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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AB11

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), known 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. On August 21, 2017, HHS solicited comments on further delaying the effective date of the January 5, 2017, final rule to July 1, 2018 (82 FR 39553). HHS proposed this action to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking. After consideration of the comments received on the proposed rule, HHS is delaying the effective date of the January 5, 2017, final rule, to July 1, 2018.

DATES: As of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the effective date of the final rule published in the *Federal Register* (82 FR 1210, January 5, 2017) is further delayed to July 1, 2018.

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

On September 30, 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) on June 17, 2015, to implement CMPs for manufacturers that 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 \$.01 (penny pricing) 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 original comment period established in the NPRM

and the reopened comment period announced in the April 19, 2016 notice were considered in the development of the final rule. The provisions of that final 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, titled “Regulatory Freeze Pending Review.”¹ In the January 5, 2017, final rule, HHS acknowledged 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 questions were 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 comments on whether that date should be further extended to October 1, 2017. HHS received 51 comments on the interim final rule, some supporting and some 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 delayed the effective date of the January 5, 2017, final rule to October 1, 2017 (82 FR 22893, May 19, 2017).

HHS subsequently published a proposed rule (82 FR 39553, August 21, 2017) to further delay the effective date of the final rule to July 1, 2018. The further delay allows necessary time to fully consider the substantial questions of fact, law, and policy raised by the rule, consistent with the aforementioned “Regulatory Freeze Pending Review,” memorandum. Requiring manufacturers to make targeted and potentially costly changes to pricing systems and business

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

procedures in order to comply with a rule that is under further consideration and for which substantive questions have been raised would be disruptive. The further delay allows HHS to consider objections regarding the timing of the effective date and challenges associated with complying with the rule, as well as other objections to the rule.

In addition, Executive Order 13765 (82 FR 8351) titled, “Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal,” specifically instructs HHS and all other heads of executive offices to utilize all authority and discretion available to delay the implementation of certain provisions or requirements of the Patient Protection and Affordable Care Act.² HHS based the January 5, 2017, final rule on changes made to the 340B Program by the Patient Protection and Affordable Care Act. HHS proposed to delay the effective date of the January 5, 2017, final rule to July 1, 2018, to allow for a sufficient amount of time to consider the regulatory burdens that may be posed by this final rule. HHS continues to examine important substantive issues in matters covered by the rule and intends to engage in additional rulemaking on these issues.

HHS received a number of comments on the proposed rule both supporting and opposing the delay of the effective date to July 1, 2018. After careful consideration of the comments received, HHS has decided to delay the effective date of the January 5, 2017, final rule to July 1, 2018. As HHS changed the effective date of the final rule to July 1, 2018, enforcement will be delayed to July 1, 2018. HHS continues to believe that the delay of the effective date provides regulated entities sufficient time to implement the requirements of the rule, as well as allowing a

² See: <https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and>

more deliberate process of considering alternative and supplemental regulatory provisions, and to allow for sufficient time for additional rulemaking.

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 finds 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 on October 1, 2017, for several weeks before a final rule delaying the effective date until July 1, 2018, would go into effect. To preclude this uncertainty in the marketplace and to ease the burdens of 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 will assist stakeholders in preparing to comply with these new program requirements.

II. Analysis and Responses to Public Comments

In the proposed rule, HHS solicited comments regarding whether we should delay the January 5, 2017, final rule to July 1, 2018. We received 97 comments containing a number of issues from covered entities, manufacturers, and groups representing these stakeholders. In this final rule, we will only respond to comments related to whether HHS should delay the January 5, 2017, final rule to July 1, 2018. We did not consider and do not address comments that raised issues beyond the narrow scope of the proposed rule, including comments related to withdrawal of the rule or comments related to broader policy matters. However, HHS intends to engage in further rulemaking on issues covered in the January 5, 2017, final rule. We have summarized the relevant comments received and provided our responses below.

Comment: Some commenters supported HHS's proposed delay of the effective date of the final rule until not only July 1, 2018, but until HHS fulfills its commitment to engage in additional rulemaking that cures the substantive legal and practical concerns with the final rule. These commenters recommend that HRSA tie the further delay of the effective date of the final rule to the completion of such rulemaking, as opposed to a certain date.

Response: HHS has decided to delay the effective date to July 1, 2018, to provide affected parties sufficient time to make needed changes to facilitate compliance and because HHS continues to examine important substantive issues arising from the January 5, 2017, final rule. After reviewing the comments received from stakeholders regarding objections on the timing of the effective date and challenges associated with complying with the final rule, HHS has determined that delaying the effective date to July 1, 2018, is necessary to consider some of the issues raised. HHS believes that delaying the effective date to July 1, 2018, provides sufficient time to address these issues and does not believe a further delay is necessary at this time.

Comment: Some commenters stated that the January 5, 2017, final rule contains several policies that are inconsistent with the 340B statute and imposes needless burdens on manufacturers. These commenters urge HHS to delay the effective date to July 1, 2018, and use the additional time to reconsider the policies included in the final rule.

Responses: HHS intends to engage in further rulemaking and believes that this delay will provide HHS with time to consider the substantial questions of fact, law, and policy raised by the rule.

Comment: Several commenters explained that a delay in the effective date of the final rule is also necessary to align with the Administration priorities of analyzing final, but not yet

effective, regulations, and removing or minimizing unwarranted economic and regulatory burdens related to the Affordable Care Act, the law that added the provisions of the 340B statute that are the subject of the final rule.

Response: HHS agrees with the commenters. Executive Order 13765 instructs agencies to use discretion to delay the implementation of certain provisions of requirements of the Patient Protection and Affordable Care Act. As previously mentioned, HHS based the January 5, 2017, final rule on changes made to the 340B Program by the Patient Protection and Affordable Care Act. As such, HHS is complying with Executive Order 13765 to delay implementation on provisions of that law that “...impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” The policies finalized in the January 5, 2017, final rule will require targeted and potentially costly changes to pricing systems and business procedures for manufacturers affected by the rule. Thus, HHS is delaying the effective date to July 1, 2018.

Comment: Some commenters recommend that HHS delay the effective date of the final rule until HHS concurrently addresses 340B covered entity compliance obligations and penalties under the 340B statute, which is necessary to strengthen the integrity of the 340B Program.

Response: HHS plans to issue separate policy documents for the different areas of the 340B program integrity provisions in the 340B statute and disagrees with the commenters advising HHS to address these issues concurrently.

Comment: Many commenters opposed delaying the effective date to July 1, 2018. Commenters recommended that HHS use its statutory rulemaking authority to balance the scales of enforcement and oversight in the 340B Program, and expressed concern that drug

manufacturers have engaged in discriminatory pricing strategies due to a lack of oversight and enforcement with respect to manufacturer behavior. They explained that various factors, including extensive data regarding overcharging covered entities, HHS's inability to address overcharges, and HHS's admission that many manufacturers are still out of compliance highlight the need for the final rule to go into effect immediately. They further explained that the January 5, 2017, final rule is critical to ensuring that drug manufacturers uphold the intent of the 340B Program. The commenters also disagreed that "a more deliberative process is needed" as there have been multiple delays and stakeholders were given various opportunities to comment.

Response: HHS does not agree that that we should enforce the final rule immediately. We are delaying the effective date of the January 5, 2017, final rule to July 1, 2018, because the delay will provide stakeholders with additional time to come into compliance and provide time to consider the substantial questions of fact, law, and policy raised by the rule. The final rule does not represent the only method for HHS to address manufacturer overcharges. In addition to the final rule, HHS performs audits of manufacturers, investigates all allegations of overcharging, and participates in settlements that have returned millions of dollars to covered entities. HHS believes that it would be disruptive to require stakeholders to make potentially costly changes to pricing systems and business procedures in order to comply with a rule that is under further consideration and for which substantive questions have been raised.

While stakeholders had the opportunity to provide comments on the final rule, the 340B Program is a complex program that is affected by changes in other areas of health care. HHS has determined that this complexity and changing environment warrants further review of the final rule.

Comment: Many commenters supported further delaying the effective date to July 1, 2018, at a minimum, and agreed with HHS that more time was needed for stakeholders to come into compliance and to consider substantial questions of fact, law and policy raised by the January 5, 2017, final rule.

Response: HHS agrees with the commenters and will delay the effective date of the January 5, 2017, final rule to July 1, 2018.

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), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act, and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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) and is therefore, not a major rule under the Congressional Review Act.

HHS does not believe that a delay of 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” 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.

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017. This final rule is not expected to be an EO 13771 regulatory action because this final rule is not significant under EO 12866.

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 by 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 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 this RFA. HHS estimates that 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.” In 2017, that threshold is approximately \$148 million. HHS does not expect this 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.”

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. Comments are welcome on the accuracy of this statement.

Dated: September 22, 2017.

George Sigounas

Administrator,

Health Resources and Services Administration.

Thomas E. Price

Secretary,

Department of Health and Human Services.

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