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**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:** Final rule; further delay of effective date.

**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.” HRSA published a final rule on January 5, 2017, that set forth the calculation of the ceiling price and application of civil monetary penalties. The final rule applied to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. In accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” HRSA issued an interim final rule that delayed the effective date of the final rule published in the *Federal Register* (82 FR 1210, (January 5, 2017)) to May 22, 2017. HHS invited commenters to provide their views on whether a longer delay of the effective date to October 1, 2017, would be more appropriate. After consideration of the comments received on the interim final rule, HHS is delaying the effective date of the January 5, 2017 final rule, to October 1, 2017.

**DATES:** As of [INSERT DATE OF PUBLICATION], the effective date of the final rule published in the *Federal Register* (82 FR 1210, (January 5, 2017)) is further delayed to October 1, 2017.

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

**SUPPLEMENTARY INFORMATION:**

**I. Background**

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)). HHS subsequently 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 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 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)) and 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, HHS issued a subsequent final rule (82 FR 12508, (March 6, 2017)) delaying the effective date to March 21, 2017, in accordance with a January 20, 2017 memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review.”<sup>1</sup> In the January 5, 2017 final rule, HHS recognized that the effective date fell during the middle of a quarter and stakeholders needed time to adjust systems and update their policies and procedures. As such, HHS stated that it intended to enforce the requirements of the final rule at the start of the next quarter, which began April 1, 2017.

After further consideration and to provide affected parties sufficient time to make needed changes to facilitate compliance, and because there were questions raised, HHS issued an interim final rule (82 FR 14332, (March 20, 2017)) to delay the effective date of the final rule to May 22, 2017, and solicited additional comment on whether that date should be further delayed to October 1, 2017. HHS received a number of comments on the interim final rule both supporting and opposing the delay of the effective date to May 22, 2017, or alternatively to October 1, 2017. After careful consideration of the comments received, HHS has decided to delay the effective date of the January 5, 2017 final rule to October 1, 2017. As the effective date of the final rule has been changed to October 1, 2017, enforcement will be correspondingly delayed to October 1, 2017. HHS continues to believe that the delay of the effective date provides regulated entities sufficient time to implement the requirements of the rule.

Section 553(d) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) requires that Federal agencies provide at least 30 days after publication of a final rule in the *Federal Register* before making it effective, unless good cause can be found not to do so. HHS

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<sup>1</sup> See: <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>.

finds that there is good cause for making this final rule effective less than 30 days after publication in the *Federal Register* given that failure to do so would result in the final rule published on January 5, 2017, going into effect for several weeks, before having a delayed effective date of October 1, 2017. To preclude this uncertainty in the marketplace and to ease the burdens on all stakeholders, HHS believes that a clear effective date is an important goal and one that becomes particularly important when it is paired with potential civil monetary penalties. The additional time provided to the public before the rule takes effect constitutes an extra quarter and will assist stakeholders in preparing to comply with these new program requirements.

## **II. Analysis and Responses to Public Comments**

In the interim final rule, we solicited comments regarding whether HHS should delay the January 5, 2017 final rule to May 22, 2017, or alternatively to October 1, 2017. We received a broad range of 51 comments from covered entities, manufacturers, and groups representing these stakeholders. In this final rule, we will only be responding to comments related to whether HHS should delay the January 5, 2017 final rule to May 22, 2017, or to October 1, 2017. Comments that raised issues beyond the narrow scope of the interim final rule, including comments related to withdrawal of the rule or comments related to policy matters, were not considered and are not addressed in this rulemaking. We have summarized the relevant comments received and provided our responses below.

*Comment:* Some commenters supported the May 22, 2017, effective date and opposed further delaying the final rule until October 1, 2017. The commenters explain that adequate enforcement of manufacturers' pricing obligations is key to the success of the 340B Program. These commenters also suggest that further delay of the final rule would result in a lack of

oversight, regulation and basic enforcements for manufacturers, which would continue to hamper the 340B Program and lessen covered entities' ability to stretch scarce resources.

*Response:* HHS decided to delay the effective date of the January 5, 2017 final rule to October 1, 2017, to provide affected parties sufficient time to make needed changes to facilitate compliance. Given the comments received from stakeholders on the interim final rule regarding the challenges with complying with the January 5, 2017 final rule, HHS determined that delaying the effective date to October 1, 2017, is necessary to provide adequate time for compliance and to mitigate implementation concerns. HHS disagrees that further delay of the final rule would result in a lack of oversight, regulation, and basic enforcements for manufacturers.

*Comment:* Many commenters opposed further delaying the effective date to October 1, 2017, and suggested that the final rule be enforced immediately. These commenters noted that overcharges in the 340B Program were a widespread problem and that during 2003 and 2005, the HHS Office of the Inspector General (OIG) issued a report,<sup>2</sup> which found that HRSA lacked the necessary oversight mechanisms to ensure that covered entities pay at or below the 340B ceiling price. The commenters further noted that because of these deficiencies, Congress amended the 340B statute to improve manufacturer compliance by directing HRSA to implement standards for calculating ceiling prices and establish civil monetary penalties for manufacturers that knowingly and intentionally overcharge 340B covered entities. Commenters said that these standards were to be implemented in 2010 and given the long delay in promulgating regulations, they do not support any further delay of the January 5, 2017 final rule. The commenters stated that civil monetary penalties are needed now because they are the only viable penalty that HRSA can impose on manufacturers that violate their 340B pricing obligations.

*Response:* HHS does not agree that that the final rule should be enforced immediately.

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<sup>2</sup> See: OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program (October 2005)*.

We are delaying the effective date of the January 5, 2017 final rule to October 1, 2017, to ensure that affected parties have sufficient time to make changes needed to facilitate compliance, which we believe will benefit all 340B stakeholders and enhance program integrity.

*Comment:* Some commenters raised concerns that the interim final rule did not satisfy APA requirements for rulemaking. Specifically, they argued that HHS had not shown good cause for delaying the effective date of the January 5, 2017 final rule without prior notice or opportunity for public comment and making that change effective immediately upon publication in the *Federal Register*.

*Response:* HHS disagrees that the good cause exemptions of the APA do not apply here. Our finding that good cause existed to waive the normal rulemaking requirements of the APA was based on our view that in this limited instance notice and public comment was impracticable, unnecessary, or contrary to the public interest. Because completion of a rulemaking with notice and comment procedures would not occur until after the previously announced effective date, we believe a delay in determining the effective date would create confusion that could disrupt orderly implementation of the January 5, 2017 final rule, and would be impracticable, unnecessary, and contrary to the public interest. In addition, we reiterate that we remain concerned that the original effective date for the January 5, 2017 final rule did not allow for sufficient time to consider the regulatory burdens that may be posed and did not provide stakeholders sufficient time to come into compliance with the new program requirements in the final rule. While there was good cause to amend the effective date of the January 5, 2017 final rule, without prior notice or opportunity for public comment and to make the action immediately effective, we note that we implemented the action on an interim basis only and provided notice and an opportunity for comment on the further delay of the effective date of the

final rule to October 1, 2017. Based on the foregoing considerations as well as the comments received on our proposal in the interim final rule to further delay the effective date, we are delaying the effective date of the final rule to October 1, 2017.

*Comment:* Many commenters supported further delaying the effective date to October 1, 2017, at a minimum, and agreed with HHS that more time was needed for stakeholders to come into compliance.

*Response:* HHS agrees with the commenters and has decided to delay the effective date of the January 5, 2017 final rule to October 1, 2017.

### **III. Regulatory Impact Analysis**

HHS examined the effects of this final 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 (Pub. L. 96-354, September 19, 1980), 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).

HHS does not believe the proposal to delay the effective date of the January 5, 2017 final rule will have an economic impact of \$100 million or more, and is therefore not designated as an “economically significant” final rule under section 3(f)(1) of the Executive Order 12866. Therefore, the economic impact of having no rule in place related to the policies addressed in the final rule is believed to be minimal, as the policies would not yet be required or enforceable.

### **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 3 percent impact on at least 5 percent of small entities.

For purposes of the RFA, HHS considers all health care providers to be small entities either by 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 health care providers across the country. HHS 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 this RFA. HHS estimates the economic impact on small entities and small manufacturers will be minimal.

### **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.” During 2013, that threshold level was approximately \$141 million. HHS does not expect this final rule to exceed the threshold.

### **Executive Order 13132 - Federalism**

HHS 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.” 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. This final rule would result in no new reporting burdens.

Dated: May 10, 2017

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**George Sigounas**  
Administrator,  
Health Resources and Services Administration.

Approved: May 15, 2017

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**Thomas E. Price**  
Secretary,  
Department of Health and Human Services.

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