The Final AMP Rule: An Overview for Stakeholders

On January 21, 2016, the Centers for Medicare & Medicaid Services (CMS) released the long-awaited Final Rule implementing changes to the Medicaid Drug Rebate Program (MDRP) under the Affordable Care Act (ACA). Among other things, the Final AMP Rule addresses changes to the Average Manufacturer Price (AMP) calculation submitted by pharmaceutical manufacturers participating in the MDRP to CMS on a monthly basis, implements the AMP-based Federal Upper Limit (FUL) on reimbursement by state Medicaid programs for multiple source drugs mandated by ACA, and requires state Medicaid programs to implement Actual Acquisition Cost (AAC)-based pharmacy reimbursement methodologies.

The Final AMP Rule will be published in the Federal Register February 1, 2016, and is effective April 1, 2016. As such, pharmaceutical manufacturers must revise their AMP methodologies to comply with the Final AMP Rule beginning with the monthly April 2016 calculation, except that manufacturers will have until April 1, 2017, to include 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 and Best Price determinations. State Medicaid programs have until June 30, 2017, to submit State Plan Amendments to CMS, to be effective April 1, 2017, implementing AAC-based pharmacy reimbursement methodologies consistent with the Final AMP Rule.

The following is an overview of key provisions of the Final AMP Rule that are relevant to pharmaceutical manufacturers, wholesalers, pharmacies and other stakeholders. Topics include:

- Line Extension Definition Remains Open for Comments
- Categorizing Single Source, Innovator Multiple Source and Noninnovator Multiple Source Drugs
- Calculating AMP
- Determining Best Price
- Assessing Bona Fide Service Fees
- Restating Base Date AMP
- Restating AMP, Best Price, Nominal Sales and Customary Prompt Pay Discounts Beyond 12 Quarters
- Implementation of AMP-Based FULs: An Aggregate Upper Limit on Pharmacy Reimbursement under State Fee-for-Service Medicaid Programs
- Mandatory Actual Acquisition Cost-Based Pharmacy Reimbursement for State Fee-for-Service Medicaid Programs
- Extension of MDRP to the Territories
- MDRP Rebates on Medicaid Managed Care Utilization
**Line Extension Definition Remains Open for Comments**

ACA prescribed that the rebate due from pharmaceutical manufacturers on drugs that are line extensions (e.g., a new formulation of a drug such as an extended-release formulation) of a single source drug or an innovator multiple source drug that is an oral solid dosage form be the higher of the rebate computed under the MDRP statute and applicable implementing regulations, or the product of: (1) the AMP of the line extension plus the highest additional rebate, calculated as a percentage of AMP, for any strength of the original single source drug or innovator multiple source drug, and (2) the total number of units of each dosage form and strength of the line extension product paid for by a state during the rebate period. CMS had proposed the following as a definition of “line extension”—a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the Food and Drug Administration (FDA) as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as a new ester, new salt or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication of an already marketed drug.

In the Final AMP Rule, CMS elected not to finalize its proposed definition. Instead, it has sought additional comments as to how to identify and define a line extension drug. Comments on this issue are due April 1, 2016.

CMS did limit the line extension provision and the higher rebate on line extension drugs prescribed by ACA only to new formulations of a drug when both the original brand name drug and the line extension drugs are manufactured by the same manufacturer or a second manufacturer with a corporate relationship to the first manufacturer. As such, a drug manufactured 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. In addition, if the initial brand name drug is not active in the MDRP because the drug is no longer sold on the market or otherwise, no alternative unit rebate amount calculation is required for the line extension product.

CMS is currently drafting system requirements for the line extension provision and expects to issue guidance to manufacturers regarding the reporting of rebate information for line extension drugs in the future. CMS also anticipates publishing additional guidance for the states regarding the reconciliation and reporting of unit rebate offset amounts related to line extension products.

**Categorizing Single Source, Innovator Multiple Source and Noninnovator Multiple Source Drugs**

Characterization of a Covered Outpatient Drug as a Single Source, Innovator Multiple Source or Noninnovator Multiple Source Drug is of critical importance under the MDRP, as the statutorily-prescribed rebates on Single Source and Innovator Multiple Source Drugs are higher than the rebates on Noninnovator Multiple Source Drugs. Specifically, the rebate for Single Source and Innovator Multiple Source Drugs is the greater of (1) 23.1% of AMP or (2) the difference between AMP and Best Price, while the rebate for Noninnovator Multiple Source Drugs is 13% of AMP.

In the proposed AMP Rule published on February 2, 2012, CMS proposed specifying in regulatory definitions that any drug approved by the FDA under a New Drug Application...
(NDA) was a Single Source or Innovator Multiple Source Drug. This raised grave concerns from manufacturers of seemingly generic products that were approved under a NDA prior to passage of the Hatch Waxman Act in 1984, which created the Abbreviated New Drug Application (ANDA) approval process, that such products would be re-categorized as Single Source or Innovator Multiple Source Drugs, thereby resulting in higher rebate liability under the MDRP on such products. In addition, many manufacturers and other stakeholders believed that the CMS interpretation was counter to that in the MDRP statute, which defines Single Source and Innovator Multiple Source Drugs by reference to approval under an “original NDA.”

While CMS has finalized its proposed regulatory definitions of Single Source, Innovator Multiple Source and Noninnovator Multiple Source Drugs by defining an “original NDA” as a NDA other than a ANDA, it has also created a narrow exception process to address certain circumstances when a drug approved under a NDA should be classified as a Noninnovator Multiple Source Drug, such as certain products approved under a paper NDA prior to the passage of the Hatch Waxman Act in 1984. Manufacturers are to classify a drug as a Single Source or Innovator Multiple Source Drug for purposes of the MDRP if approved under a NDA when adding a product to Medicaid Drug Data Reporting system after the effective date of the Final AMP Rule. If a manufacturer believes that a drug marketed under a NDA qualifies for the narrow exception because it was approved under a paper NDA prior to 1984 or approved under a Federal Food Drug and Cosmetics Act Section 505(b)(2) literature review after 1984, the manufacturer should submit materials to CMS demonstrating the basis of how the drug might qualify for the narrow exception and permit reclassification as a Noninnovator Multiple Source Drug or state that the exception does not apply.

For manufacturers with drugs currently classified as Noninnovator Multiple Source Drugs even though approved by the FDA under a NDA, the manufacturers have four quarters from the effective date of the Final AMP Rule—by the end of second quarter 2017—to apply to CMS for an exception that a drug approved under a NDA be classified as a Single Source or Innovator Multiple Source Drug.

**Calculating AMP**

**Manufacturers May Use a Build-Up or Presumed Inclusion Approach**

ACA revised the definition of AMP to include only net sales to wholesalers and retail community pharmacies (an AMP calculation under this approach is referred to herein as calculated under the “RCP AMP Methodology”). Shortly thereafter, Congress prescribed an alternative AMP methodology for injected, infused, inhaled, implanted or instilled drugs that are not generally dispensed through retail community pharmacies (5i Drugs) (an AMP calculation under this approach is referred to herein as calculated under the “5i AMP Methodology”).

CMS originally proposed mandating a build-up approach in calculating AMP under the RCP AMP Methodology. Under such an approach, pharmaceutical manufacturers would only include sales that they knew for certain went to retail community pharmacies directly or indirectly through wholesalers. After receiving a myriad of comments from various stakeholders as to the operational challenges and limitations of such an approach, CMS did
not finalize such proposal. As such, pharmaceutical manufacturers may calculate AMP using either a build-up approach or a presumed inclusion approach—whereby all direct sales to retail community pharmacies and all sales to wholesalers that are not identified as going to customers other than retail community pharmacies are included in AMP.

**Definition of Retail Community Pharmacy**

ACA defined a “retail community pharmacy” as an independent, chain, supermarket or mass merchandiser pharmacy that dispenses medications to the general public at retail prices. ACA specifically excluded from the definition of “retail community pharmacy” 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.

CMS had proposed including specialty pharmacies, home infusion pharmacies and home health providers/pharmacies in the regulatory definition of “retail community pharmacy.” In the Final AMP Rule, CMS did not include specialty pharmacies, home infusion pharmacies and home health providers/pharmacies in the definition of “retail community pharmacy.” CMS noted that sales to specialty pharmacies, home infusion pharmacies and home health providers/pharmacies should be included in AMP calculated under the RCP AMP Methodology to the extent any such pharmacies actually meet the statutory definition of “retail community pharmacy” as defined in section 1927(k)(10) of the Social Security Act. CMS went on to state that if a specialty pharmacy, home infusion pharmacy or home health care pharmacy does not dispense medications to the general public or provides medications to patients primarily through the mail, sales to such entities would be excluded from AMP calculated under the RCP AMP Methodology.

**Transfer Price of an Authorized Generic Generally Won’t Be Included in AMP**

Regardless of whether the RCP AMP or 5i AMP Methodology is utilized to calculate AMP for a product, the transfer price for the sale of an authorized generic from a primary manufacturer to a secondary manufacturer is unlikely to be included in the primary manufacturer’s AMP for the branded product. In the Final AMP Rule, CMS specifies that the transfer price of an authorized generic should only be included in the AMP for the branded product calculated by the primary manufacturer when the secondary manufacturer is “acting as a wholesaler.” The definition of “wholesaler” under the Final AMP Rule is focused on the wholesale distribution of drugs to retail community pharmacies. CMS specifically states that if the secondary manufacturer repackages and relabels the drug and subsequently sells it wholesale, the price of the drug paid by the secondary manufacturer to the primary manufacturer would not be included in the primary manufacturer’s AMP for the branded product.

**Smoothing Lagged Price Concessions and Ineligible Indirect Sales**

Under the Final AMP Rule, manufacturers are required to smooth AMP-eligible lagged price concessions in their AMP calculations, regardless of whether AMP is calculated under the RCP AMP or 5i AMP Methodology. Lagged price concessions must be smoothed at the National Drug Code (NDC)-9 level using a 12-month rolling average. CMS included an example of a smoothing calculation in the Final AMP Rule, which illustrates the same smoothing methodology mandated for use with lagged price concessions in the Average Sales Price calculation under the Medicare Part B program.
CMS declined to specify if lagged price concessions should be based on the date such concessions are earned or the date they are paid. A manufacturer has the flexibility to include lagged price concession based on either the earned date or paid date, provided the manufacturer uses one methodology uniformly.

In addition, CMS specifies that manufacturers may, but are not required to, smooth ineligible indirect sales in a manner similar to lagged price concessions.

**5i AMP Methodology**

In the Final AMP Rule, CMS chose not to further define a 5i Drug in regulation, relying solely on the statutory reference to injected, infused, inhaled, implanted or instilled drugs that are not generally dispensed through retail community pharmacies. In the Proposed AMP Rule, CMS suggested that the FDA Structured Product Labeling Routes of Administration be used to identify 5i Drugs, but CMS abandoned this approach in the Final AMP Rule. Per CMS, manufacturers may use a myriad of resources to identify 5i Drugs, including prescribing information, drug package inserts, and the FDA Structured Product Labeling Routes of Administration.

To determine whether a 5i Drug is generally dispensed through retail community pharmacies, CMS has finalized a 70/30 test, modified down from a 90/10 standard originally proposed by CMS. As such, 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. CMS has prescribed that manufacturers apply the 70/30 test monthly, but notes that manufacturers may, but are not required, to use a smoothing process over the course of a 12-month period to curb oscillating between the RCP and 5i AMP methodologies on a monthly basis.

In the Final AMP Rule, CMS clarifies that sales to entities that purchase off the Federal Supply Schedule, sales to 340B Covered Entities, sales outside the United States, sales to charitable and not-for-profit and Bona Fide Service Fees paid by a pharmaceutical manufacturer to any AMP-eligible customer are excluded from AMP when the 5i AMP Methodology is used. Such exclusions are consistent with the AMP calculation under the RCP AMP Methodology and a manufacturer’s Best Price determination for a Single Source or Innovator multiple source drug. Also excluded from the AMP calculation under the 5i AMP Methodology are direct sales to patients and sales to prisons.

CMS specifies that when the 5i AMP Methodology is used to calculate AMP, the calculation includes all sales of a product to entities other than retail community pharmacies and sales to wholesalers when for distribution to entities other than retail community pharmacies. Payments by, and discounts or rebates provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers and any other entity that does not conduct business as a wholesaler or a retail community pharmacy are included in AMP calculated under the 5i AMP Methodology.

CMS states affirmatively in the Final AMP Rule that every covered outpatient drug may have only one base date AMP. Base date AMP is used in the calculation of the additional discount on Single Source and Innovator Multiple Source Drugs under the MDRP if the AMP of those drugs increases faster than the rate of inflation based upon the consumer price index (CPI-U) compared to the Base date AMP. Under the Bipartisan Budget Act of 2015, such additional
discount will also be applicable to Noninnovator Multiple Source Drugs beginning in first quarter 2017. As such, even if the AMP calculation methodology for a 5i Drug oscillates between the RCP and the 5i AMP Methodology, the drug may have only one base date AMP. According to CMS, this is a statutory constraint, as the MDRP statute does not contemplate the calculation of two base date AMPs for the same product.

As to the calculation of quarterly AMP for a 5i Drug, CMS states that a manufacturer is to calculate quarterly AMP by summing the three monthly AMPs in the quarter, irrespective of methodology used to calculate AMP in any given month.

CMS expects to issue additional operational guidance to provide instructions and clarifications to manufacturers regarding the calculation of monthly AMPs for 5i Drugs under the 5i AMP Methodology.

**Inclusion of AMP-Eligible Sales in the Territories**

As noted above, beginning with the April 2017 monthly AMP calculation, pharmaceutical 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.

**Ignore TRICARE Retail Program Refunds**

In the Final AMP Rule, CMS clarifies that products dispensed to TRICARE beneficiaries by retail community pharmacies should be included in AMP when calculated under the RCP AMP Methodology and that manufacturers should ignore refunds paid under the TRICARE Retail Refund Program for purposes of the AMP calculation.

**Blending Two Products Into AMP**

In the Final AMP Rule, CMS addresses when it is appropriate to blend utilization of two different NDCs into one AMP calculation. CMS states that “[w]hen a single manufacturer is selling two versions of a product under the same NDA, section 1927(k)(1)(C) of the [Social Security] Act provides that the AMP be inclusive of the authorized generic product when the manufacturers sells the product to a wholesaler who distributes to the retail community pharmacies.” As such, if the same manufacturer sells two versions of the same product—such as a brand and an authorized generic—there should be one blended AMP for both products, even if sold under two different NDCs.

**Non-5i Drugs Not Generally Dispensed at Retail Community Pharmacies**

In comments to the Proposed AMP Rule, numerous stakeholders highlighted that there are oral drug products that are not generally dispensed at retail community pharmacies, such as tablets that are sold pursuant to a FDA Risk Evaluation and Mitigation Strategy (REMS) and have limited distribution through a few select specialty pharmacies. Such drugs are not 5i Drugs, since they are oral tablets or pills, and, therefore, would not qualify for the 5i AMP Methodology, but they have little, if any, distribution through retail community pharmacies. CMS did not address an alternative AMP methodology for such drugs. Rather, it appears CMS is mandating calculation of AMP for such drugs under the RCP AMP Methodology. Specifically, CMS notes that as it is permitting a presumed inclusions approach to calculating AMP, and since manufacturers can make reasonable assumptions in their AMP calculations, it is confident that there will be AMPs for oral drugs that are not generally dispensed by retail...
community pharmacies. CMS indicated that it will continue to consider this issue and will provide additional guidance or rulemaking if needed.

**Determining Best Price**

Generally, CMS did not make many changes to current methodology for determining the quarterly Best Price for Single Source and Innovator Multiple Source Drugs. In several instances, CMS finalized proposals to ensure methodological consistency between the AMP calculation and Best Price determination. Specifically, CMS finalized regulations excluding manufacturer co-payment assistance programs, manufacturer-sponsored patient refund/rebate programs, and manufacturer vouchers, whereby all of the benefits flow directly to patients and there are no concessions to retail community pharmacies or other entities, from Best Price. In addition, CMS finalized regulations excluding reimbursement by a manufacturer for recalled, damaged, expired or otherwise unsalable returned goods from Best Price. CMS also finalized regulations excluding sales outside the United States from Best Price. Direct patient sales are also excluded from a manufacturer’s Best Price determination, except when a contingent free good is linked to a patient sale. In such an event, that resulting direct to patient sale is no longer excluded from a manufacturer’s determination of Best Price.

In the Proposed AMP Rule, CMS proposed shrinking the Best Price exception related to sales to 340B Covered Entities. Under the MDRP statute and existing regulations, any sale to a 340B Covered Entity is excluded from Best Price, including sales of covered outpatient drugs to disproportionate share hospitals for inpatient use. CMS proposed that only sales to 340B Covered Entities under the 340B program would be excluded from Best Price. Numerous stakeholders commented that such an interpretation of the 340B sale exclusion in regulation would be contrary to the same exclusion contained in the MDRP statute. In the Final AMP Rule, CMS agreed, noting that “as long as the entity meets the definition of a ‘covered entity’ any prices charged by manufacturers and paid for by covered entities shall be excluded from best price.” As such, the scope of the Best Price exclusion for sales to 340B Covered Entities remains intact and any sale to a 340B Covered Entity is excluded from Best Price.

In the preamble to the Final AMP Rule, CMS makes a curious statement regarding when discounts or rebates should be accumulated when determining Best Price. Specifically, CMS states that “if a manufacturer offers multiple price concessions to two entities for the same drug transaction, such as rebates to a PBM where the rebates are designed to adjust price at the retail or provider level and discounts to a retail community pharmacy’s final drug price, all discounts related to that transaction which adjust the price available from the manufacturer should be considered in the manufacturer’s final price of that drug when determining the best price to be reported for the drug.” Best Price is defined as the lowest price paid for a covered outpatient drug by any entity in the United States in any pricing structure, except those statutorily excluded. As such, it is unclear from CMS’ discussion in the preamble to the Final AMP Rule whether it is suggesting that, at times, it may be appropriate to accumulate concessions paid to two different entities when determining Best Price.

Given the increasing prevalence of value based purchasing arrangements, CMS indicated in the preamble to the Final AMP Rule that it is considering providing guidance specific to such arrangements and their potential impact on Best Price in the future.
**Inclusion of Best Price-Eligible Sales in the Territories**

As noted above, beginning with the Best Price determination for second quarter 2017, pharmaceutical manufacturers will be required to consider sales in United States Territories— the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa—in their Best Price determinations for Single Source and Innovator multiple source drugs.

**Best Price for Authorized Generics**

In the preamble to the Final AMP Rule, CMS confirmed the existing requirement that the manufacturer of a branded product consider the transfer price of an authorized generic sold to a secondary manufacturer in the Best Price determination for the branded product of the primary manufacturer. CMS went on to note that the secondary manufacturer must report AMP and Best Price for the authorized generic and pay MDRP rebates based on utilization of the authorized generic by Medicaid beneficiaries.

On a similar note, CMS expressed in the preamble to the Final AMP Rule that in the case where the primary and secondary manufacturer “are the same company, selling two versions of the drug marketed under the same NDA, both manufacturers are responsible for determining a best price based on the lowest price available from the manufacturers for the sales of both versions of the drugs sold. In other words, we do not believe the manufacturers in this example should determine a separate best price for each NDC simply because the two manufacturers of same company identify the same drug using different NDCs.” CMS does not indicate whether affiliated entities could constitute the “same company” in the example set forth above. CMS specifically declines to discuss corporate ownership arrangements or define arrangements in the context of authorized generic sales and notes that manufacturers may make reasonable assumptions.

**Assessing Bona Fide Service Fees**

ACA excluded bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including but not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (e.g. medication compliance programs and patient education programs) from the calculation of AMP. However, existing CMS regulation excludes all bona fide service fees to any entity from the determination of Best Price. CMS prescribes the following four part test for determining if a fee is bona fide and, therefore, excluded from Best Price: any fees paid by a manufacturer to an entity (1) that represent fair market value; (2) for bona fide, itemized services 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 are 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.

In the Proposed AMP Rule, CMS proposed utilizing the existing four part test for assessing whether a fee is bona fide for the Best Price determination in AMP as well. However, CMS limited the application of the test only to administrative fees paid to retail community pharmacies and wholesalers. In the Final AMP Rule, CMS amended the bona fide service fee definition to remove the requirement that a retail community pharmacy or wholesaler receive an administrative fee in order to meet the definition of bona fide service fee for AMP.
purposes. Therefore, any fee that meets the criteria in the four part test is deemed bona fide and, therefore, excluded from AMP and Best Price regardless of the entity that received the fee.

In typical fashion, CMS declines to provide guidance as to what constitutes fair market value for an administrative or service fee. Instead, CMS notes that “[m]anufacturers should retain flexibility in determining whether service fees are paid at fair market value in light of constant changes in the pharmaceutical marketplace.” CMS does state that fair market value can be a range. It also states that manufacturers are required to document their fair market value determinations and that such documentation should make clear the methodologies or factors used to assess whether a fee is fair market value. CMS goes on to state that “we expect such determination of fair market value and documentation be made contemporaneously with the manufacturer’s agreement to pay the fee.” As such, manufacturers should be assessing whether an administrative or service fee is fair market value on an ongoing, consistent basis at the time of contracting. Such assessment should not be done retrospectively, such as on a quarterly or annual basis after the time of contracting.

As to the fourth criteria set forth above—whether or not all or a part of the fee is passed on to a downstream client or customer—CMS adopted the presumption utilized currently in assessing whether a fee is bona fide for purposes of the Average Sales Price calculation under the Medicare Part B program. A manufacturer may presume that a fee is not passed through by the recipient in the absence of evidence or notice to the contrary. CMS does not specify what is deemed to be evidence or notice to the contrary. CMS also states that “if a manufacturer has an agreement with a [Group Purchasing Organization] that any of these fees are passed on to the members or customers, they would be considered price concessions and not excluded as bona fide service fees.” It goes on to note that “a fee is not bona fide if even a portion is passed on.” It is unclear if CMS is suggesting that even the retained portion of a service fee is not bona fide even if a small portion is passed through or that the portion which is passed through is always non-bona fide but the retained portion could be a bona fide service fee.

CMS specifically notes that stocking allowances can be bona fide service fees if they meet the criteria in the four part test set forth above. On the other hand, it states affirmatively that price appreciation credits are price concessions, not bona fide service fees. “We continue to believe that price appreciation credits would likely not meet the definition of bona fide service fees. Price appreciation credits are issued by the manufacturer to adjust (increase) the wholesaler’s purchase price of the drugs in such instances when the drugs were purchased at a certain price and are remaining in the wholesaler’s inventory at the time the manufacturer’s sale price of the drug increased. These credits would amount to a subsequent price adjustment affecting the average price to the manufacturer and should be recognized for purposes of AMP…."

**Restating Base Date AMP**

As noted above, base date AMP is used in the calculation of the additional discount on Single Source and Innovator Multiple Source Drugs under the MDRP if the AMP of those drugs increases faster than the rate of inflation based upon the CPI-U compared to the base date AMP. Under the Bipartisan Budget Act of 2015, such additional discount will also be applicable to Noninnovator Multiple Source Drugs beginning in first quarter 2017.
Under the Final AMP Rule, manufacturers may report—but are not required to report—a revised base date AMP calculated in accordance with the methodology prescribed and refined in the Final AMP Rule within four quarters of April 1, 2016, or by the end of second quarter 2017. Manufacturers may choose to revise base date AMP on a product-by-product basis. Recalculated base date AMPs will be effective on a prospective basis.

**Restating AMP, Best Price, Nominal Sales and Customary Prompt Pay Discounts Beyond 12 Quarters**

In the Final AMP Rule, CMS has finalized its proposal that manufacturers may restate AMP, Best Price, Nominal Sales and Customary Prompt Pay Discounts beyond twelve quarters or thirty-six months, only if the:

1. Change is a result of drug category or market date change;
2. Change is an initial submission for a product;
3. Change is due to the prior termination of a manufacturer from MDRP for failure to submit pricing data and data must be submitted to re-enter the program;
4. Change is due to a technical correction (such as a keying error) that is not based on changes in sales transactions or pricing adjustments related to such transactions;
5. Change is to address specific rebate adjustments to states (related to either under and/or overpayments) or potential liability regarding those adjustments as required by CMS or a court order or under any internal investigations or an Office of Inspector General or Department of Justice investigation. As used above, “internal investigation” refers to an internal manufacturer pricing review, such as may occur when one manufacturer acquires another manufacturer and has concerns about the appropriateness of the acquired company’s AMP and/or Best Price methodologies.

CMS did not finalize an exception for restatement beyond the twelve quarter window for good cause in the Final AMP Rule, but is still considering the exception and other exceptions to the twelve quarter restatement window, which may be the subject of additional guidance or rulemaking.

If a manufacturer needs to restate AMP, Best Price, Nominal Sales or Customary Prompt Pay Discounts beyond the twelve quarter window, the manufacturer must submit a written request to CMS and CMS will assess the request to determine if it meets one of the five exceptions set forth above. If it does, CMS will approve the request. CMS has not set forth a timeframe in which it will review such requests.
Implementation of AMP-Based FULs: An Aggregate Upper Limit on Pharmacy Reimbursement under State Fee-for-Service Medicaid Programs

With the publication of the Final AMP Rule, CMS is now finalizing the AMP-based FULs it has been publishing in draft form for some time now.

ACA amended the existing Deficit Reduction Act of 2005 (DRA) definition of FUL by requiring CMS to calculate the FUL as no less than 175% of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs (at the NDC-9 level) for pharmaceutically and therapeutically equivalent multiple source drugs available through retail community pharmacies nationally. FULs are calculated when there are at least three FDA-approved pharmaceutically and therapeutically equivalent multiple source drug products reported by CMS by their manufacturers with monthly reported AMPs and AMP units greater than zero.

Specifically, CMS will publish the first final FULs in March 2016, which will be effective April 1, 2016. Thereafter, the FULs will be updated on a monthly basis and shall be effective the first date of the month following the publication of the update. States have 30 days after the effective date to implement the FULs. As such, the States will have until April 30, 2016, to implement the first final FULs that will be published in March 2016, with an April 1, 2016 effective date.

Under the Final AMP Rule, the AMP-based FULs are applied in the aggregate. As such, 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. Pharmacy reimbursement for drugs in one FUL group could presumably be above the AMP-based FUL for that group, so long as pharmacy reimbursement for multiple source drugs in other FUL groups is sufficiently below the AMP-based FULs for their drug group so that in the aggregate, total pharmacy reimbursement for all multiple source drugs subject to a FUL is below the FUL.

When establishing a FUL for a specific therapeutic class, in the event the FUL calculated as 175% of the weighted average AMPs is below the average retail community pharmacy acquisition cost as set forth in the National Average Drug Acquisition Cost (NADAC) survey, CMS will adopt the NADAC value as the FUL for the therapeutic class. In addition, CMS will not be calculating FULs for any 5i Drugs that are not generally dispensed at retail community pharmacies, because CMS deems such drugs are not available for purchase by retail community pharmacies on a nationwide basis. Likewise CMS will not calculate a FUL for drugs in a product group when the drugs do not have the same unit type. In such instances, CMS will contact the pharmaceutical manufacturers of the drugs in such product group to ensure the accuracy of reported unit types. CMS also stated in the Final AMP Rule that it will not calculate a FUL for a drug it has determined is not available to retail community pharmacies on a nationwide basis due to shortage or otherwise.

CMS has provided the states until June 30, 2017, (with the latest effective date of April 1, 2017) to submit a State Plan Amendment accommodating the ACA AMP-based FULs as a upper limit on pharmacy reimbursement for multiple source drugs in the aggregate for their fee-for-service Medicaid programs.
Mandatory Actual Acquisition Cost-Based Pharmacy Reimbursement for State Fee-for-Service Medicaid Programs

Under the Final AMP Rule, state Medicaid programs are required to implement Actual Acquisition Cost (AAC)-based pharmacy reimbursement methodologies for their fee-for-service Medicaid programs. As noted above, FULs will serve as an aggregate ceiling on reimbursement from fee-for-service Medicaid programs to pharmacies for multiple source drugs. As with the requirement for State Plan Amendments addressing implementation of the AMP-based FULs, CMS has provided the states until June 30, 2017, (with the latest effective date of April 1, 2017) to submit a State Plan Amendment implementing an AAC-based pharmacy reimbursement methodology for their fee-for-service Medicaid programs.

CMS has not specified a source or methodology for determining AAC, leaving flexibility for the states. 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 suggests in the preamble to the Final AMP Rule that states may conduct their own surveys of pharmacy acquisition cost or use NADAC or AMP in their AAC formulas. CMS also suggests that a state could use Wholesale Acquisition Cost (WAC) to develop and support an AAC-based model of pharmacy reimbursement. In establishing the professional dispensing fee, states should consider pharmacy costs, including the costs associated with a pharmacist’s time in checking the computer system for information about an individual’s coverage, performing drug utilization review and preferred drug list activities, measurement or compounding of covered outpatient drugs, filling the container, beneficiary counseling, providing the completed prescription to the Medicaid beneficiary, delivery, specialty packaging and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy. CMS is not mandating an AAC-based reimbursement methodology for specialty and physician-administered drugs; states retain flexibility in stipulating reimbursement for such drugs.

CMS has stated that each methodology adopted by states to implement AAC-based pharmacy reimbursement should be transparent, comprehensive and one that will allow the state to provide adequate reimbursement to Medicaid pharmacy providers in accordance with the State Plan Amendment. If proposing to use AMP in an AAC-based pharmacy reimbursement methodology, the applicable State Plan Amendment must demonstrate how disclosure of AMP-based prices is consistent with the confidentiality requirements set forth in the MDRP statute and other applicable federal regulations and statutory requirements.

In addition to the foregoing, 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 or an Indian Health Services, Indian Tribal & Tribal Organization or Urban Indian Organization (ITU) pharmacy purchased the drug off the Federal Supply Schedule. CMS specifies in the preamble to the Final AMP Rule that states may adopt the encounter rate for ITU pharmacy reimbursement, which CMS will deem to be AAC plus a professional dispensing fee, and suggests that reimbursement at the 340B Ceiling Price plus a professional dispensing fee would be appropriate reimbursement for a 340B Covered Entity or its contract pharmacy in the event a covered outpatient drug purchased at the 340B price is dispensed to a Medicaid beneficiary.

States that desire to change their ingredient cost reimbursement or the professional dispensing fee must demonstrate that such change reflects actual costs and does not
negatively impact beneficiary pharmacy access and must consider both the ingredient cost and professional dispensing fee when adjusting either or both.

**Extension of MDRP to the Territories**

Pursuant to the Final AMP Rule, the United States Territories—the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa—may submit State Plan Amendments to comply with the covered outpatient drug requirements in order to earn rebates from pharmaceutical manufacturers on their Medicaid utilization under the MDRP. Any approved State Plan Amendments would not be effective until on or after April 1, 2017.

**MDRP Rebates on Medicaid Managed Care Utilization**

ACA mandated that MDRP rebates be paid on covered outpatient drugs dispensed to Medicaid recipients enrolled in Medicaid managed care organizations with one exception—no MDRP rebates are assessed on covered outpatient drugs dispensed by disproportionate share hospitals that purchase those drugs under the 340B program. In the Final AMP Rule, CMS specifies that no MDRP rebates are due on any utilization when drugs acquired under the 340B program are dispensed to Medicaid managed care enrollees. While CMS declined to specify how state Medicaid programs are to ensure that pharmaceutical manufacturers are not billed for MDRP rebates if and when 340B drug inventory is dispensed to Medicaid managed care enrollees, it encouraged states to include language addressing the “duplicate discount” prohibition in their contracts with managed care organizations and noted such could be the subject of future guidance or rulemaking.

CMS had proposed that every Medicaid managed care organization operating in any state be required to submit a covered outpatient drug utilization report to each state Medicaid program within 30 days of the end of the quarter to facilitate billing and collection on MDRP rebates related to such claims. However, in the Final AMP Rule, CMS did not finalize this proposal in order to continue to allow states flexibility as to their billing and collection processes and noted that it may consider additional guidance or rulemaking on the subject in the future.

For more information regarding the Final AMP Rule, the MDRP, or this Client Alert, please contact **Stephanie Trunk** or **Erin Atkins** in our Washington, DC office or the Arent Fox attorney who regularly handles your matters.