



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AA89

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), referred to as the “340B Drug Pricing Program” or the “340B Program.” This final rule will apply to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. This final rule sets forth the calculation of the 340B ceiling price and application of civil monetary penalties (CMPs).

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301-594-4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 602 of Public Law 102-585, the “Veterans Health Care Act of 1992,” enacted section 340B of the PHSA, “Limitation on Prices of Drugs Purchased by Covered Entities,”

codified at 42 U.S.C. 256b. The 340B Program permits covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. REP. No. 102-384(II), at 12 (1992). Eligible covered entity types are defined in section 340B(a)(4) of the PHSA. Section 340B of the PHSA instructs HHS to enter into a pharmaceutical pricing agreement (PPA) with certain drug manufacturers. When a drug manufacturer signs a PPA, it is opting into the 340B Program and it agrees to the statutory requirement that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data obtained from the Centers for Medicare & Medicaid Services (CMS). Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111-152) (HCERA) (hereinafter referred to as the “Affordable Care Act”), added section 340B(d)(1)(B)(vi) of the PHSA, which provides for the imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary;

(II) shall not exceed \$5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under Section 340B of the PHSA that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection 340B(a)(1).

The Affordable Care Act also added section 340B(d)(1)(B)(i)(I) of the PHSA, which requires “[d]eveloping and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices...” CMPs

provide a critical enforcement mechanism for HHS if manufacturers do not comply with statutory pricing obligations under the 340B Program. HHS is also finalizing this rule to provide increased clarity in the marketplace for all 340B Program stakeholders as to the calculation of the 340B ceiling price.

Since 1992, HHS has administratively established the terms and certain elements of the 340B Program through guidelines published in the *Federal Register*, typically after publication of a notice in the *Federal Register* and opportunity for public comment. In September 2010, HHS published an advanced notice of proposed rulemaking (ANPRM) in the *Federal Register*, “340B Drug Pricing Program Manufacturer Civil Monetary Penalties” (75 FR 57230, September 20, 2010). After consideration of the comments received on the ANPRM, HHS published a notice of proposed rulemaking (NPRM) in the *Federal Register* (80 FR 34583, June 17, 2015) entitled, “340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation” to implement CMPs for manufacturers who knowingly and intentionally charge a covered entity more than the 340B ceiling price for a covered outpatient drug and to provide increased clarity on the requirements of manufacturers to calculate the 340B ceiling price on a quarterly basis. The public comment period closed on August 17, 2015, and HHS received approximately 35 comments. HHS reopened the comment period (81 FR 22960, April 19, 2016) to invite additional comment on several specific areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing), the methodology that manufacturers utilize when estimating the ceiling price for a new covered outpatient drug, and the definition of the knowingly and intentionally standard for manufacturer CMPs. The additional comment period closed on May 19, 2016, and HHS received approximately 70 comments during this additional comment period. The following section presents a summary of

the comments received, grouped by subject, and a response to each grouping. All comments on the proposals included in the NPRM and the reopening Notice were considered in developing this final rule, and changes were made as described. Other changes were also made to improve clarity and readability.

II. Summary of Proposed Provisions and Analysis and Responses to Public Comments

The revisions to 42 CFR part 10 of the final rule are described according to the applicable section of the final rule. This final rule replaces §10.1, §10.2, §10.3, and §10.10, adds a new §10.11, and eliminates §10.20 and §10.21.

General Comments

Comments received during both comment periods addressed general issues. We have summarized those comments and have provided a response below.

Comment: Several commenters urge HHS to specify that the effective date of the final rule be prospective and at least two quarters after the final rule's publication in the *Federal Register*. In addition, the commenters urge HHS to build in a significant grace period with respect to manufacturer compliance to give manufacturers sufficient time to put the necessary system capabilities in place. Other commenters asked HHS to revise the effective date of the final rule to 180 days after March 23, 2010, which would allow HHS to impose CMPs retroactively.

Response: The final rule is effective [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. HHS recognizes that the effective date falls in the middle of a quarter. As such, HRSA plans to begin enforcing the requirements of this final rule at the start of the next quarter, which begins April 1, 2017. Manufacturers that offer 340B ceiling prices as of the quarter beginning April 1, 2017, must comply with the requirements of

this final regulation. HHS believes that this timeframe provides manufacturers sufficient time to adjust systems and update their policies and procedures. HHS disagrees that the rule should be implemented retroactively. An attempt to apply the final rule retroactively would be administratively burdensome and difficult to implement for all stakeholders.

Comment: Several commenters urge HHS to defer the final rule pending the issuance of additional substantive program guidance. The commenters state that the issuance of substantive guidance first is more consistent with fundamental fairness in a civil penalty enforcement context, inasmuch as program stakeholders should understand their substantive obligations prior to any enforcement activity. The commenters also request that HHS finalize the information collection request (ICR) and gain experience first with administering the 340B ceiling price reporting system.

Response: HHS does not believe that the issuance of additional guidance is needed in order to implement this final rule. The provisions of this final rule will be effectively implemented independent of other programmatic regulations and guidances. Current policies under the 340B Program provide stakeholders with sufficient guidance regarding programmatic compliance. Regarding the ICR, HHS submitted an ICR pertaining to the collection of information for the 340B ceiling price reporting system in compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995. The Office of Management and Budget (OMB) approved the ICR on September 28, 2015, after a formal notice and comment process (80 FR 22207, April 21, 2015). This final rule contains specific information related to the calculation of the 340B ceiling price and the imposition of CMPs against manufacturers who knowingly and intentionally overcharge a covered entity; therefore, it is not necessary to implement the 340B ceiling price reporting system prior to finalizing this rule.

Comment: A commenter requests that HHS provide login credentials to state Medicaid staff to facilitate dissemination of 340B ceiling price information. Alternatively, HHS could develop a different means of providing states with quarterly updates of 340B ceiling price calculations (e.g., via designated state technical contacts).

Response: We appreciate the commenters concern, and HRSA and CMS are jointly working on alternative ways to share this information with states.

Comment: Several commenters argue that HHS does not have rulemaking authority to issue a binding ceiling price regulation, as it does not have general rulemaking authority with respect to the 340B Program. Regarding 340B ceiling prices, commenters point out that Congress directed HHS under section 340B(d)(1)(B)(i)(I) of the PHSA to establish “precisely defined standards and methodology for the calculation of ceiling prices” via “an appropriate policy or regulatory issuance.” They argue, however, that in other parts of the statute, Congress more clearly directs HHS to issue regulations. For instance, under section 340B(d)(1)(B)(vi)(I), Congress directed HHS to implement civil monetary penalties pursuant to “standards established in regulations.” Commenters argue that Congress intended to confer a different level of authority and did not give HHS authority to issue regulations in this area.

Response: HHS has the statutory authority under section 340B(d)(1)(B)(i)(I) of the PHSA to develop and publish through appropriate policy or a regulatory issuance, such as this final rule, the precisely defined standards and methodology for the calculation of 340B ceiling prices. The fact that Congress limited HHS to proceed by rulemaking with regard to other authorities in the statute does not negate the choice that Congress expressly provided to HHS in section 340B(d)(1)(B)(i)(I) to proceed through either policy or regulation.

Comment: Some commenters suggest that the rule should require manufacturers to provide background information to HHS regarding 340B sales, including information such as the identity of the 340B covered entity billed for a given drug and the shipping location of the drug.

Response: HHS appreciates these comments; however, they are beyond the scope of this final rule.

Comment: Commenters noted that the rule only addressed one of the 340B Program integrity improvements required by the Affordable Care Act – CMPs for manufacturers. They suggested that HHS should not finalize this rule and should instead issue a new, comprehensive NPRM that addresses all the improvements as required by the Affordable Care Act. For instance, the commenters opposed the implementation of CMP procedures absent HHS’s creation of an Administrative Dispute Resolution (ADR) process.

Response: HHS is choosing to issue separate rulemakings for the different areas of the 340B Program integrity improvements that the Affordable Care Act mandates and for which HHS has rulemaking authority. HHS is addressing the administrative dispute resolution process and issued an NPRM August 12, 2016, in the *Federal Register* (81 FR 53381). HHS anticipates finalizing the administrative dispute resolution regulation after the comments have been reviewed and considered.

Comment: Commenters note that the Affordable Care Act requires manufacturers to report to HHS the 340B ceiling price each quarter as well as any prior period lagged price concessions that could affect prior quarter 340B ceiling prices by changed average manufacturer price (AMP), Best Price, and unit rebate amounts (URA). The commenter further notes that the proposed rule did not address this circumstance. They suggested that HHS establish a secure

protocol to submit pricing and publish for comment its proposed process for manufacturer reporting of such submissions.

Response: Section 340B(d)(1)(B) of the PHSA requires HHS to develop a system to verify the accuracy of 340B ceiling prices calculated by manufacturers and charged to covered entities. HHS recognizes the utility of the type of policy mentioned in the comments and plans to publish guidance on the particular components of the 340B ceiling price reporting system.

Subpart A – General Provisions

A. Purpose and Summary of 340B Drug Pricing Program – §10.1 and §10.2

Section 10.1 and §10.2 of the rule provide general information concerning section 340B of the PHSA, “Limitation on Prices of Drugs Purchased by Covered Entities.” Section 10.1 provides the purpose of part 10 and §10.2 provides a summary of section 340B of the PHSA, which instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered outpatient drugs under which the amount to be paid to manufacturers by certain statutorily defined covered entities does not exceed the 340B ceiling price. Manufacturers participating in the 340B Program are required to provide these discounts on all covered outpatient drugs sold to participating 340B covered entities. HHS did not receive any comments with respect to these sections and is finalizing these sections as proposed.

B. Definitions – §10.3

In the proposed rule, HHS sought to define several terms that were used throughout the regulation. These terms included: “340B Drug,” “Average Manufacturer Price,” “Ceiling price,” “CMS,” “Covered entity,” “Covered outpatient drug,” “Manufacturer,” “National Drug Code,” “Pharmaceutical Pricing Agreement,” “Quarter,” “Secretary,” and “Wholesaler.” HHS did not receive comment on the following terms, which are finalized in this rule as proposed:

“Average Manufacturer Price,” “Ceiling Price,” “CMS,” “National Drug Code,” “Pharmaceutical Pricing Agreement,” and “Secretary.” For the remaining terms, HHS received specific comments and have summarized those comments below.

1. 340B Drug

Proposed §10.3 set forth a definition of the term “340B drug” as a covered outpatient drug, as defined in section 1927(k) of the Social Security Act (SSA), purchased by a covered entity at or below the 340B ceiling price required pursuant to a PPA with the Secretary. Based on the comments received, HHS is removing this definition from the final rule, as HHS believes that the definition is unnecessary. HHS received the following comment regarding the definition of a 340B drug.

Comment: Several commenters suggest that HHS remove the proposed definition of a “340B drug” as the term is not used in the 340B statute or proposed regulations and as drafted could lead to confusion and uncertainty. The proposed definition also narrowly defines the circumstances under which a 340B covered entity can acquire the drug.

Response: After consideration of the comments received with respect to this definition and in light of the definition of covered outpatient drug as set forth in section 1927(k) of the SSA, which is also defined in this final rule, HHS does not believe the definition is necessary and is, therefore, removing the definition of a 340B drug from this final rule.

2. Covered entity

The proposed rule defined the term covered entity as an entity that is listed in section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database. HHS received several comments regarding the proposed definition of covered entity and have summarized them below.

Comment: Several commenters supported the proposed definition of “covered entity” as it included both registration and database listing requirements. They explain that HHS’s proposal will improve the integrity of the Program, assist manufacturers in meeting their obligations, and strengthen manufacturer Medicaid compliance. Commenters urge HHS to include in the definition of covered entity that an organization must both: (1) be in compliance with the duplicate discount and diversion prohibitions; and (2) be registered and appear on the 340B database as a participating entity during the quarter in which the transaction is made.

Response: The term covered entity is defined, in accordance with section 340B(a)(4) of the PHSA, to mean an entity that is listed in the statute and meets all of the requirements in section 340B(a)(5) pertaining to diversion and duplicate discounts. As the definition imposed in this final rule already includes that a covered entity must comply with section 340B(a)(5), it is not necessary for the definition to specify compliance with the requirements pertaining to diversion and duplicate discounts. The process for appearing on the 340B database is separate and distinct from compliance with the requirements in section 340B(a)(5), and all covered entities listed on the 340B database are expected to be in compliance with this provision of the statute.

3. Covered outpatient drug

The term covered outpatient drug was defined in the proposed rule as having the meaning set forth in section 1927(k) of the SSA. HHS received several comments on the proposed definition and has summarized them below.

Comment: A few commenters recommended that HHS limit the definition of “covered outpatient drug” to only the definition at section 1927(k)(2) of the SSA, and not include the “limiting definition” of covered outpatient drugs in section 1927(k)(3) of the SSA to prevent

manufacturers from limiting 340B pricing to drugs that are reimbursed separately, as opposed to those reimbursed under bundled payment methodologies. Commenters note that CMS is increasingly moving towards the use of bundled payments and other types of value-based purchasing models with the goal of 50 percent of all Medicaid payments being made under alternative payment models by 2018. Therefore, they argue, it is highly likely that an increasing number of covered entities will no longer be eligible for 340B pricing for Medicaid patients if section 1927(k)(3) of the SSA is incorporated into this regulation. Commenters urge the development of a definition of "covered outpatient drug" that is specific to the 340B Program and does not track with the Medicaid statute, which is limited to the Medicaid Drug Rebate Program (MDRP).

Response: Section 340B(b)(1) of the PHSA states that the term "covered outpatient drug" has the meaning set forth in section 1927(k) of the SSA. Section 1927(k) includes the limiting definition and HHS does not believe that the interpretation of covered outpatient drug is contrary to the purpose of the 340B Program. We disagree that covered entities will not be eligible for the 340B Program as a result of this provision.

4. Manufacturer

HHS defined the term manufacturer in the proposed rule as having the meaning set forth in section 1927(k) of the SSA. HHS received several comments on the proposed definition and has summarized them below.

Comment: For the term "manufacturer," commenters urge HHS to incorporate its long-standing guidance that a manufacturer "must hold legal title to or possession of the national drug code (NDC) for the covered outpatient drugs." The commenter explains that the PPA has

reflected this provision. This is important because there could be distinct legal entities that own distinct NDCs and are different manufacturers for purposes of the 340B Program.

Response: Section 340B(b)(1) of the PHSA defines the term as having the meaning set forth in section 1927(k) of the SSA. Given the 340B statute's direct reference to section 1927(k) of the SSA, HHS does not believe that this term needs to be further defined in this final rule. However, for 340B Program purposes, a manufacturer would be the entity holding legal title or possessing the NDC in question.

Comment: Commenters urged HHS to clarify the distinction between "manufacturers" and "wholesalers." They suggest HHS specify that "traditional" wholesale distribution operations and contract packaging and repackaging operations do not make an entity a "manufacturer" that can be subject to CMPs.

Response: The definition of "manufacturer" is finalized at §10.3. To the extent that a wholesale distributor meets the definition of "manufacturer," it would need to meet the requirements for manufacturers as defined in this rule.

5. Quarter

The term quarter is defined in the proposed rule as a calendar quarter, unless otherwise specified. HHS received several comments on this term, which are summarized below.

Comment: Several commenters support that 340B ceiling prices are calculated based on calendar quarters. However, the commenters argue that the proposed rule does not recognize the two-quarter lag between when a sales transaction occurs and when the applicable 340B ceiling price becomes effective. They urge HHS to clarify that 340B ceiling price calculations are based on sales transactions from two prior calendar quarters. They feel this is supported because calculating the 340B ceiling price for a particular calendar quarter in the immediate preceding

quarter is not possible because AMP and Best Price for the quarter are not calculated and reported to CMS until 30 days after the end of a quarter.

Response: HHS agrees with the commenters. HHS notes that the 340B ceiling price is calculated based on data received from CMS that incorporates the quarterly pricing lag. For purposes of this final rule, HHS is interpreting the 340B ceiling price calculation provision at section 340B(a)(1) to be the AMP reported from the preceding calendar quarter minus the URA. Section 10.10(a) of this final rule, pertaining to the calculation of the 340B ceiling price, has been modified to align with the 340B statute pertaining to AMP calculations made in the preceding calendar quarter. For instance, the pricing data from the first quarter in any given year is not due to be reported to CMS until 30 days into the second quarter. Therefore, the pricing data from the first quarter cannot be used to price drugs until the third quarter. The definition of quarter will be finalized as proposed.

6. Wholesaler

The proposed rule defines wholesaler as the term as set forth in 42 U.S.C. 1396r-8(k)(11). HHS received several comments, which are summarized and responded to below.

Comment: Commenters suggest that HHS uniformly refer to the applicable sections of the SSA (as opposed to the reference to the United States Code) for purposes of consistency and to avoid any potential confusion. Other commenters note that the term "wholesaler" as defined in section 1927(k)(11) of the SSA is focused on the distribution to retail community pharmacies, which are entities that cannot qualify as 340B covered entities. They state further that while retail community pharmacies may serve as contract pharmacies, not all 340B covered entities maintain contract pharmacy arrangements. The commenters do not think it is appropriate to utilize a definition that focuses on drug distribution and retail community pharmacies. In

addition, commenters urge HHS to ensure that specialty pharmacies, including radio pharmacies and nuclear pharmacies, are not included in the term “manufacturer” or “wholesaler” and, therefore, that the 340B ceiling price is not required to be offered by specialty pharmacies, although they may elect to do so. Unlike “specialty distribution,” which can be an entity that performs the same function as a wholesaler, specialty pharmacies are pharmacies that receive, rather than distribute drugs.

Response: After consideration of the comments received on the term wholesaler, HHS is removing this term from the final rule. The term “wholesaler” as defined at section 1927(k)(11) of the SSA is not appropriate for 340B Program purposes for the reasons cited by commenters and it is not necessary to define this term in the final rule. With respect to “specialty distribution” or “specialty pharmacy,” HHS notes that it is the manufacturer’s responsibility to ensure compliance with 340B Program requirements, including the requirements set forth in this final rule.

Comment: Commenters urge HHS to clarify that (1) traditional wholesale distribution operations (e.g., purchasing or holding for resale or distribution) and (2) contract packaging and repackaging operations (i.e., where the product does not bear the repackages labeler code) will not cause an entity to be a “manufacturer” that is potentially subject to CMPs. Instead, manufacturers subject to the 340B Program's pricing obligations (and potentially CMPs) should be limited to entities whose NDC labeler code appears on a drug product, as this approach is consistent with CMS and the MDRP.

Response: Although HRSA recognizes that wholesalers often act as independent entities, a manufacturer’s failure to ensure that covered entities receive the 340B ceiling price through its

distribution arrangements with wholesalers may be grounds for assessment of civil monetary penalties as set forth in this final rule.

Subpart B – 340B Ceiling Price

A. Ceiling price for a covered outpatient drug – Calculation of 340B ceiling price - §10.10(a)

In the proposed rule, HHS recognized that the 340B ceiling price for a covered outpatient drug is equal to AMP minus the URA, and will be calculated using six decimal places. HRSA proposed to publish the 340B ceiling price rounded to two decimal places.

HHS received numerous comments on this provision in the proposed rule. In this final rule, HHS has decided to remove the terms “package size” and “case package size” and plans to address these operational elements concerning the 340B ceiling price calculation in future guidance associated with the 340B Program ceiling price reporting system. HHS has addressed specific comments with respect to this issue below.

Comment: Several commenters expressed concern that the terms “package size” and “case package size” are confusing and not in the 340B statute. Commenters argue that “case package size” is not a metric tabulated or reported under other price reporting programs or currently used by manufacturers. Commenters suggest HHS clarify the terms to assist stakeholders in understanding how 340B ceiling prices are calculated and to ensure consistency in the methodology used by manufacturers to calculate 340B ceiling prices. Commenters also urge HHS to refrain from introducing new variables without analysis and an understanding of the overall ceiling price calculation. Other commenters stated that case/package size was proposed in an effort to assist HHS in providing sales prices for an 11-digit NDC; however if the unit type and units per package are consistent with the units in the 11-digit NDC, then the sales price can be derived without using any other value.

Response: After consideration of the comments received, HHS has decided to remove “package size” and “case package size” from the final rule as the statute only speaks to the 340B ceiling price calculation as being AMP minus URA. HHS does plan to further elaborate on the manner that the terms relate to the 340B ceiling price calculation, and its use by the market, in future guidance associated with the 340B Program ceiling price reporting system.

Comment: Some commenters noted that the proposed rule would require calculation of the ceiling price to six decimal points and that the necessity of this added complexity is unclear. They suggested that the ceiling prices be reported and calculated in dollars and cents with two decimal places. Several commenters support and appreciate that HHS plans to publish the ceiling price rounded to two decimal places, which makes it easier for covered entities to determine if manufacturers are charging them appropriately.

Response: HHS has concluded that the data utilized for the 340B ceiling price calculation should be in the same format as reported to CMS. CMS has indicated in Manufacturer Release No. 82 (November 1, 2010) that when AMP is submitted to the Drug Data Reporting for Medicaid (DDR) system, it should be rounded to six decimal places. In Manufacturer Release No. 46 (April 18, 2000), CMS modified the rounding methodology for the URA and required manufacturers to round URA calculations to four digits and because the field codes require six digits, CMS “pads” positions five and six with zeros. HRSA receives both the AMP and URA data from CMS at six decimal places. For the purposes of calculating the 340B ceiling price, HHS has decided that data utilized for the calculation of the 340B ceiling price will be rounded to six decimal places in an effort to ensure an accurate 340B ceiling price. HHS will then make the 340B ceiling price available in the secure 340B ceiling price system rounded to two decimal places in an effort to ensure certainty in the market place.

Comment: Some commenters urge HHS to clarify in the final rule that the ceiling price calculation is based on the quarterly AMP as opposed to a monthly AMP.

Response: AMP is described in section 340B(a)(1) of the PHSA as the AMP for the drug under title XIX of the SSA in the preceding calendar quarter. The AMP used for the calculation of the 340B ceiling price is a quarterly AMP sent to HRSA by CMS on a quarterly basis. We agree with the commenters and have modified the final rule to clarify that the 340B ceiling price is based on quarterly AMP data.

Comment: Commenters argue that the ceiling price calculation mechanics are unclear given that HHS has not yet implemented the ceiling price verification mechanism and website for covered entities. Other commenters request that HHS provide a detailed, standardized 340B ceiling price methodology, including a written formula.

Response: With respect to the 340B ceiling price calculation, HHS has determined that this final rule will be limited to the elements necessary to calculate the 340B ceiling price as defined at section 340B(a)(1) of the PHSA. This final rule sets forth the 340B ceiling price calculation as AMP minus URA. The development of the 340B ceiling price reporting system is proceeding under a separate ICR process that is operational in nature and is not contingent upon the specific provisions contained in this final rule. This ICR was submitted and approved by OMB on September 28, 2015, after a formal notice and comment process (80 FR 22207, April 21, 2015, OMB No. 0915-0327).

Comment: Some commenters encourage HHS to require both manufacturers and CMS to report URA values to HHS for verification and resolution of anomalies or discrepancies.

Response: The reporting obligations of manufacturers and HRSA's receipt of pricing information from CMS are outside the scope of this rule.

B. Ceiling price for a covered outpatient drug--Exception – §10.10(b)

Where the URA equals the AMP for a drug, the section 340B ceiling price formula would result in a ceiling price of zero. The statute, however, clearly contemplates a payment to a manufacturer and the act of purchasing covered outpatient drugs. Setting a zero dollar ceiling price would run counter to the statutory scheme and lead to unintended consequences, including operational challenges. For example, some information technology systems are not able to generate invoices for any prices less than \$0.01 and manufacturers may not be able to generate an electronic data interchange price update for an item that does not have a price of at least \$0.01. The NPRM therefore proposed that when the 340B ceiling price calculation resulted in an amount less than \$0.01, a manufacturer charge a \$0.01 per unit of measure.

In light of the comments received on this particular policy (when ceiling price calculations result in a ceiling price that equals a zero, or “penny pricing”), HHS reopened the comment period (81 FR 22960, April 19, 2016) to solicit additional comment and determine whether or not alternatives raised in the comments regarding the penny pricing policy would be more appropriate. HHS also sought to provide the public with adequate opportunity to comment on alternatives to penny pricing.

The specific alternatives raised by commenters on the NPRM included the Federal Ceiling Price (FCP), the most recent positive 340B ceiling price from previous quarters, and nominal price. Some commenters stated that the FCP, which is the basis for certain Federal government program drug purchases, would be a viable alternative. Other commenters suggested that charging a ceiling price from previous quarters in which the ceiling price was greater than \$0.00 would be reasonable. Finally, several commenters suggested that nominal pricing, which is a term used in the MDRP, would be more appropriate. Other commenters

suggested that manufacturers should be able to utilize any reasonable pricing methodology that they choose.

In the reopening of the comment period published in the *Federal Register*, HHS received numerous comments supporting and opposing the alternatives to penny pricing. Several commenters opposed to the alternatives expressed that any alternatives to penny pricing would violate the 340B ceiling price formula and would reward manufacturers for raising prices faster than inflation. In addition, commenters opposed to the alternatives explained that they would directly conflict with the intent of the 340B Program by increasing costs for covered entities. Other commenters opposing the penny pricing policy suggested that the policy would result in drug shortages, stockpiling, diversion, harm to patients and abuse. Among support for several of the alternatives, these commenters recommended that HHS allow manufacturers to select a reasonable pricing methodology in accordance with their duty of good faith under the PPA.

After consideration of the comments received, HHS is finalizing the penny pricing policy as proposed. This long-standing policy reflects a balance between the equities of different stakeholders and establishes a standard pricing method in the market. Specific comments are addressed below.

Comment: Several commenters support the maintenance of the current HHS penny pricing proposal, believing it is the best approach for calculating the 340B ceiling price, that it is well-established and effective, and that it is consistent with HHS' existing policy. Many commenters were concerned that any alternatives to penny pricing would be inconsistent with the statute. Commenters encouraged HHS to consider the unintended impact that changing the penny pricing policy would have on the covered entities and the vulnerable populations they serve and supported finalizing the original penny pricing proposal. Commenters recommended

that if alternate proposals were considered, HHS put forward more detailed models for thorough review and analysis of impact on covered entities.

Response: HHS agrees with the commenters supporting the current policy and is finalizing the penny pricing policy as proposed. HHS has established the penny pricing policy that allows for the next positive price (\$0.01) when the calculation of the 340B ceiling price is zero. This policy is consistent with the timing of the 340B ceiling price calculation (preceding calendar quarter), and it appropriately aligns with the requisite data points (i.e., AMP and URA) for the 340B ceiling price as set forth in section 340B(a)(1) of the PHSA. HHS believes that the proposed alternatives to penny pricing would be inconsistent with the 340B ceiling price formula established in section 340B(a) of the PHSA and would raise 340B ceiling prices above the statutory formula in ways that would be inconsistent with the statutory scheme. HHS believes that the penny pricing policy best effectuates the statutory scheme.

Comment: Some commenters stated that the inflationary penalty used to calculate the URA was established to discourage manufacturers from raising the price of drugs faster than inflation (i.e., the rebate percentage increases when a manufacturer increases the price of a brand-name drug). Further, commenters believed that any alternative policy to penny pricing would reward manufacturers for raising prices faster than inflation. Commenters stated that the inflationary penalty used to calculate the URA was intentionally established by Congress to discourage manufacturers from raising the price of drugs faster than the rate of inflation and that any alternative to penny pricing would ignore this core component of the pricing formula established by Congress.

Response: Under the MDRP, CMS indexes quarterly AMPs to the rate of inflation (Consumer Price Index adjusted for inflation-urban). Section 1927(c)(2)(A) of the SSA provides

that if the AMP increases at a rate faster than inflation, the manufacturer pays an additional rebate amount which is reflected in an increased URA. Historically, because of the basic rebate and the inflation factor, section 1927(c)(2)(A) of the SSA could increase the rebate amount manufacturers must pay to the States, and result in negative 340B ceiling prices. Due to the provision in section 1927(c)(2)(D) of the SSA that limits the unit rebate amount to 100 percent of the AMP, effective January 1, 2010, an increase in the basic rebate and inflation factor would not result in a negative 340B price, but could result in a zero 340B ceiling price. The methodologies proposed as alternatives to penny pricing would decrease the effect of the inflationary component of the statutory formula established by Congress (AMP increasing faster than inflation).

Comment: Commenters acknowledged HHS' authority and obligation to define the term "ceiling price," but argued that a literal interpretation of the statutory text that would result in a calculated 340B ceiling price of zero dollars is an absurd outcome.

Response: The calculation of the 340B ceiling price is defined in section 340B(a)(1) of the PHSA as AMP minus URA. Under the MDRP, CMS indexes quarterly AMPs to the rate of inflation (Consumer Price Index adjusted for inflation-urban). Section 1927(c)(2)(A) of the SSA provides that if AMP increases at a rate faster than inflation, the manufacturer pays an additional rebate amount which is reflected in an increased URA, which could result in a 340B ceiling price of zero. Although infrequent, HHS notes that there are instances when the 340B ceiling price does calculate to a zero price. For example, in the first calendar quarter of 2016, approximately 1 percent of all drugs listed under the 340B program for that quarter resulted in a zero price.

For the reasons described in the previous responses, HHS does not believe that it is consistent with the statutory scheme to set the price at zero. In this circumstance, HHS is

therefore requiring that manufacturers charge a \$0.01 for the drug, which we believe best effectuates the statutory scheme by requiring a payment.

Comment: Several commenters stated that the 340B statute does not address situations where the 340B ceiling pricing calculation results in zero and therefore the PPA should govern. Commenters argued that while the PPA does not directly address what should occur when the 340B pricing formula results in zero, it provides that the agreement “shall be construed in accordance with Federal common law” which requires the parties “gap fill” by negotiating ambiguous requirements in good faith. Other commenters offered criteria under which the duty of good faith would be met by a reasonable pricing methodology to include that the policy is readily and objectively verifiable, is statutorily supported, and represents a favorable discount to covered entities.

Response: The U.S. Supreme Court has stated that PPAs are not transactional, bargained for contracts, and that “PPAs simply incorporate statutory obligations and record the manufacturers’ agreement to abide by them” (*Astra USA v. Santa Clara County*, 563 U.S. 110, 118 (2011)). Moreover, the PPA indicates that any ambiguities shall be interpreted in a manner that best effectuates the statutory scheme, not that any ambiguities should be negotiated between the parties. 340B Program requirements are based on the manner in which the Department interprets the statute, and are not subject to a contractual negotiation process. For the reasons previously stated, the Department has determined that penny pricing is the policy that best effectuates the statutory scheme.

Comment: Commenters suggested that HHS institute a similar policy to address zero prices as the Veterans Administration (VA) uses to implement the Master Agreement for FCP prices given to certain Federal purchasers pursuant to the Veterans Health Care Act of 1992, the

same legislation that created the 340B Program. They state that the VA interprets its program, which is similar to the 340B Program, to require a good faith negotiation to set a reasonable price in the event of a negative or zero FCP.

Response: Contrary to the commenters' position, the approach utilized by the VA under its separate Prime Vendor Program supports the penny pricing policy. Similar to this final rule, the VA sets the price of a negative or zero priced FCP at \$0.01. The VA's assumption for these drugs is, therefore, that prices are set at \$0.01. While the VA also has an additional mechanism through which manufacturers can request nominal increases in the prices of drugs (Department of Veterans Affairs, Dear Manufacturer Letter, February 24, 1993), the VA's ability to increase prices by a nominal amount above this default is based on statutory authority that does not apply to the 340B Program. Title 38 U.S.C. 8126(a)(2) states that prices may nominally exceed the statutory formula if the VA determines it "to be in the best interests of the Department or such Federal agencies." There is no similar authority in the 340B statute to exceed the basic price calculation, and therefore HHS does not have the same ability to adjust the pricing formula set by statute.

Comment: Many commenters strongly objected to the penny pricing policy. They argued that HHS did not articulate a non-arbitrary, non-capricious reason as to why a \$0.01 price is reasonable. Some commenters stated that there is no material difference between zero and \$0.01, and since HHS has already stated that zero is not reasonable, \$0.01 is also not reasonable. They also argued that the price of zero or one penny fails to cover the costs of goods sold, so cannot be considered the "purchase" of product. Commenters argued that the penny pricing policy would result in an illegal taking of private property by the government. They also argued the policy would result in "arbitrary" or "confiscatory" price controls.

Response: The longstanding penny pricing policy attempts to strike a balance that best effectuates the statutory scheme while ensuring that a zero ceiling price does not result. There is no requirement in the statute that the price paid must cover the costs of the drug. Reading such a requirement into the statute would require the evaluation of the costs of not only zero priced drugs, but any drug with a 340B ceiling price that is only a nominal amount. HHS does not believe that such a system is consistent with the statute. The sale of a drug for a cost less than manufacturing costs still constitutes a “purchase” and does not result in the taking of private property.

HHS disagrees with commenters that there is no material difference between setting the price at zero and \$0.01. Setting the price at \$0.01 requires a payment and therefore ensures that there is a purchase within the meaning of the statute and, as a practical matter, between the buyer and seller. Setting the price at zero rather than \$0.01 would lead to operational challenges. We understand, for instance, that some information technology systems are not able to generate invoices for any prices less than \$0.01 and manufacturers may not be able to generate an electronic data interchange price update for an item that does not have a price of at least \$0.01.

Manufacturer participation in the 340B Program is also voluntary, albeit required in order to participate in the MDRP. Moreover, it is important to note that a manufacturer controls when a product reaches a zero 340B ceiling price through its own pricing decisions. If a manufacturer does not wish to offer a zero 340B ceiling price, the manufacturer may choose not to participate in the 340B Program or may alter its drug pricing practices so as not to cause a zero 340B ceiling price. For example, when AMP increases more quickly than the rate of inflation, the manufacturer must pay a greater Medicaid rebate, which can also cause a zero 340B price. A manufacturer can control AMP by adjusting the prices that it charges for drugs.

Comment: Some commenters stated the penny pricing proposal is likely to result in and/or increase the potential for drug shortages and diversion, requiring manufacturers to adopt burdensome and costly “alternate allocation procedures” to correct for the market-distorting effect of HHS’ policies. Commenters further stated the continuation of penny pricing policy would further exacerbate drug shortages, particularly for generic drugs, given that in the first quarter 2017 generic drugs will be subject to an additional rebate in the URA formula if the AMP for such drugs rises faster than inflation. Given this, the penny pricing provision would result in potential of stockpiling, diversion, harm to patients, and abuse of controlled substances. Commenters were also concerned that there could be an increase in risk evaluation and mitigation strategy (REMS) drugs and drugs for which there is a grey or black market.

Response: The penny pricing policy has been in place for many years and HHS does not have evidence that the policy causes significant risks of stockpiling, diversion, harm to patients, and abuse of controlled substances. HHS has existing policy with regard to manufacturer limited distribution plans for sales of covered outpatient drugs to eligible 340B entities under the 340B Program. Manufacturers may address any resultant market distribution challenges by developing and executing a plan for limited distribution to all purchasers of the affected drug, including 340B covered entities when penny pricing occurs. Manufacturers are currently able to develop appropriate limited distribution protocols. HHS will be sensitive to plans to address drug shortages, stockpiling, and oversupplying of drugs subject to abuse or with REMS warnings.

Comment: Many commenters stated their desire for the flexibility to use any or all of the alternative methods to penny pricing proposed. Manufacturer flexibility and discretion to adopt reasonable approaches to setting the 340B ceiling price when the ceiling price calculates to zero

allows manufacturers to recover their costs while providing a discounted rate commensurate with the intent of the 340B statute.

Response: HHS believes it is most appropriate to establish a standard price calculation in this circumstance, as it is not practical to allow all manufacturers to choose from a variety of methods that could result in pricing variations that could create market disruption and uncertainty. Therefore, we are finalizing the penny pricing policy as proposed.

Comment: Some commenters were in favor of utilizing nominal pricing (less than 10 percent of AMP in the same quarter for which the AMP is computed) as an alternative to penny pricing. Commenters also noted that the MDRP uses this methodology, and that nominal price is a term that appears nine times in the Medicaid statute. They stated further that Congress has demonstrated support for applying this concept by listing 340B covered entities first among the six potential recipients to whom manufacturers may extend a nominal price without impacting best price. Commenters stated that nominal price addressed HHS' concern that "prices must be based on the immediately preceding calendar quarter."

Response: While the term nominal price appears in the Medicaid drug rebate statute, it is entirely absent from the 340B statute. Covered entities can receive a nominal price without impacting a manufacturers' best price for purposes of Medicaid calculations; however, nominal pricing is unrelated to the statutorily-mandated 340B Program pricing calculation. Although the nominal pricing alternative is based on the calendar quarter in which AMP is calculated, consistent with the timing of the 340B ceiling price calculation, it does not appropriately align with the requisite data points (i.e., AMP and URA) for the 340B ceiling price as set in section 340B(a)(1) of the PHSA. HHS will therefore finalize penny pricing as proposed.

Comment: Some commenters favored the utilization of the most recent positive AMP or the last positive, non-zero ceiling price as an alternative to penny pricing. This approach would result in a significant discount to covered entities and would be analogous to the process under MDRP where manufacturers are required to report the most recent positive AMP if AMP equals zero. Carrying forward the most-recent, positive quarterly 340B ceiling price would have the practical effect of establishing a realistic covered entity purchase price, and would reduce the risk of diversion posed by penny pricing.

Response: The MDRP and the 340B Program are authorized under different statutes. While the commenter attempts to draw a comparison between the Medicaid AMP policy and the 340B penny pricing policy, AMP is not the only component of the 340B ceiling pricing formula, as the calculation also includes the URA.

In addition, utilizing the AMP calculation from the last positive quarter would not align with the statutory requirement at section 340B(a)(1) of the PHSA that the 340B ceiling price be based on the preceding calendar quarter's data and could encourage manufacturers to manipulate pricing data. In addition, this method ignores the portion of the congressionally mandated pricing formula regarding the inflation adjustment. Therefore, HHS has determined that this alternative is not an adequate alternative and will finalize this rule as proposed.

Comment: Many commenters were in favor of utilizing the FCP as an alternative to penny pricing. Commenters also suggested the FCP offers an objectively verifiable benchmark and conveys a significant discount to covered entities without driving stockpiling and diversion.

Response: The FCP has some similarities in intent and price-setting methodology to the 340B ceiling price. However, the FCP is generally computed once each calendar year and does not align with the requirement that 340B ceiling prices be calculated on a quarterly basis.

Additionally, the FCP is not computed using the required calculation points of AMP and URA. Moreover, there is no mention of the FCP in the 340B statute. Therefore, HHS has determined that FCP is not an adequate alternative and will finalize this rule as proposed.

Comment: Some commenters requested an exception to the penny pricing policy for orphan drugs. They suggest that when 340B sales volume exceeds a given threshold (e.g., 15 percent), a manufacturer should be permitted to utilize an alternative 340B price, such as its lowest commercial price.

Response: When an orphan drug meets the definition of a covered outpatient drug, it would be subject to the requirements as set forth in this final rule. Further, the statute does not contemplate an alternative pricing methodology for orphan drugs.

C. Ceiling price for a covered outpatient drug--New drug price estimation – §10.10(c)

In general, calculation of the current quarter 340B ceiling price for each covered outpatient drug is based on pricing data from the immediately preceding calendar quarter. For new drugs, there is no sales data from which to determine the 340B ceiling price. HHS published guidelines in 1995 describing ceiling price calculations for new drugs (60 FR 51488, October 2, 1995) and the final rule will replace these guidelines.

In the NPRM, HHS proposed that manufacturers estimate the 340B ceiling price for a new covered outpatient drug as of the date the drug is first available for sale, and provide HHS an estimated 340B ceiling price for each of the first three quarters the drug is available for sale. HHS also proposed that, beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the 340B ceiling price as described in proposed 42 CFR 10.10(a). Under the proposed rule, the actual 340B ceiling price for the first three quarters would also have been calculated and manufacturers would have been required to provide a refund or credit to any

covered entity that purchased the covered outpatient drug at a price greater than the calculated 340B ceiling price. HHS proposed that any refunds or credits owed to a covered entity would be provided by the end of the fourth quarter.

HHS received comments supporting and opposing the various components of its proposal on new drug price estimation. Commenters requested clarification on de minimis refunds under the proposed policy, price estimation methodologies, and whether refund policies stated in this regulation apply to all refunds, not just those corresponding to new drugs. Several commenters supported a specific methodology for calculating new drug prices, which included setting the price of the new covered outpatient drug as wholesale acquisition cost (WAC) minus the applicable rebate percentage (i.e., 23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and drugs approved exclusively for pediatric indications, and 13 percent for generics). Commenters argued that this price would eliminate the need to estimate the price for the first three quarters and would result in a reasonable 340B ceiling price. Given the comments received regarding setting a specific methodology, when HHS reopened the comment period, HHS sought comment on this issue. HHS specifically requested comment on setting the estimation at WAC minus the applicable rebate percentage.

After consideration of the comments received, HHS is modifying the final rule to require that manufacturers estimate, using a standardized methodology, the 340B ceiling price for a new covered outpatient drug until there is AMP data available to calculate an actual 340B ceiling price as set forth in 340B(a)(1) of the PHSA. The methodology set forth in this final rule for the estimated 340B ceiling price is WAC minus the appropriate rebate percentage. Once the AMP is known, and no later than the fourth quarter that the drug is available for sale, manufacturers would be required to calculate the actual 340B ceiling price based on AMP for the time under

which the 340B ceiling price was estimated. The manufacturer is then required to offer a repayment to the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

For example, if a manufacturer with a PPA has a new drug approved for sale in February, and that drug meets the definition of covered outpatient drug, the 340B price estimation requirements would apply for at least one full calendar quarter. During that time, the manufacturer would estimate the 340B ceiling price at WAC minus the appropriate rebate percentage until the manufacturer can calculate an AMP for the product, resulting in an actual 340B ceiling price based on that AMP. The estimation can occur for up to the first three calendar quarters of availability, at which point the manufacturer will have the necessary pricing data to calculate the 340B ceiling price based on section 340B(a)(1) of the PHSA.

Since manufacturers must offer repayments as set forth in this section, it is incumbent on them to contact affected covered entities as part of that process. During initial contact, a manufacturer and a covered entity may both determine that a given overcharge is not significant, or agree to other payment options such as netting or crediting. In these instances, both parties are free to pursue mutually agreed-upon alternative refund arrangements. HHS has summarized and provided a response to the comments below.

Comment: HHS received comments generally supporting and opposing the proposal to price new covered outpatient drugs at WAC minus the Medicaid minimum discount rebate percentages (i.e., 23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and drugs approved exclusively for pediatric indications, and 13 percent for generics) until an AMP derived ceiling price can be identified after the third full quarter in which

the drug became available. In addition, commenters suggested that HHS should not require subsequent pricing revisions or a refund once the actual price is determined. The commenters stated that such an approach would be simpler, while resulting in reasonable proxies for the final 340B ceiling prices.

Response: The 340B ceiling price is calculated based upon AMP minus URA data supplied by CMS that is reported by manufacturers under the MDRP. Given that the AMP for a new covered outpatient drug may not be known for a period of time after the drug comes to market, HHS sought a balance between a standardized and universally applicable interim pricing requirement, while also ensuring that covered entities ultimately receive the 340B ceiling price as defined by the statute. Therefore, we have added to the final rule that new covered outpatient drugs should be estimated and sold to 340B participating covered entities using a standardized formula for the estimation at WAC minus the applicable Medicaid drug rebate percentage until an actual 340B ceiling price can be determined based on AMP. HHS believes a standardized formula for the calculation of the estimation will create stability in the market and provide transparency and consistency in the process. While the commenter's suggested approach may be feasible, HHS does not believe that it is reflective of statutory intent. In addition, HHS has maintained in the final rule that once an actual 340B ceiling price can be determined, manufacturers will be obligated to refund any difference between the estimated 340B price and the actual 340B ceiling price. If a manufacturer refuses to refund covered entities after it has been determined covered entities were overcharged during the time the 340B ceiling price was estimated, that could meet the knowingly and intentionally standard to apply a CMP. This has been clarified in §10.11 of this final rule.

Comment: HHS received several comments from covered entity groups expressing concern that the proposed new drug price estimation method, based on WAC minus the appropriate rebate percentage, would result in prices that are significantly higher than estimates derived from other methods. Commenters stated that WAC-derived pricing is often 30 percent higher than prices available to group purchasing organizations and that 340B ceiling prices are typically much lower than this estimation.

Response: HHS believes that the final rule ensures that covered entities will be able to receive the 340B ceiling price as defined in statute by requiring manufacturers to offer a refund to covered entities after the estimation period and within 120 days of determining there was an overcharge.

Comment: Several commenters suggested that the 340B Program follow Medicaid policy towards rebates for new drugs, whereby prices are determined from the beginning by AMP (rather than WAC) minus the applicable discount percentage. The commenters argued that policy alignment with Medicaid would greatly simplify rebate program administration, and minimize the need for future reconciliation of overcharges. Commenters also suggested that HHS should reevaluate such a formula for new drug pricing to see how closely it aligns with AMP derived pricing after the initial estimation period.

Response: The CMS Medicaid Covered Outpatient Drug Rule (81 FR 5270, February 1, 2016) refers to AMP-based pricing only when a new version of an existing drug comes to market. In the case of a new drug, the Medicaid program does not utilize AMP-based pricing, as there are no prior sales data to base it on. Therefore, initial prices must be based on another price point. HHS believes that using a standardized formula, WAC minus the appropriate rebate

percentage, to estimate 340B ceiling prices prior to an AMP being available is the most appropriate way to implement pricing requirements with regards to new drugs.

Comment: Regarding the timeframe for new drug price calculations, several commenters suggested that new drug pricing follow the VA policy, whereby manufacturers are required to provide an initial (provisional) FCP statutory discount percentage to the WAC for 30 days, followed by a temporary pricing period predicated on the first 30 days of commercial sales, and permanent ceiling pricing taking effect after the first quarter by applying the statutory discount to the non-Federal AMP as it becomes available. Commenters cited the VA timeframe, whereby an estimated (WAC-based) price is used for the first month that a new drug is available, followed by a switch to a temporary (AMP-based) price.

Response: HHS believes that it is appropriate to minimize any restatements of pricing that occur as a new 340B drug comes to market. The VA timeframe does not correlate to the quarterly pricing that occurs in the 340B Program. Therefore, HHS has finalized the rule to estimate drug pricing as WAC minus the appropriate rebate percentage until an actual 340B ceiling price can be computed based on AMP.

HHS also notes that a provisional FCP is not required by the VA, it is optional. In addition, if a provisional FCP is established, it is not valid for just the first 30 days. It remains valid until the first temporary FCP comes due or is established, which could be up to 75 days from launch.

Comment: Commenters suggested that new drug calculations should not be subject to the two-quarter lag typical of other price calculations. These commenters recommended establishing an “interim” (WAC minus the appropriate rebate percentage) ceiling price through the first full quarter, followed by pricing based on the AMP, which can be established with one quarter of

data. Other commenters suggested establishing provisional 340B ceiling prices for new drugs based on MDRP statutory discounts applied to an available U.S. sales reference price (e.g., WAC reduced by estimates for quarterly URA values), thus eliminating the need for restatements at a later date.

Response: The 340B ceiling price is set by the statute and manufacturers are required to charge covered entities that ceiling price. Therefore, manufacturers are required to issue refunds if it is determined that a covered entity paid a price higher than the 340B ceiling price. HHS has also decided to standardize the pricing estimation during the period for which there is not an AMP available to calculate an actual 340B ceiling price. HHS believes that WAC minus the rebate percentage serves as a fair and reasonable estimated 340B ceiling price.

Comment: Commenters among the drug manufacturer community stated that it is not necessary to provide price estimates past the first full quarter, so that less time will elapse where a new drug ceiling price is estimated instead of being based on actual market data. Others stated that two quarters was sufficient to calculate prices based off the first quarter's sales data. Commenters argued that a shorter estimate period would reduce administrative burdens, and lessen the need for retroactive refunds.

Response: HHS agrees that an AMP for a new covered outpatient drug may be established after one full quarter has elapsed. Under the final rule, once the AMP is known, and no later than the fourth quarter that the drug is available for sale, manufacturers would be required to calculate the actual 340B ceiling price based on the AMP for the time under which the ceiling price was estimated. The estimation can occur for up to the first three calendar quarters of availability, at which point the manufacturer will have the necessary pricing data to calculate the 340B ceiling price based on section 340B(a)(1) of the PHSA. The manufacturer

must offer to refund or credit the covered entity the difference between the estimated ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

Comment: Commenters were concerned that the proposed timeframe for manufacturers to issue refunds or credits is too short. Commenters requested that the refund process for overestimated new drug prices follow the Medicaid approach of allowing 12 quarters for price restatements, followed by 2 quarters for the refund to occur. Other commenters wrote in support of the proposed fourth quarter standard.

Response: The NPRM proposed that refunds or credits be provided to entities by the end of the fourth quarter. HHS agrees additional time may be necessary to issue refunds. Therefore, HHS has changed the NPRM's fourth quarter standard in the final rule. In addition, the final rule states that manufacturers must offer to refund or credit the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred. HHS believes that 120 days allows the manufacturer and the covered entity an opportunity to first determine whether the overcharge is significant, and if not, whether to make repayment options such as crediting or netting.

Comment: Commenters argued that the proposed refund procedure is inconsistent with the 1995 guidance (60 FR 51488, October 2, 1995) where covered entities are responsible for initiating the refund process, and must do so without a third-party intermediary and that the refund requests should be made by the end of the fourth full quarter after a new drug comes to market.

Response: Manufacturers are required by statute to provide covered entities the statutorily defined 340B ceiling price. Therefore, once a manufacturer determines there is an overcharge related to new drug price estimation as set forth in this final rule, manufacturers must notify covered entities affected and appropriately refund them accordingly. This final rule replaces the 1995 guidance in its entirety.

Comment: Commenters stated that requiring refunds following ceiling price recalculations would be inconsistent with the 340B statute because such refunds would impose an undue cost on manufacturers.

Response: In accordance with section 340B(a)(1) of the PHSA, 340B ceiling prices for covered entities must “not exceed an amount equal to the average manufacturer price for the drug under title XIX of the SSA in the preceding calendar quarter, reduced by the rebate percentage” outlined in section 340B(a)(2)(A) of the PHSA. Since the necessary predicate of an AMP cannot be known until a drug has been on the market for a preceding calendar quarter, we have determined that using a reasonable, standardized estimate in the interim, followed by refunds as the AMP is calculated, achieves the programmatic goal of assuring that covered entities receive refunds owed in both a timely and a complete manner. Regarding the cost to manufacturers, this policy involves using similar mechanisms currently in use for other refunds routinely issued by manufacturers, and does not represent a significant added cost.

Comment: Commenters requested clarification on what is meant by the “expected” versus the “actual” price, in addition to requests for clarification on methods for developing expected or estimated prices for new drugs.

Response: For the purposes of this rule, “expected” can be understood as the initial (estimated) 340B ceiling price that is charged to a covered entity when there is not yet an AMP

to use in the 340B ceiling price calculation. HHS has added to this final rule a standardized formula to the new drug price cost estimation, which is WAC minus the appropriate rebate percentage. The “actual” 340B ceiling price is the price of a new drug once there is an AMP in place that is used to calculate the 340B ceiling price per statute.

Comment: Commenters requested clarification on the potential role of wholesalers and distributors in the refund process, specifically in identifying covered entities entitled to a refund based on new drug price estimation.

Response: The role of wholesalers and distributors is dependent on how individual manufacturers contract with these third parties to distribute 340B drugs. Whether wholesalers and distributors play a role in the refund process is determined by individual manufacturers and their business operations with these stakeholders. The requirement to refund a covered entity as outlined in the final rule rests with the manufacturers. A manufacturer may use a third party to assist in ensuring they meet those requirements.

Comment: Several commenters requested that there be an exemption for de minimis refund amounts resulting from differences between initial ceiling price estimates and the establishment of a retroactive actual ceiling price after the first three quarters that a new drug becomes available. Commenters cited administrative burden in issuing refunds for all overcharges, regardless of their significance. Commenters representing both the manufacturer and the covered entity communities were broadly supportive of a defined threshold, as well as a stated timeframe for refunds to be issued.

Response: Manufacturers are obligated to offer repayments within 120 days of the determination that an overcharge occurred. HHS does not agree that the final rule should set a materiality threshold, and believes this is best approached by marketplace arrangements and in

good faith negotiation between the parties. To the extent that a manufacturer and covered entity agree that a de minimis threshold for refunds should be established, such a threshold can be established through mutual agreement between the manufacturer and covered entity.

Comment: Regarding overcharges resulting from differences between estimated and actual ceiling prices, a number of commenters requested that overcharges be netted in a manner similar to MDRP regulations. The commenters stated that the MDRP permits manufacturers to aggregate the impact of restated prices on each sale to determine the net amount due after pricing restatements and that states are not permitted to retain excess rebate amounts paid upon recalculations. Commenters suggested that because the MDRP and 340B Program are closely intertwined, they should be consistently administered and allow a similar netting approach as to minimize administrative and financial burden of refunding 340B covered entities.

Response: To the extent there is an agreement between the manufacturer and covered entity, HHS does not intend to prevent manufacturers from using the industry's practice of netting overcharges and undercharges, or to restate ceiling prices based on pricing data submitted to CMS. However, the 340B statute is specific to ensuring each covered outpatient drug is offered at or below the 340B ceiling price. Once it is determined that an overcharge occurred, a manufacturer and a covered entity, in good faith, may both determine that a given overcharge is not significant, or agree to other payment options such as netting or crediting. In these instances, both parties are free to pursue mutually agreed-upon alternative refund arrangements.

Comment: Many commenters suggested that covered entities be held liable for undercharges that occur during a new drug's estimated pricing period.

Response: Given the nature of the standardized estimated 340B ceiling price calculation described in this final rule, HHS views the likelihood of undercharges to be low. Because WAC

is typically higher than the 340B ceiling price and the estimation for new drugs finalized in this rule is based on that amount, we believe that new estimation undercharges will be minimal. Section 340B(a)(10) of the PHSA states that there is no prohibition on larger discounts being offered to covered entities. In addition, the statute is specific in addressing when a manufacturer overcharges a covered entity and it does not address refunds by covered entities if the manufacturer provides a price below the 340B ceiling price. Therefore, it will not be addressed in the final rule.

Comment: Commenters requested clarification on whether the refund policy described in this rule would apply to all overcharges identified during price restatements, and not just those that occur as sales data can be applied to new drug pricing. Commenters also requested that HHS codify a formal refund procedure in regulation and that the Affordable Care Act requires the 340B Program to develop a refund mechanism.

Response: The refund requirements as set forth in this final rule apply as it relates to new drug price estimations. Specific procedures for refunds are outside the authority of this final rule and will be addressed in future guidance. HHS is finalizing this refund requirement as proposed and continues to believe that an instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations resulting from pricing data submitted to CMS occur.

Comment: Commenters requested that HHS define “new drug” in this rule, suggesting the use of NDC-11 or package size as criteria. Commenters suggested a clarification that a new package size is not a new drug, suggesting that new prices can be derived off known unit prices, with any subsequent refunds occurring under the existing reconciliation process. Commenters suggested a clarification that a new package size of an existing drug should not be considered a

new drug for purposes of this rule and that the 340B ceiling price should use the per unit pricing data (NDC-9) from the existing package sizes already in the market.

Response: For the purposes of this final rule, a new covered outpatient drug is any drug that does not have a previous quarter AMP calculation from which a price can be derived. HHS does not believe this distinction needs to be clarified in the final rule, and additional policy on this issue may be developed if the need arises.

D. Manufacturer civil monetary penalties General – §10.11(a)

Section 340B(d)(1)(B)(vi) of the PHSA provides for the imposition of civil monetary penalties on manufacturers that knowingly and intentionally charge a covered entity a price for a 340B drug that exceeds the ceiling price. At §10.11(a) of the NPRM, HHS proposed that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the 340B ceiling price, as defined in §10.10, for a covered outpatient drug, may be subject to a civil monetary penalty not to exceed \$5,000 for each instance of overcharging a covered entity. As indicated in the NPRM, pursuant to a delegation of authority, OIG will have authority to impose a CMP. The initial release of the NRPM did not define the term “knowing and intentional,” but based on comments received, HHS reopened the NPRM comment period (81 FR 22960, April 19, 2016) to seek comment on the definition of the knowing and intentional standard for purposes of HHS’ CMP authority. HHS offered possible options on how the term should be defined. HHS understands that intent is difficult to define, therefore, input was solicited on circumstances in which the requisite intent should and should not be inferred. In particular, HHS solicited comment on the concept that manufacturers would not be considered to have the requisite intent in the following circumstances:

- The manufacturer made an inadvertent, unintentional, or unrecognized error in calculating the ceiling price;
- A manufacturer acted on a reasonable interpretation of agency guidance; or
- When a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly situated non-340B covered entities.

HHS received numerous comments recommending the terms knowingly and intentionally be further defined in the final rule. Commenters generally supported the listed examples of circumstances where the requisite intent is not demonstrated, and a number of commenters suggested additional examples. Commenters also raised concern over ensuring the terms knowingly and intentionally are not overly prescriptive such that they limit the use of a CMP. In the final rule, HHS sought balance between a clear and enforceable definition and the need to approach each instance of an overcharge with a full view of the surrounding circumstances. Given these two goals, HHS is finalizing the rule as proposed and has provided additional examples of conduct that would not be considered to meet the threshold of “knowing and intentional” action in this supplementary information section in response to comments. In addition, as a general principle, HHS will defer to OIG to determine whether a given situation constitutes a ‘knowing and intentional’ 340B drug overcharge based on the specific case being investigated. HHS believes this will provide the flexibility necessary to evaluate an instance of overcharging on a case-by-case basis. Below is a summary of the comments received, and HHS’ responses.

Comment: Commenters provided additional examples to be considered as not meeting the knowing and intentional threshold, such as periods of estimations for new drugs.

Response: HHS agrees that the period of time for which a manufacturer is estimating a 340B ceiling price for new drugs as set forth in this final rule may not meet the knowingly and intentionally standard, as long as the manufacturer also ensures that the covered entities are refunded according to §10.10(c). However, if a manufacturer does not offer to refund a covered entity per §10.10(c) of the final rule, that may constitute a knowing and intentional overcharge. The final rule has been modified accordingly. Examples of circumstances where HHS would assume that a manufacturer did not “knowingly and intentionally” overcharge a covered entity are:

- The manufacturer made an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price;
- The manufacturer sells a new covered outpatient drug during the period the manufacturer is estimating a price based on this final rule, as long as the manufacturer offers refunds of any overcharges to covered entities within 120 days of determining an overcharge occurred during the estimation period;
- When a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase; or
- When a covered entity chooses to order non-340B priced drugs and the order is not due to a manufacturer’s refusal to sell or make drugs available at the 340B price.

We note that these examples are not exhaustive, and are intended to provide an indication of some types of actions that would not be considered “knowing and intentional” overcharges.

In the NPRM, the last two examples above were included in the text of the regulation defining instances of overcharging. Upon consideration of public comments, HHS believes that the last two examples above should be construed as particular circumstances under which an instance of overcharging did not occur as opposed to examples of what would constitute an instance of overcharging. As a result, HHS is not including these two examples in the final regulatory text defining an instance of overcharging, but rather providing them here as examples of instances where overcharging did not occur. As a general principle, HHS will defer to OIG to determine whether a given situation constitutes a ‘knowing and intentional’ overcharge based on the specific case being investigated.

Comment: Some commenters suggested that HHS adopt the definition of “knowingly” from the HHS OIG CMP regulations. Under these regulations, the term “knowingly” is defined as “a person, with respect to information, has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required” (42 CFR section 1003.102 (e)). A few commenters noted that under the canons of statutory construction, agencies must assume Congress intended each word or phrase to have a distinct meaning.

Response: HHS does not believe it is appropriate to incorporate additional language over and above the statutory language “knowingly and intentionally” that would limit OIG further in applying this penalty. Each factual case is different and will be evaluated separately to determine if it may warrant a penalty as set forth in this final rule. After consideration of the comments received, HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: Commenters offered specific definitions of the term “intentionally.” Several commenters requested that “intentionally” be defined as “not due to a mathematical miscalculation, clerical oversight, or similar inadvertent error.” A few commenters requested that the term “intentionally” be defined as “consciously committing an act or omission that results in an overcharge.” Commenters requested that, when defining the terms “knowingly” and “intentionally,” HHS incorporate definitions such as “actual knowledge by the manufacturer, its employees, or its agents of the instance of overcharge” or “acting consciously and with awareness of the acts leading to the instance of overcharge.” Commenters interpreted the statute to say that it must be “knowing and intentional” on the part of the manufacturer both that the amount charged exceeds the ceiling price and that the entity charged is in fact a covered entity.

Response: HHS appreciates commenters’ proposed definitions of “knowingly and intentionally,” and also acknowledges commenters’ concerns about HHS’ proposed definitions. HHS agrees that in cases where a manufacturer established that the overcharge in question was as a result of an isolated act of simple negligence or inadvertent math error, then the penalty would not typically apply. However, the facts and circumstances of each case would need to be taken into account. For example, if a manufacturer inadvertently developed an unreliable process that resulted in negligent errors, but later there is knowledge of such systematic failures that results in errors in the 340B ceiling price calculation that causes overcharges, this could be sufficient to meet a knowingly and intentionally standard. After consideration of the comments received, HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: Several commenters believed that the statute’s requirement that conduct must be both “knowing” and “intentional” to impose CMPs sets up a specific and demanding standard

and some covered entities were concerned that the proposed definitions set the bar so high as to have little practical value in ensuring that they receive appropriate prices under the 340B Program. They stated that the intent standard is contrary to Congress' intent to give HHS a meaningful enforcement tool, and it will not deter manufacturers from overcharging under the 340B statute. Further, they noted that the Supreme Court wrote that through CMP provisions "Congress thus opted to strengthen and formalize HHS' enforcement authority" (*Astra USA v. Santa Clara County*, 563 U.S. 110, 121-22 (2011)). Other commenters were concerned that the proposed definitions would not amount to the heightened threshold for intent outlined in the statute, meaning that the proposed definitions would capture lesser forms of misconduct than Congress had intended.

Response: While HHS agrees that the use of the terms knowingly and intentionally as set forth in the statute set a high standard for imposing penalties, HHS believes it will serve as an enforcement tool to ensure manufacturers are charging covered entities at or below the 340B ceiling price. HHS appreciates commenters' proposed definitions of "knowingly and intentionally," and also acknowledges commenters' concerns about HHS' proposed definitions. HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: HHS provided several possible definitions for knowing and intentional when it reopened the comment period: (1) actual knowledge by the manufacturer, its employees, or its agents of the instance of overcharge; (2) willful or purposeful acts by, or on behalf of, the manufacturer that lead to the instance of overcharge; (3) acting consciously and with awareness of the acts leading to the instance of overcharge; and/or (4) acting with a conscious desire or

purpose to cause an overcharge or acting in a way practically certain to result in an overcharge. HHS received a number of comments on the proposed definitions.

Response: HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: With respect to the language in the notice of reopening of comment period (81 FR 22960, April 6, 2016) that “manufacturers do not need to intend specifically to violate the 340B statute; but rather to have knowingly and intentionally overcharged the 340B covered entity,” several commenters expressed concern that this is inconsistent with the statutory text. These commenters argued that in order to be subject to CMPs, the manufacturer must specifically intend to violate the 340B statute, not solely intend to charge a price that is higher than the 340B ceiling price.

Response: HHS agrees that CMPs will be applied to a manufacturer that knowingly and intentionally overcharges a covered entity. The specific intent to violate the 340B statute is not necessarily required to be shown to warrant an application of the penalty provision.

Comment: Commenters expressed concern that any further definition of the terms “knowing” and “intentionally” will constrain HHS’ ability to judge whether a CMP is appropriate in a given instance. If HHS determines that further definition is necessary, they suggested using an exclusionary approach, stating specific actions that do not rise to the level of requisite intent, rather than an approach that names only specific actions that will be considered “knowing and intentional” in this context. Commenters generally supported the listed examples of circumstances where the requisite intent is not demonstrated and requested that the examples be explicitly characterized as non-exhaustive. Several commenters suggested adding a catch-all provision to the list of examples, such as “other situations in which it is reasonable not to infer

that a manufacturer acted ‘knowingly and intentionally,’” or “any other situation not presenting circumstances of a deliberate effort to disobey the law with regard to the 340B program.”

Response: HHS agrees with the commenter’s approach. Therefore, instead of defining these terms in an inclusive manner, HHS has chosen to provide OIG the flexibility to determine what constitutes “knowingly” and “intentionally” overcharging a covered entity in a particular instance. In addition, HHS provides examples above regarding circumstances that would not meet the threshold of knowingly and intentionally overcharging a covered entity.

Comment: With respect to the proposed example “the manufacturer made an inadvertent, unintentional, or unrecognized error in calculating the ceiling price,” one commenter suggested including an error “identifying the eligibility of an entity to receive the 340B discount.”

Response: HHS did not include the suggestion to include an error in “identifying the eligibility of an entity to receive the 340B discount” in the final rule to retain flexibility that the penalty be applied only where appropriate. However, it should be noted that 340B covered entities are listed on the 340B public database, and those listed are entitled to the 340B ceiling price.

Comment: Regarding the proposed example “a manufacturer acted on a reasonable interpretation of agency guidance,” a commenter was concerned that the example was overly broad, since manufacturers may decide what is reasonable, and this, therefore, may create a loophole for manufacturers to avoid CMPs. They recommended, at a minimum, clarifying that this is an objective reasonableness standard, as determined by HHS and/or OIG. Several other commenters suggested adding exceptions for reasonable interpretations of laws, regulations, and the pharmaceutical pricing agreement. Further, one commenter stated that in circumstances

where the statute and agency guidance conflict, it is reasonable for the manufacturer to adopt practices consistent with the statute.

Response: HHS agrees that the proposed example that, “a manufacturer acted on a reasonable interpretation of agency guidance,” was overly broad. OIG would need to consider each circumstance of a 340B drug overcharge on a case by case basis to determine if that circumstance constitutes a “knowing and intentional action.

Comment: With respect to the proposed example, “when a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers,” commenters were concerned that this is overly broad. They recommended that HHS only provide a safe harbor for manufacturers with valid limited distribution plans, and revise §10.11 of the final rule to address other situations where a manufacturer fails to make 340B drugs available to covered entities to the same extent as to non-340B providers. They argued that the statute states CMPs are issued when manufacturers “knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum available price under subsection (a)(1).” Section 340B(a)(1) of the PHSA requires that “the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such a drug is made available to any other purchaser at any price.” Therefore, if a manufacturer does not comply with the nondiscrimination provision in subsection (a)(1), this constitutes an overcharge for purposes of the CMP provision. Other commenters recommended that HHS delete this example, because it would allow any manufacturer to develop alternative allocation procedures to disregard the ceiling price whenever demand exceeds supply.

Response: HHS agrees that the proposed example, “when a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers,” was overly broad. OIG would need to consider each circumstance of a 340B drug overcharge on a case by case basis to determine if that circumstance constitutes a “knowing and intentional action.

Comment: Commenters suggested that the proposed example, “when a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers,” a manufacturer would not have the requisite intent if a covered entity chooses to purchase the manufacturer’s product through a channel other than the subset of distributors through which the 340B ceiling price is available. Another commenter suggested that the example read instead, “...as long as the manufacturer offers covered entities the opportunity to purchase on terms consistent with those offered to other similarly-situated entities in the same class of trade.”

Response: In general, HHS agrees that the penalty provisions typically would not be appropriate in a case where a covered entity chooses to purchase a covered outpatient drug knowing that the price charged exceeds the 340B ceiling price. However, in the case where there was sufficient evidence to conclude that this result was due to actions by the manufacturer that were knowing and intentional, a penalty may be appropriate. Although it may be reasonable to believe that such a circumstance is extremely unlikely to arise, HHS does not believe it is appropriate or necessary to exclude a possibility that may occur.

Comment: A number of commenters suggested additional examples of situations that they believe do not meet the “knowing and intentional” standard. Some of the examples suggested by commenters include, but are not limited to, the following:

- Instances of intentional failure to issue refunds to covered entities, because HHS has not yet established procedures for issuing refunds;
- A case where a manufacturer was not aware it was selling to a covered entity;
- A case where a distributor failed to give a covered entity a 340B price through no fault of the manufacturer;
- Situations where there is a reasonable disagreement and no established law or agency guidance or circumstances where the manufacturer acted based on reasonable assumptions in the absence of (or in the face of conflicting) guidance, provided such assumptions are consistent with the requirements and intent of section 340B of the PHSA and any implementing regulations, and a written or electronic record outlining these assumptions is maintained; and
- When a manufacturer has established a uniformly applied limited distribution system or risk evaluation and mitigation strategy (“REMS”).

Response: HHS appreciates the efforts commenters made in enumerating conduct they believed should be exempt from examples of knowingly and intentionally selling a drug above its 340B ceiling price. OIG will review these circumstances on a case-by-case basis along with the facts for each instance. Rather than try to anticipate every circumstance that might occur, HHS believes it more appropriate to retain flexibility. To the extent that manufacturers identify situations where uncertainty results in unnecessary costs, HHS will respond as such circumstances arise and may provide additional guidance in the future.

Additionally, since manufacturers are named in statute as being responsible for setting appropriate 340B ceiling prices, they must be responsible for the conduct of business partners with whom they have contracted. Nevertheless, inadvertent clerical errors, as long as they are corrected as soon as identified, would not be considered to be a “knowing and intentional” overcharge.

Comment: Commenters recommended including as an exemption from being considered an overcharge and meeting the knowing and intentional threshold when a manufacturer acted on credible evidence that a covered entity is engaged in diversion of 340B drugs. They stated that if a manufacturer has evidence a covered entity is improperly diverting a drug, it should be able to charge the covered entity a price above the 340B ceiling price. It is argued that this option would create a check on 340B drug diversion, since manufacturers have better and timelier access to sales data than does HHS.

Response: HHS does not believe that unilaterally overcharging a covered entity based upon suspicion of diversion is warranted under the statutory language. Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity. Manufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly.

E. Manufacturer civil monetary penalties--Instance of overcharging – §10.11(b)

At §10.11(b) of the proposed rule, HHS defined an instance of overcharging for the purpose of imposing a CMP as any order for a certain covered outpatient drug, by NDC, which results in a covered entity paying more than the 340B ceiling price. An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other

NDC or discounts provided on the same NDC on other transactions, orders, or purchases. HHS also proposed that manufacturers have an obligation to ensure that the 340B ceiling price is provided through distribution arrangements made by the manufacturer. An instance of overcharging may occur at the time of initial purchase or at subsequent ceiling price recalculations. The recalculations are due to pricing data submitted to CMS that results in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity. Finally, HHS proposed that a manufacturer's failure to provide the 340B ceiling price is not considered an instance of overcharging when a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase. Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer refuses to sell or makes drugs available at the 340B ceiling price.

HHS received comments supporting and opposing the proposed §10.11(b). Some commenters opposed certain components of the proposed definition, including the proposal to (1) define the term based on orders; (2) require manufacturers to ensure 340B pricing regardless of distribution arrangements; (3) prohibit offsets; (4) consider as an instance of overcharging when a manufacturer fails or refuses to provide funds at the time of initial purchases or during subsequent ceiling price recalculation; and (5) clarify that a manufacturer's failure to provide the 340B ceiling price if a covered entity did not initially identify such purchases as 340B eligible or that covered entity orders of non-340B drugs will not be subsequently considered an instance of overcharging unless the manufacturers refuses or makes drugs available at the 340B ceiling price. These commenters claimed that HHS does not have the statutory authority to define the term as such or that such definition does not meet the "knowingly and intentionally" standard.

At the same time, other commenters supported these components of the proposed definitions as they ensure that covered entities have access to covered outpatient drugs under the 340B Program. Specific comments are addressed below.

Comment: Commenters wrote in opposition to the definition of an instance of overcharging as any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price. Some commenters asked HHS to define an instance of overcharging more restrictively and on a per-unit basis rather than a per-order basis. Doing so would allow OIG to impose penalty amounts commensurate with the severity of the violation.

Response: HHS has determined to finalize the definition of instance as proposed. An instance of overcharging is any order for a certain covered outpatient drug, by NDC, which results in a covered entity paying more than the 340B ceiling price, as defined in §10.3 of this final rule, for a covered outpatient drug. Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC in that order. This includes any order placed with a manufacturer or through a wholesaler, authorized distributor, or agent. A single order may contain one or more NDCs; thus a violation of this provision may constitute more than one instance depending on the number of NDCs in the order. HHS believes that changing the definition to a per-unit basis is restrictive and overly burdensome as current purchasing occurs at the 11-digit NDC versus a per-unit basis. Finalizing the rule as proposed strikes the right balance in applying the appropriate penalties.

Comment: Commenters asked HHS to clarify that the “order” is the single purchase order, rather than separate line items within a single purchase order. Commenters claimed that defining an instance of overcharging based on “orders” may be interpreted to include situations

in which estimated 340B ceiling prices for new drugs were too high and the manufacturer did not issue refunds to covered entities in the time that the rule would require.

Response: Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC in that order. If a covered entity orders a single bottle of a covered outpatient drug four times in a month, it would be considered four instances of overcharging. A single order may contain one or more NDCs; thus a violation of this provision may constitute more than one instance depending on the number of NDCs in the order. With regards to new drug price estimation and refunds to a covered entity, HHS addresses those requirements in §10.10 of this final rule. If refunds in this circumstance are not offered to covered entities within 120 days of the determination by the manufacturer that an overcharge occurred, it may be considered as meeting the definition of knowingly and intentionally overcharging the covered entity and the definition of instance would apply. This is in alignment with the statute that requires manufacturers to provide covered entities the 340B ceiling price.

Comment: Some commenters suggested that an instance of overcharging be defined as each product ceiling price reported by a manufacturer to HRSA that contains a price that the manufacturer knows and intends to be in excess of the price as calculated. Other comments recommended further defining the term to add details related to the instance. For example, some recommended inclusion of the following language: all mispriced purchases within a quarter on a particular drug to a particular customer, intentionally incorrect ceiling prices reported to HRSA that actually result in overcharges to one or more registered covered entities, and incorrect treatment by a manufacturer of a registered covered entity as an organization ineligible for the 340B ceiling price. Other commenters asked HHS to include in the definition of instance of

overcharging, a manufacturer's failure to offer a covered outpatient drug to a covered entity to the same extent that the drug is offered to other purchasers.

Response: HHS declines to include additional language as raised by the commenters. While the examples provided may result in a covered entity being charged above the 340B ceiling price, they relate more to defining the knowing and intentional standard, which will be determined by OIG on a case-by-case basis. HHS believes it is important to provide the necessary flexibility for OIG to determine the facts surrounding a specific case. HHS also notes that it is the actual sale of the covered outpatient drug above the 340B ceiling price by the manufacturers to the covered entity that is the subject of the overcharge per the statute.

Comment: Commenters opposed the proposed extension of the manufacturer's responsibility to ensure that covered entities have access to 340B pricing for covered outpatient drugs sold by wholesalers and distributors. They contend that manufacturers should not be responsible for the conduct of their agents, since an agent's actions are not knowing and intentional on the part of the manufacturer and since these actions are not within the manufacturers' control. A number of commenters pointed out that manufacturers may provide wholesalers and distributors the 340B pricing but covered entities may not purchase drugs at 340B pricing because wholesalers and distributors may add fees that may raise the price of drugs above the 340B ceiling price. Clarification was requested related to when actions by a wholesaler would be attributed to manufacturers when assessing CMPs, and whether a distribution fee charged by a wholesaler could cause an overcharge.

Response: Manufacturers are ultimately responsible for ensuring a covered entity receives a drug at or below the 340B ceiling price as stated in the statute and per this final rule. Manufacturers also have control over the distribution of covered outpatient drugs, including

those distributed by wholesalers, distributors, and agents wherein the terms and conditions of the sales set through these distribution arrangements are set by the manufacturer via a contract agreed to and between the manufacturer and the distributors. This final rule applies solely to manufacturers, even though other third parties have a role in ensuring the covered entity receives a drug at or below the 340B ceiling price. Manufacturers must consider the wholesaler role in this process and work out issues in good faith and in normal business arrangements regarding the assurance that the covered entity is receiving the appropriate prices. Failure to ensure the covered entities are receiving the 340B ceiling prices through a third party may be grounds for the assessment of CMPs under this final rule. HHS does clarify, however, that fees charged directly by a wholesaler or other distributor are not considered part of the 340B ceiling price and would not be considered as part of assessing an instance of an overcharge.

Comment: Commenters asked for a clarification that specialty pharmacies are not considered “specialty distribution or wholesalers” and thus are not required to provide 340B pricing. Other commenters claimed that the requirements set forth under this section are not consistent with the non-discrimination policy, which allows manufacturers to establish alternate allocation procedures. Commenters requested clarification that CMPs would not apply in a situation where a covered entity purchased product in the marketplace when the manufacturer was employing a distribution system compliant with HRSA's non-discrimination guidance (340B Program Notice Release No. 2011-1.1 (May 23, 2012)). Some commenters asked HHS to clarify that a refusal by the covered entity to purchase drugs through a limited distribution arrangement should not be interpreted as the manufacturer’s refusal to sell or make drugs available at the 340B price for purposes of CMPs.

Response: All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system. If a manufacturer is using a specialty pharmacy to distribute covered outpatient drugs, it must ensure the covered entity is not overcharged if drugs are accessed through that pharmacy. As to comments suggesting that the rule is inconsistent with the current non-discrimination policy, HHS does not believe that is the case. Consistent with section 340B(a)(1) of the PHSA, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs when such drugs are sold through limited distributors or specialty pharmacies. Manufacturers may continue to develop limited distribution procedures provided that those arrangements follow HHS established policy. HHS will take into consideration whether a manufacturer has submitted an alternate allocation plan to HHS when a manufacturer is being investigated for a possible overcharge, whether this plan is compliant with the 340B non-discrimination policy, and whether the manufacturer is following its plan.

Comment: Commenters argued that HHS is attempting to interpret and apply the “shall offer” provision through this rule. Some commenters claimed that CMPs do not apply to a shall offer provision until a manufacturer signs a PPA that includes that provision.

Response: Section 340B(a)(1) of the PHSA provides that a manufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price. This particular provision of section 340B(a)(1) is separate and distinct from the provision pertaining to the calculation of 340B ceiling prices. Because this final rule is applicable to the provision of section 340B(a)(1) pertaining to the calculation of the 340B ceiling price, the language in the statute regarding “shall offer” will not be addressed in this final rule.

Comment: Commenters asked HHS not to finalize the proposed rule provision that an instance of overcharging would be considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases. They argue that offsetting is an industry practice and should not meet the knowing and intentional standard. Still other commenters pointed out that HHS has not developed a process for refunds and without such a standardized refund process, the use of offsets should be allowed. For these reasons, the commenters asked that HHS finalize the regulation to allow for offsets. Commenters also claimed that if finalized, HHS would make the offering of sub-ceiling prices mandatory rather than voluntary. Calculating refunds based only on restatements that lower the ceiling price, without accounting for restatements that raise the ceiling price, would transform the voluntary nature of offering sub-ceiling prices into a requirement. Other commenters favored allowing offsetting but providing covered entities a mechanism to contest the offsets.

Response: As proposed, and finalized in this rule, an instance of overcharging is considered at the 11-digit NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases. The 340B statute is specific to ensuring each covered outpatient drug is offered at or below the 340B ceiling price. However, HHS does not intend to prevent manufacturers from using the industry's practice of netting overcharges and undercharges, or from restating ceiling prices based on pricing data submitted to CMS, to the extent that there is agreement between the manufacturer and covered entity.

In regards to comments based on the refund process, HHS has finalized that an instance of an overcharge may occur at the time of initial purchase or when subsequent ceiling price

recalculations occur and the manufacturer refuses to refund or issue a credit to a covered entity. HHS has clarified in the final rule that this would include refusal to refund covered entities according to §10.10(c) of the final rule with regards to new drug price estimation and would include refusal to refund a covered entity after restatements to CMS. If a covered entity is not refunded when there is an overcharge, the covered entity, in essence paid above the 340B ceiling price. While HHS has finalized in this rule the requirement to refund if there is an overcharge, the specific refund procedures will be addressed under separate guidance. Until there is final guidance in place regarding refund procedures, manufacturers and covered entities should work in good faith and refund in a reasonable manner that is documented by the parties involved.

Regarding the statement that not allowing offsets would force manufacturers to sell below 340B ceiling prices, the statute is specific in addressing when a manufacturer overcharges a covered entity and it does not address refunds by covered entities if the manufacturer provides a price below the 340B ceiling price. Therefore, it will not be addressed in the final rule.

Comment: Some commenters asked HHS not to finalize the rule as proposed related to penalizing a manufacturer for failure or refusal to refund or credit a covered entity. They pointed out that HHS has not developed a mechanism to provide such subsequent price recalculations and has not established or operationalized a mechanism to retroactively revise 340B pricing based on revised Medicaid metrics. Other commenters stated that finalizing the rule is premature since HHS has not developed a process for credits and refunds.

Response: HHS has finalized that an instance of an overcharge may occur at the time of initial purchase or when subsequent ceiling price recalculations occur and the manufacturer refuses to refund or issue a credit to a covered entity. This would include refusal to refund covered entities according to §10.10(c) of the final rule with regards to new drug price estimation

and would include refusal to refund a covered entity after restatements to CMS. If a covered entity is not refunded when there is an overcharge, the covered entity, in essence paid above the 340B ceiling price. The final rule requires a refund if there is an overcharge and specific refund procedures will be addressed under separate guidance. HHS does not believe that the requirements of this rule are dependent on the separate issue of how to operationalize a refund process. Until there is final guidance in place regarding the refund procedures, manufacturers and covered entities should work in good faith and refund in a reasonable manner that is documented by the parties involved.

Comment: Some commenters supported the rule as proposed but asked HHS to allow covered entities time to request a reclassification of prior purchases as 340B eligible. They asked that HHS finalize the rule to require manufacturers to honor a covered entity's request to reclassify a purchase from non-340B to 340B and to issue a corresponding refund if a covered entity requests such a reclassification within 365 days of purchase.

Response: HHS continues to maintain the decision that a manufacturer's failure to provide the 340B ceiling is not considered an overcharge if the covered entity did not initially identify the purchase to the manufacturer as 340B eligible at the time of purchase. HHS does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Therefore, HHS has removed this example from the final regulation and instead includes it as an example of what would not be considered an instance of overcharging in the preamble to this rule. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. If a covered entity wishes to reclassify a previous purchase as 340B, covered entities should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction. The

covered entity retains responsibility for ensuring full compliance and integrity of its use of the 340B Program.

Comment: Commenters supported the proposal that it could be considered an instance of overcharging when a manufacturer’s documented refusal to sell or make drugs available at the 340B price results in the covered entity purchasing at the non-340B price. However, some commenters asked HHS to clarify the term “documented refusal” mentioned in the preamble. They suggested that the following examples not constitute a documented refusal:

- Communications between a manufacturer (or a wholesaler) and a covered entity relating to verifying eligibility for 340B prices prior to a sale, or
- A manufacturer’s failure to provide the 340B ceiling price to a covered entity that has violated the prohibition against diversion or duplicate discounting.

Response: Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer’s documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price. When a manufacturer’s documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer’s sale at the non-340B price could be considered an instance of overcharging. An example of “documented refusal” would include any type of manufacturers’ written communication related to reasons a manufacturer is not providing 340B ceiling prices to either a single covered entity or group of covered entities. HHS does not agree that a manufacturer could consider not selling a 340B drug at the 340B ceiling price to a covered entity based on possible non-compliance with program requirements. Regarding verifying the eligibility of a covered entity, the 340B public database lists all covered entities eligible to purchase 340B drugs in any given quarter. The

340B public database should be used by all stakeholders to determine and verify covered entity eligibility. In addition to the example provided above as “documented refusal,” OIG would also review information related to such a circumstance on a case-by-case basis to determine if a manufacturer has overcharged a covered entity and whether the threshold is met to apply CMPs. HHS notes that we are removing this specific example from the final regulation and include it as an example of what would not be considered an instance of overcharging in the preamble to this rule.

Comment: Some commenters requested that HHS not require that an act be “intentional” when imposing CMPs and that the penalty be higher than \$5,000.

Response: Section 340B(d)(1)(B)(vi) of the PHSA provides for the imposition of civil monetary penalties on manufacturers that knowingly and intentionally charge a covered entity a price for purchase of a drug that exceeds the 340B ceiling price. Additionally, section 340B(d)(1)(B)(vi)(II) of the PHSA states that CMPs “shall not exceed \$5,000 for each instance of overcharging.” Therefore, HHS has no authority to modify the standard of intent, and any CMPs assessed will be done in accordance with the amount specified in the 340B statute, as adjusted annually for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74).

Comment: A few commenters stated that when imposing CMPs, certain documentation should be required to establish that there was a “knowing and intentional” overcharge. They suggested that evidence should include documentation that the manufacturer received a request for the ceiling price by the covered entity, and either refused in writing to provide the ceiling price, or failed to execute a ceiling price transaction within a specified period of time.

Response: The OIG will determine, upon review of the case, the appropriate documentation and other information that may be required to determine if a CMP should be applied.

Comment: Commenters requested that the rule specify that HHS should not attempt to recover any penalties until at least 60 days after the end of any appeal or judicial review. It was also requested that, should a party seek data in relation to a CMP proceeding from a third party, such as a wholesaler or software vendor, the party seeking data may compensate the third party for their assistance, and that the third party may require that compensation. Commenters also recommended that the rule provide for confidentiality requirements in CMP proceedings, in order to ensure the confidentiality of 340B pricing.

Response: HHS understands the importance of maintaining the confidentiality of 340B ceiling price data and will handle such data accordingly. More broadly, the pertinent procedures outlined in 42 CFR parts 1003 and 1005 will be followed in matters involving the imposition of CMPs and any appeals therefrom.

Comment: Several commenters suggested that the funds collected from CMPs should be directed to OIG to support the enforcement of CMPs, to the HRSA Office of Pharmacy Affairs, and for HHS to create a 340B ceiling price database.

Response: While HHS appreciates these comments, they are beyond the statutory authority of the 340B Program and this final rule.

Comment: Several commenters supported HHS delegating the authority to levy CMPs to OIG, and recommended that the delegation of authority to OIG be explicitly stated in the regulation, rather than mentioned in the preamble. Additionally, several commenters were also concerned that at proposed §10.11(a), in the sentence “This penalty will be imposed pursuant to

the procedures at 42 CFR part 1003 and 1005” the term “procedures” may be read to not encompass definitions and standards for CMPs. Therefore, they suggested modifying the sentence to state, “Pursuant to a delegation of authority, the HHS Office of Inspector General (OIG) will have the authority to bring CMP actions utilizing the definitions, standards, and procedures applied to civil monetary penalties under 42 CFR Parts 1003 and 1005.” It was also suggested to add a definition of “knowingly and intentionally” to section 1003.101 of the OIG regulations.

Response: HHS does not believe it necessary to add the delegation of authority to OIG in the regulatory text. HHS believes that pursuant to a separate delegation of authority, OIG has the authority to handle CMP actions utilizing the definitions, standards, and procedures applied to civil monetary penalties under 42 CFR Parts 1003 and 1005, as applicable. Consistent with the proposed rule, we have finalized the regulatory text indicating that CMPs will be imposed pursuant to the procedures contained at 42 CFR part 1003. No further rulemaking is required to apply the procedures at 42 CFR part 1003 to the imposition of CMPs. HHS will monitor activities relating to the evaluation and pursuit of CMPs and, if necessary, will consider issuing additional guidance about procedures applicable to such actions.

Comment: A few commenters were concerned about the decision to delegate CMP actions to OIG. They stated that HHS has not identified a specific delegation, and that 42 CFR parts 1003 and 1005 only provide for the imposition of CMPs under specific statutory authorities, which do not include the 340B statute’s CMP provisions. They argued that unless OIG amends their regulations to apply them to a 340B proceeding, HHS will need to develop, take comments on, and ultimately finalize a new proposal setting out procedures for seeking and

imposing CMPs against manufacturers. A few commenters noted that some portions of 42 CFR parts 1003 and 1005 are inapplicable in a 340B context.

Response: As noted above, a delegation of authority to OIG for a CMP from the Secretary of HHS is sufficient. HHS does not perceive there to be any conflict between the procedural aspects of 42 CFR part 1003 and the imposition of CMPs. HHS notes that 42 CFR part 1005 applies to appeals of exclusions and civil monetary penalties and assessments and would not be directly relevant to the initial imposition of a CMP. Accordingly, HHS finalized the regulatory text indicating that CMPs will be imposed pursuant to the applicable procedures contained at 42 CFR part 1003. No further rulemaking is required to apply the procedures at 42 CFR part 1003 to the imposition of CMPs. HHS will monitor activities relating to the evaluation and pursuit of CMPs and, if necessary, will consider issuing additional guidance about procedures applicable to such actions.

III. Regulatory Impact Analysis

HHS has examined the effects of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and

reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB).

This final rule will not have economic impacts of \$100 million or more in any 1 year, and, therefore, has not been designated an “economically significant” rule under section 3(f)(1) of Executive Order 12866. The 340B Program as a whole creates significant savings for entities purchasing drugs through the program, with total savings estimated to be \$6 billion in CY 2015.¹ However, this final rule would not significantly impact the Program. This final rule codifies

¹ In CY 2015, 340B covered entities spent approximately \$12 billion on the total purchases of 340B drugs under the 340B Program. This data was obtained from the 340B Prime Vendor Program. This amount represents 2.6 percent of the overall prescription drug market. Assuming covered entities pay 25 to 50 percent less than non-340B prices, HHS calculated the estimated total savings in CY 2015 to be approximately \$6 billion.

current policies, some of which have been modified, regarding calculation of the 340B ceiling price and manufacturer civil monetary penalties. HHS does not anticipate that the imposition of civil monetary penalties would result in significant economic impact.

The 340B Program uses information that already must be reported under Medicaid to calculate the statutorily defined 340B ceiling price as required by this final rule. Because the components of the 340B ceiling price are already calculated by the manufacturers under the MDRP and reported to CMS, HHS does not believe this portion of the final rule would have an impact on manufacturers. The impact on manufacturers would also be limited with respect to calculation of the 340B ceiling price as defined in this final rule due to the fact that manufacturers regularly calculate the 340B ceiling price and have been doing so since the program's inception.

Separate from calculation of the 340B ceiling price, manufacturers are required to ensure they do not overcharge covered entities, and a civil monetary penalty could result from overcharging if it met the standards in this final rule. HHS envisions using these penalties in rare situations. Since the Program's inception, issues related to overcharges have been resolved between a manufacturer and a covered entity and any issues have generally been due to technical errors in the calculation. For the penalties to be used as defined in the statute and in this rule, the manufacturer overcharge would have to be the result of a knowing and intentional act. Based on anecdotal information received from covered entities, HHS anticipates that this would occur very rarely if at all.

This rulemaking also proposes that a manufacturer charge a \$0.01 per unit of measure for a drug with a 340B ceiling price below \$0.01. A small number of manufacturers have informed HRSA over the last several years that they charge more than \$0.01 for a drug with a ceiling price

below \$0.01. However, this is a long-standing HRSA policy, and HRSA believes the majority of manufacturers currently follow the practice of charging a \$0.01. Therefore, this portion of the regulation would not result in a significant impact. This final regulation would allow HRSA to enforce the policy in a manner that would require the manufacturer to charge a \$0.01, and it is likely that manufacturers would charge \$0.01 in order to avoid the imposition of a civil monetary penalty for overcharging a covered entity. HRSA believes manufacturers that currently do not comply will come into compliance, which will result in the covered entity paying less for these drugs. There will be a cost transfer from the covered entity to the manufacturer.

HHS recognizes that certain administrative costs would be incurred for compliance with this final rule. HHS does not collect data related to such administrative costs, and compliance costs are expected to vary significantly. HHS believes it is reasonable to assume that manufacturers would use one-half to one full-time compliance officer to ensure compliance with the requirements in this final rule. According to the Bureau of Labor Statistics, the mean annual wage for a pharmaceutical compliance officer (NAICS 325400, occupation code 13-1041) is \$80,170 in 2015. Inclusion of benefits and overhead (resulting in a total labor cost of 1.5 times mean annual wage) yields a total annual cost of \$120,255 for one compliance officer. Thus, the estimated annual cost for labor across all 600 manufacturers is between \$36,067,500 and \$72,153,000.

We received the following comments on the anticipated impacts on drug manufacturers:

Comment: Regarding the proposed rule's regulatory impact analysis, some commenters disagree that the proposed rule is "not likely to have an economic impact of \$100 million or more in any 1 year" and objects to its failure to designate the proposed rule as economically significant. They argue that resources that would be required to comply with the obligations of

this proposed rule would extend beyond a compliance officer and would include the re-writing and implementation of new policies and procedures, and the training of staff.

Response: The proposed rule and the policies finalized herein codify several current policies, some of which have been modified, regarding the calculation of the 340B ceiling price and introduce manufacturer civil monetary penalties. HHS reviewed the comments submitted in response to the NPRM, and has attempted to minimize burden for both manufacturers and covered entities in its formulation of the final rule, specifically regarding the policy of estimating new drug prices (see §10.10(c)). With the modification made in this final rule, we believe that stakeholders' administrative burdens' with respect to this policy will be minimal. Through the comments that HHS received during both comment periods on the estimation of new drug prices, commenters expressed support for this approach and maintained that it created an even playing field across all stakeholders as the calculation of the 340B ceiling price is easily verifiable by covered entities and reduces administrative burden. HHS also understands that based on the comments received, the methodology for calculating new drugs as set forth in this final rule is already taking place in the marketplace and will thus not create any additional burden.

Manufacturers have always been required to ensure that they do not overcharge covered entities per the section 340B(d)(1). This final rule incorporates a penalty for knowingly and intentionally overcharging covered entities, as discussed in subsequent sections of this final rule (see §10.11(a)). Under current practice, HHS encourages manufacturers and covered entities to work in good faith to resolve any pricing discrepancies. HHS anticipates this practice to continue and anticipates that the imposition of penalties to occur only on a rare basis. The remaining policies in the proposed rule and finalized in this rule reflect current 340B Program policy and should not result in significant economic impacts.

Comment: Commenters note that manufacturers would have to build into their systems the capacity to identify all sales transactions with covered entities at the originally charged price, as well as any recalculated price, for up to three full years after the original transaction. They explain that these prices along with issuing the actual refunds to the covered entities could easily exceed \$100 million per year.

Response: We note that the 340B Program uses data that manufacturers already report to CMS under the MDRP (AMP, URA) to calculate the statutorily defined 340B ceiling price. As these components of the 340B ceiling price are already calculated by manufacturers under the MDRP, HHS does not believe that this will cause additional burden on manufacturers.

The Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a three percent impact on at least five percent of small entities.

The final rule would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of this final rule on the industry as a whole, the data necessary to project changes for specific manufacturers or

groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program.

This final rule clarifies statutory requirements for manufacturers, including small manufacturers, and codifies current ceiling price calculation policies in regulation. HHS is unaware of small manufacturers who do not follow the ceiling price policies finalized by this regulatory action. The specific elements required as part of the calculation of the ceiling price are elements that manufacturers are already required to utilize as part of their participation in the 340B Program. HHS expects that these elements would continue to be available. Therefore, calculation of the ceiling price would not result in an economic impact or create additional administrative burden on these businesses.

HHS has determined, and the Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small manufacturers; therefore, we are not preparing an analysis of impact for the purposes of the RFA. HHS, estimates that the economic impact on small manufacturers will be minimal and less than three percent.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by

State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.” In 2015, that threshold level is approximately \$144 million. HHS does not expect this final rule to exceed the threshold.

Executive Order 13132 - Federalism

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” This final rule would not “have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” The provisions in this final rule would not adversely affect the following family elements: family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under Section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. This final rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. Changes finalized in this rulemaking would result in no new reporting burdens.

List of Subjects in 42 CFR Part 10

Biologics, Business and industry, Diseases, Drugs, Health, Health care, Health facilities, Hospitals, 340B Drug Pricing Program.

Dated: October 3, 2016 _____

James Macrae,

Acting Administrator,

Health Resources and Services Administration.

Approved:

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

For the reasons set forth in the preamble, the Department of Health and Human Services revises

42 CFR part 10 to read as follows:

PART 10 - 340B DRUG PRICING PROGRAM

Subpart A – General Provisions

Sec.

10.1 Purpose.

10.2 Summary of 340B Drug Pricing Program.

10.3 Definitions.

Subpart B – 340B Ceiling Price

10.10 Ceiling price for a covered outpatient drug.

10.11 Manufacturer civil monetary penalties.

AUTHORITY: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b) (PHSA), as amended.

Subpart A – General Provisions

§10.1 Purpose.

This part implements section 340B of the Public Health Service Act (PHSA) “Limitation on Prices of Drugs Purchased by Covered Entities.”

§10.2 Summary of 340B Drug Pricing Program.

Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered outpatient drugs under which the amount to be paid to manufacturers by certain statutorily-defined covered entities does not exceed the 340B ceiling price.

§10.3 Definitions.

For the purposes of this part, the following definitions apply:

Average Manufacturer Price (AMP) has the meaning set forth in section 1927(k)(1) of the Social Security Act, as implemented in 42 CFR 447.504.

Ceiling price means the maximum statutory price established under section 340B(a)(1) of the PHSA and this section.

CMS is the Centers for Medicare & Medicaid Services.

Covered entity means an entity that is listed within section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database.

Covered outpatient drug has the meaning set forth in section 1927(k) of the Social Security Act.

Manufacturer has the meaning set forth in section 1927(k) of the Social Security Act, as implemented in 42 CFR 447.502.

National Drug Code (NDC) has the meaning set forth in 42 CFR 447.502.

Pharmaceutical Pricing Agreement (PPA) means an agreement described in section 340B(a)(1) of the PHSA.

Quarter refers to a calendar quarter unless otherwise specified.

Secretary means the Secretary of the Department of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Subpart B – 340B Ceiling Price

§10.10 Ceiling price for a covered outpatient drug.

A manufacturer is required to calculate the 340B ceiling price for each covered outpatient drug, by National Drug Code (NDC) on a quarterly basis.

(a) *Calculation of 340B ceiling price.* The 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the Unit Rebate Amount (URA) and will be calculated using six decimal places. HRSA will publish the 340B ceiling price rounded to two decimal places.

(b) *Exception.* When the ceiling price calculation in paragraph (a) of this section results in an amount less than \$0.01 the ceiling price will be \$0.01.

(c) *New drug price estimation.* A manufacturer must estimate the 340B ceiling price for a new covered outpatient drug as of the date the drug is first available for sale. That estimation should be calculated as wholesale acquisition cost minus the appropriate rebate percentage until an AMP is available, which should occur no later than the 4th quarter that the drug is available for sale. Manufacturers are required to calculate the actual 340B ceiling price as described in paragraph (a) of this section and offer to refund or credit the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

§10.11 Manufacturer civil monetary penalties.

(a) *General.* Any manufacturer with a pharmaceutical pricing agreement that knowingly and intentionally charges a covered entity more than the ceiling price, as defined in §10.10, for a covered outpatient drug, may be subject to a civil monetary penalty not to exceed \$5,000 for each instance of overcharging, as defined in paragraph (b) of this section. This penalty will be imposed pursuant to the applicable procedures at 42 CFR part 1003. Any civil monetary penalty assessed will be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHSA.

(b) *Instance of overcharging.* An instance of overcharging is any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in §10.10, for that covered outpatient drug.

(1) Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent.

(2) Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer.

(3) An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases.

(4) An instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations due to pricing data submitted to CMS or new drug price estimations as defined in §10.10(c) result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity.

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