and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this proposed priority only on a reasoned determination that its benefits would justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

We propose to fund through this priority TA to State VR agencies to improve the quality of VR services and of the competitive integrated employment outcomes achieved by individuals with disabilities, and ultimately to increase the percentage of individuals with disabilities who receive services through the State VR agencies who achieve competitive integrated employment outcomes. This proposed priority would promote the efficient and effective use of Federal funds.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: June 12, 2015.

Michael K. Yudin,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2015–14940 Filed 6–16–15; 8:45 am]

BILLING CODE 4000–01–P

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, HHS.

ACTION: Notice of proposed rulemaking.

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

DATES: Submit comments on or before August 17, 2015.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AA89, by any of the following methods. Please submit your comments in only one of these ways to

minimize the receipt of duplicate submissions. The first is the preferred method.

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow instructions for submitting comments. This is the preferred method for the submission of comments.
- Email: *340BCMPNPRM@hrsa.gov.* Include 0906–AA89 in the subject line of the message.
- Mail: Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.

All submitted comments will be available to the public in their entirety.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION: The President encourages Federal agencies through Executive Order 13563 to develop balanced regulations by encouraging broad public participation in the regulatory process and an open exchange of ideas. The Department of Health and Human Services (HHS) accordingly urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any data to support your positions. If you have questions before submitting comments, please see the ''For Further Information'' box above for the names and contact information of subject-matter experts involved in this proposal's development. We must consider all written comments received during the comment period before issuing a final rule.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please contact HRSA's Regulations Officer at: Room 14–101, 5600 Fishers Lane, Rockville, MD 20857; or by telephone at 301–443–1785, to obtain this information in an accessible format. This is not a toll free telephone number.

Please visit *http://www.HHS.gov/regulations* for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

I. Background

Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act (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, as amended. Section 340B of the PHSA instructs HHS to enter into a pharmaceutical pricing agreement (PPA) with certain drug manufacturers. If a drug manufacturer signs a PPA, it agrees 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 reported to 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 not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

(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 this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

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

Since 1992, HHS has administratively established the terms and certain elements of the 340B Program through guidelines published in the **Federal Register**, typically after notice and opportunity for comment. In September 2010, HHS published two advanced notices of proposed rulemaking (ANPRM) in the **Federal Register**, 340B Drug Pricing Program Administrative Dispute Resolution Process (75 FR 57233 (September 20, 2010)) and 340B Drug Pricing Program Manufacturer Civil Monetary Penalties (75 FR 57230 (September 20, 2010)). The administrative dispute resolution process remains under development and is not included in this notice of proposed rulemaking. HHS intends to address dispute resolution in future rulemaking.

In the manufacturer civil monetary penalties ANPRM, HHS sought comments relevant to this provision and requested comment on nine identified areas: (1) Existing Models; (2) Threshold Determination; (3) Administrative Process Elements; (4) Hearing; (5) Appeals Process; (6) Definitions; (7) Penalty Computation; (8) Payment of Penalty; and (9) Integration of Civil Monetary Penalties with Other Provisions in the Affordable Care Act. The request for comments on existing models requested comments on the appropriateness on the use and adaptation of the procedures codified at 42 CFR part 1003, which includes procedures for the imposition of civil monetary penalties by the HHS Office of the Inspector General. HRSA received 15 comments on the ANPRM. The comments received have been considered in the development of this notice. HHS is also proposing this rule to provide increased clarity in the marketplace for all 340B Program stakeholders as to the calculation of the 340B ceiling price. HHS encourages all stakeholders to provide comments on this notice of proposed rulemaking.

II. Summary of the Proposed Regulations

The proposed revisions to 42 CFR part 10 of the regulations are described according to the applicable section of the regulations. The United States District Court for the District of Columbia recently vacated the 340B Program Regulations at 42 CFR part 10 relating to Orphan Drugs. *PhRMA* v. *HHS, No. 13–01501 (D.D.C. May 23, 2014).* This NPRM proposes to replace sections 10.1, 10.2, 10.3, and 10.10 with the provisions of this NPRM, add a new section 10.11, and eliminate sections 10.20 and 10.21.

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. Manufacturers participating in the 340B Drug Pricing Program (340B Program) are required to provide these discounts on all covered outpatient drugs sold to participating 340B covered entities.

§ 10.3 Definitions

The Department is proposing to revise the following definitions: ''ceiling price,'' ''covered entity,'' ''covered outpatient drug,'' and ''manufacturer.''

The Department is proposing to add the following definitions: ''340B drug,'' ''Average Manufacturer Price (AMP),'' ''CMS,'' ''National Drug Code (NDC),'' ''quarter,'' and ''wholesaler.''

The definitions for ''Pharmaceutical Pricing Agreement (PPA),'' and ''Secretary'' would remain in the section, and the definitions for ''Group purchasing organization (GPO),'' ''orphan drug,'' and ''participating drug manufacturer'' would be removed from the section.

Subpart B—340B Ceiling Price

§ 10.10 Ceiling Price for a Covered Outpatient Drug

A manufacturer must calculate the ceiling price for all of its covered outpatient drugs on a quarterly basis. The calculation of the 340B ceiling price for a 340B drug is established by statute. Under section 340B(a) of the PHSA, the 340B ceiling price for covered outpatient drugs is calculated by subtracting the unit rebate amount (URA) from the average manufacturer price (AMP) for the smallest unit of measure and will be calculated using six decimal places. To ensure the final price is operational in the marketplace, HRSA then multiplies this amount by the drug's package size and case package size. HRSA will publish the 340B ceiling price rounded to two decimal places.

Under the Medicaid Drug Rebate Program, CMS indexes quarterly AMPs to the rate of inflation (Consumer Price Index adjusted for inflation-urban). Section 1927(c)(2)(A) of the Social Security Act provides that with respect to single source and innovator multiple source drugs, if the AMP increases at a rate faster than inflation, the manufacturer must pay an additional rebate amount which is reflected in a higher URA. Historically, because of the basic rebate and the inflation factor, section 1927(c)(2)(A) could increase the rebate amount a manufacturer must pay to States, resulting in negative 340B prices. As of January 1, 2010, a provision in section 1927(c)(2)(D) of the Social Security Act effectively limited the unit rebate amount to 100 percent of the AMP. Thus, an increase in the basic rebate and inflation factor would not result in a negative 340B price, but could result in a zero 340B price.

Exception: Penny Pricing and Distribution

HHS recognizes that when the URA equals the AMP in the calculation of the 340B ceiling price, it is not reasonable for a manufacturer to set a 340B ceiling price to $0.00 per unit of measure. HHS proposes that a manufacturer charge a $0.01 per unit of measure for a drug with a ceiling price below $0.01. For those 340B drugs whose calculated price is less than $0.01, the effective ceiling price will be $0.01 per unit of measure.

Manufacturers may not use the prior quarter's pricing, wholesale acquisition cost (WAC), or any other non-340B contract price in place of the penny pricing, as 340B ceiling prices must be based on the immediately preceding calendar quarter pricing data. Using the prior quarter pricing or some other price would nullify the pricing formula.

New Drug Price Estimation

Calculation of the current quarter ceiling price for each covered outpatient drug is based on pricing data from the immediately preceding calendar quarter. For new drugs, there will be no sales data from which to determine the 340B ceiling price. HHS published final guidelines in 1995 describing ceiling price calculations for new drugs (60 FR 51488 (October 2, 1995)). HHS is proposing to codify the longstanding policy from the 1995 final guidelines in these regulations. HHS proposes that a manufacturer will continue to estimate the 340B ceiling price for the first three quarters a new covered outpatient drug is available for sale. The ceiling price calculation described in paragraph (a) of this section will be required beginning with the fourth quarter the drug is available for sale. A manufacturer must calculate the actual 340B ceiling price for the first three quarters the drug was available for sale and refund or credit covered entities that purchased the covered outpatient drug above the calculated 340B ceiling price no later than the end of the fourth quarter after the drug is available for sale. 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 price estimation requirements would apply. The manufacturer would estimate the 340B ceiling price for the first three calendar quarters of availability. Beginning with the fourth quarter (October 1–December 31), the manufacturer will have the necessary pricing data to calculate the ceiling price based on section 340B(a)(1) of the PHSA. The manufacturer would then calculate the actual 340B ceiling price for the first three quarters and refund or credit covered entities which paid above the calculated ceiling price during those quarters. The refunds and credits must be completed by the end of the fourth quarter.

HRSA solicits comments on all aspects of the 340B ceiling price methodology proposed.

§ 10.11 Manufacturer Civil Monetary Penalties

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 a covered entity, as defined in paragraph (b) of this section. 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. Pursuant to a delegation of authority, the HHS Office of Inspector General (OIG) will have the authority to bring 340B CMP actions utilizing the standards applied to other civil monetary penalties under 42 CFR parts 1003 and 1005.

Instance of Overcharging

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 ceiling price, as defined in § 10.10, 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. Likewise, 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. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent. 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. 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 and the manufacturer refuses to refund or issue a credit to a covered entity. 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'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 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.

All requirements for offering the 340B ceiling price to covered entities apply regardless of the distribution system. Specialty distribution, regardless of justification, must ensure 340B covered entities purchase covered outpatient drugs at or below the ceiling price. Manufacturers commonly use wholesalers to distribute drugs on their behalf. This regulation and associated penalties applies solely to manufacturers, even though other parties, such as wholesalers, have a role in ultimately ensuring the covered entity receives a 340B drug at or below the ceiling prices. Manufacturers should 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 receives the appropriate price as outlined in this regulation. A manufacturer's failure to ensure that covered entities receive the appropriate 340B discount through its distribution arrangements may be grounds for the assessment of civil monetary penalties under this regulation.

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 proposed rule is not likely to 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 $3.8 billion in FY 2013.[1] However, this proposed rule would not significantly affect the impact of the program. This proposed rule incorporates current policies regarding calculation of the ceiling price and introduces manufacturer civil monetary penalties. HHS does not anticipate that the imposition of civil monetary penalties would result in significant economic impacts.

The 340B Program uses information which already must be reported under Medicaid to calculate the statutorily defined 340B ceiling price as required by this proposed rule. Because the components of the ceiling price are already calculated by the manufacturers under the Medicaid program and reported to CMS, HHS does not believe this portion of the proposed rule would have an impact on manufacturers. The impact on manufacturers would also be limited with respect to calculation of the ceiling price as defined in this proposed rule due to the fact that manufacturers regularly calculate the 340B ceiling price and have been 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 proposed rule. The use of those penalties would probably be rare. 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, a manufacturer would only be subject to those penalties when the overcharge was a result of a knowing and intentional act. Based on anecdoctal 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 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 will not result in a significant impact. This proposed 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

[1] In FY 2013, 340B covered entities spent approximately $7.5 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 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 FY 2013 to be approximately $3.8 billion.

monetary penaly for overcharging a covered entity. Therefore, HRSA believes manufacturers that currently do not comply will come into compliance, which will result in the covered enity paying less for these drugs. This will be a cost transfer from the covered entity to the manufacturer.

HHS recognizes that some administrative costs would be incurred for compliance with this proposed rule. HHS does not collect data related to such administrative costs from manufacturers, 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 proposed rule. According to the Bureau of Labor Statistics, the mean annual wage for a pharmaceutical compliance officer (NAICS 325400, occupation code 13–1041) is $74,620 in 2014. Inclusion of benefits and overhead (resulting in a total labor cost of 1.5 times mean annual salary) yields a total annual cost of $111,930 for one compliance officer. Thus the estimated annual cost for labor across all 600 manufacturers is between $33,579,000 and $67,158,000.

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.

This proposed 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. While it is possible to estimate the impact of this proposed rule on the industry as a whole, the data necessary to project changes for specific manufacturers or groups of manufacturers were not available. This proposed rule clarifies statutory requirements for all manufacturers, including small manufacturers, and proposes current ceiling price calculation policies be codified in regulation. HHS is not aware of small manufacturers which currently do not follow the ceiling price policies proposed in this regulatory action. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers.

HHS therefore estimates that the economic impact on small entities 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 proposing ''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 2013, that threshold level is approximately $141 million. HHS does not expect this proposed rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This proposed 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 proposals in this notice of proposed rulemaking, if implemented, 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. HHS invites additional comments on the impact of this proposed rule from affected stakeholders.

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 proposed rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. Changes proposed in this rulemaking would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

Dated: March 6, 2015.

Sylvia M. Burwell,

Secretary.

List of Subjects in 42 CFR Part 10

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

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR part 10 as follows:

■ 1. Revise 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), 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:

340B drug is a covered outpatient drug, as defined in section 1927(k) of the Social Security Act, purchased by a covered entity at or below the ceiling price required pursuant to a pharmaceutical pricing agreement with the Secretary.

Average Manufacturer Price (AMP) has the meaning set forth in 1927(k)(1) of the Social Security Act.

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

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.

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 of employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Wholesaler has the meaning set forth in 42 U.S.C. 1396r–8(k)(11).

Subpart B—340B Ceiling Price

§ 10.10 Ceiling price for a covered outpatient drug.

A manufacturer is required to calculate 340B ceiling prices 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) for the smallest unit of measure minus the Unit Rebate Amount (URA) and will be calculated using six decimal places. To ensure the final price is operational in the marketplace, HRSA then multiplies this amount by the drug's package size and case package size. 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 ceiling price for a new covered outpatient drug as of the date the drug is first available for sale and must provide HRSA an estimated ceiling price for each of the first three quarters the drug is available for sale. Beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the ceiling price as described in paragraph (a) of this section. A manufacturer must calculate the actual ceiling prices for the first three quarters and refund or credit any covered entity which purchased the covered outpatient drug at a price greater than the calculated ceiling price. The refunds or credits for the first three quarters must be provided to covered entities by the end of the fourth quarter.

§ 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 a covered entity, as defined in paragraph (b) of this section. This penalty will be imposed pursuant to the 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 result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity.

(5) 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's refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price.

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 393

[Docket No. FMCSA–2014–0428]

RIN 2126–AB67

Parts and Accessories Necessary for Safe Operation: Federal Motor Vehicle Safety Standards Certification for Commercial Motor Vehicles Operated by United States-Domiciled Motor Carriers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM), request for comments.

SUMMARY: FMCSA proposes to amend the Federal Motor Carrier Safety Regulations (FMCSRs) by requiring United States-domiciled (U.S.-domiciled) motor carriers engaged in interstate commerce to use only commercial motor vehicles (CMV) that display a certification label affixed by the vehicle manufacturer or a U.S. Department of Transportation (DOT) Registered Importer, indicating that the vehicle satisfied all applicable Federal Motor Vehicle Safety Standards (FMVSS) in effect at the time of manufacture. If the certification label is missing, the motor carrier must obtain, and a driver upon demand present, a letter issued by the vehicle manufacturer stating that the vehicle met all applicable FMVSS in effect at the time of manufacture.

DATES: You may submit comments by August 3, 2015.

ADDRESSES: Comments to the rulemaking docket should refer to Docket ID Number FMCSA–2014–0428- or RIN 2126–AB67, and be submitted to the Administrator, Federal Motor Carrier Safety Administration using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.