Evaluation process was codified in EPA regulation for greenhouse gas emission standards for model years 2017–2025 light-duty vehicles, which requires EPA to determine no later than April 1, 2018, whether the standards for model years 2022–2025 are appropriate.[3] In November 2016, EPA issued a proposed determination for the Mid-Term Evaluation.[4] On January 12, 2017, the EPA Administrator signed the Final Determination of the Mid-Term Evaluation.

Some stakeholders previously commented that they were preparing studies to inform the Mid-term Evaluation that were not ready for submission during the previous Mid-term Evaluation comment periods. This additional comment period provides an opportunity for commenters to submit to EPA additional studies and other materials as well as to complete the preparation of their comments, or submit additional comments in light of newly available information. There is an existing body of EPA analyses and public comments already in the docket. Please note that the agency is primarily interested in comments relevant to the reconsideration of the Final Determination, rather than the Technical Assessment Report (TAR), which is not being reopened for comment in this document. Additionally, NHTSA has been working closely with stakeholders to develop its forthcoming rulemaking since the March 2017 joint document with EPA, and encourages commenters wishing to inform those efforts to directly participate in NHTSA's rulemaking process.

EPA's reconsideration will be conducted in accordance with the regulations EPA established for the Mid-term Evaluation at 40 CFR 86.1818–12(h). These regulations state that in making the required determination as to whether the existing standards are appropriate under section 202(a) of the Clean Air Act, the Administrator shall consider the information available on the factors relevant to setting greenhouse gas emission standards under section 202(a) of the Clean Air Act for model years 2022 through 2025, including but not limited to:

- The availability and effectiveness of technology, and the appropriate lead time for introduction of technology;
- The cost on the producers or purchasers of new motor vehicles or new motor vehicle engines;
- The feasibility and practicability of the standards;
- The impact of the standards on reduction of emissions, oil conservation, energy security, and fuel savings by consumers;
- The impact of the standards on the automobile industry;
- The impacts of the standards on automobile safety;
- The impact of the greenhouse gas emission standards on the Corporate Average Fuel Economy standards and a national harmonized program; and
- The impact of the standards on other relevant factors.[5]

Pursuant to 40 CFR 86.1818–12(h)(1)(viii), EPA also invites comments on the following other factors relevant to setting greenhouse gas emission standards under section 202(a) of the Clean Air Act for model years 2022 through 2025:

- The impact of the standards on compliance with other air quality standards;
- The extent to which consumers value fuel savings from greater efficiency of vehicles;
- The ability for OEMs to incorporate fuel saving technologies, including those with ''negative costs,'' absent the standards;
- The distributional consequences on households;
- The appropriate reference fleet;
- The impact of the standards on advanced fuels technology, including but not limited to the potential for high-octane blends;
- The availability of realistic technological concepts for improving efficiency in automobiles that consumers demand, as well as any indirect impacts on emissions;
- The advantages or deficiencies in EPA's past approaches to forecasting and projecting automobile technologies, including but not limited to baseline projections for compliance costs, technology penetration rates, technology performance, etc.;
- The impact of the standards on consumer behavior, including but not limited to consumer purchasing behavior and consumer automobile usage behavior (*e.g.* impacts on rebound, fleet turnover, consumer welfare effects, etc.); and
- Any relevant information in light of newly available information.

In addition, EPA seeks comment on the use of alternative methodologies and modeling systems to assess both analytical inputs and the standards, including but not limited to the Department of Energy's (DOE's) Argonne National Laboratory's Autonomie full vehicle simulation tool and DOT's CAFE Compliance and Effects Model.

In accord with the schedule set forth in its regulations, the EPA intends to make a Final Determination regarding the appropriateness of the model year 2022–2025 greenhouse gas standards, and potentially the model year 2021 greenhouse gas standard, no later than April 1, 2018.

In this document, in the interest of harmonization between the GHG and CAFE programs, EPA is also requesting comment on the separate question of whether the light-duty vehicle greenhouse gas standards established for model year 2021 are appropriate. In its July 26, 2017, ''Notice of Intent To Prepare an Environmental Impact Statement for Model Year 2022–2025 Corporate Average Fuel Economy Standards,'' NHTSA stated that as part of its upcoming CAFE rulemaking, it may evaluate the model year 2021 standards it finalized in 2012 to ensure they remain ''maximum feasible'' (See 82 FR 34742). Please provide comment on the continued appropriateness of the model year 2021 GHG standards based on the application of the factors described above or any other factors that commenters believe are appropriate.

Dated: August 10, 2017.

Elaine L. Chao,

Secretary, Department of Transportation.

Dated: August 10, 2017.

E. Scott Pruitt,

Administrator, Environmental Protection Agency.

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BILLING CODE 6560–50–P

[3] 77 FR 62624 (October 15, 2012). NHTSA is statutorily required to conduct a de novo rulemaking on MY 2022 to 2025 standards for light-duty vehicles. NHTSA has recently taken the first step in this process by publishing the ''Notice of Intent To Prepare an Environmental Impact Statement for Model Year 2022–2025 Corporate Average Fuel Economy Standards'' on July 26, 2017.

[4] 81 FR 87927 (Dec. 6, 2016).

[5] 40 CFR 86.1818–12(h)(1).

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: Notice of proposed rulemaking; further delay of effective date.

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.'' HHS is soliciting comments on delaying the effective date of the January 5, 2017 final rule that 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. HHS proposes to delay the effective date of the final rule published in the **Federal Register** (82 FR 1210, January 5, 2017) to July 1, 2018. HHS proposes this action in order to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking, as set forth below.

DATES: Submit comments on or before September 20, 2017.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB11, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow instructions for submitting comments. This is the preferred method for the submission of comments.
- *Email: 340BCMPNPRM@hrsa.gov.* Include 0906–AB11 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

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 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 $.01 (penny pricing) for each unit of a drug 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 several comments to 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).

II. Proposal To Delay the Effective Date of the Final Rule

HHS proposes to further delay the effective date of the January 5, 2017 final rule because it continues to examine important substantive issues in matters covered by the rule. HHS intends to engage in additional rulemaking on these issues. HHS believes that the proposed delay will allow for necessary time to more 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 procedures in order to comply with a rule that is under further consideration and for which substantive questions have been raised would be disruptive. We also believe additional time is needed to more fully consider previous 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, 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 5, 2017 final rule is based on changes made to the 340B Program by the Patient Protection and Affordable Care Act. HHS is proposing to delay the effective date of the January 5, 2017 final rule to July 1, 2018, to also allow for a sufficient amount of time to more fully consider the regulatory burdens that may be posed by this final rule.

At this time, HHS seeks public comments regarding the impact of delaying the effective date of the final rule, published January 5, 2017, for an additional nine months from the current

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

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

effective date of October 1, 2017 to July 1, 2018, while a more deliberate rulemaking process is considered. HHS encourages all stakeholders to provide comments on this proposed rule.

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 (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, 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 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'' proposed 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, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule is not expected to be an EO 13771 regulatory action because this proposed 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 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 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 proposed 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 proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This proposed 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 proposed rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. This proposed rule would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

George Sigounas,

Administrator, Health Resources and Services Administration.

Approved: August 16, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

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