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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: Interim final rule; further delay of effective date with comment.

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.” The January 5, 2017 final rule sets forth the calculation of the ceiling price and application of civil monetary penalties, and applies to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. This interim final rule delays the effective date of the final rule published in the *Federal Register* (82 FR 1210, (January 5, 2017)) to May 22, 2017. Commenters are also invited to provide their views on whether a longer delay of the effective date to October 1, 2017, would be more appropriate.

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 May 22, 2017. Comments on the delay of the effective date to May 22, 2017, as well as comments on alternatively delaying the effective date further to October 1, 2017, must be submitted on or before [INSERT 30 DAYS AFTER DATE OF PUBLICATION].

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.
- E-mail: 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. Please do not submit confidential commercial 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

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 on 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 calculation equals zero (80 FR 34583, (June 17, 2015)). The public comment period closed in August 2015, and HRSA received approximately 35 comments. After review of the initial comments, HHS reopened the comment period (81 FR 22960, (April 19, 2016)) to invite additional comment on specific areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers utilize 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 on manufacturers who overcharge a covered entity. The comment period closed May 19, 2016, and HHS received approximately 70 additional 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.”¹ In the January 2017 final rule, HHS recognized that the effective date fell in the middle of a quarter and that 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

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

final rule at the start of the next quarter, which began April 1, 2017. However, after further consideration and to provide affected parties sufficient time to make needed changes to facilitate compliance, and because there are substantive questions raised, we intend to engage in longer rulemaking. In addition, HHS believes that it is important to ensure that this rulemaking – as well as the implementation of this rule – is coordinated with and takes into consideration overall 340B Program implementation. HHS has therefore decided to delay the effective date of the final rule to May 22, 2017, and is inviting comments on whether to delay that date further to October 1, 2017. As the effective date of the final rule has been moved to May 22, 2017, and may be further delayed, enforcement will be correspondingly delayed. HHS believes that the delay of the effective date is necessary to consider questions of fact, law, and policy raised in the rule, consistent with the “Regulatory Freeze Pending Review” memorandum. In addition, HHS believes that the delay of the effective date is necessary to provide regulated entities sufficient time to implement the requirements of the rule.

II. Good Cause for Interim Final Rulemaking

Under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.), a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Pursuant to 5 U.S.C. 553(b)(3)(B), HHS finds that good cause exists to waive normal rulemaking requirements for the immediate delay of the effective date to May 22, 2017. HHS believes that a notice-and-comment procedure, in this limited instance, is impracticable, unnecessary, and contrary to the public interest.

In order to promote the public interest in fulfilling the “Regulatory Freeze Pending Review” memorandum instruction to agencies to review substantial questions of fact, law, and

policy in regulations not currently in effect, HHS feels that it is necessary to delay immediately the effective date of this rule. In addition, the January 20, 2017, Executive Order entitled, “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 The January 2017 final rule is based on changes made to the 340B Program by the Patient Protection and Affordable Care Act. It is impracticable to gather comments prior to the effective date of March 21, 2017. HHS continues to be concerned that the previously announced effective date for the January 2017 final rule does not allow for a sufficient amount of time to consider the regulatory burdens that may be posed by this issuance and does not provide regulated entities sufficient time to come into compliance with the requirements of the rule.

The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because public health, safety, and welfare could be harmed by allowing the final rule to go into effect without a delay. There are substantive questions raised, and HHS will be further considering questions of fact, law, and policy presented by the rule consistent with the “Regulatory Freeze Pending Review” memorandum. In this unique circumstance, allowing the regulation to become effective while further consideration is ongoing, prior to further proper consideration of all the relevant facts, would exacerbate the burdens conveyed in comments submitted in the prior rulemaking. Requiring manufacturers to make targeted and potentially costly changes to pricing systems and business procedures in order to come into compliance with a rule that is itself subject to further agency consideration and for which there are substantive

² See: <https://www.whitehouse.gov/the-press-office/2017/01/20/executive-order-minimizing-economic-burden-patient-protection-and>

questions raised would be disruptive. Given the comments, it appears that objections regarding the timing and challenges of compliance with the rule, 82 FR 1211, as well as other objections to the rule, may not have been adequately considered, thereby requiring additional time and public comment before the rule goes into effect. Providing a public comment period before delaying the effective date is impracticable given the impending deadline.

HHS also finds that good cause exists for immediate implementation of this interim final rule and waiver of the Administrative Procedure Act's 30-day delay in the effective date. The 30-day delay is normally intended to give affected parties time to adjust their business practices and make preparations before a final rule takes effect. Because the action being taken delays the effective date to May 22, 2017, at the earliest, a 30-day delay in effect of this action is unnecessary. The effective date delay will permit those subject to the rule extra time to comply with the rule until at least May 22, 2017.

III. Regulatory Impact Analysis

HHS has examined the effects of this interim 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 that 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” interim 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 has determined, and the Secretary certifies, that this interim 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. HHS welcomes comments concerning the impact of this interim final rule on small manufacturers and small health care providers.

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 was approximately \$141 million. HHS does not expect this rule to exceed the threshold.

Executive Order 13132 - Federalism

HHS has reviewed this interim final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” This interim 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 interim 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 interim final rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. This interim final rule would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

Dated: March 13, 2017.

James Macrae,

Acting Administrator,

Health Resources and Services Administration.

Approved: March 15, 2017.

Thomas E. Price,

Secretary,

Department of Health and Human Services.

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