the definition of "retail community pharmacies." Under the finalized definition, a pharmacy is only considered to fall into this group to the extent that it is an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that dispenses medications to the general public at retail prices and is not otherwise excluded from the definition.

Medicaid Reimbursement Based on Actual Acquisition Cost ("AAC")

One of the AMP Final Rule provisions that could have a significant impact on pharmacies is CMS's requirement that state Medicaid programs reimburse pharmacies based on AAC rather than Estimated Acquisition Cost ("EAC"). EAC is the state' best estimate of the prices generally and currently paid by providers for a drug. Reimbursement based on EAC generally relies on Average Wholesale Price ("AWP") or Wholesale Acquisition Price ("WAC"). Citing OIG reports issued in the early 2000s, CMS indicates that AWP-reimbursement is flawed, potentially resulting in increased reimbursement for covered outpatient drugs. Controversy concerning reported AWP prices resulted in more than a decade of litigation, some of which incredibly is still winding its way through state court systems.

CMS defines AAC as the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. In determining AAC, states retain flexibility on the appropriate method and can establish AAC based on several benchmarks including NADAC files, AMP, surveys, or even WAC so long as the state can provide data to support a model of reimbursement using WAC prices that is consistent with §447.512(b).

As of the end of 2015, only a handful of states, including Alabama, Colorado, Idaho, Iowa, Louisiana, and Oregon, include AAC as a component in determining ingredient cost. Another subset of states, including Alaska, Delaware, and Nevada, rely on the NADAC files, which would qualify as AAC under CMS's definition (data based on **Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State**). Therefore, the vast majority of states will need to undergo State Plan Amendments ("SPAs") to convert their current methodology to one based on AAC. These states have until April 1, 2017 to submit and acquire approval from CMS for the SPA.

The transition from AWP to AAC has not always been easy or smooth for states. As we previously **blogged**, in July 2014, Mississippi attempted to replace its AWP methodology to one based on AAC, resulting in a revolt by Mississippi pharmacies. Mississippi reverted back to AWP pricing after less than 8 weeks.

As evidenced by Mississippi's experience and as noted by commenters, the transition to AAC could impact pharmacies' decisions to participate in Medicaid. CMS downplays this concern, responding that it has no reason to believe that pharmacies will leave the Medicaid program or that patient care will suffer given that several states are already using AAC-based methodologies. However, if Mississippi's experience is any indicator, states are going to have to balance network adequacy concerns in implementing this change.

It is also important to note that states using AAC-based methodologies have dispensing fees that are two to five times higher than those of states with ingredient cost methodologies based on AWP or WAC (compare e.g., AAC-based states: Iowa (dispensing fee of $11.73) and Alabama ($10.64) to non-AAC states: Ohio ($1.80) and Missouri ($4.09)). Several commenters noted that AAC-based ingredient costs methodologies will require states to increase dispensing fees. In response to these and other concerns on the dispensing fee, CMS:

- Finalizes the replacement of the term "dispensing fee" with "professional dispensing fee" to reinforce its position that the dispensing fees should reflect the pharmacist's professional services and costs

associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary.
- Reiterates that states must meet the requirement at 1902(a)(30)(A) of the Social Security Act and ensure that reimbursement is consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access.
- Requires that states consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either or both of these components.

As a result, as the majority of states move to AAC-based ingredient cost methodologies, they will be forced to consider and examine their professional dispensing fees in light of the AAC reimbursement levels. It is likely that we will see professional dispensing fees increase in these states moving to AAC-based methodologies. Here, again, the big winner is likely to be consultants, as many states will hire consultants to conduct new cost of dispensing studies.

The final rule also clarified that the requirement that reimbursement be based off of AAC is limited to Medicaid fee-for-service and is not required for Medicaid managed care organizations. Medicaid managed care organizations retain the flexibility to reimburse drugs' ingredients costs and professional dispensing fees "at the levels necessary to achieve adequate access to a network of providers."

Authors

Theresa Carnegie

Theresa C. Carnegie is a Mintz attorney who advises health care clients on a wide array of transactional, regulatory, compliance, fraud and abuse matters, and health law issues. She counsels health plans, pharmacy benefit managers, pharmacies, device manufacturers, and distributors.

Ellyn Sternfield

Ellyn L. Sternfield is a Mintz Special Counsel with an extensive background in government health care enforcement. She provides insight to clients with compliance concerns and helps clients facing potential state or federal investigations.

Jordan Cohen

Lauren Moldawer