



Billing Code: 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AB18

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 May 7, 2018, HHS solicited comments on further delaying the effective date of the January 5, 2017, final rule to July 1, 2019. HHS proposed this action to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for any 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, 2019.

DATES: As of July 1, 2018, the effective date of the final rule published in the *Federal Register* on January 5, 2017 at 82 FR 1210, delayed March 6, 2017 at 82 FR 12508, March 20, 2017 at 82 FR 14332, May 19, 2017 at 82 FR 22893, and September 29, 2017 at 82 FR 45511, is further delayed until July 1, 2019.

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

HHS published a notice of proposed rulemaking (NPRM) on June 17, 2015, to implement civil monetary penalties (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 \$0.01 (penny pricing) for each unit of a drug when the ceiling price calculation equals zero (80 FR 34583, June 17, 2015). After review of the 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.

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

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. HHS solicited additional comments on whether that date should be further extended 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 later solicited comments on delaying the effective date to July 1, 2018 (82 FR 39553, August 21, 2017) and subsequently delayed the January 5, 2017, final rule to July 1, 2018 (82 FR 45511, September 29, 2017).

HHS issued a proposed rule and solicited additional comments to further delay the effective date to July 1, 2019, and received a number of comments both supporting and opposing the delay (83 FR 20008, May 7, 2018). After consideration of the comments received, HHS has decided to delay the effective date of the January 5, 2017, final rule to July 1, 2019. As HHS changed the effective date of the final rule to July 1, 2019, enforcement will be delayed to July 1, 2019. HHS continues to believe that the delay of the effective date will provide regulated entities with needed time to implement the requirements of the rule, as well as allowing a more deliberate process of considering alternative and supplemental regulatory provisions, and to allow for sufficient time for any additional rulemaking. HHS intends to engage in additional or alternative rulemaking on these issues, and believes it would be counterproductive to effectuate the final rule prior to issuance of additional or alternative rulemaking on these issues. HHS is developing new comprehensive policies to address the rising costs of prescription drugs. These

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

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 of the January 5, 2017, final rule to July 1, 2019.

HHS does not believe this delay will adversely affect any of the stakeholders in a meaningful way.

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 or for rules that grant or recognize an exemption or relieve a restriction. 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 July 1, 2018, several weeks before the final rule delaying the effective date until July 1, 2019, 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 to prepare for compliance with these new program requirements.

II. Analysis and Responses to Public Comments

In the proposed rule, HHS solicited comments regarding the impact of delaying the effective date of the final rule, published January 5, 2017, to July 1, 2019, while a more deliberate rulemaking process is undertaken. HHS received 29 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, 2019. We did not consider and do not address comments

that raised issues beyond the narrow scope of the proposed rule, including comments related to broader policy matters. However, HHS is considering 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: Commenters disagree with HHS that delaying implementation of the rule has no adverse effect given that other more significant remedies are available to entities who believe that they have been overcharged by manufacturers. Commenters request that HHS explain what these “significant remedies” are, as they believe that remedies do not exist. Commenters state they cannot audit manufacturers or sue companies in court. In addition, manufacturers can decide not to participate in the 340B program’s current voluntary dispute resolution process, and a proposal to make the process mandatory has been withdrawn. Currently, covered entities cannot check if they are being charged the right price. Any further postponement would prevent Congress’ intent that HHS has meaningful oversight and enforcement authority.

Response: HRSA’s website describes how it carefully reviews pricing discrepancies brought to its attention. In cases in which the 340B Program’s ceiling price appears to have been violated, covered entities are provided the details necessary to settle any discrepancy with the manufacturer directly. It is in the manufacturer’s best interest to ensure that they are appropriately reporting AMP and URA to CMS, as well as providing the 340B Program ceiling price to 340B Program covered entities. Inaccuracies in any of this pricing information will negatively impact other drug pricing programs, such as Medicaid or Veterans Affairs programs. Further, misreporting pricing data to CMS could lead to State and Federal False Claims Act liability, which has the potential to carry triple damages and other significant monetary penalties.

Comment: Some commenters stated that HHS alleges in the proposed rule that the delay will not adversely affect stakeholders, which ignores the extent of overcharges as documented in

OIG reports. HHS also stated that “a small number of manufacturers have informed HHS over the last several years that they charge more than \$0.01 for a drug with a ceiling price below \$0.01” and that it “believes” a majority of manufacturers follow the “long-standing HHS policy” on penny pricing. HHS’s statement that it merely “believes” most manufacturers are following the policy demonstrates that HHS has not attempted to investigate the extent of noncompliance. The penny pricing policy serves as a disincentive for manufacturers to raise drug prices much quicker than the rate of inflation and the rule should be implemented immediately in order to meet the Administration’s goal of lowering drug prices. Until penny pricing is codified in a regulation, there is less incentive for manufacturers to comply and the final rule should be effective immediately.

Response HHS has consistently stated that “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.” (e.g., 80 FR 34586, June 17, 2015; 82 FR 1227, January 5, 2017). The commenter does not provide evidence that a majority of manufacturers are not following the practice of charging \$0.01 for a drug with a ceiling price below \$0.01. HRSA’s website describes how it carefully reviews pricing discrepancies brought to its attention. Through these and other mechanisms, HRSA monitors the program for noncompliance and maintains its belief that a majority of manufacturers follow the long-standing practice of charging \$0.01 for a drug with a ceiling price below \$0.01.

Comment: Many commenters oppose delaying the effective date to July 1, 2019. Commenters express concern that until the January 5, 2017, final rule is implemented, covered entities remain unprotected from overcharges that can further exacerbate the negative effects of

high-cost drugs. They contend that all accountability in the Program is placed on covered entities, and manufacturers are not being held accountable. They contend that the January 5, 2017, final regulation would have provided covered entities with access to a secure database to confirm ceiling prices. These commenters explain that without access to ceiling price information, covered entities have to rely on HRSA to confirm any instances in which the covered entity suspects that it was overcharged by a manufacturer, thereby hampering any meaningful enforcement against manufacturers. They conclude that continued delay of the final rule inhibits the ability of covered entities to verify whether or not manufacturers' calculations of ceiling prices are correct. The commenters request that HHS should implement the January 5, 2017, rule immediately.

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, 2019, because the delay will allow HHS to consider additional rulemaking. 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 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 and delaying the final rule affords HHS the opportunity to consider alternative and

supplemental regulatory provisions and to allow for sufficient time for any additional rulemaking.

Comment: The commenters also disagreed that “a more deliberative process is needed” as HHS has already spent 8 years considering and responding to multiple delays and stakeholders were given various opportunities to comment. HHS has not complied with the statutory deadline to promulgate the regulation and any further delay is unreasonable and violates the Administrative Procedure Act. Rather than implement the CMP Rule, HHS would reward those manufacturers that are flouting ceiling price requirements. Comments assert that the final rule would give HHS an effective penalty to impose on manufacturers that overcharge covered entities and to deter other manufacturers from doing so. In addition, commenters contend that HHS does not have authority to replace Congress’ judgment with its own and ignore the requirements of the law. They urge HHS to immediately implement the January 5, 2017, final rule.

Response: HHS believes it would be counterproductive to effectuate the final rule prior to consideration of additional or alternative rulemaking as HHS is in the process of developing new comprehensive policies to address the rising costs of prescription drugs not limited to the 340B Program. As such, HHS is delaying the effective date of the January 5, 2017, final rule until July 1, 2019. In addition, HHS believes this delay will not adversely impact covered entities and will instead save the healthcare sector compliance costs, as discussed in the January 5, 2017, final rule. Therefore, the rule is being delayed to July 1, 2019.

Comment: Some commenters supported HHS’s proposed delay of the effective date of the final rule until not only July 1, 2019, 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 decided to delay the effective date to July 1, 2019, 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, 2019, is necessary to consider some of the issues raised. HHS believes that delaying the effective date to July 1, 2019, provides sufficient time to address these issues in junction with HHS's stated intention to consider undertaking additional or alternative rulemaking on these issues.

Comment: Some commenters stated that the January 5, 2017, final rule contains several policies that are inconsistent with the 340B statute and imposes unnecessary costs and needless administrative burdens on manufacturers. They believe that manufacturers should not be required to make updates to their systems, policies, and business practices to comply with the January 5, 2017, final rule if further changes or additional rulemaking will be forthcoming. These commenters urge HHS to delay the effective date to July 1, 2019, 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 public comments received. Requiring manufacturers to make targeted and potentially costly changes to pricing systems and business procedures to comply with a rule that is under further consideration would be disruptive. Therefore, HHS is delaying the January 5, 2017, final rule to July 1, 2019.

Comment: Several commenters explained that a delay in the effective date of the final rule is also necessary to align with the Administration's 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 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 the 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, 2019.

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 related to drug pricing in government programs, including the 340B Program, and disagrees with the commenters advising HHS to address these issues concurrently.

Comment: Many commenters supported further delaying the effective date to July 1, 2019, at a minimum, and urged HHS to take the opportunity to refocus the 340B Program on its mission, and issue new reforms and new ceiling price and CMP rule as expeditiously as possible.

Response: HHS agrees with the commenters and will delay the effective date of the January 5, 2017, final rule to July 1, 2019.

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).

This final rule will not have economic impacts of \$100 million or more in any 1 year, and, therefore, has not been designated an “economically significant” rule under section 3(f)(1) of Executive Order 12866. The 340B Program as a whole creates significant savings for entities purchasing drugs through the program; however, this final rule would not have an economically significant impact on the Program.

When the 2017 Rule was finalized, it was described as not economically significant. Therefore, delay of 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, delay of these civil penalties is unlikely to have an economically significant impact.

Additionally, the 2017 Rule codified the practice of manufacturers charging \$0.01 for drugs with a ceiling price below \$0.01, which the 2017 Rule RIA described as “[...] a long-standing HRSA policy, and HRSA believes the majority of manufacturers currently follow the practice of charging \$0.01.” Delay of this rule will delay the codification of this practice, but since it is already a longstanding policy and widespread practice, the impact of delay is not likely to be economically significant.

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017. This rule is not subject to the requirements of EO 13771 because this rule results in no more than *de minimis* costs.

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, 2018, over 12,800 covered entities participate in the 340B Program, which represent safety-net health care providers across the country.

In addition, the rule would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of the rule on the industry as a whole, the data necessary to project changes for specific or groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program. 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.

Dated: May 30, 2018.

George Sigounas

Administrator,

Health Resources and Services Administration.

Approved: May 31, 2018.

Alex M. Azar II

Secretary,

Department of Health and Human Services.

[FR Doc. 2018-12103 Filed: 6/1/2018 11:15 am; Publication Date: 6/5/2018]