regardless of whether it is a reimbursement, allowance, or direct payment to a vendor, it is considered ''supplemental wages'' as defined in 26 CFR 31.3402(g)–1(a) (see also IRS Publication 15, Employer's Tax Guide). You owe taxes on the WTA itself because, like most other relocation allowances, it is taxable income. To reimburse you for the taxes on the WTA itself, your agency computes the WTA by using the grossed-up withholding formula below and the appropriate supplemental wage rate, as specified in IRS Publication 15. This rate, along with examples of how to calculate the WTA, is published in an FTR bulletin available at *https://gsa.gov/ftrbulletins*. The formula for calculating the WTA is:

$$WTA = R/(1 - R) \times Expense$$

Where R is the withholding rate for supplemental wages.

Note to § 302–17.24: Your agency must deduct withholding for FICA (Medicare and Social Security), as the WTA does not cover such expenses.

§ 302–17.30 [Amended]

■ 16. Amend § 302–17.30 by removing from paragraph (a) ''25 percent''.

■ 17. Amend § 302–17.40 by adding a sentence to the end of paragraph (b) and revising paragraph (c) to read as follows:

§ 302–17.40 How does my agency calculate my CMTR?

* * * * *

(b) * * * Examples of how to calculate the CMTR are published in an FTR bulletin available at *https://gsa.gov/ftrbulletins*.

(c) The formula for calculating the CMTR is:

$$CMTR = F + (1 - F)S + (1 - F)L$$

Where:

F = Your Federal marginal tax rate
S = Your state marginal tax rate, if any
L = Your local marginal tax rate, if any

* * * * *

§ 302–17.60 [Amended]

■ 18. Amend § 302–17.60 by removing paragraph (d) and its accompanying table.

■ 19. Amend § 302–17.61 by revising paragraph (b) to read as follows:

§ 302–17.61 Is the WTA optional under the two-year process?

* * * * *

(b) When deciding whether or not to receive the WTA, you should consider the following:

(1) If you expect that your marginal Federal tax rate will be equal to or higher than the supplemental wage rate for the calendar year in which you received the majority of your relocation reimbursements, you may want to elect to receive the WTA.

(2) If you expect that your marginal Federal tax rate will be less than the supplemental wage rate for the calendar year in which you received the majority of your relocation reimbursements, you may want to decline receiving the WTA to avoid or limit possible overpayment of the WTA, the so-called ''negative RITA'' situation. In a ''negative RITA'' situation, you must repay some of the WTA in Year 2. However, even if your marginal Federal tax rate will be less than the supplemental wage rate, you may want to accept the WTA so that your initial reimbursement is larger.

(3) Examples showing relocation allowances paid by accepting or declining the WTA are published in an FTR bulletin available at *https://gsa.gov/ftrbulletins*.

§ 302–17.62 [Amended]

■ 20. Amend § 302–17.62 by removing the last sentence from paragraph (b).

[FR Doc. 2019–25411 Filed 11–22–19; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2345–IFC3]

RIN 0938–AT09

Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories 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 period, we amended the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, the Commonwealth of Puerto Rico, and the Virgin Islands of the United States) beginning April 1, 2017. Subsequently, in the November 15, 2016 **Federal Register**, we published an interim final rule with comment period (IFC) to further delay the inclusion of the U.S. territories in the regulatory definitions of ''States'' and ''United States'' until beginning April 1, 2020. This IFC further delays the inclusion of the territories in the definitions of ''States'' and ''United States'' until beginning April 1, 2022.

DATES:

Effective date: These regulations are effective on January 24, 2020.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 24, 2020.

ADDRESSES: In commenting, please refer to file code CMS–2345–IFC3. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three 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–IFC3, 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–IFC3, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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 website as soon as possible after they have been received: *http://regulations.gov*. Follow the search instructions on that website to view public comments.

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) (final rule). The final rule 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). The final rule 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 final rule became effective on April 1, 2016. However, the regulatory definitions of ''States'' and ''United States'' under § 447.502 were amended to include 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 that U.S. territories may use existing waiver authority to elect not to participate in the MDR program consistent with the statutory waiver standards. Specifically, 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 that, effective with the change in the definition of ''United States'', drug manufacturers would be required to include prices paid by entities in 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. Interim Final Rule With Comment Period Published November 15, 2016

Based on initial discussions with the U.S. territories, it became evident that interested U.S. territories would not be ready to implement the program by April 1, 2017. Specifically, the territories needed 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 COD proposed rule, which requested that we 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), that is, beginning April 1, 2017. However, despite this 1-year delay, it became 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 for 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 heard from various stakeholders who reiterated many of the concerns that were summarized in the final rule (81 FR 5224) that drug manufacturers would 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. For these reasons, in the November 15, 2016 **Federal Register**, we published an interim final rule with comment period (IFC) (81 FR 80003) that amended the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories beginning April 1, 2020 rather than April 1, 2017 (interim final rule).

C. Impracticability of Implementation by April 1, 2020

Based on further discussions with the U.S. territories since the publication of the interim final rule, we have learned that while the territories are making progress towards developing their Medicaid Management Information Systems (MMIS), only one territory would be prepared to implement the MDR program by April 1, 2020. In particular, Puerto Rico has been delayed in its development of the necessary components of the MMIS system due to the natural disasters experienced by the territory over the past 2 years, and has specifically requested another delay in the inclusion of U.S. territories in the definitions of ''States'' and ''United States''.[1]

We considered whether it would be feasible to delay the inclusion of U.S. territories in the definitions of ''States'' and ''United States'' for only those territories that are not prepared to implement the MDR program by April 1, 2020. However, since all five territories are referenced in each definition, the effect of a delay for only certain territories would possibly modify the previously finalized definitions rather than merely delay their effective dates. Additionally, a delay for only certain territories would only be feasible if we were also able to expressly permit manufacturers to continue treating sales to the territories not yet included in the definitions of ''States'' and ''United States'' as excluded from their calculations of AMP and best price. Such changes would require us to

[1] Angela M. Avila Marrero, Executive Director of Puerto Rico Health Insurance Administration (ASES for its acronym in Spanish) letter to John Coster, Director of the Division of Pharmacy, Disabled and Elderly Health Programs Group, Centers for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, March 21, 2019.

undertake full notice and comment rulemaking ahead of the April 1, 2020 effective date. As discussed in section III. of this IFC, we have determined that there is insufficient time to undertake full notice and comment rulemaking ahead of the April 1, 2020 effective date.

As discussed in section I.B. of this IFC, the U.S. territories have the ability to seek a waiver from the requirements that they would have to meet when classified as ''States'', but doing so would impose some burdens on a territory, and 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 covered outpatient drugs 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. As stated previously, we heard from various stakeholders that drug manufacturers would likely be prompted to increase drug prices, including prices paid by U.S. territory Medicaid programs. While territories that need more time to prepare to implement the MDR program could seek the appropriate waiver, it would result in such territories realizing an increase in their Medicaid drug costs without the offsetting benefit of receiving Medicaid rebates.

II. Provisions of the Interim Final Rule With Comment Period

For the reasons discussed in section I.C. of this IFC, this IFC 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, 2022 rather than April 1, 2020.

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 sections I.B. and C. of this IFC, in light of the longer time frames needed by territories for planning, budgeting and developing systems necessary to implement the MDR program, the competing demand on system development resources, the long time frames for manufacturer pricing determinations, and particularly delays caused by the natural disasters experienced by Puerto Rico over the past 2 years, 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 MDR program.

As previously stated, we considered whether it would be feasible to delay the inclusion of U.S. territories in the definitions of ''States'' and ''United States'' for only certain territories, but the effect of such a delay would possibly modify rather than merely delay the previously finalized definitions. Additionally, such a delay would only be feasible if we were to undertake full notice and comment rulemaking ahead of the April 1, 2020 effective date to expressly permit manufacturers to continue treating sales to the territories not yet included in the definitions of ''States'' and ''United States'' as excluded from their calculations of AMP and best price. We have determined that there is insufficient time to undertake full notice and comment rulemaking ahead of the April 1, 2020 effective date. Issuance of a proposed rule would be impracticable, and contrary to public interest such that a delay of the inclusion of U.S. territories in the definitions of ''States'' and ''United States'' would not become effective until after public comments are submitted, considered, and addressed in a final rule, which would not become effective until after the April 1, 2020 effective date.

Thus, we find good cause to waive the requirement for proposed rulemaking because the short time frame remaining 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 IFC further delays the inclusion of the U.S. territories in the regulatory definitions of ''States'' and ''United States'' under § 447.502 until beginning April 1, 2022. This delay does not impose any new or revised information collection requirements or burden. Consequently, there is no need for review of this action 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 IFC 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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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). This rule does not reach the economic threshold of an annual effect

on the economy of $100 million or more and thus is not considered a major rule. To estimate the potential impact of this rule, we reviewed current levels of Medicaid prescription drug expenditures in the 5 U.S. territories with Medicaid programs. In 4 of the 5 territories, total prescription drug spending in fiscal year (FY) 2018 was about $29 million (American Samoa, Guam, Northern Mariana Islands, and the U.S. Virgin Islands) as reported in the CMS–64 financial management reports. In Puerto Rico, prescription drug spending was not reported separately. We estimated prescription drug spending by assuming that 17 percent of managed care expenditures went towards prescription drugs; 17 percent is consistent with our analysis of managed care expenditures on drugs in Medicaid and data from the Medicaid drug rebate data system. Using this assumption, we estimated that drug expenditures in Puerto Rico were about $366 million in FY 2018. In total, we estimate Medicaid drug spending in the 5 territories was about $395 million in FY 2018.

Using this estimate as a baseline for territory spending on prescription drugs in Medicaid, we believe delaying the inclusion of the territories in the definitions of ''States'' and ''United States'' does not reach the economic threshold of an annual effect on the economy of $100 million or more for the following reasons. First, while territory prescription drug expenditures after rebates may be lower once territories participate in the MDR Program, this effect may be partially offset by an increase in gross prices when manufacturers are required to report territory drug sales for Medicaid Best Price, and therefore the impact of a delay in territory participation in the MDR Program is expected to be modest.

Second, as a condition of joining the MDR Program the territories will be required to expand their drug coverage to include every COD of every manufacturer that has a National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services. Currently, the territories have significantly more flexibility in establishing their own drug formularies and can choose which drugs of which manufacturers they will cover. We believe this may also lead to increased prescription drug spending and offsetting some portion of the reductions in net drug spending due to the rebates.

Third, given the varying sizes of the territories (in population), it is nearly impossible to claim that all territories will experience the same economic impact if they were to join the MDR program. For example, based on the information from the CMS–64 financial management reports American Samoa's drug spending represented 1 percent of its total Medicaid spending compared to the 21 percent in the U.S. Virgin Islands.

Due to limitations in the data from the territory Medicaid programs, we are unable to quantify these effects. However, we believe that it is likely the financial impact of extending the Medicaid drug rebates to territory programs is less than $100 million.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of lnformation and Regulatory Affairs designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 IFC 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 IFC 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 2019, that threshold is approximately $154 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.

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 interim final rule's designation under E.O. 13771 will be informed by public comments received.

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 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 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, 2022, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands and American Samoa.

United States means the 50 States and the District of Columbia and, beginning April 1, 2022, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands and American Samoa.

* * * * *

Dated: October 31, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 19, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–25514 Filed 11–21–19; 11:15 am]

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