PRACTICAL LAW COMPANY®

Out of bounds: CMS proposed rule for AMP under Medicaid

www.practicallaw.com/8-518-2213

Donna Lee Yesner, Stephen E Ruscus and Andrew D Ruskin
Morgan Lewis

Medicaid, the US federal healthcare assistance programme for the poor, is administered by the US States through plans approved by the Department of Health and Human Services (HHS). Among the benefits that Medicaid provides is payment for outpatient drugs, including drugs administered by a physician in an outpatient setting, if billed separately from a medical service.

To reduce Medicaid expenditure for outpatient drugs, Congress enacted legislation in 1990 to create the Medicaid Drug Rebate Program (MDRP). In particular, Medicaid payment for an outpatient drug covered by the law is prohibited, unless the drug manufacturer pays rebates on its covered drugs to the States. These rebates are measured using a statutory defined price point called the Average Manufacturers Price (AMP). Further statutory changes to how AMP is calculated were made by statute in 2006. After HHS regulations implementing this statute were legally challenged, in 2010 Congress again amended the definition of AMP.

In February 2012, the Centers for Medicare and Medicaid Services (CMS), a component of HHS, published a new proposed rule for determining AMP. This article explores some of the problematic aspects of CMS' proposals to regulate the MDRP, including its questionable exercise of delegated authority. In particular, it examines:

- Historical regulation of AMP.
- Expansion of the MDRP.
- Determining indirect sales to retail community pharmacies.
- Calculating AMP for 5i drugs.
- Best Price.
- The new requirements for line extensions.
- Treatment of coupons, vouchers and co-payment assistance.
- New definition of wholesaler and the authorised generic rule on AMP.
- Changes to CMS' policy on restatements of AMP and Best Price.

HISTORICAL REGULATION OF AMP

Legislative background and AMP

In 1990, to reduce Medicaid expenditure for outpatient drugs, Congress enacted section 1927 of the Social Security Act (*42 U.S.C. §1396r-8*) (Medicaid drug rebate statute), which created the MDRP:

- The MDRP emulates the managed care technique of leveraging the payer's share of the market for outpatient drugs, to obtain rebates from drug manufacturers.
- The law coerces manufacturers to pay rebates to the US States. It prohibits Medicaid payment for an outpatient drug covered by the law, unless the drug manufacturer contracts with the Secretary of HHS to pay rebates on all its covered drugs. The terms of the contract needed to satisfy this requirement are specified by the Medicaid drug rebate statute.
- Although the rebate formula varies, depending on whether a drug is an innovator or non-innovator drug, all Medicaid rebates are measured using AMP.
- Before 2007, manufacturers applied the statutory AMP definition to their individual situations based on guidance from the CMS.

In 2006, the Deficit Reduction Act (DRA) (*Pub. L. No 109-171, § 6001, 120 Stat. 54 (2006) (codified in scattered sections of 42 U.S.C.)*):

- Made AMP the basis for Medicaid payment for multiple source drugs, as well as for manufacturer rebates.
- Authorised HHS to specify by regulation a standard methodology for calculating AMP consistent with the Medicaid drug rebate statute.

However, the regulation authorised by the DRA was challenged by retail pharmacy groups as contrary to the Medicaid drug rebate statute, and in 2010 Congress amended the definition of AMP.

On 2 February 2012, CMS published a new proposed rule for determining AMP (*Medicaid Program; Covered Outpatient Drugs, 42 C.F.R. § 447.500-.522 (77 Fed. Reg. 5318-5367, Feb. 2, 2012)*) (proposed rule). However, the proposed rule not only addresses the calculation of AMP, but also attempts to impose new contract obligations on manufacturers through regulatory changes, which are unrelated to the determination of AMP.

Calculating AMP

The terms of the Medicaid drug rebate agreements set out in section 1927 of the Social Security Act are not negotiable. Manufacturers must agree to these terms to secure Medicaid coverage of their drugs. In particular, the statutory terms specify:

- A uniform rebate formula.
- The method for computing the drug pricing points used in the formula, including AMP.

Congress delegated the authority to the Secretary of HHS to administer these agreements and ensure compliance with their terms. This authority was delegated by the Secretary of HHS to CMS. The contract terms cannot be unilaterally amended by

HHS. Initially, Congress delegated no authority to HHS to issue any regulations that could impact manufacturers' contractual obligations. Virtually all manufacturers of pharmaceutical and biological products have entered into Medicaid drug rebate agreements, because:

- The MDRP covers all prescription drugs and biological products approved by the FDA and provided to beneficiaries on an outpatient basis.
- Medicaid-covered drugs represent such a large percentage of total sales.

The applicable rebate formula specified in the Medicaid drug rebate statute differs depending on whether a drug is approved by the US Food and Drug Administration (FDA) as either:

- A new drug or a biological product.
- A generic drug under abbreviated new drug approval procedures.

With few exceptions:

- The basic rebate formula for innovator drugs (including those sold under an authorised generic label) and biological products is 23.1% of the AMP, as defined in the Medicaid drug rebate statute, or the difference between AMP and the manufacturer's Best Price, as defined in the Medicaid drug rebate statute. These drugs are also subject to an inflation penalty, measured by increases in AMP from the first quarterly rebate period after launch to the current period, compared to the Consumer Product Index-Urban.
- For all other drugs, the formula is 13% of AMP.

The product of this calculation is called the Unit Rebate Amount (URA). This is multiplied by the number of units of the drug paid for by Medicaid in a given State during the period. This yields the manufacturer's rebate liability to that State for the period. By signing the rebate agreement, a manufacturer agrees to:

- Calculate and report AMP and Best Price.
- Pay the States' rebate claims.

Until 2007, manufacturers calculated AMP and Best Price based on their interpretation of the Medicaid drug rebate statute, and programme guidance from CMS, applying them to their own systems for capturing business transactions. Accordingly, there were many variations in the methodologies for calculating reported prices, particularly AMP. AMP, which had been defined in the Medicaid drug rebate statute and agreement as the average price paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, was susceptible to different interpretations. This was because, among other reasons, the Medicaid drug rebate statute did not define "retail pharmacy class of trade".

To standardise methodologies for calculating AMP, Congress directed HHS in the DRA to promulgate a regulation that specified standards for determining AMP. The DRA also based the Medicaid pharmacy payment rate for multiple source drugs on a multiplier of AMP. Despite the limited delegation of authority in the DRA to issue regulations, the rule implementing the AMP provision of the DRA went beyond the determination of AMP:

- It established a new definition of multiple source drugs subject to AMP-based reimbursement.
- Imposed mandatory obligations on manufacturers unrelated to AMP under their rebate agreements.
- The DRA rule also included in the term "retail pharmacy class of trade" almost all direct and indirect sales and price concessions to buyers of outpatient drugs, which the retail pharmacies asserted was contrary to the plain meaning of the Medicaid drug rebate statute.

Retail pharmacies complained that the AMP regulation did not fairly reflect the average price they paid, and should not include discounts, rebates, and other price concessions generally unavailable to retail pharmacies. Litigation ensued and use of AMP as the Medicaid pharmacy payment rate for multiple source drugs was enjoined (*Nat'l Ass'n of Chain Drug Stores v. US Department of Health and Human Services, 631 F.Supp.2d 23 (D.D.C. 2009)*).

To address these concerns, the Affordable Care Act (ACA) (*Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010),* amended by *Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (to be codified primarily in scattered sections of 42 U.S.C.)*):

- Changed the definition of AMP in the stautue.
- Overruled many of the provisions in the AMP regulation that had been authorised by the DRA.

Specifically, the ACA limited AMP to prices paid both:

- Directly by retail community pharmacies.
- By wholesalers for drugs distributed to retail community pharmacies.

Although the ACA did not delegate additional authority to alter the terms of the rebate agreements by regulation, it anticipated that CMS would issue a final AMP regulation under its DRA authority, that conformed to the ACA amendments to the Medicaid drug rebate statute.

CMS responded to the ACA by:

- Promptly withdrawing those portions of the AMP regulation that governed the definition of a multiple source drug.
- Withdrawing those portions of the AMP regulation that specified the transactions included and excluded in the AMP calculation.
- Advising manufacturers to calculate and report AMP based on the terms of the Medicaid drug rebate statute.

By withdrawing portions of the AMP regulation, CMS:

- Effectively mooted the pending lawsuit that had challenged the DRA regulation as inconsistent with the Medicaid drug rebate statute.
- Allowed manufacturers to make reasonable assumptions in applying the Medicaid drug rebate statute, as amended by healthcare reform legislation.

However, the new definition of AMP raised several issues that needed to be resolved by CMS. Unfortunately, the proposed rule:

- Creates more issues than it resolves.

- Imposes significant new administrative and compliance burdens on manufacturers.
- Creates obligations by regulation that exceed the authority delegated to CMS, as the administrator of the statutory specified drug rebate agreements.

EXPANSION OF THE MEDICAID DRUG REBATE PROGRAMME

The most objectionable proposal by CMS is to expand the scope of the MDRP, which is implemented through manufacturer agreements. The Medicaid drug rebate statute, throughout, expressly applies to the States (with a capital "S"), both in terms of manufacturers' and the Secretary of HHS's responsibilities. In this context, the term States refers to the autonomous States, that is, the original States and those admitted to the union by Congress under Article IV of the Constitution. Under the Constitution, States are treated differently from territories, which are the property of the US and lack the rights of States.

Since the start of the MDRP 20 years ago, the parties have agreed in the form agreement implementing the programme that the term States means the 50 States and the District of Columbia, although the Capitol is not a State. In the proposed rule, CMS has suddenly decided to enlarge the definition of States, as used in the statute and contracts, to include the territories of Puerto Rico, the Virgin Islands, the Northern Mariana Islands, Guam, and American Samoa. CMS thinks it would be good policy to allow these territories to participate in the MDRP as beneficiaries of manufacturers' contracts with HHS. None of these territories has been granted Statehood by Congress.

This proposal is highly objectionable, because the term States has a specific meaning. CMS has no authority to promulgate a regulation that would:

- Expand the scope of the Medicaid drug rebate statute.
- Alter the terms of manufacturers' rebate agreements, to impose new substantive duties that conflict with the Medicaid drug rebate statute and agreement terms required for participation in the MDRP.

CMS' longstanding interpretation of the term States, which it included in its standard contract with manufacturers, excludes the territories. Therefore, the intent and effect of the proposed regulation is to impose additional rebate liability on manufacturers not presently covered by the statute and contracts.

As such, the proposed regulation is a change in the law and the terms of the agreements required for Medicaid coverage, not a clarification of an ambiguous statutory or contract term. Congress has never indicated any intent to include the territories in the MDRP. Nor has it granted authority to CMS to change the requirements for participation in the MDRP or add new manufacturer obligations to their rebate agreements. Only Congress can change the scope of the programme. Without such authority, this unilateral change to the contract terms is precluded by the contracts.

In addition to increasing the volume of rebates for which manufacturers would be responsible, the proposed change would require manufacturers to include transactions in the territories in their pricing calculations from which the URA is derived. The territories are subject to very different local laws, including single payer systems and price controls not applicable to the States. They have very different pricing structures that reflect foreign market considerations and different distribution arrangements. In some cases, the sales are made by an affiliate that does not sell in the States.

Including transactions in the territories could generally be expected to drive down reported prices and increase the URA, which is the basis for State Medicaid rebate claims. The total volume of commercial sales in the territories may not drastically impact the average price paid to a manufacturer. However, the Best Price to any buyer in the territories would probably be lower, perhaps considerably lower, than any Best Price in the States, thereby setting the Medicaid price for the States and greatly increasing the manufacturer's total rebate liability.

Even if the territories developed acceptable plans and the capability to capture prescription payment use accurately, manufacturers' systems are not designed to process sales data generated in the territories, making compliance with the programme very difficult. In short, even if CMS had discretion to alter manufacturers' contract obligations by regulation, which it does not, the proposal to expand the programme to the territories is not reasonable.

DETERMINING INDIRECT SALES TO RETAIL COMMUNITY PHARMACIES

AMP has always included prices paid to manufacturers by wholesalers for drugs the wholesalers subsequently distribute to retail pharmacies. In calculating AMP, manufacturers are not parties to wholesalers' sales and do not possess their distribution information. Although the ACA narrowed the definition of wholesaler, and limited the classes of trade that could be treated as retail, it did not alter the need to separate:

- Included indirect sales to pharmacies.
- Excluded indirect sales to other end customers.

There are two ways that manufacturers can limit inclusion of indirect sales prices in AMP to those paid by wholesalers for drugs resold to retail community pharmacies:

- The first is to:
  - include in the calculation all wholesaler sales;
  - remove indirect sales to non-retail community pharmacy classes of trade, which can be identified through chargeback data received from the wholesaler.

  When manufacturers contract with end customers that purchase through wholesalers, the wholesalers:
  - invoice at the contract price;
  - issue a claim for the difference between the contract price and the price paid by the wholesaler. This generates a record the manufacturer can use to verify the customer.
- The second is to include only wholesaler purchases when the units are resold to retail community pharmacies.

Both methods have inherent problems with accuracy, but one is far more difficult to administer than the other.

Analysis

Historically, manufacturers have followed the "top down" method in ascertaining excluded classes of trade. This is problematic because manufacturers do not have contracts with all end customers of wholesalers. Since the beginning of the MDRP, CMS permitted manufacturers to assume that all sales to wholesalers for which there were no chargeback claims were resold to the retail pharmacy class of trade and included in AMP. Before the ACA, this made sense, since:

- There were fewer categories of customers excluded from AMP.
- The excluded classes (for example, government, 340B entities, hospital inpatient, and Health Maintenance Organizations (HMOs)) that purchased indirectly tended to contract with manufacturers.

However, under the amended AMP definition:

- It is more likely that some non-retail customers would not be identified through chargeback data, and would be included in the calculation.
- The definition of wholesaler now includes distributors that resell under their own label, including other manufacturers, for which there would be no chargeback data. Therefore, manufacturers could not determine the end customers of these "wholesalers" without sales information from the distributors.

However, the "bottom up" approach is worse because:

- It entirely depends on manufacturers obtaining resellers' sales data, to which they have no access. In the past, data that manufacturers have been able to obtain from wholesalers has frequently been incomplete, and the integrity of it cannot be assured.
- The administrative effort and cost of obtaining and verifying data from wholesalers and distributors is far greater than using manufacturers' chargeback data to identify excluded customers.

The proposed rule:

- Would require manufacturers to exclude sales to wholesalers, unless they could be documented as distributed to retail community pharmacies.
- Would not permit manufacturers to use their own verifiable chargeback data to remove clearly ineligible indirect sales units and associated dollars, and assume the remaining sales by wholesalers were resold to retail community pharmacies. CMS reasoned that this method could result in the inclusion of some sales that were distributed to non-retail customers.

However, this concern may be misplaced. Except when wholesalers distribute to manufacturers' contract customers and receive a credit (for which there would be chargeback records) the price wholesalers pay a manufacturer for a drug is generally unaffected by the type of customer to which the wholesaler later resells the drug. Therefore, leaving a unit sold to a wholesaler at the Wholesaler Acquisition Cost in the calculation only impacts on AMP to the extent a sizeable number of direct sales to pharmacies are discounted. The likelihood of impact from over- or under-inclusion of transactions in AMP is greater for generic drugs, which are typically sold to pharmacies at a discount, than for brands which are not.

The problem with the proposed rule's requirement to include only documented wholesaler sales to pharmacies is two-fold:

- To date, industry experience with wholesaler sales data has been that the data is incomplete, inaccurate, and unverifiable. This is particularly worrying, as manufacturers must certify the accuracy of AMP. Verification of reseller sales would require access to proprietary information of entities with which manufacturers compete, and they may object to providing such data. Indeed, a regulation that depends on getting a competitor's sales data raises serious anti-trust concerns.
- If manufacturers cannot include wholesaler sales without proof that the units were distributed to retail community pharmacies, it will lead to gross under-inclusion of retail sales:
  - nearly all government purchases and most institutional purchases are under manufacturer contracts. Therefore, if drugs are distributed to these excluded classes of trade through wholesalers, the sales are documented and identifiable;
  - by contrast, most sales of drugs by wholesalers to their own customers, that is, customers that do not have contracts with manufacturers, are to retail community pharmacies;
  - if both contract sales and undocumented indirect sales were excluded, AMP would be based primarily on direct sales to pharmacies, resulting in substantial under-inclusion.

Operationally, if AMP were limited to direct sales to pharmacies and only those wholesaler sales documented as distributed to retail community pharmacies, it could lead to skewed results. Additionally, identification and inclusion of wholesaler gross sales would be delayed until well after the sales are made. This is because the wholesaler sales could not be included until the end customer is identified through wholesaler-provided data. Under the currently used "top down" method, wholesaler sales are included when made with the removal of excluded sales lagging behind.

CALCULATING AMP FOR 5I DRUGS

One of the most problematic reforms is a belated amendment to the exclusions from the AMP calculation for infusion, inhalation, instilled, implanted, and injected drugs not generally dispensed through a retail community pharmacy (5i drugs). These classes of drugs are not self-administered and therefore are not generally dispensed by retail pharmacies.

When AMP was defined in the ACA to exclude rebates and discounts provided to non-retail customers, such as physician offices, clinics and hospitals, which are the primary buyers of physician-administered drugs, the anticipated effect was an increase in the average price. Safety net providers were concerned that an increase in AMP on these drugs would increase their purchase prices, because they buy covered drugs under this programme at a percentage below AMP. Manufacturers that agree to participate in the 340B programme sell to eligible safety net providers at no more than AMP reduced by the Medicaid rebate amount (*42 U.S.C. §256b*). A lower AMP also means manufacturers pay smaller rebates when Medicaid pays for these drugs.

By contrast, providers other than those participating in the 340B programme are hurt by a lower AMP when reimbursed by Medicaid for multiple source drugs at a percentage above AMP. After the ACA was enacted, Congress amended the statutory definition of AMP to exempt 5i drugs from the requirement to exclude non-retail transactions. However, Congress was exceptionally sloppy in its execution of the amendment.

Section 2503(a)(2)(B)(IV) of the Patient Protection and Affordable Care Act excluded from AMP payments received from, and rebates or discounts provided to, specific categories of entities and "any other entity that does not conduct business as a wholesaler or retail community pharmacy". This by definition would include government pharmacies and covered entities under the 340B programme.

Public Law 111-226 (*§ 202, 124 Stat. 2394 (2010)*) amended this section, by creating an exception to this exclusion for 5i drugs. Literally, the exception covers transactions with government buyers involving 5i drugs. The amended provision unintentionally includes payments by, and discounts and rebates provided to, government and 340B buyers in the AMP for 5i drugs. The alternative for manufacturers was to assume, in the absence of guidance to the contrary, that Congress intended that the AMP for 5i drugs would be similar to the Average Sales Price reported for physician-administered drugs under Medicare Part B, and should exclude discounts to government and 340B entities.

Another problem with Public Law 111-226 is that it did not include in AMP prices paid by wholesalers for drugs distributed to entities other than retail community pharmacies. While the amendment to section 2503(a)(2)(B)(IV) might be read as including payment received by non-retail customers when sold to them directly, manufacturers do not receive payment from these entities when they order drugs from wholesalers.

Therefore, the ACA as amended literally precludes inclusion of prices paid when drugs are sold to these end customers indirectly, while simultaneously requiring inclusion of discounts and rebates provided to these buyers. If included price concessions were netted against the direct sales of the drug to non-retail customers and the few indirect sales to retail community pharmacies, it could produce a negative number. To prevent what appeared to be the inadvertent consequence of a poorly drafted amendment, manufacturers have assumed that Congress intended to include in AMP the indirect sales of 5i drugs to which included price concessions relate.

CMS' proposed rule establishes a different methodology for calculating AMP for 5i drugs, and in doing so simply ignores the problems created by the language and structure of the ACA. The proposed rule:

- Assumes for the purposes of the 5i AMP that both direct and indirect sales to the categories of customers listed in section 2503(a)(2)(B)(IV) are included in 5i AMP.
- Assumes that a government customer is not within the category of an "entity that does not conduct business as a wholesaler or a retail community pharmacy".
- Attempts to set standards for determining which of the two AMP methodologies apply:
  - first, it would use the route of administration to determine whether the drug is a 5i drug;
  - second, it would use a fixed percentage of sales to determine whether the drug is generally not dispensed through retail community pharmacies.

This proposal, which is completely impractical, creates one of the biggest administrative hurdles in implementing the ACA amendments.

Drugs that are primarily administered by physicians are still sold by retail pharmacies, and they are also dispensed through specialty pharmacies and home healthcare distributors, which CMS proposes to classify as retail pharmacies. If the volume of sales through theses channels hovers around 10%, the proposed demarcation line, it could easily vacillate from this figure between reporting periods. This would create havoc for manufacturer calculations. The two methodologies would produce very different results and cause big swings that have no correlation to prices actually paid.

Worse, manufacturers of innovator drugs pay inflation penalties if their current-period AMP exceeds the inflation rate since establishment of the baseline AMP at the time of market introduction. If a manufacturer's baseline AMP is based on the non-retail AMP methodology, and it crosses the 10% threshold in a quarter, so that the regular retail AMP applies, the resulting exclusion of discounts and rebates to non-retail customers will likely create the appearance of a price increase, thereby triggering the additional rebate inflation penalty. This scenario could repeat itself again and again without the manufacturer ever actually increasing any prices, unless there were alternate baseline AMPs for the same drug or its prices were recalculated to match the methodology applicable in the current reporting period.

CMS thought it could use the same 10% percentage rule that the Department of Veterans Affairs (VA) uses to determine whether to include only wholesaler sales or only non-wholesaler sales in the average non-federal manufacturer price. As a policy matter, if a manufacturer's methodology has changed due to its sales mix, the VA requires manufacturers to recalculate previously submitted prices used in determining whether current prices have exceeded inflation over the past year. However, the VA's average price calculation is an annual one and does not depend on a constant baseline. Therefore, if necessary, it is not particularly burdensome to do a single annual recalculation. From an operational perspective, the prospect of having to continuously switch methodologies and recalculate baseline AMP on a monthly or quarterly basis is nightmarish.

Further, for providers of multiple source drugs, there could be large discrepancies between the purchase price and the payment rate, which could be constantly fluctuating. To avoid these unnecessary problems, CMS should let the manufacturer classify the drug and retain the classification over time.

Analysis

BEST PRICE

Like AMP, the term Best Price as used in the Medicaid drug rebate statute and rebate agreement is defined in 42 U.S.C. §1396r-8. Manufacturers calculated this price point based on the statutory definition and guidance from CMS. The DRA:

- Authorised CMS to regulate the determination of AMP.
- Gave CMS discretion with respect to the determination of Best Price in discrete areas, such as including new categories of customers within the nominal price exemption (*Pub. L. No. 109-171, § 6001, 120 Stat. 54, 56 (codified at 42 U.S.C. 1396r-8)*).

However, CMS included rules on calculating Best Price in its DRA regulation in 2007. As the ACA did not amend the Best Price provisions, CMS did not withdraw those portions of the DRA regulation. However, in the final regulation implementing the statutory amendments to AMP, CMS again decided to issue regulations governing Best Price.

However, the proposed rule does much more than propose rules to make the two pricing methodologies consistent. It changes the statutory definition of Best Price incorporated in the rebate agreements:

- The Medicaid drug rebate statute defines Best Price as the lowest price available to any customer with certain exceptions. It is a single transaction price with a single customer, and includes all subsequent adjustments to that price available to that customer. It is not the lowest net price realised by the manufacturer on the sale of a drug, after all discounts to all customers and payments of fees to other entities in the distribution chain are taken into account.
- The proposed rule would alter the definition of Best Price in manufacturers' contracts. It would provide that Best Price includes, except for specified exemptions, "all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly".

By using this vague language regarding associated transactions that adjust prices, CMS appears to be including administrative fees paid to non-purchasing third parties (such as Group Purchasing Organizations, which negotiate and administer contracts but do not purchase and sell drugs) as if these fees actually reduced the price paid by buyers of their products. Therefore, a fee paid to a non-buyer "associated" with the sale of a drug would be treated as a price concession to the buyer, unless the fee passes the criteria for a bona fide service fee paid to a buyer, including the requirement that the fee not be passed through to the buyer.

However, manufacturers are not privy to transactions between GPOs and their members, and therefore have no basis to know if fees paid for administrative services are shared. As a result of this regulation, manufacturers would have to treat an amount that the manufacturer did not make available to the buyer as a price concession to the buyer, even if it did not lower the purchase price. This is not consistent with the Medicaid drug rebate statute and rebate agreement. In addition, the proposed rule would include these fees in 5i AMP, thereby unfairly lowering the payment rate for multiple source drugs. It would be much fairer and far less burdensome if CMS would allow exclusion of GPO fees unless the manufacturer knows a portion has been passed through to the purchaser.

Further, CMS should use the Federal Anti-Kickback Act (*42 U.S.C. § 1320a-7b(b)*) for guidance in dealing with fees to GPOs. The Anti-Kickback Act and implementing regulations recognise that:

- Entities that negotiate contract prices on behalf of others are not themselves buyers.
- Administrative fees paid to these entities are not discounts covered by the separate and distinct discount exemption and safe harbour regulation, which govern sales transactions to which the fees relate. HHS' safe harbour and pricing regulations should treat administrative fees and discounts consistently.

Manufacturers also contract with different customers for different prices on different transactions involving the same unit of a drug, as it moves through the distribution chain from warehouse to patient. For example:

- A manufacturer may contract with a wholesaler to buy its product at a 2% prompt pay discount (that is, if the wholesaler pays within a set time).
- It may also contract with a healthcare provider to buy the drug at a fixed price through the wholesaler, which distributes it at the manufacturer's contract price for a fee.
- It may also provide a rebate to a government or commercial health plan that pays the provider.

Even if the manufacturer's net realisation is impacted by multiple transactions, none of the distinct customers receives a price that aggregates discounts provided to the others.

Although the proposed rule would include only those associated discounts that adjust the price, it does not say the price to which it refers is the transaction price available to the customer, rather than the amount the manufacturer realises after all discounts and rebates to all customers are provided. It would be completely inconsistent with the statutory and contractual definition of Best Price to combine discounts to separate customers in separate transactions when calculating the single lowest price to a customer, when no single customer had a right to nor received the aggregated discounts.

Another major problem with CMS' proposed rule on Best Price is its proposed treatment of drugs sold to entities eligible to participate in the 340B programme. The Medicaid drug rebate statute is very clear that prices charged to entities described in the 340B statute (*42 U.S.C. §256b*), are excluded from Best Price (*Social Security Act § 1927(c)(1)(C), 42 U.S.C. 1396r-8 (2000)*). The exclusion is based on their status as a covered entity, not on the classification of the drug.

However, the proposed rule would include in Best Price manufacturer prices charged eligible entities for orphan drugs that are outside the programme. In addition, CMS stated in the proposed rule that it is also considering including in Best Price inpatient sales to new categories of hospitals added to the programme by the ACA. This proposal misreads the Medicaid drug rebate statute, though it is consistent with CMS' past interpretation of the Best Price exemption for prices to 340B entities. Previously, in response to CMS' view that the exemption for prices charged to 340B entities is determined by whether a drug is purchased

under the 340B programme, Congress enacted a clarification that sales of inpatient drugs to disproportionate share hospitals, which are outside the 340B programme, are still included in the Best Price exemption.

Apparently, CMS continues to believe that Congress did not consider all prices charged to covered entities to be exempt when it enacted the Best Price exemptions, even though it clarified that the exemption for inpatient drugs to Disproportionate Share Hospitals (DSHs) is simply part of the broader exemption for sales to 340B entities. CMS should not repeat this past mistake and jeopardise manufacturers' ability to provide deep discounts to safety net providers on non-340B drugs, until Congress can again clarify the meaning of the exemption.

NEW REQUIREMENTS FOR LINE EXTENSIONS

AMP and Best Price are assigned to drugs based on the labeller code and product code portions of the National Drug Code (NDC) maintained in the FDA database. Historically, when the FDA approved a new drug product in a family of products based on the same active ingredient, often through a supplemental New Drug Application (NDA), the product received a new NDC and was considered a new product with its own baseline AMP.

Competition, market opportunity, and increased efficacy and safety drive most decisions to change the form of a drug. However, as a policy matter, Congress was concerned that manufacturers were changing the formulations of drugs approved under NDAs, such as an extended release formulation of a drug, to:

- Change the product code.
- Establish a new baseline AMP.
- Increase prices without the inflation penalty.

Therefore, Congress imposed a new duty on manufacturers to calculate alternate additional rebate calculations based on the increase in AMP of the original drug in their URAs for line extensions of oral solid drugs, which it defined as new formulations, and to use the method that yielded the highest rebate amount. The ACA is clear that this obligation is effective prospectively. As decisions to develop existing products were made before the statue was enacted, it seems reasonable to interpret the law as prospective in reach as well as in practice, that is, as applicable to new formulations approved after enactment of the ACA.

The proposed rule would apply the alternate additional rebate calculation requirement to oral solid drugs based on four chemical types indicated in the FDA approval records (2, 3, 4 and 6). These cover not only changes in the form of a drug that would result in a new product code, but changes in inactive ingredients, such as preservative or stabilisers that may not result in a new product code. The only change in formulation that would not be covered is a change in dosage strength.

The proposed rule would also apply the new requirement based on a new approved indication for a drug, which would not result in any change to the product or its NDC. Indeed, a drug in a single form could have originally applied for multiple indications, and then received successive approvals for new uses, without ever changing the original formulation. Moreover, obtaining approval of a new indication is tantamount to a new drug approval. Including a new indication in the definition of new formulation makes no sense.

The proposed rule would also apply to:

- Combination products that reduce patient costs.
- Changes in delivery systems intended to improve patient safety.
- Formulation changes intended to deter abuse of narcotics.

Such changes, which provide real healthcare benefits and are clearly not intended to avoid inflation penalties, have development costs, which manufacturers should be able to recoup. It is simply bad policy to create unnecessary impediments to innovation and improvement of pharmaceutical therapies.

In addition to this broad definition of new formulation, the proposed rule would apply to all pre-existing oral solid drugs that could be classified as new formulations of an original oral solid drug. Therefore, it would impose a burden on manufacturers to:

- Identify all oral solid drugs that they currently sell that received an approval from the FDA indicating one of the four chemical types, except for new strengths.
- Obtain both the baseline AMP and current AMP for the original drug, even if they do not own it and do not have access to that information.

Applying this requirement to pre-existing drugs is fraught with problems:

- Manufacturers can plan to obtain baseline AMP in the future by including it as a condition in a transaction to acquire or license the right to sell a line extension of an original drug. However, the proposed rule would require manufacturers to obtain this information when they have no ability to force another company to provide it, long after the deal was completed and the original owner may have good reason to protect its own product's pricing information. Manufacturers could be forced to stop selling a line extension because they could not comply with the new requirement. Even if a manufacturer wanted to divest a line extension that it acquired, it may not be able to sell it because all prospective buyers except the owner of the original drug would have the same problem obtaining the necessary pricing information.
- More importantly, when two manufacturers sell competing forms of a drug, requiring them to share current pricing information, this raises serious anti-trust concerns.
- A manufacturer cannot verify the accuracy of the AMP obtained from another company that it would have to use in its URA calculation. For the same reason that CMS did not oblige manufacturers to obtain pricing data from competitors in implementing the authorised generic provisions of the DRA, it should not oblige manufacturers to share monthly or quarterly AMP with their competitors.

TREATMENT OF COUPONS, VOUCHERS AND CO-PAYMENT ASSISTANCE

One improvement that CMS made to the regulation of AMP concerns the treatment of price concessions to consumers of prescription drugs. The withdrawn regulation set out a complicated five-prong test for determining how to treat a coupon, voucher, or other offer of assistance from a manufacturer to a consumer, in the form of a discount off the retail price or assistance with his insurance co-pay amount.

These manufacturer programmes, which reduce the retail price paid by an uninsured patient or an insured patient's share of the retail price, are not intended to provide the dispensing pharmacy with a discount or financial benefit from the manufacturer's offer. Instead, they are intended to make the pharmacy whole through redemption of the coupon or voucher, or in some cases to compensate it for incurring programme administrative costs.

The proposed rule recognises that when the benefit flows only to the consumer, and the pharmacy is reimbursed at a normal rate, the value of the consumer benefit is not a price concession to the manufacturer's customer, and should not be included in the average price paid by pharmacies for drugs they dispense. Accordingly, the proposed rule would simplify the test for excluding redemption payments from AMP and Best Price, by reducing the criteria to one: no portion of the consideration from the manufacturer for purchasing a prescription of its drug can go to the pharmacy as a discount, rebate or price concession.

However, this revision remains confusing, because it would exclude from price calculations only co-payment assistance programmes that "provide free goods that are not contingent on future purchase". In other words, it does not use the term co-payment assistance as it is normally used, that is, assistance with an insured patient's share of the price charged by the dispensing provider.

As a consequence, the proposed rule would remove the previously ambiguous condition that there be no "negotiation" between the manufacturer and a third party, such as a managed care organisation, in determining the amount of the assistance to the insured patient. At the same time, it appears to exclude any manufacturer assistance payment to a pharmacy if the pharmacy is paid in part by the patient's health plan. Such a reading makes no sense, as it would negate application of the new price concession test to the majority of patient benefits provided by manufacturers, even though no portion of the benefit provided to the consumer reduces the price paid by the dispensing provider. If an assistance payment adjusts any price, it is the retail price paid by the patient.

The proposed co-payment provision is particularly problematic for expensive physician-administered drugs. These drugs are often covered by programmes in which manufacturers provide assistance to patients with high co-payment obligations. As with drugs dispensed through pharmacies, there is no purchase obligation and the provider of this type of drug is simply made whole by the payment.

It seems likely that CMS, in referring to the provision of free goods through manufacturer assistance, meant patient assistance programmes, rather than co-payment assistance. However in either case, the final rule needs to clarify that manufacturer co-payments to providers on behalf of patients are not price concessions to the providers.

NEW DEFINITION OF WHOLESALER AND THE AUTHORISED GENERIC RULE ON AMP

Another positive aspect of the proposed rule is its adherence to the change in law that governs the treatment of authorised generics. A manufacturer holding title to the original NDA of an authorised generic drug must only include the sales of this drug in AMP when sold by the manufacturer directly to a wholesaler (*42 C.F.R. 447.506(b)*).

An authorised generic is a drug sold under an NDA under a different labeller code than the brand. Before the ACA, companies that purchased a product directly from manufacturers and resold under a different labeller code were not considered wholesalers, because the DRA regulation defined wholesalers as excluding sales to re-labellers.

Accordingly, direct sales to distributors or other manufacturers that sold authorised generic drugs under their own generic labels were not sales by the owner of the drug to wholesalers. At the same time, the sale by the owner of the drug to the same entity was included in Best Price. As sales of the brand diminished, and sales of the authorised generic increased, this disparity between the treatment of sales to re-labellers in AMP and Best Price of the brand caused a huge differential between calculated AMP and Best Price, forcing manufacturers to pay enormous rebates.

Fortunately, the ACA defined the term "wholesaler" to include any entity that engages in the wholesale distribution of drugs, including distributors and manufacturers that sell the brand manufacturer's drug under a different labeller code. Therefore, by statute, manufacturers began to include their direct sales to sellers of authorised generic drugs, regardless of whether they sold the drugs under their own label.

The proposed rule recognises this change and would require inclusion of such sales in the AMP of the brand as well as Best Price, bringing parity to the treatment of these sales, consistent with the Medicaid drug rebate statute. What the proposed rule did not address is the operational issue of how to capture the total purchase price in AMP, as these deals are typically structured so that the authorised seller's purchase price consists of a transfer amount and a royalty paid on the resale.

At present, it appears that primary manufacturers could estimate the transaction price, but due to lagged realisation, would have to continuously restate their AMP to ensure the actual sales data for the period is accurate. A simple solution would be to allow manufacturers to include lagged upward price adjustments in a smoothing formula, along with their lagged downward adjustments.

CHANGES TO CMS' POLICY ON RESTATEMENTS OF AMP AND BEST PRICE

For many years, manufacturers routinely restated AMP and Best Price as reported to CMS. This was because:

- They were required to adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjusted the price actually realised, and subsequent transactions regularly adjusted the prices that had been reported in prior periods.
- They corrected computational errors and data processing errors.

Manufacturers implemented changes to previously paid rebate amounts through credits or additional rebate payments. Price revisions resulting from changes in methodology or improved price reporting systems could also be made retroactively. However, CMS required the changes to be approved before taking effect, which was a very lengthy process.

Before the ACA, CMS modified these procedures in three respects:

- Under the DRA, AMP revisions were no longer required when the revision would be solely as a result of data relating to lagged price concessions.
- With the establishment of standard methodologies in the DRA regulation, CMS no longer required its approval.
- CMS published a rule that time barred restatements of AMP and Best Price after 12 quarters, if the manufacturer had not submitted the restated prices to CMS by the cut-off date, regardless of reason for the restatement (*Manufacturer Reporting Requirements, 42 C.F.R. § 447.534 (2004)*). This absolute limitation on restatements had serious programme consequences. For example:
  - incorrect baseline AMP had a continuous impact on rebate calculations, and data discrepancies between CMS and manufacturer records could not be reconciled;
  - most importantly, if a manufacturer believed its AMP or Best Price was inaccurate during the year preceding the restatement window due to a computational error, and the error resulted in underpayment of rebates to the States, it could only notify CMS of the error but could not correct the reported value (even though it remained potentially liable for the underpayment). Permission to revise values in the CMS database was granted on an ad hoc basis.

Under the proposed rule, the requirement to adjust AMP remains basically unchanged. Similarly, manufacturers would still be required to report AMP revisions within 12 quarters, except when the revision would be solely as a result of data relating to lagged price concessions. Revisions to monthly AMP would require revisions to quarterly AMP and vice versa.

However, the proposed rule specifies five instances in which a submission outside the 12-quarters would not be rejected by CMS. These instances would not include methodology changes or different data, except in the case of a change that is required by CMS, a court order, a government audit or investigation, or an internal investigation to address underpayments to States. For example, submission of a revision outside 12-quarters would be permitted when the revision is required "due to a technical correction, that is, not based on any changes in sales transactions or pricing adjustments from such transactions".

In addition, the proposed rule contemplates further permission to report revisions to AMP, Best Price, customary prompt pay discounts, or nominal prices for a period in excess of 12 quarters, from the quarter in which the data were due based on the approval of CMS for good cause. If granted, a manufacturer would be permitted to revise its methodology for calculating its reported prices, and to restate AMP and Best Price to address underpayments and potential liability regarding those underpayments that may extend outside of that 12-quarter period.

CMS is considering proposing a "good cause" option to extend the time limit for filing a recalculation request, similar to that used in Medicare. The good cause contemplated by the rule would be predicated on a concern that reported prices caused an underpayment to the States, and that the discovery of the error was likely the result of an internal review. Given this, it is unclear when a restatement is covered by the fifth exception (required to address underpayments or potential underpayments as required by an internal investigation) and when it would fall within the discretionary good cause provision, and require CMS approval. Restatements outside the 12-quarter period would not be permitted if they would result in overpayments to the States. It is likely that a manufacturer would simply restate reported prices if on an internal review it believed they were non-compliant.

The proposed rule suggests that approval would be required if the manufacturer is uncertain as to whether the change is required. Otherwise, it appears that the basis for the good cause exception may already be covered.

SUMMARY

When Congress created the MDRP two decades ago, and required manufacturer rebate agreements based on prices calculated and reported to CMS, no one appreciated the complexity of present day business transactions in the pharmaceutical industry. What were once thought to be simple calculations (the average price paid by pharmacies and wholesalers that distribute to pharmacies and the single lowest price paid by a commercial customer) became in practice rather difficult to apply. The administrative resources and systems required to comply with this programme are huge.

CMS has compounded the problem by failing to grasp the roles and functions of all the players that move drugs from plant to patient, and when relationships exist or do not exist between:

- Manufacturers and direct buyers of their products.
- Customers of resellers.
- Contract customers that buy indirectly through distribution agents.
- Entities that facilitate the purchase of products but do not buy or sell them.
- Downstream consumers of dispensed drugs.
- Third parties that pay for the drugs.

Further, CMS has begun assuming a role that far exceeds that contemplated by the programme, and is exceeding its limited authority to regulate certain discrete aspects of the programme. In many respects, the proposed rule disregards the organic statute and the integrity of the contracts through which manufacturers agree to make prices available to the Medicaid programme, and usurps the role of Congress by imposing greater obligations on manufacturers through regulatory changes to the contract terms.

If CMS does not reconsider, its actions raise an interesting issue: can CMS terminate a contract and oust a manufacturer from the MDRP if the manufacturer is adhering to the statutory requirements for a rebate agreement, but declines to comply with unauthorised regulatory changes to the terms of its contract?

CONTRIBUTOR DETAILS

DONNA LEE YESNER

Morgan Lewis
T +1 202 739 5887
F +1 202 739 3001
E *dyesner@morganlewis.com*
W *www.morganlewis.com*

Qualified. District of Columbia, 1983

Areas of practice. Healthcare and government contracts.

Recent transactions

- Acquisition and reimbursement of federal healthcare supplies and services.
- Compliance with laws and regulations governing the Veterans Health Care Act, Medicaid, Medicare, Tricare, and 340B drug discount programmes, and public policy affecting these programmes, and healthcare fraud.
- Advising companies regarding compliance with federal drug pricing programme requirements and the impact of these requirements on their business.
- Writing and speaking frequently on federal drug pricing programmes.

ANDREW D RUSKIN

Morgan Lewis
T +1 202 739 5960
F +1 202 739 3001
E *aruskin@morganlewis.com*
W *www.morganlewis.com*

Qualified. District of Columbia, 2003; New York, 1997

Areas of practice. Healthcare regulation.

Recent transactions

- Advising pharmaceutical and medical device companies on healthcare regulatory matters.
- Advising on Medicare and Medicaid coverage, reimbursement, price reporting, and compliance issues affecting these entities.
- Advocating client positions to the Centers for Medicare and Medicaid Services and other government agencies.
- Advising on structuring arrangements with distributors, wholesalers, managed care organisations, patients, and others to avoid fraud, abuse and price reporting concerns.

STEPHEN E RUSCUS

Morgan Lewis
T +1 202 739 5870
F +1 202 739 3001
E *sruscus@morganlewis.com*
W *www.morganlewis.com*

Qualified. District of Columbia, 1996

Areas of practice. Healthcare and government contracts.

Recent transactions

- Federal drug pricing programmes, including compliance with laws and regulations governing Medicaid, Medicare, the 340B drug discount programme, and pricing under the Veterans Healthcare Act.
- Government contracts including Federal Supply Schedule and other commercial item contracts for pharmaceuticals and medical devices.