Government of the Virgin Islands of the United States
DEPARTMENT OF HUMAN SERVICES
Medicaid Division

UNITED STATES VIRGIN ISLANDS DEPARTMENT OF HUMAN SERVICES MEDICAID PROGRAM

AMENDED PUBLIC NOTICE

January 19, 2023

Introduction:

The Virgin Islands Medicaid Program, administered under the Department of Human Services, is providing public notice that it is intending to submit to the federal Centers for Medicare & Medicaid Services (CMS) a request for a waiver under Section 1115 of the Social Security Act (the Act). The intent of this public notice is to inform you of the following:

1. That we are intending to submit this Section 1115 waiver to initially waive the mandate that the Virgin Islands Medicaid Program participate in the federal Medicaid Drug Rebate Program (MDRP);
2. Provide the public with a 30 day comment period to review and comment on the Section 1115 waiver we are submitting. This comment period will begin on January 20, 2023 and end on February 20, 2023; and
3. Inform you that we will hold two public hearings to receive comments on the Section 1115 Waiver proposal.

The Virgin Islands Medicaid Program is applying under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with Section 1927 of the Act that mandates participation in the MDRP, and the Medicaid program is requesting that the waiver be effective January 1, 2023.

Overview:

The MDRP is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. All fifty states and the District of Columbia cover prescription drugs under the MDRP, which is authorized by Section 1927 of the Act.

The MDRP is designed to offset overall costs of prescription drugs under the Medicaid Program by requiring drug manufacturers to enter into, and have in effect, a National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs.

Manufacturers are responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program.

In addition to signing an NDRA, drug manufacturers are required to enter into agreements with two other Federal programs in order to have their drugs covered under Medicaid: a pricing agreement for the Section 340B Drug Pricing Program, administered by the Health Resources and Services Administration, and a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule. The Virgin Islands Medicaid Program currently has two (2) Federally Qualified Health Centers (FQHC) that participate under the Section 340B Drug Pricing Program. The medications dispensed by these two providers are not eligible for the rebate since they in essence have already been discounted under the manufacturer pricing agreement for the Section 340B Drug Pricing Program.

On February 1, 2016, the CMS published the "Medicaid Program; Covered Outpatient Drug" Final Rule with Comment Period (CMS-2345-FC) in the Federal Register (81 FR 5170). As part of that final rule with comment period, CMS 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 U.S. Virgin Islands) beginning April 1, 2017. Inclusion of the territories in the definitions of "States" and "United States" requires Territories to participate in the MDRP. Additionally, CMS indicated in the "Covered Outpatient Drug" final rule that territories are able to use existing waiver authority under Title XIX of the Act to elect not to participate in the MDRP, consistent with statutory provisions (81 FR 5170, 5204).

On November 15, 2016, CMS published an interim final rule with comment period 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). However, on November 21, 2019, CMS issued "Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in the Definitions of States and United States" Interim Final Rule with comment period that further delayed the inclusion of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands) in the definitions of "States" and "United States" from April 1, 2020 until April 1, 2022. Then on November 19, 2021, the inclusion was further delayed mainly due to the public health emergency until January 1, 2023. Because of the inclusion of territories in the definition of States and United States, the Virgin Islands Medicaid Program will be required to participate in the MDRP effective January 1, 2023. However, the Virgin Islands Medicaid Program is allowed to use the 1115 waiver authority to elect not to participate in the MDRP.

In light of the statutory MDRP directive, the Virgin Islands Medicaid Program is seeking an 1115 waiver initially exempting it from the requirement to participate in the MDRM. The Virgin Islands Medicaid Program is requesting that the exemption from participating in the MDRP be effective from January 1, 2023.

Executive Summary of Section 1115 Waiver:

The Virgin Islands is proposing to conduct a cost-benefit analysis under this Section 1115 Demonstration Waiver to determine the financial and program viability and benefit of participation in the MDRP program or to continue to waive participation in Section 1902(a)(54) and continue our fee-for-service drug program with modifications under the terms of the demonstration rather than under the requirements of Section 1927 of the Act.

Since the cost-benefit analysis will take some time to complete, and this process will extend beyond the January 1, 2023 implementation date for the MDRP, the Virgin Islands is requesting, at this time, a Section 1115 demonstration waiver to completely waive participation in the Federal MDRP.

Upon completion of the cost-benefit analysis, and the assessment of its results, the Virgin Islands Medicaid Program will determine whether to continue to maintain the Section 1115 waiver and continue its current drug program with modifications rather than the requirements of Section 1927, or end the Section 1115 waiver, and implement the MDRP.

Historically, Medicaid funding for the Virgin Islands has been limited annually under Section 1108 of the Act. Additionally, the federal matching rates for the Virgin Islands and the other territories are set statutorily. Those matching rates currently range from 83% to 90%. In contrast, state federal matching rates are set using a formula based on state per capita income, reflecting the relative financial ability of states to fund their share of the program from their own revenues. In addition, states are not capped in the amount of federal funding they may receive annually.

It is unclear how MDRP participation may impact the USVI program, beneficiaries, and providers, so it is important that the USVI study and consider potential outcomes prior to making a final determination. Although it is anticipated that the MDRP will offset costs of prescription drugs under the USVI Medicaid Program, the USVI wants to study the impacts on pharmacy providers, closed formularies, individual rebate contracts, and rebates passed on directly to the territory and compare those to the costs of its current drug program.

In addition, and unlike many states, the USVI has no in-house Medicaid pharmacy staff, further complicating MDRP participation.

Demonstration Goals and Objectives:

The overall goals of the cost-benefit analysis demonstration are to evaluate: 1) whether joining MDRP will be both financially advantageous and ensure continued access to pharmacy services and benefits for Medicaid beneficiaries in the USVI and the section 1115 demonstration waiver is no longer necessary; or 2) whether the USVI should continue this 1115 demonstration waiver and their fee-for-service drug program with modifications outside of the requirements of Section 1927 of the Act.

Program, Beneficiary, and Provider Impacts:

During the course of the performance of the cost-benefit analysis under the Section 1115 waiver there will be no changes in the current Virgin Islands Medicaid Program for our beneficiaries or our providers resulting from the performance of this cost-benefit study, including the provision of our Medicaid Program prescription drug program. The USVI does not propose any changes to the Medicaid health care delivery system during this Demonstration including its fee-for service drug program. Demonstration enrollees will include all Medicaid enrollees, and they will continue to receive services through the Territory's fee-for-service delivery system. Therefore, we do not expect that the Section 1115 demonstration waiver study will have any impact on Medicaid beneficiaries, covered prescription drugs, pharmacy providers, or the overall operation of the current fee-for-service drug program.

Expenditure and Enrollment Impacts:

We do not expect any significant changes in drug expenditures, overall program expenditures, or in enrollment during the course of the Section 1115 Waiver cost-benefit analysis. There are currently 14 on-island pharmacies. The Medicaid Program has been averaging approximately $18 million per year in total drug expenditures over the past 4.5 years. Currently there are over 37,000 Medicaid enrollees. Enrollees have been increasing approximately 2,500 per year as a result of various Medicaid eligibility expansions. We do not

expect enrollment to be impacted by this Section 1115 waiver. Therefore, during the course of this Section 1115 waiver we expect normal growth in terms of enrollment, drug expenditures, and overall program expenditures to continue. Additionally, since overall federal Medicaid expenditures are subject to an annual allotment, there is no risk of an impact on the federal budget.

Hypothesis and Evaluation Questions:

The focus of the demonstration evaluation will be to study the unique pricing and geographical challenges of On-Island Pharmacies relative to the Covered Outpatient Drugs (COD) Final Rule, and how participation in the MDRP would impact their current status as pharmacy providers for the USVI Medicaid program. Additionally, the Demonstration will evaluate the possible net MDRP cost savings for the USVI Medicaid program; and comparing that to the impact of the potential additional costs from the MDRP requirements for reimbursing at Actual Acquisition Cost (AAC), higher professional dispensing fees (PDF) based on conducted survey, the administrative costs of implementation, and ongoing operation of the MDRP.

Hypothesis: Would the USVI joining the MDRP, factoring its additional costs and savings, be more financially and programmatically advantageous to the USVI Medicaid Program than continuing its current fee-for-service Medicaid drug program with modifications?

Questions:

1. Will joining the MDRP assure the network capacity of On-Island Pharmacy providers remains at least consistent with the existing capacity prior to implementation?
2. Assuming that the higher professional dispensing fee will impact either option (i.e., continuing current program or moving to AAC), what is the cost differential between the current drug program and MDRP?
3. What is the current cost and rebates of products?
4. What will be the administrative/vendor cost to initially implement the program and administer the program on an ongoing basis?
5. What additional savings could be gained by entering into CMS approved supplemental rebate agreements or by participating in the newly approved multiple best price (value-based purchasing) purchasing groups?

Waiver and Expenditure Authorities:

The CMS final rule (CMS-2345-FC) allows the territories to "opt out" of the MDRP and Section 1115(a)(1) of the Act allows us to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act that requires the Virgin Islands Medicaid program to participate in the MDRP. Thus, the USVI is requesting Section 1115(a)(2) expenditure authority to maintain our current fee-for-service Medicaid drug program delivery system for pharmaceutical drugs.

Public Review and Comment Process:

The complete version of the application and copy of this full notice will be available for public review on the Virgin Islands Department of Human Services website U.S. Virgin Islands DHS (gov.vi) under news and events section.

Paper copies are available to be picked up in person at the following Virgin Island Department of Human Services locations:

STT/STJ: Medicaid Director's Office
Knud Hansen Complex, Bldg. A
1303 Hospital Ground
St. Thomas, VI 00802

STX: Medicaid Director's Office
#47 Mars Hill Complex
Frederiksted, VI 00840

Two public hearings will be held regarding the Demonstration application:

1. The Public Hearing for St. Thomas will be held virtually on January 23, 2023 from 2:00PM-3:00PM (AST). The following is the Teams Meeting link to that hearing:

   Join conversation (microsoft.com)

2. The Public Hearing for St. Croix will be held virtually on January 25, 2023 (Postponed from January 20, 2023) from 10:00AM-11:00AM (AST). The following is the Teams Meeting link to that hearing:

   Join conversation (microsoft.com)

Public comments may be submitted up to 30 days of the date of this notice (February 20,2023). Hard copy questions or public comments may be addressed to the Virgin Islands Medicaid Director at the above two addresses or hand delivered to the Virgin Islands Medicaid Director at the above two addresses up to 30 days of the date of this notice (February 20, 2023). Additionally, public comments may be submitted to Gary Smith via email at providerrelationsmap@dhs.vi.gov.

After the Virgin Islands Medicaid reviews comments submitted during this public comment period, it will submit a revised application to CMS. Interested parties will also have an opportunity to officially comment during the 30-day federal public comment period; the submitted application will be available for comment on the CMS website at https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html.