

The Impact of the AMP Final Rule: Legal, Operational, and Financial Considerations

The Average Manufacturer Price Final Rule's Effect
on Drug Pricing and Contracting (Part 1)

June 12, 2016

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Background and Effective Dates

- The AMP Final Rule was published on February 1, 2016
 - “Medicaid Program: Covered Outpatient Drugs” (81 FR 5170-5357)
- It implements revisions to the Medicaid Drug Rebate Program made by the Affordable Care Act
- Most provisions are effective April 1, 2016
 - Implementation is delayed for “5i” drugs until July 1, 2016
 - The expansion of the MDRP to Puerto Rico/U.S. territories takes effect April 1, 2017



Scope of the Final Rule

- The Final Rule addresses these key areas:
 - Defines “Average Manufacturer Price” (AMP) and other rebate program terms and standards
 - For reimbursement of multiple-source drugs, establishes the FUL (Federal Upper Limit) based on AMP, to set the maximum aggregate reimbursement to retail pharmacies by the state Medicaid program
 - An FUL is established when there are 3 therapeutically equivalent “A rated” drugs, innovator and or non-innovator, at the NDC-9 level
 - An FUL is not less than 175% of the weighted average monthly AMPs
 - For other drugs (single source or multi-source), modifies the standard for reimbursement from “Estimated Acquisition Cost” (EAC) to “Actual Acquisition Cost” (AAC)
 - Pharmacy payment rates must be evaluated in relation to AMP, national survey data such as NADAC or state-specific survey data
 - Establishes a professional dispensing fee

Calculation of the MDRP Rebate

- For a manufacturer's drugs to be covered, the manufacturer agrees (with CMS) to pay a rebate on each unit of its "covered outpatient drugs" reimbursed under the Medicaid program
- Based on pricing metrics a manufacturer reports (monthly and/or quarterly), CMS calculates the Unit Rebate Amount (URA) for each drug

Non-innovator multiple source drugs = 13% of AMP

Single source / innovator multiple source drugs

"Basic Rebate"

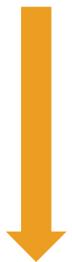
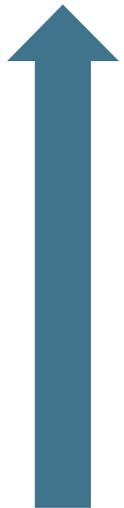
- 23.1% of AMP or 17.1% for clotting factors or exclusively pediatric indication only; or
- AMP minus Best Price

"Additional Rebate" equal to the difference between the current quarter's AMP and the "base date AMP," adjusted for inflation

- "Base date AMP" is the AMP for the first full quarter in which the product is marketed.

Financial Impact

- Many of the changes made by the Affordable Care Act and the AMP Final Rule increase manufacturers' rebate liability
 - The Medicaid program expanded
 - The MDRP will include Puerto Rico/U.S. Territories
 - The MDRP expanded to include Medicaid MCO utilization
 - The minimum (basic) rebate percentages increased
 - For line extensions, the additional rebate will be higher → higher URA
 - Base date AMP does not reset for a line extension of an oral solid dosage form
 - Blending brand/authorized generic AMPs is restricted
- Few changes decrease rebates
 - URA is capped at 100% AMP



Price Calculation and Reporting - AMP

- “Average Manufacturer Price” (AMP) is defined.
 - AMP is based on manufacturer sales in the US to Retail Community Pharmacies, either directly or indirectly (through wholesalers).
 - In determining AMP-eligible sales, as is the prevailing practice, manufacturers may **presume** that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, *in the absence of data to the contrary concerning actual distribution*.
 - The Presumed Inclusion approach should be applied consistently in Standard AMP and the alternative 5i AMP calculations

Price Calculation and Reporting

- Other revisions address, among other issues:
 - Authorized Generics;
 - the use of a smoothing methodology for estimating lagged price concessions, AMP-ineligible sales, and the alternative 5i AMP threshold;
 - the multi-part test for determining bona fide service fees;
 - and the identification and rebate calculation for line extension products, which is the only issue open for additional comment.

Price Calculation and Reporting – 5i AMP

- An alternative AMP calculation will be used for drugs that are “**not generally dispensed through retail community pharmacies**”, and specifically “5i” drugs (i.e., inhalation, infusion, instilled, implanted, or injectable drug).
 - Identified, based on manufacturer understanding of how the drug is administered
- Applicable if at least 70 percent of sales are to entities other than RCPs
 - Determined based on units at the NDC-9 level
 - Evaluated monthly, for a period of time “such as a 12-month period”
- The methodology is the same as for Standard AMP; the sales included/excluded are different.
- Excludes sales, prices and concessions to government, patients, charitable and not-for-profit pharmacies, and patient benefit programs
- Non-5i drugs not dispensed through RCPs remain unaddressed.

Class of Trade for Specialty Pharmacy

- CMS proposed but did not finalize an approach to include sales to certain entities in AMP if they were “conducting business as” Retail Community Pharmacies or wholesalers
- In the Final Rule, CMS interprets the definition of “retail community pharmacy” to include a **specialty pharmacy, home health care pharmacy, or home infusion pharmacy** if it otherwise meets the RCP definition (such that sales to these classes of trade may need to be included in AMP)
 - It may dispense medications to the general public at retail prices
 - It is not primarily a mail-order pharmacy
 - It is licensed
- Requires individualized determination or reasonable assumption

Authorized Generics

- CMS finalized its proposed definition: An AG is a drug approved under an NDA that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark or packaging than the brand
- Under the Final Rule, the “primary manufacturer” of the branded drug must include the AG sales to a “secondary manufacturer” in AMP when:
 - The primary manufacturer sells directly to a wholesaler or
 - The secondary manufacturer is acting as a wholesaler for drugs distributed to RCPs
 - CMS does not define “engaged in the wholesale distribution” or “acting as a wholesaler”
 - But it explains when a secondary manufacturer does not do so:
 - It relabels or repackages the drug and sells the repackaged authorized generics to wholesalers

Price Calculation and Reporting – Best Price

- Best Price is based on *a single or multiple transactions* (not a quarterly average) per unit
 - Capsule, tablet, ML, each, TDP, AHF, or gram
 - Stacking price concessions (chargeback + rebate + discount)
 - BP includes prompt payment discount
- Best Price is the lowest price paid for a Covered Outpatient Drug by any entity in the US, with limited exceptions
 - In addition to wholesalers and retail community pharmacies, includes hospitals for inpatient use, nursing homes, HMOs, and commercial third-party payers

Best Price

- A manufacturer is a Best Price-eligible entity when it meets the definition of “wholesaler”, *i.e.*, it engages in wholesale distribution of drugs to retail community pharmacies
 - Sales to manufacturers for clinical trials do not reach RCPs
- Authorized generics sales are an exception
 - Manufacturers are specifically listed as Best Price-eligible customers

Bona Fide Service Fees

- Historically, service arrangements with relevant entities that do not meet a multi-part bona fide service fees test must be treated as price concessions.
- The ACA expressly excluded “bona fide service fees” from AMP calculation
- The ACA definition included certain enumerated wholesaler fees
 - Distribution stocking fees
 - Inventory management fees
 - Product stocking allowances
 - Fees associated with administrative services agreements and patient care programs
 - medication compliance, patient education
- Differing interpretations regarding whether the enumerated fees also needed to meet the test

Bona Fide Service Fees

- The Final Rule affirms the multi-part test
- It does not limit the fee to one paid to a wholesaler or RCP
- The “bona fide service fee” test has multiple elements, including that the fee represents *fair market value* and it is paid for a *bona fide, itemized service* that is actually performed and *the fee is not passed through to the end customer*
 - CMS declined to define FMV
 - FMV is documented as part of a manufacturer’s reasonable assumptions
 - Must be services on behalf of the manufacturer
 - Must enumerated services be subject to the full test?

Value Based Pricing

- Final Rule provides no specific guidance, but CMS states that guidance is under consideration for these “unique” arrangements
 - Effect on Best Price would be addressed
 - Interest in clarity for States and Medicaid programs regarding such arrangements
 - CMS recognizes value of such arrangements “especially when they benefit patients”
- Revision of bundled sale definition may impact the utility of bundling as a mechanism for these arrangements

Bundled Sales

- Price concession is *conditioned upon* purchase (or some other performance requirement) of the same drug, a different NDC-9 or another product, or *price concessions are greater* than outside of the bundled arrangement
 - Performance requirements include achievement of market share, inclusion or tier placement on a formulary
- Discounts including (“~~but not limited to~~”) discounts resulting from a contingent arrangement are allocated proportionally to all drugs or products in the bundle
 - to the total dollar value of the units in the bundle
- Not a bundle if:
 - The price or discount is not contingent upon another product or performance requirement
- May only the contingent discounts be allocated?

340B Drug Discounts

- CMS revised its proposed approach to clarify that Best Price excludes “any prices charged to a [340B] covered entity”, consistent with statute
 - Does it apply to situations where the entity was not eligible?
- Under the Final Rule, the state plan must describe the reimbursement methodology for 340B covered entities and contract pharmacies, and Indian Health Service, Tribal and urban Indian pharmacies. Drugs purchased under other federal programs will be reimbursed at that price (AAC).
- The **Medicaid Managed Care Final Rule** (May 6, 2016) requires Medicaid MCOs to exclude utilization data for drugs purchased at 340B discounts from reports going to States for Medicaid drug rebate invoicing, when states do not require submission of managed care drug claims data from covered entities directly.
 - In the **OIG Report on State Efforts to Prevent Duplicate Discount within Medicaid MCOs** (June 2016), the OIG recommended CMS to require States to use claim-level methods to identify 340B claims, rather than relying only on provider-level methods to identify 340B claims that most states are currently utilizing.*

*For example, California utilizes both provider-level as well as claim-level methods to identify 340B claims to prevent duplicate discounts.

Questions?



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July 13, 2016 at 3 PM - 4 PM ET

Samuel R. Nussbaum, M.D., Strategic Consultant, EBG Advisors

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