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DRA POLICY QUESTIONS

Subject	Question	Response
AMP	Are all PBM administrative fees excluded from AMP and considered in BP or just those related to PBM mail order rebates?	In general, administrative fees are excluded from AMP and BP only if they meet the criteria for bona fide service fees. For PBMs, other than mail order, all administrative fees are excluded from AMP and best price.
AMP	May a manufacturer opt to smooth sales that are excluded from AMP?	No. For the purposes of Medicaid, only the discounts, rebates, and other price concessions associated with sales included in AMP should be used in the 12-month rolling average to estimate the value of lagged price concessions.
AMP - Assumptions	Can a statement/chart of the monthly AMP methodology be included with the first monthly AMP submission?	No, but in accordance with section II(i) of the Medicaid Drug Rebate Agreement manufacturers are to retain their assumptions/AMP methodology.
AMP - Calculation	If a manufacturer chooses to restate their base date AMP, will they have to calculate three monthly AMPs first and then use the quarterly weighted methodology to arrive at a new quarterly base date AMP, or may they simply calculate a single quarterly AMP?	Manufacturers that recalculate their base date AMP to reflect the revisions of AMP as specified in the final rule need only calculate the base date AMP based on a quarterly AMP.
AMP - Calculation	Should manufacturers calculate the quarterly weighted AMP by summing the three monthly AMP units and applicable AMP dollars for each NDC-9 and then divide the dollars by the units?	Yes, manufacturers should calculate the quarterly weighted AMP by summing the three monthly AMP units and applicable AMP dollars for each NDC-9 and then dividing the dollars by the units.
AMP - Calculation	Should sales to wholesalers in Puerto Rico and other U.S. territories be included in the AMP calculation?	Sales to Puerto Rico and other U.S. territories are not to be included in the AMP calculation.

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AMP - Reporting Monthly AMPs under the Court Order	In light of the Order issued by the United States District Court for the District of Columbia in the case of *National Association of Chain Drug Stores and National Community Pharmacists Association v. United States Department of Health and Human Services et al.*, are manufacturers required to report monthly Average Manufacturer Prices (AMPs) to CMS?	Yes, the responsibilities of drug manufacturers for reporting monthly and quarterly AMPs, required in the regulation published on July 17, 2007, at 42 CFR Section 447.510, are not affected by the Court's Order. While CMS is generally enjoined from publishing, or otherwise disclosing these data, we do not read the Order to preclude the collection by CMS of monthly or quarterly AMP data from drug manufacturers. Accordingly, we expect manufacturers to comply with our regulation and report AMPs within the timeframes specified in the regulation.
AMP - Reporting	How should zero or negative AMPs be handled?	If there is a zero or negative AMP, we recommend that manufacturers report the most recent prior positive AMP.
AMP - Reporting	Further, if one of the monthly AMPs is negative, does the manufacturer use the negative monthly AMP or the previous quarter's reported AMP?	In general, with respect to a negative monthly AMP reporting, the manufacturer reports the most recent prior month's positive AMP. However, the actual calculated monthly AMP should be used to calculate the quarterly AMP. If this quarterly AMP is negative, report the prior quarter's AMP.
Authorized Generics	If an authorized generic product is sold or transferred to a secondary manufacturer, but not launched by that manufacturer into the commercial market until a later date, is the primary manufacturer obligated to report best price (BP) based on the transfer price at the time of sale or may the primary manufacturer include the sale when it actually authorizes the secondary manufacturer to launch the product?	The final rule provides that the primary manufacturer include the best price of an authorized generic drug in its calculation of best price when the drug is being sold by the primary manufacturer to the secondary manufacturer. In accordance with this provision, we expect that the primary manufacturer report a BP which incorporates the transfer price at the time of sale to the secondary manufacturer for the quarter in which the sale occurs, regardless of when the product is launched.
Authorized Generics	Since royalty payments are amounts paid to the primary manufacturer by the secondary manufacturer, should these payments be added to the transfer price to determine the transaction price for BP?	Yes, we expect manufacturers to include royalty payments in the transfer price.

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Authorized Generics	Please clarify if the primary manufacturer is required to include the transfer price received from the secondary manufacturer in the AMP of the brand name drug when authorized generic products are repackaged or relabeled under the secondary manufacturer's NDC.	The final rule provides that the primary manufacturer include sales of the authorized generic product only when such drugs are being sold by the primary manufacturer to a wholesaler. Accordingly, to the extent that the secondary manufacturer does not qualify as a wholesaler, the primary manufacturer does not include the transfer price to the secondary manufacturer in the AMP calculation for the brand name drug.
Authorized Generics	If a primary manufacturer ceases marketing the brand version of the product, but continues to supply product to the secondary manufacturer, at what point does the primary manufacturer's obligation to report pricing data on its own behalf cease?	As discussed in the final rule, if a primary manufacturer no longer sells the brand drug and the secondary manufacturer purchases an authorized generic version of the drug and changes the NDC, a primary manufacturer is responsible for paying rebates on its drugs still in the supply chain and must supply a termination date equal to the shelf life of the last stock sold under the primary manufacturer's NDC. The final rule provides that the primary manufacturer supply pricing data for four quarters beyond the shelf life of the drug.
Base Date AMP	Because of the administrative burden and cost due to data limitations, can a manufacturer make reasonable assumptions when necessary to recalculate the base date AMP to comply with the provisions of the final rule?	The regulation provides that for the purposes of recalculating the base date AMP, manufacturers must use actual and verifiable pricing records.
Base Date AMP	Who is responsible for recalculating and certifying the base date AMP for a product that has been purchased/ sold?	The manufacturer that holds current legal title to the labeler code for the product is responsible for recalculating the base date AMP and complying with the certification requirements.
Base Date AMP	Can a manufacturer elect to recalculate a base date AMP to reflect the customary prompt pay discount only and not the other revisions to AMP?	No. Section 447.510(c)(2) provides that a manufacturer may report a revised base date AMP to CMS. However, a recalculated base date AMP must only reflect revisions to AMP provided for in section 447.504. Accordingly, we expect that any base date AMP recalculation be consistent with the methodology in that provision.

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Base Date AMP	Should the effective date of all recalculated base date AMPs be denoted as October 1, 2007 or the actual quarter in which the revised AMP is submitted to CMS (which can be no later than the four calendar quarter deadline following the publication of the final rule, or September 30, 2008)?	In light of the effective date of the regulation, a recalculated base date AMP should be denoted as October 1, 2007 regardless of the date submitted to CMS within the four calendar quarter deadline. Prior quarter adjustments (PQAs) will be generated back to the October – December 2007 quarter when the submission is later than that quarter.
Best Price Reporting	How is best price to be reported to CMS monthly? There is not a field on the DDR monthly Pricing Data file layout.	Best price is to be reported quarterly, not monthly to CMS.
Bona Fide Service Fee	Please clarify whether administrative services related to the administration of a rebate contract must be associated with services that involve the efficient distribution of drugs to meet the criteria of bona fide service fee?	Administrative service fees related to the administration of a rebate contract that meet the statutory definition of a bona fide service fee are excluded from the determination of AMP.
Bundling	A manufacturer offers discounts on multiple products under a single contract. The available discount and resulting price for each product in the contract is independent and not contingent on the discount or pricing of any other product in the contract, on the purchase of any other product in the contract or on some other performance requirement (such as the achievement of market share or inclusion or tier placement on a formulary). Furthermore, the same discounts and prices are available to customers that want to contract for these drugs individually under separate contracts. Once the separate pricing for each product is agreed to, a single contract is created that reflects terms and conditions that apply to all of the products included in the contract. In this situation, are the products bundled within the meaning of §447.502?	No. Where a discount or price concession is established independently and not conditioned upon any other purchase or performance requirement (for example the achievement of market share, inclusion or tier placement on a formulary), or where the discount is not greater than if purchased outside a multi-product arrangement, there is no bundle within the meaning of section 447.502. Manufacturers may use a single contract without triggering the bundled sale definition where there are no contingencies between products and, as specified in the question, the pricing and discounts for each product are established independently and are available when the drugs are contracted for separately.
Bundling	Where the fact pattern is the same as in the previous question, but the manufacturer in a separate contract or arrangement offers a discount of 10% on the prices available as per the previous question on Products A and B if the customer achieves a 20% market share on Product A, how should the 10% discount be allocated?	Where a separate contract or arrangement provides a discount on the price of both products if a market share requirement is met, a bundled sale exists and a manufacturer should allocate the discount across the products. In the example presented, the 10% discount should be allocated proportionately to Products A and B as part of the bundled arrangement.

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Bundling	If a manufacturer renegotiates a contract that originally met the definition of a bundled sale to remove all contingencies but continues to contract with the same payer for the same products, would this still be considered a bundled arrangement if a single new contract is signed, if individual contracts are signed with the same payer on the same day, or if they have the same end dates for administrative convenience?	If a manufacturer renegotiates a contract so that it meets the requirements given in the first bundling question and response in that sales are not bundled, these drugs will not be considered bundled regardless of the fact the products are listed in the same contract or that multiple contracts have the same execution or ending date.
Bundling	How does the new regulation apply to the treatment of existing contractual arrangements? Are manufacturers required to revise previous quarters' submissions to reflect the regulation? If not, is there any grandfathering for existing arrangements such that changes will not have to be made to those arrangements until they have ended according to their terms?	The final rule is effective on October 1, 2007; it is not retroactive prior to October 1, 2007. It does not provide for grandfathering of any existing contractual arrangements.
Dispensing Fee	Does CMS intend that a profit component be included in the dispensing fee?	CMS has not separately identified profit as a component of the dispensing fee, defined in the AMP-Medicaid Prescription Drug final rule, as we believe the components of the dispensing fee we have already identified allow for a reasonable profit. We continue to afford States the flexibility to set reasonable dispensing fees to appropriately pay pharmacies for their costs.
Federal Upper Limit (FUL)	Will FULs be established when only the brand and an authorized generic are on the market?	Per the AMP/Medicaid Pharmacy final rule, a Federal Upper Limit (FUL) will be established when the FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent. This would include drug groups that include only the brand name and the first new generic or authorized generic drug. However, the outlier policy established by CMS in calculating a FUL does not apply when only the brand and authorized generic drug are available.

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Nominal Price	How are nominal prices to be reported to CMS monthly? There is no field on the DDR Monthly Pricing Data file layout.	Nominal prices are reported quarterly, not monthly, to CMS.
Nominal Price	Where can a manufacturer find a comprehensive list of State-owned or operated Nursing Home Facilities?	The comprehensive list is posted on the Medicare website at http://www.medicare.gov/Nursing/Overview.asp. Download the database under Nursing Home Compare Section. Filter the list by "Type of Ownership" and narrow the selection to "Government - State" Nursing Home facilities.
Nominal Price	Should manufacturers who sell drugs at less than 10 percent of AMP to 340B covered entities, state-owned or operated nursing facilities or ICF/MR facilities through a federal supply schedule (FSS) contract include these sales in their nominal price reporting?	No. Manufacturers are not required to submit reports concerning prices charged under the FSS. Therefore, manufacturers should include only those sales in nominal price that would otherwise be included in best price.
Patient Assistance Programs	The preamble to the final rule states that Patient Assistance Program (PAPs) sales are excluded from AMP when drug products are provided free or when financial assistance is provided to low income individuals and families. The best price exclusion for PAP sales is the same regarding assistance to low income individuals and families, but does not refer to free goods. Is the standard different for AMP and best price?	In accordance with the regulations, Patient Assistance Programs (PAPs) are excluded from AMP and best price, provided they meet the criteria listed in the preamble of the final rule at 72 Fed. Reg. 39188-39189. We recognize that the discussion regarding PAPs in the preamble is not entirely consistent; however, we intend to clarify the criteria in our future rulemaking. Until that clarification is issued, we intend for the more specific criteria listed in the preamble with respect to AMP apply equally to AMP and best price.
Patient Assistance Programs	According to the preamble, the exclusion from best price of sales to Patient Assistance Programs (PAPs) applies when the individual is not eligible for Medicare and does not have other public or private prescription drug coverage. Does this apply in general to individuals with any prescription drug coverage or only when the drug provided through the PAP is otherwise covered?	As discussed in the prior response, the criteria on pages 39188-39189 of the preamble, concerning when PAPs are excluded from AMP, are also to be used for the best price exclusion.

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Patient Assistance Programs	The preamble to the final rule states that in order for sales to Patient Assistance Programs (PAPs) to be excluded from AMP the pharmacy may not collect any additional payment other than a bona fide service fee. The preamble discussion concerning the exclusion of PAP sales from best price does not state that a bona fide service fee may be collected. Did CMS intend to make this distinction?	The intent of the final regulation is to ensure that pharmacies do not receive any price concessions and that the entire amount of the subsidy is made available to the patient. As long as the pharmacy receives a bona fide service fee, that fee and any associated sales are excluded from both AMP and best price.
Patient Assistance Programs	The preamble discussion of the PAP exclusion for both AMP and best price states that the pharmacy may not receive any additional payment other than the benefit amount. What is meant by "benefit amount"?	The benefit amount is the value of the free good or financial assistance provided to the low income individual and family. It could be the cost of the free good to the pharmacy or patient, or the reduction in the amount paid by the individual to the pharmacy for the drug; for example, the price discount (fixed or percentage) under the program.
Patient Assistance Programs	The preamble states that sales to Patient Assistance Programs (PAPs) are excluded from AMP and best price only when provided to low income individuals and families "as determined by CMS". Does CMS plan to establish a definition of "low income" for this purpose?	CMS is not defining "low income" for this purpose and at this time will not require manufacturers to submit their PAPs to CMS for approval.
Patient Assistance Programs	If a drug manufacturer donates drug products to a foundation that manages the Patient Assistance Program (PAP) should that donated product be treated as a free good?	Yes, the donation would be excluded from AMP and best price as a free good.
Patient Assistance Programs	If a drug manufacturer donates drug products to a foundation that manages the Patient Assistance Program (PAP) would the AMP and best price exclusions apply in the same manner whether the drug manufacturer or the foundation determine the amount of assistance to be provided ?	Yes, as long as the PAP meets the criteria set out in the preamble.

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PBM Rebates	Rebates to PBMs, except for their mail order pharmacy purchases are now excluded from AMP. However, many PBMs do not separate their data between mail order pharmacy purchases and non-mail order purchases nor do they provide detailed data for plans under them. In these situations, may a manufacturer exclude the entire PBM rebate, consistent with the general meaning of the rule that sales may only be excluded based on actual data?	The AMP final rule requires that all sales, rebates, discounts and price concessions to mail order pharmacies, including mail order sales to PBMs, be included in AMP. We expect that manufacturers will take steps to obtain the necessary data to exclude non-mail order PBM rebates. Until they obtain such data, manufacturers may make reasonable assumptions consistent with the statute, regulations, and their customary business practices.
Physician-Administered Drugs	Has the list of the top 20 multiple source physician-administered drugs been distributed? If so, where can I go to find this list?	The top 20 list is posted on the CMS website at http://www.cms.hhs.gov/DeficitReductionAct/40_PhysicianAdministeredDrugs.asp
Posting Timeline for AMP and FUL	Where can I find the Medicaid Average Manufacturer Price/Federal Upper Limits Timeline?	The Average Manufacturer Price/Federal Upper Limits Timeline is posted on the CMS website at http://www.cms.hhs.gov/DeficitReductionAct/Downloads/AMPFULTimeline.pdf