Summary of Proposed AMP Regulation

Subject	Current Rule	Proposed Rule	Comment
Medicaid Drug Rebate Program (MDRP)			
Inclusion of Territories	The Medicaid Drug Rebate statute authorizes the Secretary of the Department of Health and Human Services (HHS) to enter into a Medicaid Drug Rebate Agreement on behalf of the States and specifies the terms of the agreement that manufacturers must execute to participate in the MDRP. The statute doesn't define the term "States," but the Rebate Agreement defines the term to mean the 50 States and the District of Columbia. For 20 years, the MDRP has applied only to the 50 States making up the United States and the District of Columbia. Rebates have only been due to the States and the District of Columbia and data included in the pricing calculations is limited to that resulting from transactions in the 50 States and the District of Columbia.	Would define the terms "States" and "United States" in the implementing regulation to include U.S. territories (Puerto Rico, Virgin Islands, Guam, Northern Mariana Islands, and American Samoa).	Would increase rebate liability by expanding the number of covered prescriptions in the event the territories have approved Medicaid plans, and could increase rebate liability by including prices available in the territories in Best Price. Could also lower Average Manufacture Price (AMP) by including sales transactions in the territories and thereby lower the federal upper limit (FUL) and the reimbursement rate for pharmacies throughout the United States. Would require manufacturers to include data in their price reporting systems that may not be captured in the financial records of domestic transactions. Raises fairness issues as pricing structures are different in the territories. Statutory authority to expand the rebate agreement terms by regulation is highly questionable.
Medicaid Managed Care	The DRA Rule did not address Medicaid Managed Care.	Would implement the statutory requirement that rebate agreements include prescriptions paid by Medicaid Managed Care as well as Fee-for-Service. Would require Medicaid Managed Care plans to capture utilization data and provide it to the States and would only exempt prescriptions dispensed by a health maintenance organization (HMO)	The Proposed Rule does not address drugs dispensed by covered entities (other than HMOs) that are paid by Medicaid Managed Care plans. Payment of rebates on 340B drugs would conflict with section 340B of the Public Health Service Act. The Proposed Rule also does not address whether drugs paid by a Medicaid Managed Care plan and now covered

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		from the program if the HMO is a 340B-covered entity.	by a rebate agreement must be treated the same as drugs paid by Medicaid Fee-for-Service (i.e., they can be subject to prior authorization but cannot be excluded by Medicaid Managed Care plans from the plans' formularies).
Covered Outpatient Drugs	Covered drugs include over-the-counter (OTC) drugs dispensed pursuant to a prescription. The DRA Rule defined "Single Source Drug" as including products approved under a Biologics License Application (BLA), and defined "Innovator Multiple Source Drug" as one originally marketed under an original New Drug Application (NDA).	OTC drugs will only be considered covered drugs if they have a National Drug Code (NDC) listed electronically with the FDA and they are dispensed pursuant to a prescription. Pre-1962 Multiple Source Drugs that were not originally marketed under an original NDA but for which an NDA has since been granted (505(b)(2) drugs) would be considered "Non-Innovator Multiple Source Drugs." Other 505(b)(2) drugs would be treated as brands.	CMS did not clarify what manufacturers' responsibilities are with respect to OTCs with NDCs listed electronically with the FDA. CMS also did not propose how to treat biosimilars approved under the abbreviated BLA pathway pursuant to section 351(k) the Public Health Service Act. These biological products would be covered drugs, but they don't fall into any of the categories used to apply the rebate program rules.
AMP Calculation			
Wholesaler Sales	The DRA Rule didn't address methodology for determining wholesaler distribution of drugs to their own customers in absence of manufacturer verifiable data. Industry practice was for manufacturers to identify excluded indirect sales using their own chargeback data and assume remaining wholesaler sales were to the retail pharmacy class of trade, which is a broader category than retail community pharmacies.	The Proposed Rule would prohibit the inclusion of sales to wholesalers in AMP unless a manufacturer has documentary evidence that the drugs sold to the wholesalers were distributed to retail community pharmacies. Would no longer permit, manufacturers to assume wholesaler sales to noncontract customers (for which there is chargeback data) are to retail community pharmacies.	Obtaining data from wholesalers has been problematic. It has been incomplete and inaccurate and is not verifiable. The Proposed Rule could result in the exclusion of a significant number of unverifiable sales, which could skew the average depending on the manufacturer's circumstances (e.g., if a manufacturer sells directly to included classes of trade at a discount, fewer sales at the wholesale acquisition cost (WAC) could lower the AMP).

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			The Proposed Rule raises a concern that it would impose upon manufacturers a duty to try to obtain proprietary information from wholesalers, but manufacturers' ability to obtain complete and accurate wholesaler data is uncertain, and the reliability of the data cannot be ensured.
Line Extensions	The DRA Rule didn't address new statutory requirement for alternate additional rebate calculation. Formula for alternate additional rebate calculation was provided as guidance following the enactment of healthcare reform.	Defines line extension based on chemical types (2, 3, 4, and 6) captured in FDA approval records, including changes to inert ingredients, combinations, and new indications. Would require manufacturers to (1) identify the original approved drug for every distinct oral solid formulation of an oral solid drug they sell except for a different strength; (2) obtain the baseline AMP for both the original drug and every new formulation going back to the beginning of the program; (3) calculate an alternate additional rebate for each new oral solid formulation every month; and (4) compare and report the lower of the two alternative additional rebates. Does not apply if the original drug has been discontinued, but applies if a manufacturer does not sell the original drug. Would apply to changes to formulations intended to prevent abuse of narcotics.	Having to perform alternate calculations for all line extensions of oral solid drugs approved since the beginning of the program (instead of those approved after enactment) on a monthly basis is burdensome and unfair, as manufacturers had no way to consider the impact of the new rule on prior business decisions. Would require manufacturers to obtain baseline data and pricing data for drugs they do not sell from competitors on a monthly basis in order to perform the calculation, which raises serious antitrust issues. Statute equates line extension with new formulation but only one chemical type used by the FDA is for new formulations. Treating new indications as line extensions makes no sense here, as the drugs are unchanged and the manufacturers have no visibility into their clinical uses, but this has little effect on the calculation, as the NDC will remain the same.

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Sales to Specialty Pharmacies and Home Healthcare	The DRA Rule included specialty pharmacies and home healthcare distributors in AMP unless drugs were dispensed by nursing homes through home healthcare.	Would include specialty pharmacies and home healthcare distributors within the definition of "retail community pharmacies" and would include discounts and rebates to these classes of trade in AMP.	Not limited to drugs sold primarily through these channels. Doesn't address treatment of specialty pharmacies that are mail-order pharmacies, which are excluded from the definition of "retail community pharmacies," or whether these customers would be considered "retail" for purposes of applying 5i AMP methodology.
Administrative Fees	The DRA Rule created a Bona Fide Service Fee test for fees paid to purchasers. PPACA excluded Bona Fide Service Fees paid to wholesalers and retail community pharmacies, including but not limited to specified fees commonly paid to these customers, including fees associated with administrative services agreements.	The Proposed Rule would continue to require that fees meet its Bona Fide Service Fee criteria, even for those fees that are specified in the statute. Would not create a blanket exemption for group purchasing organization (GPO) fees (to the extent paid on included sales) even though paid to third parties, because of the risk that fees would be passed on to their members. Would not specify any particular method for determining fair market value (FMV) but would require reasonable assumptions consistent with supporting documentation that provide basis for FMV determination. Would exclude fees paid for price appreciation provided through credits.	The average sale price (ASP) rule allowed manufacturers to presume fees are not passed through to customers absent evidence to the contrary. Otherwise, these fees would always be included as reductions to the purchase price even though Congress called them out for exclusion from AMP and the purchasers did not receive any portion of the fees. Further, fees that are expressly excluded by statute and are not passed through would still be included as a de facto price concession to the purchaser if a manufacturer does not itemize the services or cannot document FMV.
Coupons, Coinsurance Support, and PAP	The DRA Rule includes a multipronged test to determine whether these arrangements with patients are excludable from AMP and Best Price.	Would reduce the requirements to one: no portion of the consideration can go to the retail community pharmacy as a discount, rebate, or price concession.	The proposed revision to this exclusion removes the ambiguous requirement that there be no "negotiation" with a third party, such as a managed care organization (MCO), in determining the amount of

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			the support. However, the Proposed Rule would exclude only those copayment assistance programs that "provide free goods that are not contingent on future purchases." Copayment assistance programs generally provide point-of-service discounts to patients equal to some portion of their coinsurance liability, not free goods. The reference to free goods in this context is misplaced and confusing, creating uncertainty as to what may actually be excluded.
Sales to Government Health Plans and Insurers	The DRA Rule excluded all rebates paid to Medicare, Medicaid, Tricare, state pharmaceutical assistance programs (SPAPs), and commercial health plans, but not the underlying sales to the pharmacies reimbursed by these plans.	The Proposed Rule would require manufacturers to exclude from AMP rebates paid to insurers but not the underlying sales to the pharmacies. It would also exclude Tricare-reimbursed prescription units from gross sales, even though Tricare is acting as an insurer as defined. It would also exclude rebates to Medicaid, SPAPs, and Medicare Part D, and Part D coverage gap discounts, but does not clearly require inclusion of the underlying sale to the pharmacies as it does with insurers.	There should be consistency between the treatment of government and commercial health plans where the plan is functioning as an insurer, i.e., paying the provider for a prescription dispensed to a patient. The purchase price paid for a drug by a retail community pharmacy exists independent of any rebate provided by the drug's manufacturer to a payer on behalf of the pharmacy's customer, regardless of whether the payer is a government or commercial plan. These rebate transactions are not associated with the manufacturer's sale to the pharmacy and should be ignored.
5i Drugs	The DRA Rule did not differentiate among types of drugs for purposes of AMP calculation. By statute, payments from and discounts and rebates provided to entities that do not do business as wholesalers or retail	Would implement the statutory exception to the exclusions from AMP by including all sales dollars and units for 5i drugs received from and all discounts and rebates provided to entities that do not do business as	If CMS follows the VA model, it is unclear whether it would (a) follow the VA rule that the methods are mutually exclusive or (b) require a combination of all sales, as is the case with ASP.

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	community pharmacies are excluded from the calculation of AMP, except for inhalation, infusion, instilled, implanted, and injectable (5i) drugs that are not generally dispensed by retail community pharmacies. Many manufacturers have been using a modified ASP methodology to calculate 5i AMP.	wholesalers or retail community pharmacies. Carves out payments received from and discounts and rebates provided to government purchasers and payers. Would determine a drug's status as a 5i drug based on route of administration. Would base determination of whether a drug is generally not dispensed by retail community pharmacies on the VA's 90%/10% model for determining whether to use the direct customer methodology in lieu of wholesaler sales for calculating the non-federal average manufacturers price (NFAMP). Would include sales to pharmacy benefit managers (PBMs) and MCOs in 5i AMP.	If a drug crosses the 10% threshold, the VA requires the manufacturer to recalculate its prior NFAMP using the current methodology so price comparisons for inflation purposes are based on the same methodology. However, the VA's calculation is an annual one. Shuttling back and forth between retail and 5i AMP because an arbitrary line is crossed will create huge swings in AMP and play havoc with the additional rebate calculation. If specialty pharmacies and home healthcare distributors that often distribute 5i drugs are within the definition of retail community pharmacy, these sales should count in whatever percentage CMS uses to determine whether the drugs are or are not generally dispensed through retail community pharmacies, which would mean more Medicare Part B drugs would fall outside the 5i calculation. A higher retail AMP means higher rebates but also higher 340B prices and would not trigger substitution of AMP for ASP. Finally, it is unclear what is meant by sales to PBMs and MCOs as these entities are generally insurers not purchasers. It would be more consistent with retail AMP and fairer to providers reimbursed on the basis of AMP to exclude payments to insurers from the calculation.

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Base AMP Recalculation (ACA)	The DRA Rule allowed manufacturers to recalculate their base date AMP within four quarters of the effective date of the final rule at their discretion if they had supporting data. CMS did not provide the same relief when it published its rule withdrawing the DRA Rule and advising manufacturers to follow the statute.	The Proposed Rule would again permit manufacturers to restate base date AMP within the same time period at their discretion if they have supporting data.	Assuming the ACA changes to AMP caused it to increase, because manufacturers have not been permitted to restate base-date AMP since the enactment of those changes, CMS should allow manufacturers that had to include additional rebate penalties in their unit rebate amounts (URAs) to adjust their prior-period URAs as well as the base-date AMPs that resulted in those penalties. CMS needs to address potential need for two base-date AMPs for 5i drugs.
Best Price			
BP Definition	Best Price is defined by statute as the lowest price available to any manufacturer, wholesaler, retailer, provider, etc., with certain statutorily specified exemptions. It is a single transaction price provided to a single customer, not an aggregation of discounts available to distinct customers in the chain of distribution that would not be available in the aggregate to any of them.	The Proposed Rule would redefine Best Price to include discounts and rebates "associated" with the sale of a drug to a customer, rather than the price available to that customer. Tries to match methodologies used for AMP and Best Price.	Appears the Proposed Rule would require fees paid to nonpurchasers like GPOs, which arrange for purchase terms, to be included in the purchase price negotiated by the GPOs, unless the fee meets the Bona Fide Service Fee test. Although the original Best Price rule still excludes rebates paid to PBMs that are not intended to adjust the price available to the health plan, it appears that fees paid to PBMs would be "associated" with included rebate transactions, even if not intended to be passed through, and thus would be included as an adjustment to the plan's price unless the fee meets the Bona Fide Service Fee test. Does not address aggregation of a discount provided to one customer on its purchase with a discount provided to a different customer in an unrelated subsequent

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BP PHS Exclusion	The DRA Rule didn't address new statutory exclusion of orphan drugs from the 340B program. Medicaid statute exempts prices charged to covered entities and clarifies that nonprogram sales to disproportionate share hospitals (DSHs) for inpatient use are exempt, but not those to other 340B hospitals.	Would include sales of orphan drugs to newly added categories of 340B hospitals in Best Price. Considering inclusion of other non-program sales such as sales to hospitals for inpatient use where not exempt by statute.	Although the statute exempts prices charged covered entities, Congress had to clarify that it intended for inpatient sales to DSHs to be exempt from Best Price, because CMS had previously decided to include these non-program sales in Best Price. Would discourage voluntary sales to certain hospitals at deep discounts. Could complicate compliance if HHS's proposed rule excludes sales based on orphan indication.
Nominal Price	The DRA Rule included only statutory exemptions for nominal prices.	Would add two new discretionary categories to the exemption: pharmacies of qualified charitable organizations that are not covered by the 340B program and certain teaching institutions.	Permits exclusion of drugs that are not donated but for which a nominal price is charged to student health clinics and other nonprofits.
Authorized Generics (AG)	The DRA Rule required inclusion of sales of an AG-labeled drug in AMP of the brand if sold by the owner of the NDA directly to a wholesaler, which the DRA Rule defined as excluding distributors and manu-facturers that sold the drug under their own NDC. At same time, the DRA Rule required inclusion of sales of an AG drug by the owner of the NDA to an own-label manufacturer or distributor in Best Price of the brand. Caused a large discrepancy between AMP and Best Price for a drug with significant AG sales.	The Proposed Rule would require inclusion of direct sales of an AG-labeled drug to a manufacturer or distributor selling under its own NDC in AMP of the brand. Would continue to require separate price reporting and payment of rebates of the drug by the owner of the NDC under which it is sold.	Conforms rule to statutory definition of wholesaler and treats sales to manufacturers and distributors of AGs the same in AMP and Best Price. Because the term "manufacturer" includes a distributor that owns the NDC for the drug it distributes, the terms are really interchangeable. Reduces gap between AMP and Best Price of the brand. Operational issues exist as to how to include total transaction price in AMP when the price is provided through a transfer price and a lagged payment on the resale.

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Restated AMP and Best Price	By regulation, CMS established a 36-month cut-off for submitting restated AMP and Best Price values, even if a manufacturer believed that the change was necessary for prior-period submissions to be compliant and the previously reported prices resulted in an underpayment to the States. Changes required as a result of a government audit or investigation were not barred.	Would allow manufacturers to restate prices reported outside the window if the reason for the restatement falls into one of five categories, such as technical errors, revisions to launch dates, and corrections of prices that caused underpayments pursuant to government audits or investigations or internal investigations. Corrections that result in credits will not be allowed. In addition, CMS is considering a relaxation to the three-year rule for good cause, meaning a change in methodology that resulted in underpayment to the States.	If the good cause basis is intended to capture a methodology rationale predicated on concerns with False Claims Act liability, this basis for restating drug pricing seems to be subsumed in the proposed category that covers data omissions and other errors, as well as methodology corrections resulting from internal investigations. If it is intended to capture discretionary changes, it makes little sense that a manufacturer would want to restate in order to increase its rebate payments for the affected period.