DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC)
Frequently Asked Questions

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The following Frequently Asked Questions (FAQs) respond to questions raised by various stakeholders regarding the Covered Outpatient Drug Final Rule with Comment (final rule) (CMS-2345-FC) that was published in the Federal Register on February 1, 2016 (81 FR 5170) as well as the State Medicaid Director Letter (#16-001) that was issued on February 11, 2016. These answers are intended to provide guidance regarding the Social Security Act (the Act) and Federal regulations, and we may issue additional FAQs in the future.

Pharmacy Reimbursement: Actual Acquisition Cost, Professional Dispensing Fee, National Average Drug Acquisition Cost (NADAC), State Plan Amendments

Q1: If a state is already using actual acquisition cost (AAC) as their reimbursement methodology, does the state need to file a State Plan Amendment (SPA) or provide assurances that the current formula meets requirements established in the final rule? Is there a requirement for such states to file a SPA to provide assurance that the state's current dispensing fee amount meets the requirements of the final rule?

A1: If a state is already making payment for prescription drugs under its state plan based on AAC, it may continue to use that methodology. However, if a state decides to change its AAC model of reimbursement, (e.g., the state decides to use the National Average Drug Acquisition Cost (NADAC) instead of a state survey to implement a payment methodology based on AAC), the state must submit a new SPA through the formal SPA process for review.

Additionally, the state should review its currently approved professional dispensing fee (PDF) to determine if, in light of the regulation (42 CFR 447.518), the PDF needs to be revised and a SPA needs to be submitted. The state does not have to submit a new SPA to provide assurance that its dispensing fee is reasonable.

Furthermore, we expect that all states, even those currently operating under an AAC reimbursement methodology, will evaluate their current state plans to determine if a SPA will be required to comply with the reimbursement requirements (including, but not limited to, AAC, PDF, 340B and the federal upper limits (FULs)).

Q2: Will there be an annual review of PDFs that are required as part of SPA approvals?

A2: No, CMS will not perform an annual review of PDFs; however, states must consider both the ingredient cost reimbursement and the PDF reimbursement when proposing changes to ensure that total reimbursement to the pharmacy provider is calculated in accordance with requirements of section 1902(a)(30)(A) of the Act.

Q3: Will CMS be providing guidance to states to ensure that states include reasonable components in their cost of dispensing survey?

A3: To the extent that a state is conducting a cost of dispensing survey, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider's cost to dispense the drug

product to a Medicaid beneficiary. States have the flexibility to set PDFs, including using national or regional data from another state and we do not require that a state use a specific standard or methodology such as a survey to do so.

Further, states are not required to use a specific formula or methodology such as a cost study or use an inflation update where cost studies are not conducted; however, the burden is on each state to ensure that pharmacy providers are reimbursed in accordance with the requirements in section 1902(a)(30)(A) of the Act. CMS will review each SPA submission against these standards (see 81 FR 5311).

Q4: After a state evaluates changing reimbursement to actual acquisition cost plus an increased PDF and the state determines that the total cost of their pharmacy reimbursement will be increased compared to current costs, will CMS allow an adjustment in the PDF that would result in a cost neutral outcome?

A4: The intent of the new reimbursement methodology requirements is not necessarily to result in a cost neutral outcome. The requirements are to more accurately reflect the pharmacy providers' actual prices paid to acquire drugs and the professional services required to fill a prescription. Each state's AAC reimbursement methodology and proposed professional dispensing fee will be reviewed through the SPA process to ensure they are meeting the requirements of this final rule.

Q5: If a state can prove that they are under the aggregate limits of AAC and PDF and have strong participation by pharmacies, are they required to adopt the AAC and PDF reimbursement methodology at the individual claim level?

A5: All states are required to adopt the AAC and professional dispensing fee methodology; however, it is not required to be adopted at the individual claim level, but in the aggregate. In accordance with the regulatory requirements at 42 CFR 447.512(b), the state is responsible for establishing a payment methodology, that must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the AAC plus a professional dispensing fee or the providers' usual and customary charges to the general public. In conjunction with this the state is also responsible to ensure that pharmacy reimbursement is consistent with the requirements of section 1902(a)(30)(A) of the Act, which specify that provider reimbursement rates should be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access.

Q6: If NADAC is updated monthly, and a drug has a price change before the next monthly NADAC file is published, can states backdate NADAC in order to reimburse pharmacy providers correctly?

A6: The NADAC files have weekly updates posted on Medicaid.gov that reflect any price changes that have occurred since the last posted monthly file. States using the NADAC for their AAC reimbursement methodology will have access to the weekly updates of the NADAC to ensure pharmacies are reimbursed with the most updated NADAC pricing.

Q7: Please confirm whether the final rule's AAC-based reimbursement policy applies to how states pay for drugs administered by providers in hospital clinic areas as part of hospital outpatient services, whether they are paid as part of the service or separately.

A7: AAC reimbursement requirements for covered outpatient drugs extend to retail community pharmacy providers where drugs are covered by Medicaid under the state's covered outpatient drug pharmacy benefit and are not reimbursed as part of a service. Physician-administered drugs are not required to meet AAC reimbursement requirements.

Q8: Are state Medicaid programs required to implement NADAC or are other pricing methodologies acceptable so long as the state reimburses below the FUL in the aggregate? If states are required to implement NADAC, what is the date by which states are required to implement NADAC?

A8: The FULs represent an aggregate upper limit, which gives states flexibility to determine payment rates for individual drugs in accordance with the approved state plan. For drugs that have a FUL calculated, a state can use the calculated FUL price for reimbursement, or they can use another metric, such as an AAC, for reimbursement, as long as that metric will allow the state to remain within the FUL aggregate. Generally, we can say with certainty that if a state uses the NADAC to reimburse for those drugs that have a FUL calculated, the state will not exceed the FUL aggregate. However, if a state wants to use another AAC metric for reimbursement (other than NADAC) for drugs that have a FUL calculated, the state must demonstrate that its AAC metric will allow them to remain within the FUL aggregate. CMS will allow the states four quarters from the effective date of the final rule with comment, which is April 1, 2016, to revise their state plan, if necessary, and submit a SPA with an effective date no later than April 1, 2017, to comply with requirements of 42 CFR 447.512(b).

Federal Upper Limit (FUL)

Q9: Please clarify when the FULs become effective and by what date States are required to implement the FULs in the aggregate.

A9: As noted in the final rule with comment, we recognize that states may need to revise their state plans to accommodate the reimbursement provisions of the final rule and are allowing states four quarters from the effective date of the final rule to submit a SPA to comply with these provisions. However, states are required to implement pharmacy reimbursement limits, in the aggregate, in accordance with 42 CFR 447.512 and 447.514 as of the effective date of this final rule (81 FR 5310). CMS issued the first set of Affordable Care Act (ACA) FULs on March 29, 2016, and those FULs were effective on April 1, 2016.

Q10: If a state is using a reimbursement methodology based on AAC, does it still have to conduct an aggregate FUL analysis? Or, can it be assumed that they are below the aggregate?

A10: Not necessarily. In the case where a state is using the NADAC to meet the AAC reimbursement benchmark, for drugs that have a FUL calculated, states would generally not exceed the FUL aggregate. However, if a state uses another reimbursement benchmark to establish their AAC model of reimbursement, such as a state survey of retail prices, the state cannot assume that the FUL aggregate will not be exceeded.

Q11: Is the use of the FUL file mandatory for all states?

A11: States are required to implement the limits set by the ACA FULs in their reimbursement methodologies as of the effective date of the final rule with comment, that is, April 1, 2016. The FULs are to be applied as an aggregate upper limit, so the states have flexibility to determine payment rates for individual drugs in accordance with the approved State plan, such that the total reimbursement for all drugs to which the FUL applies does not exceed the FUL in the aggregate. Many states have FULs as part of their "lower of" logic in their state plans already. While we recognize that many states will be using NADAC or their own AAC methodology, and many of these values will be below the FULs, we still ask that states include in their state plans, either as a part of their lower of methodology or in a separate entry or description in the state plan, how they intend to meet the FULs in the aggregate.

Q12: Is there a possibility for a product to have an FUL and not a NADAC?

A12: CMS will not publish a FUL price for a FUL product group where the agency does not have a corresponding NADAC to compare to the 175 percent of the weighted average of AMPs for the FUL product group. For further information please see the Methodology and Data Elements Guide on the Medicaid.gov website

at on the Medicaid.gov website at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html.

Q13: If a state is using the current FUL as part of their fee-for-service (FFS) lower-of reimbursement algorithm, can the state begin using the new AMP-based FULs on April 1, 2016 without filing a SPA?

A13: States are required to apply the ACA FULs, in the aggregate, as of the effective date of the final rule with comment, that is, April 1, 2016. A SPA is not required to begin applying the ACA FULs in the aggregate.

Q14: Since the FULs are effective April 1, 2016, but States have 4 quarters to revise and submit a SPA it seems to imply that ingredient cost reimbursement changes and PDF changes do not need to occur simultaneously. Is this correct, or do they need to occur at the same time as part of the SPA? For example, could a State start utilizing new AMP-based FULs on April 1, 2016, but not change their PDF until April 1, 2017?

A14: Pharmacy provider reimbursement rates should be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, in accordance with section 1902(a)(30)(A) of the Act. As states revise their reimbursement for the ingredient cost of a drug to stay within the FUL, they should also consider whether their current dispensing fee continues to provide adequate reimbursement for the cost of dispensing a prescription to a Medicaid beneficiary, as well as the need to submit a SPA. If a state determines that any change to reimbursement rates are needed, they are responsible for submitting a SPA demonstrating compliance with applicable requirements in the final rule with comment.

Q15: Can CMS provide further clarification regarding what is meant by "nationwide availability," especially with respect to drugs that are experiencing shortages?

A15: A FUL will only be calculated when pharmaceutically and therapeutically equivalent multiple source drug products are available for purchase by retail community pharmacies on a nationwide basis (see 81 FR 5300, 5302-5304).

CMS plans to regularly monitor the availability of drugs by reviewing the FDA drug shortage list for drugs that have a FUL calculated, but are not likely to have enough supply in the market to meet current demand. Further, CMS plans to monitor weekly pricing changes available to us in the most current national survey of pricing to consider changes to the multiplier used to calculate the FULs, based on average retail community pharmacies' acquisition costs. It is also important to note that CMS currently publishes a monthly and weekly file of NADAC pricing values, which states can use to monitor those changes in average retail community pharmacies' acquisition costs as they apply the FUL aggregate reimbursement. CMS will not calculate a FUL for a given drug if the agency determines that there is a lack of availability of that drug to retail community pharmacies on a nationwide basis.

Reimbursement to 340B Covered Entities and Indian Health Services (IHS)

Q16: Are 340B ceiling prices available to states? If not, how are states supposed to ensure that reimbursement is not greater than the 340B ceiling price plus a PDF?

A16: The 340B ceiling prices can be calculated by the states using the formula in section 340B of the Public Health Service Act, which is based on the average manufacturer price (AMP) minus the unit rebate amount (URA).

Q17: In the SMD letter (#16-001) published on February 11, 2016, CMS indicated that states that pay IHS and Tribal providers through encounter rates can continue to pay that rate and that it will satisfy the requirements of 42 CFR 447.518(a)(2), which specify that the state's payment must be in accordance

with the definition of AAC. Can CMS please clarify that reimbursement at the encounter rate is available to all states, not just those that already reimburse using the encounter rate.

A17: Reimbursement to IHS and Tribal providers through the encounter rate is an option available to all states as a means to satisfying the requirement to reimburse such providers in accordance with the requirements at 42 CFR 447.518(a)(2).

Q18: Are drugs reimbursed through the encounter rate eligible for rebates through the Medicaid Drug Rebate Program?

A18: As stated in the above response, reimbursement to IHS and Tribal providers through the encounter rate is an option available to all states as a means to satisfying the requirement to reimburse such providers in accordance with the requirements at 42 CFR 447.518(a)(2). However, states that choose to utilize the encounter rate for reimbursement should be aware that since it is an "all-inclusive rate" (or bundled payment), any drug included in that rate is not eligible for rebates through the Medicaid Drug Rebate Program, as it does not meet the definition of a "covered outpatient drug" at section 1927(k)(2) and (3) of the Act. In order to meet the definition of "covered outpatient drug" and therefore be eligible for rebates, amongst other requirements, there must be a direct reimbursement for the drug and it cannot be reimbursed as part of a bundled payment.

Q19: Please clarify that state flexibility to reimburse in the aggregate extends to reimbursement rates for I/T/U pharmacies and FSS drugs, and that states can establish rates that are based on a variety of data sources, which may include FSS prices, national and State price surveys, AMP data, and other price benchmarks.

A19: The new AAC requirements were designed to more accurately reflect the pharmacy providers' actual prices paid to acquire drugs and the professional services required to fill a prescription. We agree that each state is able to establish rates that satisfy (or are consistent with) AAC and may be based on a variety of data sources, which may include FSS prices, and other pricing benchmarks.

<u>Reimbursement and Managed Care Organizations (MCOs)</u>

Q20: Please verify that the AAC methodology for determining Medicaid reimbursement will only apply to FFS and that Medicaid MCOs that are paid a capitated fee by the state for benefits that include provision of Covered Outpatient Drugs are permitted to establish payment terms with prescription drug providers that do not take AAC into account.

A20: The provisions of this final rule related to pharmacy payments do not apply to MCO payment or reimbursement methodologies, including MCO providers participating in the 340B program.

<u>Average Manufacturer Price (AMP)</u>

Q21: Is there a threshold for determining the amount of prescriptions that are delivered through the mail that will exempt a specialty pharmacy from the Retail Community Pharmacy definition? The rule uses the term "primarily" – is this to be interpreted as greater than 50 percent of prescriptions? Is it based on number of prescriptions or sales volume?

A21: As noted in the comment and response in the preamble to the final rule (81 FR 5216), CMS declined to set a threshold in order to allow flexibility to recognize changes that take place in the pharmaceutical marketplace with regard to mail order business. CMS further noted that manufacturers may make reasonable assumptions that a pharmacy is a retail community pharmacy when the majority of the drugs are not dispensed through the mail. A "majority" is generally determined as greater than 50 percent,

which could be interpreted as greater than 50 percent. In addition, in cases where a single entity owns both a retail community pharmacy and a mail order pharmacy, manufacturers may exclude the sales to the mail order side of business and include sales to the retail community pharmacy side when calculating AMP, and include the mail order sales when they are calculating AMP for a 5i drug not generally dispensed through retail community pharmacies. Since the definition of retail community pharmacy at 1927(k)(11) of the Act excludes a pharmacy that "dispenses prescription medications primarily through the mail", CMS believes the number of prescriptions dispensed would be a reasonable basis to determine whether the pharmacy dispenses "primarily through the mail."

Q22: How are AMPs determined for drugs not available from retail community pharmacies that are also not considered 5i drugs, such as oral oncology or topical products only available from mail order specialty pharmacies?

A22: As discussed in the final rule (81 FR 5250), if a specialty pharmacy meets the definition of a retail community pharmacy at section 1927(k)(10) of the Act, sales for such drugs would be included in AMP. This is true even in the event there are a low number of AMP eligible sales. Because CMS is permitting manufacturers to use a presumed inclusion approach when calculating AMP, and to make reasonable assumptions, an AMP will likely be generated for such drugs.

Q23: Can CMS clarify its expectation when it comes to a situation where a labeler may have two different NDC-9s (that is not an authorized generic situation) that are the exact same drug (for example if an old labeler code is being terminated and replaced with a new labeler code)? Should the manufacturer calculate the two NDC-9s separately or merge the data together for one price across both NDC-9s?

A23: CMS does not require that two separate NDC-9s be blended, however, the agency believes that in certain circumstances, a manufacturer may blend the AMPs of two NDC-9. For example, if a manufacturer acquires a product from a different labeler and has made necessary arrangements with the prior manufacturer, it may have product with the old labeler code (ex. 12345) as well as product from its own labeler code (ex. 67890) in the market at the same time while the supply of the drug under the old labeler code is depleted. Since the two NDC-9s are essentially the same product/strength combination, it may be reasonable to blend the AMPs and report the same AMP for both NDCs. As always, it is recommended that manufacturers retain written documentation of any reasonable assumptions made in the calculation of AMP. Manufacturers may contact CMS for further guidance and discussion as the facts and circumstances of each case should be evaluated independently.

<u>Best Price</u>

Q24: By lowest price available for Best Price, do you mean the lowest price offered or the lowest price achieved?

A24: The lowest price available means it is the lowest price available to the best price eligible entity. The best price must include applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price eligible entities. See 42 CFR 447.505(b) and section 1927(c) of the Act.

We have provided the following example:

If a manufacturer sells a drug to a hospital but also provides a rebate to a PBM (which is excluded from best price); however, the PBM rebate is designed to subsequently adjust the drug price available from the manufacturer to the hospital (the best price eligible entity), the rebate or discount is included in the best price (see 42 CFR 447.505(c)(17)).

Q25: Can CMS please confirm that inpatient prices provided to 340B eligible children's hospitals, critical access hospitals, rural referral centers, sole community hospitals, and freestanding cancer hospitals may be excluded from AMP and Best Price?

A25: As discussed in the final rule, any prices provided by manufacturers to 340B covered entities are excluded from AMP and best price. This would include inpatient manufacturer prices provided to children's hospitals, critical access hospitals, rural referral centers, sole community hospitals, and freestanding cancer hospitals, where those entities qualify as 340B entities as described in regulation (see 81 FR 5253, 5257-5258).

For specific questions regarding whether a covered entity meets the definition of covered entity as described in section 340B(a)(4) of the Public Health Service Act, please contact the Health Resources and Services Administration (HRSA) at 340Bpricing@hrsa.gov.

Q26: Are nominal price sales to non-profit family planning clinics that do not qualify as 340B covered entities exempt from a manufacturers' Best Price?

A26: Yes, to the extent they meet the requirements defined in the final regulation at 42 CFR 447.508(a)(4) and (5). This section of the regulation provides that nominal price sales to entities would be excluded from best price when purchased by an entity that is:

- Described in section 501(c)(3) of the Internal Revenue Code (IRC) of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or Operated; and,

- Providing the same services to the same type of population as a covered entity described in 340B(a)(4) of the Public Health Service Act, but does not receive Federal funding under a provision of law referred in such section.

To determine whether an entity is "non-profit or charitable organization" under 501(c)(3) of the Internal Revenue Code (IRC), the IRS has an on-line tool and manufacturers can access that tool at https://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/Exemption-Requirements-Section-501(c)(3)-Organizations. As specified in the final rule, using this readily available information, manufacturers may make certain reasonable assumptions, in the absence of specific guidance, in their determinations of whether an entity is a non-profit or charitable organization, provided those reasonable assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations(81 FR 5226).

The second prong of the regulation provides that the entity must provide services similar to 340B entities listed at 340B(a)(4) but do not receive Federal funding under this section of the law. The entities listed at http://www.hrsa.gov/opa/eligibilityandregistration/ include Title X Family planning clinics and sexually transmitted disease clinics. Therefore, to the extent non-profit family planning clinics provide the same types of services as Title X Family Planning clinics and/or sexually transmitted disease clinics, the nominal price sales to these entities would be exempt.

Authorized Generic (AG) Drugs

Q27: If a manufacturer markets both the branded drug and the AG version (in essence the same drug but marketed under two different NDCs) should the manufacturer blend sales and discounts of the branded drug and AG drug to result in a single AMP that would be reported for both the branded drug and AG drug? Further, can you please confirm that such a manufacturer should calculate Best Price as the lowest price between the branded drug and AG drug, and that lowest price for either would apply to both the branded and AG NDCs?

A27: Section 1927(k)(1)(C) of the Act requires that in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application (NDA) approved under section 505(c) of Federal Food, Drug and Cosmetic Act (FFDCA), AMP shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies. Therefore, as stated in a comment and response in the final rule, when a manufacturer is selling two versions of a product (both the AG and the brand) under the same NDA, in such cases the price of the drug would be blended for AMP, even if the manufacturer distinguishes the two products using different NDCs (81 FR 5260). Furthermore, as discussed in the final rule (81 FR 5260), CMS does not believe the manufacturer should determine a separate best price for each NDC simply because the two manufacturers of the same company identify the same drug using different NDCs.

Q28: In the case when two manufacturers sell the same product under different NDCs, but the manufacturers are part of the same parent company, CMS indicated that the same Best Price should be reported for both NDCs. Under these circumstances, would the transfer sales be included in the AMP or would the transfer sales to the AG not be included in the AMP calculation?

A28: Regulations at 42 CFR 447.506(c) indicate that a primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or an innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding the NDA.

Transfer sales that take place between two manufacturers would be included in AMP only to the extent the secondary manufacturer is acting as a wholesaler in accordance with section 1927(k)(11) of the Act.

Bona Fide Service Fees (BFSF)

Q29: Must distribution service fees, inventory management fees and the other services referenced in the BFSF provision of the AMP definition be subjected to the regulatory BFSF test? The preamble could be read to suggest that these fees are always BFSFs without analysis under the regulatory test.

A29: Even though there were specific examples of bona find service fees provided in statute, the four-part test remains the definitive test to qualify a payment as a bona fide service fee. Therefore, manufacturers are responsible for meeting all four parts of the definition of bona fide service fee before a fee can qualify as a bona fide service fee (see 81 FR 5177-5178).

Line Extension Drugs

Q30: Could you please confirm that manufacturers must use the alternative methodology in their Unit Rebate Amount (URA) calculations for quarters beginning January 1, 2010 for line extension drugs that were on the market as of that date, regardless of the approval date? For manufacturers of such drugs that have been waiting for the final rule before adjusting their rebates back to 1Q 2010, will CMS set up any special process for these retroactive rebate adjustments?

A30: The statutory line extension provisions went into effect on January 1, 2010. It is the manufacturers' responsibility to identify their line extension drugs, calculate rebates, and pay the states consistent with the statute as of this effective date, regardless of the approval date of the drugs.

The line extension provisions that are finalized in the final rule with comment are effective prospectively as of April 1, 2016. CMS will not be setting up any special process for retroactive rebate calculations for

line extension drugs; therefore, manufacturers of line extension drugs should ensure that all rebates for line extension drugs are calculated and paid appropriately to states as of January 1, 2010.

Q31: When calculating the alternative rebate for a line extension drug, must the labeler consider the highest additional rebate ratio ever incurred for an initial drug, or is the highest additional rebate ratio determined by the ratio for the current quarter only?

A31: Effective April 1, 2016, each quarter, the labeler of the line extension drug should determine the initial brand name listed drug for its line extension drug taking into consideration which active initial drug has the highest additional rebate ratio for that quarter. Additionally, the labeler of the line extension drug needs to ensure that the NDC of the initial drug with the highest additional rebate ratio is updated in the Drug Data Reporting for Medicaid (DDR) system, as appropriate, each quarter.

Q32: Can you confirm that manufacturers of extended release formulations will have to calculate the alternative line extension AMP starting April 1, 2016, since extended release formulations are specifically mentioned in the statutory language that established the alternative line extension formula?

A32: The requirements of the line extension provision of the final rule are effective as of the effective date of the final rule (April 1, 2016).

Reporting Requirements

Q33: For the Affordable Care Act (ACA) Base Date AMP, does the recalculation only go back to 2Q 2016 or would it go back further due to the length of time it has taken for the Final Rule to be published?

A33: A manufacturer's recalculation of its ACA Base Date AMP value can be reported any time during the four quarters allowable period per the final rule with comment beginning 2Q 2016.

Q34: When computing monthly AMP, should manufacturers be calculating all the calculation components at the NDC-9 or just the smoothing components?

A34: In accordance with regulations at 42 CFR 447.510(d)(2), monthly AMP is calculated based on a weighted average of prices for all the manufacturer's package sizes (NDC 11) of each covered outpatient drug sold by the manufacturer during a month. It is calculated as the net sales divided by the number of units sold, excluding goods or any other items specifically excluded in statute or regulation. In accordance with the requirements of 42 CFR 447.510(d)(2)(iii) the smoothing of lagged price concessions occurs at the NDC-9 level as part of the monthly AMP calculation.

Q35: If a manufacturer has a negative monthly AMP, should they use the most recent valid monthly AMP in the quarterly calculation?

A35: CMS has previously provided guidance regarding the reporting of zero or negative AMP in Manufacturer Release #80 (January 5, 2010) in which we specify that if a calculated monthly AMP is zero or negative, we recommend that manufacturers report the most recent prior month's positive AMP. However, the actual calculated monthly AMP should be used to calculate the quarterly AMP. If the quarterly AMP is zero or negative, we recommend that manufacturers report the most recent positive AMP value. Please see Manufacturer Release #80: *https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-080.pdf*

Sales to Territories

Q36: If a manufacturer is currently not selling to entities or providers located in Puerto Rico and the U.S. Territories, will they be required to sell covered outpatient drugs to the U.S. Territories going forward (April 2017)?

A36: The final rule does not require that a drug manufacturer sell its drugs to certain purchasers.

Q37: For smoothing of lagged price concessions and inclusion of sales from the U.S. Territories, should a manufacturer include the sales from the U.S. Territories in the 12 months of data for smoothing as of April 1, 2017 (going back to May 2016), or should they only include it in the smoothing only as of April 1, 2017 and prospectively?

A37: Given the one year delay in the effective date of the definitions of states and United States, manufacturers should begin using sales data in their smoothing process beginning with sales that occur as of April 1, 2017.