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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2345-IFC]

RIN 0938-AT09

Medicaid Program; Covered Outpatient Drug; Delay in Change in Definitions of States and United States

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

ACTION: Interim final rule with comment period.

SUMMARY: The Covered Outpatient Drug final rule with comment period was published in the February 1, 2016 **Federal Register**. As part of that final rule with comment, we amended the regulatory definitions of “States” and “United States” to include the U.S. territories (American Samoa, the Northern Mariana Islands, Guam, the Commonwealth of Puerto Rico, and the Virgin Islands) beginning April 1, 2017. This interim final rule with comment period delays the inclusion of the territories in the definition of “States” and “United States” until April 1, 2020.

DATES: Effective date: These regulations are effective on [Insert date of publication in the **Federal Register**].

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-2345-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways

listed)

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2345-IFC,
P.O. Box 8016,
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By express or overnight mail. You may send written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2345-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.
4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:
 - a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Wendy Tuttle, (410) 786-8690.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. Introduction

The Covered Outpatient Drug final rule with comment period was published in the February 1, 2016 **Federal Register** (81 FR 5170). That final rule with comment period implemented provisions of section 1927 of the Social Security Act (the Act) that were added by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). That final rule with comment period also revised other requirements related to CODs, including key aspects of Medicaid coverage and payment and the Medicaid Drug Rebate (MDR) program under section 1927 of the Act. The rule became effective on April 1, 2016. However, the regulatory definitions of “States” and “United States” under §447.502, included the U.S. territories

(American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) beginning April 1, 2017.

We stated in the preamble to the final rule with comment period that U.S. territories may use existing waiver authority to elect not to participate in the MDR program consistent with the statutory waiver standards. The Northern Mariana Islands and American Samoa may seek to opt out of participation under the broad waiver that has been granted to them in accordance with section 1902(j) of the Act. Puerto Rico, the Virgin Islands, and Guam may use waiver authority under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with the applicable requirements of section 1927 of the Act (81 FR 5203 through 5204).

We also stated in the final rule with comment period that, effective with the change in the definition of “United States,” drug manufacturers would be required to include prices paid by entities located in one of the U.S. territories in the same manner in which they include prices paid by entities located in one of the 50 states and District of Columbia (81 FR 5224) in their calculations of average manufacturer price (AMP) and best price. This change requires manufacturers to include eligible sales and associated discounts, rebates, and other financial transactions that take place in the U.S. territories in their calculations of AMP and best price once the revised definitions of States and United States become effective, regardless of whether the U.S. territories seek to waive participation in the MDR program.

B. Impracticability of Implementation by April 1, 2017

Based on discussions with the U.S. territories, it has become evident that interested U.S. territories could not be ready to implement the program by April 1, 2017, although a few territories have expressed interest in participating once they have made the necessary systems changes. Specifically, the territories need time to develop and change electronic claims

processing systems to identify and report utilization (taking into account all of the complexities in tracking utilization by National drug code numbers) and to match utilization with the unit rebate amounts to generate rebate invoices. Further, these systems must be capable of collecting, reporting, validating and tracking drug utilization on an ongoing basis. In addition, they require extensive advance planning and budgeting. We received comments during the comment period of the proposed rule which requested that CMS delay the inclusion of the territories in the MDR program because the manufacturers and territories would need this additional time to implement provisions necessary to include territories in all aspects of the MDR program. We took these comments into consideration and in the final rule delayed the inclusion of the territories into the definitions of States and United States until 1 year after the effective date of the final rule (81 FR 5203, 5204). Despite this 1 year delay, it has since become evident that we underestimated the timeline required, particularly in light of other demands on territorial systems development and the fact that the territories are at various stages of planning and development with respect to these systems. While the U.S. territories have the ability to seek a waiver from the requirements that they would have to meet when classified as “states,” doing so would impose some burdens on a territory, particularly for those territories that are not included in the broad waiver authority under section 1902(j) of the Act. Moreover, waivers under section 1115 of the Act are limited to requirements applicable to states or territories under section 1902(a) of the Act, and would not apply to the requirements placed on drug manufacturers that sell in the territories. These manufacturers cannot be waived from the section 1927 of the Act requirements under which manufacturers must include sales that take place in the U.S. territories when determining AMP and best price.

We have heard from various stakeholders who have reiterated many of the concerns that were summarized in the final rule with comment (81 FR 5224) that drug manufacturers will

likely be prompted to increase drug prices, including prices paid by U.S. territory Medicaid programs. This would result in the U.S. territories that receive a waiver realizing an increase in their Medicaid drug costs without the offsetting benefit of receiving Medicaid rebates.

Furthermore, the increase in Medicaid costs could adversely impact territories because of their Medicaid funding cap.

II. Provisions of the Interim Final Rule

For the reasons discussed in the Background section, this interim final rule with comment period amends the regulatory definitions of “States” and “United States” under §447.502 to include the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) beginning April 1, 2020 rather than April 1, 2017.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

As discussed in section I.B. of this interim final rule with comment period, in light of the longer time frames needed by territories for planning, budgeting and developing systems necessary to implement the Medicaid drug rebate program, the competing demand on system development resources, and the long time frames for manufacturer pricing determinations, we believe it is necessary to provide territories and manufacturers with advance notice of any change in the timing for the inclusion of territories in the Medicaid drug rebate program. Issuance of a

proposed rule would be impracticable because it would result in a notice of the final rule without sufficient time for territories or manufacturers to adjust their actions to take into account the revised timing. Thus, we find good cause to waive the requirement for proposed rulemaking because the short time frame before the inclusion of territories would otherwise take effect does not permit sufficient time to both undertake proposed rulemaking and provide the necessary advance notice for territories and manufacturers to meaningfully adjust planning and systems development to accommodate the revised timing. Furthermore, we find good cause to waive the requirement for proposed rulemaking because it would be contrary to public interest to delay notifying manufacturers of the change in the timing of the territorial inclusion in light of the potential that, absent sufficient advance notice, drug manufacturers may raise prices on drugs sold in the territories and thereby increase drug costs for both Medicaid and non-Medicaid consumers in the territories.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

IV. Collection of Information Requirements

This rule's delay in including the territories in the definitions of "States" and "United States" until April 1, 2020, does not impose any new or revised information collection, reporting, recordkeeping or third-party disclosure requirements or burden. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this

preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

We have examined the impact of this 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 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this interim final rule with comment period will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis

if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this interim final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately \$146 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

- 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

- 2. Section 447.502 is amended by revising the definitions of “States” and “United States” to read as follows:

§447.502 Definitions.

* * * * *

States means the 50 States and the District of Columbia and, beginning April 1, 2020, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

United States means the 50 States and the District of Columbia and, beginning April 1, 2020, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

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CMS-2345-IFC

Dated: October 5, 2016.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2016-27423 Filed: 11/14/2016 8:45 am; Publication Date: 11/15/2016]