



Billing Code: 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AB19

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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking; effective date change.

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.” HRSA published a final rule on January 5, 2017, that set forth the calculation of the 340B ceiling price and application of civil monetary penalties.

On June 5, 2018, HRSA published a final rule that delayed the effective date of the 340B ceiling price and civil monetary rule until July 1, 2019, to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking. After further consideration of the issue, the Department of Health and Human Services (HHS or Department) proposes to cease any further delay of the rule and change the effective date from July 1, 2019, to January 1, 2019.

DATES: Submit comments on or before [INSERT DATE 21 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906-AB19, 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.
- E-mail: 340BCMPNPRM@hrsa.gov. Include 0906-AB19 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. Please do not submit commercial confidential information or personal identifying information that you do not want in the public domain.

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

SUPPLEMENTARY INFORMATION:

I. Background

HHS published a notice of proposed rulemaking (NPRM) in June 2015 to implement civil monetary penalties (CMPs) for manufacturers who knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity regarding the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis and how the ceiling price is to be calculated; and to establish the requirement that a manufacturer charge a \$.01 (penny pricing policy) for drugs when the ceiling price calculation

equals zero (80 FR 34583, (June 17, 2015)). The public comment period closed on August 17, 2015, and HRSA received 35 comments. After review of the initial comments, HHS reopened the comment period (81 FR 22960, (April 19, 2016)) to invite additional comments on the following areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers use when estimating the ceiling price for a new covered outpatient drug; and the definition of the “knowing and intentional” standard to be applied when assessing a CMP for manufacturers that overcharge a covered entity. The comment period closed May 19, 2016, and HHS received 72 comments.

On January 5, 2017, HHS published a final rule in the *Federal Register* (82 FR 1210, (January 5, 2017)). Comments from both the NPRM and the reopening notice were considered in the development of the final rule. The provisions of that rule were to be effective March 6, 2017; however, through a series of rules, HHS delayed the effective date of the January 5, 2017 final rule until July 1, 2019 (83 FR 25943, June 5, 2018).

II. Proposal to Change to Effective Date of the Final Rule from July 1, 2019, to January 1, 2019

HHS proposes to cease any further delay of the January 5, 2017 final rule and to change the effective date from July 1, 2019, to January 1, 2019. As the effective date will be the first day of the quarter, the implementation date and the effective date will be the same. In its most recent rulemaking delaying the effective date of the January 5, 2017 final rule, HHS stated that it “is developing new comprehensive policies to address the rising costs of prescription drugs. These policies will address drug pricing in government programs, such as Medicare Parts B & D, Medicaid, and the 340B Program. Due to the development of these comprehensive policies, we are delaying the effective date for the January 5, 2017, final rule to July 1, 2019.” (83 FR 25944)

The Department has determined that the finalization of the 340B ceiling price and civil monetary penalty rule will not interfere with the Department's development of these comprehensive policies. Accordingly, the Department no longer believes a delay in the effective date is necessary and is proposing to change the effective date of the rule from July 1, 2019, to January 1, 2019.

The provisions included in the January 5, 2017 final rule were subject to extensive public comment, and have been delayed several times. As such, HHS believes that it has considered the full range of comments on the substantive issues in the January 5, 2017 final rule.

HHS believes that finalization of this proposed change to the effective date of the January 5, 2017 final rule would satisfy its obligation to implement the statutory provisions enacted by Congress in 2010 to create civil monetary penalties.

HHS seeks public comments specifically regarding the impact of ceasing any further delay of the January 5, 2017 final rule, including any potential disruptions to implementation, and changing the effective date from July 1, 2019, to January 1, 2019.

HHS encourages all stakeholders to provide comment on this proposed rule. A comment period of 21 days is sufficient to provide affected parties the opportunity to provide their views as this rule is uncomplicated and simply proposes to change an effective date. Moreover, affected parties have had multiple opportunities to provide comments on the appropriate effective date of the January 5, 2017 final.

III. Regulatory Impact Analysis

HHS has examined the effects of this proposed 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, 13563, and 13771

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).

HHS does not believe that the proposal to change the effective date of the January 5, 2017 final rule from July 1, 2019, to January 1, 2019, will have an economic impact of \$100 million or more in any 1 year, and is therefore not designated as an “economically significant” proposed 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 purchases estimated to be \$19 billion in CY 2017. This proposed rule to implement the January 5, 2017 proposed rule would codify current policy, 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.

When the 2017 Rule was finalized, it was described as not economically significant. Therefore, changing the effective date of the 2017 Rule is also not likely to have an economically significant impact.

Specifically, the RIA for the 2017 Rule stated that, “[...]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 [2017] 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.” Since the civil penalties envisioned in the 2017 Rule were expected

to be rare, changing the effective date of these civil penalties is unlikely to have an economically significant impact.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations “to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This rule is not subject to the requirements of Executive Order 13771 because this rule results in no more than *de minimis* costs.

HHS is seeking specific comments on the potential financial and other impact on covered entities and manufacturers if the final rule were effective on January 1, 2019.

The Regulatory Flexibility Act (RFA)

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 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. Approximately 600 drug manufacturers participate in the Program. While it is possible to estimate the impact of the proposed rule on the industry as a whole, the data necessary to project changes for specific manufacturers or groups of manufacturers were not available, as HRSA does not collect the

information necessary to assess the size of an individual manufacturer that participates in the 340B Program. For purposes of the RFA, HHS considers all health care providers to be small entities either by virtue of meeting the Small Business Administration (SBA) size standard for a small business, or for being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of \$7 million to \$35.5 million. As of January 1, 2017, over 12,000 covered entities participate in the 340B Program, which represent safety-net healthcare providers across the country. HHS has determined, and the Secretary certifies that this proposed 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 this RFA. HHS estimates that the economic impact on small entities and small manufacturers will be minimal and less than 3 percent. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers and small health care providers.

HHS also seeks comments on any impacts of affected parties to reduce by six months, the effective date of the 2017 final rule from July 1, 2019 to January 1, 2019.

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 2018, that threshold is approximately \$150 million. HHS does not expect this 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 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 proposal to rescind the June 5, 2018 final rule and make the January 5, 2017 final rule effective as of January 1, 2019 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 rule would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

List of Subjects in 42 CFR Part 10

Biologics, Business and industry, Diseases, Drugs, Health, Health care, Health facilities, Hospitals.

Dated: October 26, 2018.

George Sigounas

Administrator,

Health Resources and Services Administration.

Approved: October 30, 2018.

Alex M. Azar II

Secretary,

Department of Health and Human Services.

[FR Doc. 2018-24057 Filed: 10/31/2018 11:15 am; Publication Date: 11/2/2018]