receiving facility; the type and quantity of the airbag waste (*i.e.,* airbag modules and airbag inflators) received; and the date which it was received. Shipping records and confirmations of receipt must be made available for inspection and may be satisfied by routine business records (*e.g.,* electronic or paper financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt).

(2) Once the airbag waste arrives at an airbag waste collection facility or designated facility, it becomes subject to all applicable hazardous waste regulations, and the facility receiving airbag waste is considered the hazardous waste generator for the purposes of the hazardous waste regulations and must comply with the requirements of 40 CFR part 262.

(3) Reuse in vehicles of defective airbag modules or defective airbag inflators subject to a recall under the National Highway Traffic Safety Administration is considered sham recycling and prohibited under 40 CFR 261.2(g).

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938 and 6939g.

Subpart A—General

■ 6. Section 262.14 is amended by revising paragraphs (a) introductory text and (a)(5) to read as follows:

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) Provided that the very small quantity generator meets all the conditions for exemption listed in this section, hazardous waste generated by the very small quantity generator is not subject to the requirements of parts 124, 262 (except §§ 262.10 through 262.14) through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA and the very small quantity generator may accumulate hazardous waste on site without complying with such requirements. The conditions for exemption are as follows:

* * * * *

(5) A very small quantity generator that accumulates hazardous waste in amounts less than or equal to the limits in paragraphs (a)(3) and (4) of this section must either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which, if located in the U.S., is:

(i) Permitted under part 270 of this chapter;

(ii) In interim status under parts 265 and 270 of this chapter;

(iii) Authorized to manage hazardous waste by a state with a hazardous waste management program approved under part 271 of this chapter;

(iv) Permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill is subject to part 258 of this chapter;

(v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit, is subject to the requirements in §§ 257.5 through 257.30 of this chapter;

(vi) A facility which:

(A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or

(B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation;

(vii) For universal waste managed under part 273 of this chapter, a universal waste handler or destination facility subject to the requirements of part 273 of this chapter;

(viii) A large quantity generator under the control of the same person as the very small quantity generator, provided the following conditions are met:

(A) The very small quantity generator and the large quantity generator are under the control of the same person as defined in § 260.10 of this chapter. ''Control,'' for the purposes of this section, means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to ''control'' such generators.

(B) The very small quantity generator marks its container(s) of hazardous waste with:

(*1*) The words ''Hazardous Waste''; and

(*2*) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);

(ix)–(x) [Reserved]

(xi) For airbag waste, an airbag waste collection facility or a designated facility subject to the requirements of § 261.4(j) of this chapter.

* * * * *

[FR Doc. 2018–25892 Filed 11–29–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AB19

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule; effective date change.

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 published a final rule on January 5, 2017, that set forth the calculation of the 340B ceiling price and application of civil monetary penalties. On June 5, 2018, HHS published a final rule that delayed the effective date of the 340B ceiling price and civil monetary rule until July 1, 2019, to consider alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking. On November 2, 2018, HHS issued a proposed rule to solicit comments to change the effective date from July 1, 2019, to January 1, 2019, and to cease any further delay of the rule. HHS proposed this action because it determined that the January 5, 2017, final rule has been subject to extensive public comment, and had been delayed several times. HHS has considered the full range of comments on the substantive issues in the January 5, 2017, final rule. After consideration of the comments received on the effective date of the proposed rule, HHS is changing the effective date of the January 5, 2017, final rule, to January 1, 2019.

DATES: The effective date of the final rule published in the **Federal Register** on January 5, 2017, at 82 FR 1210, and delayed March 6, 2017 at 82 FR 12508, March 20, 2017 at 82 FR 14332, May 19, 2017 at 82 FR 22893, September 29,

2017 at 82 FR 45511, and June 5, 2018 at 83 FR 25944, is changed to January 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) 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 how the ceiling price is to be calculated; 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 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 NPRM and the reopening notification were considered in the development of the final rule. The provisions of that rule were to be effective March 6, 2017; however, through a series of rules, HHS delayed the effective date of the January 5, 2017, final rule until July 1, 2019 (83 FR 25943, June 5, 2018). On November 2, 2018, HHS issued a proposed rule (83 FR 55135) to cease any further delay of the January 5, 2017, final rule and to change the effective date from July 1, 2019, to January 1, 2019. HHS received a number of comments both supporting and opposing the delay. After consideration of the comments received, HHS has decided to change the effective date of the January 5, 2017, final rule to January 1, 2019. The substantive provisions included in the January 5, 2017, final rule were subject to extensive public comment, and have been delayed several times. HHS has considered the full range of comments on the substantive issues in the January 5, 2017, final rule.

In previous rulemaking, delaying the effective date of the January 5, 2017, final rule, HHS stated that it ''is developing new comprehensive policies to address the rising costs of prescription drugs. These 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 for the January 5, 2017, final rule to July 1, 2019.'' (83 FR 25944)

However, as explained in the proposed rule, HHS has determined that the finalization of the 340B ceiling price and civil monetary penalty rule will not interfere with HHS's development of these comprehensive policies. Accordingly, HHS no longer believes a delay in the effective date is necessary and is changing the effective date of the rule from July 1, 2019, to January 1, 2019. The implementation date and the effective date will be the same.

II. Analysis and Responses to Public Comments

In the NPRM, HHS solicited comments to change the effective date from July 1, 2019, to January 1, 2019, and cease any further delay of the rule. HHS received approximately 160 comments, which contained a number of issues from covered entities, manufacturers, and groups representing these stakeholders. In this final rule, HHS will only respond to comments related to whether HHS should change the effective date of the January 5, 2017, final rule to January 1, 2019. HHS did not consider and does not address comments that raised issues beyond the narrow scope of the NPRM, including comments related to broader policy matters. HHS has summarized the relevant comments received and provided its responses below.

Comment: Some commenters urge HHS not to change the effective date to January 1, 2019, and to further delay the rule to refocus the 340B Program on its mission, and issue new reforms. Commenters also express concern that the new ceiling price system has not yet been released, substantive guidance on the system has not been issued, and stakeholders will not have had an opportunity to gain experience in the system before the enforcement mechanism for the system becomes effective. These commenters recommend that HHS delay implementation until it rolls out the new ceiling price system in a thoughtful manner. Finally, the commenters state that first issuing substantive guidance on the new pricing system would be more consistent with fundamental fairness in a civil penalty enforcement context, inasmuch as program stakeholders should understand their substantive obligations and the timeframes for compliance prior to any enforcement activity.

Response: HHS does not believe that the issuance of additional guidance is needed in order to implement this final rule. Current policies under the 340B Program already provide stakeholders with sufficient guidance regarding programmatic compliance. More specifically, the January 5, 2017, final rule contains information related to the calculation of the 340B ceiling price and the imposition of CMPs against manufacturers who knowingly and intentionally overcharge a covered entity. In addition, the development of the 340B ceiling price reporting system has proceeded under a separate information collection request (ICR) process that is operational in nature and has not been contingent upon the specific provisions contained in the January 5, 2017, final rule. The ICR was submitted and approved by OMB on September 28, 2015, after a formal notice and comment process (80 FR 22207, April 21, 2015, OMB No. 0915–0327). HHS plans to release the 340B ceiling pricing reporting system shortly and HHS will communicate further information through its website. HRSA will also ensure all impacted stakeholders receive education and training to prepare to utilize the 340B ceiling price reporting system.

Comment: Commenters disagree with HHS that changing the effective date of the rule is necessary. Commenters also disagree that HHS has meaningfully responded to comments or considered the full range of comments on the substantive issues in the January 5, 2017, final rule, despite the rule being delayed several times. Commenters urge HHS to fully reconsider substantive comments on the January 5, 2017, final rule as the rule contains several policies that are inconsistent with the 340B statute and imposes unnecessary costs and needless administrative burdens on manufacturers.

Response: HHS has decided to change the effective date of the final rule to January 1, 2019, as the rule has been

subject to extensive public comment. HHS believes that it has had adequate time to consider comments on the substantive issues in the January 5, 2017, final rule. The rule is consistent with the 340B statute. HHS has the statutory authority under section 340B(d)(1)(B)(i)(I) of the PHSA to develop and publish through appropriate policy or regulatory issuance, the precisely defined standards and methodology for the calculation of 340B ceiling prices. HHS has undertaken the effort to issue the January 5, 2017, final rule to comply with this statutory provision. Section 340(d)(1)(B)(vi) of the PHSA also provides for the imposition of sanctions in the form of civil monetary penalties against manufacturers that knowingly and intentionally charge a covered entity a price for a 340B drug that exceeds the 340B ceiling price. HHS believes that CMPs provide a critical enforcement mechanism for HHS if manufacturers do not comply with statutory pricing obligations under the 340B Program.

Comment: Some commenters express concern that HHS has not provided an adequate rationale for its change of view on the need for additional rulemaking and HHS has not released information related to the ''comprehensive policies'' that it has suggested it intends to promulgate. The commenters explain that HHS made a decision to change course and put the Final Rule into effect before it has fully analyzed and explained to the public its conclusions on key issues it identified as requiring further consideration. The commenters contend that this contradicts the deliberative rulemaking principles at the heart of the Administrative Procedures Act.

Response: The effective date of the final rule, for which comments were collected multiple times, has now been delayed for almost two years. It has now been more than eight years since Congress instructed HHS to issue regulations concerning CMPs. The issues that HHS was examining are well documented in the January 5, 2017, final rule. Furthermore, HHS does not believe that a January 1, 2019, effective date will undermine the comprehensive policies under consideration within the Department to address rising drug prices. Given the significant delays, HHS feels that it would be more efficient for the rule to go into effect and assess the need for further rulemaking and guidance after the rule is in effect.

Comment: Some commenters express concern that HHS has not fully considered any new comprehensive policies that will curb the rising cost of drug prices and the 340B Program's impact on those rising prices. The commenters state that in previous rulemaking, HHS has stated that it would be counterproductive to effectuate the final rule prior to a more deliberative process of considering additional or alternative drug reform measures as HHS is in the process of developing new comprehensive policies to address the rising cost of prescription drugs, not limited to the 340B Program. These comments also explain that there is no basis for HHS to suddenly move up the effective date by six months and there is no material development that rationally justifies HHS's change of view on the need for additional rulemaking. They urge HHS to further delay until additional rulemaking is completed, as opposed to specifying a date certain.

Response: HHS disagrees with the commenters. HHS has issued several policies related to lowering prescription drug prices, particularly in the Medicare Program. HHS also notes that as previously discussed in other rulemaking related to this issue, HHS continues to explore other policy documents related to drug pricing in government programs, including the 340B Program.

In addition, commenters have not demonstrated that the finalization of the January 5, 2017, final rule would interfere with HHS's development of these comprehensive policies. As such, HHS does not believe that any further delay is necessary and is changing the effective date of the final rule from July 1, 2019, to January 1, 2019.

The effective date of the final rule has been delayed for nearly two years, which has provided affected entities more than enough time to prepare for its requirements.

Comment: Several commenters urge HHS to specify that the January 5, 2017, final rule's effective date is at least two quarters after the final rule's publication in the **Federal Register**. These commenters raise that in the January 5, 2017, final rule, HHS explicitly noted that the implementation date would be April 1, 2017, the beginning of the next quarter thereby providing a full quarter for implementation. They believe that HHS should follow the same logic here and anticipate publication of a final rule around January 1, 2019, with implementation coinciding with the beginning of the second quarter of 2019, April 1, 2019. They contend that many companies have not completed operational and other process changes because manufacturers fully expected that HHS would revisit the rule and address the rule's significant infirmities. These commenters raise that HHS previously indicated that it would delay the January 5, 2017, final rule to July 1, 2019, and an abrupt change such as this, with fewer than 60 days to implement, makes it difficult for companies—particularly smaller manufacturers—to upgrade their operational systems in time to ensure compliance with the rule. These commenters explain that there is no precedent where the established effective date of a rule imposing substantial compliance burdens on regulated parties was accelerated. Finally, these commenters state that reducing the effective date by six months will negatively affect their ability to come into compliance, which could be compounded by the implementation of the CMP provisions.

Response: Based on the review of the comments received, HHS has determined that the January 5, 2017, final rule will be effective January 1, 2019. The implementation date and the effective date will be the same. Unlike the previous rule, which was effective in the middle of a quarter, this rule is effective at the beginning of a quarter. HHS does not agree that a further delay is necessary for implementation. Manufacturers that offer 340B ceiling prices as of the quarter beginning January 1, 2019, must comply with the requirements of the January 5, 2017, final rule. HHS believes that since the January 5, 2017, final rule was issued, stakeholders have had sufficient time to adjust systems and update their policies and procedures.

Comment: Some commenters urge HHS to publish the ceiling price data on a secure website shortly after January 1, 2019, because the website is essential for effective enforcement of the 340B Program. These commenters explain that entities have no way of detecting overcharges and are at the mercy of manufacturers.

Response: While the ceiling price reporting system is not directly governed by this rule, HHS agrees that covered entities will be able to utilize the system to detect overcharges. As previously stated, the 340B ceiling pricing reporting system is forthcoming, and HHS will convey further updates through its website. HRSA will ensure all impacted stakeholders receive education and training on how to utilize the system.

Comment: Many commenters supported changing the effective date to January 1, 2019, and stated that any other delay would be unreasonable and would continue to reward manufacturers that are flouting ceiling price requirements. The commenters urge HHS to promptly enforce the final rule in order to bring drug companies

into compliance and to ensure that 340B providers are able to ''stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services'' as Congress intended. The commenters state that the rule is entirely consistent with HHS's stated goal of addressing the issue of the rising costs of prescription drugs. These commenters also explain that CMPs are an important deterrent to manufacturers who knowingly overcharge entities and initiatives to strengthen manufacturer transparency should be supported.

Response: For reasons stated above, HHS agrees with the commenters that any other delay is unreasonable and will change the effective date of the January 5, 2017, final rule, to January 1, 2019.

III. Regulatory Impact Analysis

HHS has 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 (September 19, 1980, Pub. L. 96–354), 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 this final rule to change the effective date of the January 5, 2017, final rule from July 1, 2019, to January 1, 2019, will have an economic impact of $100 million or more in any 1 year, and is therefore not designated as an ''economically significant'' final 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, with total purchases estimated to be $19 billion in CY 2017. This final rule to implement the January 5, 2017, final rule would codify current policies regarding calculation of the 340B ceiling price and manufacturer civil monetary penalties. HHS does not anticipate that the imposition of civil monetary penalties would result in significant economic impact.

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

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This rule is not subject to the requirements of Executive Order 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 three percent impact on at least five percent of small entities.

The final 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 Program. While it is possible to estimate the impact of the final rule on the industry as a whole, the data necessary to project changes for specific manufacturers or groups of manufacturers were not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program. For purposes of the RFA, HHS considers all health care providers to be small entities either by virtue of 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 healthcare 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 the purposes of this RFA. HHS estimates

that the economic impact on small entities and small manufacturers will be minimal and less than 3 percent.

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 2018, that threshold is approximately $150 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 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.'' The proposal to rescind the June 5, 2018, final rule and make the January 5, 2017, final rule effective as of January 1, 2019, 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. Changes finalized in this rule would result in no new reporting burdens.

Dated: November 27, 2018.

George Sigounas,

Administrator, Health Resources and Services Administration.

Approved: November 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–26223 Filed 11–29–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1695–CN]

RIN 0938–AT30

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects an error that appeared in the final rule with comment period published in the **Federal Register** on November 21, 2018, entitled ''Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.'' Specifically, this document corrects the public comment period end date. The corrected date is January 2, 2019.

DATES:

Effective date: This correction is effective November 29, 2018.

Comment period: To be assured consideration, comments on the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes in FR Doc. 2018–24243 of November 21, 2018 (83 FR 58818), must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on January 2, 2019.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (410) 786–4617.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2018–24243 of November 21, 2018 (83 FR 58818), entitled ''Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs'' (hereinafter referred to as the CY 2019 OPPS/ASC final rule with comment period), there was an error that is identified and corrected in the Correction of Errors section below.

II. Summary of Errors

On page 58818, we made an error in the **DATES** section under the heading ''Comment period.'' We inadvertently stated that comments on the payment classifications assigned to the interim Medicare Ambulatory Payment Classification (APC) assignments and/or status indicators of new or replacement Level II Healthcare Common Procedure Coding System (HCPCS) codes in the final rule with comment period must be received no later than 5 p.m. EST on December 3, 2018. The corrected date is January 2, 2019, 60 days from the date of filing for public inspection.

III. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA and section 1871(e)(1)(B)(i) mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date of the APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this correcting document does not constitute a rulemaking that would be subject to these requirements. This correcting