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

March 27, 2023

Ms. Heather Ross
Director,
Division of Eligiblity & Coverage Demonstrations
Centers for Medicaid and CHIP Services
Center for Medicaid and Medicaid Services
1115demorequests@cms.hhs.gov

Dear Ms. Ross:

Subject: USVI Submission of MDRP Section 1115 Wavier

The USVI Department of Human Services, Medicaid Program, submits the enclosed Section 1115 waiver proposal and 6 attachments. The intent of the Section 1115 waiver is to exempt the USVI from the Medicaid Drug Rebate Program (MDRP) under Section 1927 effective January 01, 2023 and continue our current fee-for service drug program. During this waiver period we will conduct a cost benefit analysis to determine the financial and program viability of participation in the MDRP or continuing our current fee-for-service program with modifications.

Pursuant to 42 CFR 431.408 the USVI completed the required public notice process as described in the demonstantion proposal and documented in the 6 attachments to that proposal. The USVI did not receive any written comments to our proposal and received one verbal comment during the hearing process. None of this impacted the draft waiver proposal.

Thank you for you help in the development of this 1115 waiver proposal and for you consideration of this request for formal approval. If you have an questions, do not hesitate to contact me at Gary.Smith@dhs.vi.gov.

Sincerely,

[redacted]

Gary A. Smith
Medicaid Director

U.S. Virgin Island Medicaid Drug Rebate Program (MDRP)

1115 Waiver Demonstration Application

U.S. Virgin Islands - Medicaid Drug Rebate Program (USVI-MDRP) 1115 Waiver Demonstration

March 2023 – Final CMS Submission

Contents

SECTION I. NARRATIVE SUMMARY OF THE 1115 WAIVER DEMONSTRATION

A. Introduction and General Background Information on the Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP), authorized by Section 1927 of the Social Security Act, is a program that includes Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers to help to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. All 50 states and the District of Columbia cover prescription drugs under the MDRP.

The MDRP is designed to offset overall costs of prescription drugs under the Medicaid Program by requiring drug manufacturers to have a National Drug Rebate Agreement (NDRA) with the Secretary of the U.S. 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 respective state 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: 1) a pricing agreement for the Section 340B Drug Pricing Program, administered by the U.S. Health Resources and Services Administration; and 2) a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule.

On February 1, 2016, 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 Rule, 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" allows Territories to participate in the MDRP. Additionally, CMS indicated in the Rule that territories are able to use existing waiver authority under Title XIX of the Social Security Act to elect not to participate in the MDRP, consistent with statutory provisions (81 FR 5170, 5204).

In two subsequent interim final rules issued in November 2016 and November 2019 respectively, CMS delayed the effective date for territory participation in the MDRP. The first rule change delayed the effective date from April 1, 2017 to April 1, 2020, and the next delayed it by two additional years to April 1, 2022 and the implementation date to January 1, 2023.

B. Application Request and Rationale for Proposed 1115 Waiver Demonstration

The CMS Final Rule (CMS-2345-IFC) permits U.S. territories to use existing waiver authority to elect not to participate in the MDRP consistent with the statutory waiver standards. Specifically, the Northern Mariana Islands and American Samoa may seek to opt out of participation in the MDRP under the broad waiver authority in section 1902(j) of the Social Security Act. Puerto Rico, the U.S. Virgin Islands (USVI), and Guam may use waiver authority under section 1115(a)(2) 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). The Virgin Islands has elected to conduct a cost-benefit analysis under an 1115 demonstration to determine the financial viability and benefit of participation in the MDRP program or to waive participation in Section 1902(a)(54) and continue their fee-for-service drug program with modifications under the terms of the demonstration rather than under the requirements of 1927.

However, 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.

Section 1902(a)(54) of the Social Security Act requires that a State Plan, which provides medical assistance for covered outpatient drugs as defined in Section 1927(k), must comply with the requirements of Section 1927. Therefore, 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.

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

Historically, Medicaid funding for the USVI has been limited under the Section 1108 of the Social Security Act. The FMAP for the USVI and the other territories is set statutorily, and is currently permanently set at 83%. In contrast, state FMAPs 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.

It is unclear how MDRP participation may impact the USVI 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.

C. Demonstration Goals

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.

D. Demonstration Population

The USVI has over 37,000 Medicaid enrollees. The number of enrollees has grown approximately 2,500 per year over the last ten years as a result of various eligibility expansions.

E. Eligibility

The USVI covers eligibility categories as follows:

Eligibility Category	**Federal Regulatory Citation**
Cash Assistance/TANF-OAA	42CFR435.100-170
MAGI Populations: Children Parents Single Adults	42CFR435.603
Title IV-E	42CFR435.403(g)
ABD	42CFR435.20
Medically Needy	42CFR435.308
Dual Eligible	42CFR411.163
Post Eligibility Institutionalized	42CFR435.733

F. Medicaid Delivery System and Covered Benefits

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 will have any impact on Medicaid beneficiaries, covered prescription drugs, pharmacy providers, or the overall operation of the current fee-for-service drug program.

II. HYPOTHESIS AND QUESTIONS

The focus of the demonstration evaluation will be to study the unique pricing and geographical challenges of On-Island Pharmacies relative to 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, and the administrative costs of implementation, and ongoing operation of the MDRP.

A. Hypothesis and Questions

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?

The above questions come with a myriad of sub questions. For example, if the USVI did not join the MDRP but restructured their current drug program would that be a cost saving? These types of analyses will be included in the final report and ultimate determination.

B. Financial Data

VI Drug Claims Actuals & projections FY 2018 - FY 2025			
FY	**Total**	**Federal**	**VI**
Actuals			
2018	10,841,838	10,253,678	588,160
2019	15,394,900	15,394,900	0
2020	17,994,422	16,543,634	1,450,788
2021	27,211,312	24,272,492	2,938,820
2022	29,534,156	26,344,468	3,189,688
Totals	100,976,628	92,809,172	8,167,456
Projections			
2023	32,055,285	26,605,887	5,449,399
2024	34,791,626	28,877,050	5,914,576
2025	37,761,550	31,342,086	6,419,463
Totals	104,608,462	86,825,023	17,783,438

C. Pharmacy Provider Participation

Current Program Year – Pharmacy Provider Data

2022: 14 On-Island Pharmacy Providers. Drug expenditures have been averaging approximately $20 million per year over the past 5 years.

SECTION III. METHODOLOGY

The Demonstration will employ both quantitative and qualitative design techniques. The quantitative analysis will rely on evaluation of pharmacy expenditures relative to expected (Brand, Generic and Inflationary percentages) cost savings to measure projected rebates. The qualitative analysis will rely on information gathered through stakeholder engagement.

A. Evaluation Design

Qualitative methods will be employed to evaluate:

- Any adverse effects to On-Island Pharmacy Providers should USVI participate in the MDRP; and
- How Participation in the MDRP would impact On-Island Pharmacy Provider status in the USVI Medicaid program.

Quantitative methods will be used to evaluate:

- MDRP rebate savings relative to current program costs.

B. Data Sources

The Demonstration will rely on data developed by the USVI PBM and the USVI MMIS and any other data necessary from the pharmacies, contractors, and USVI Department of Health and Human Services. Drug prices and costs associated with the MDRP will be provided by CMS.

SECTION IV. COMPLIANCE WITH PUBLIC NOTICE PROCESS

Public notice was published on the DHS website at the following link U.S. Virgin Islands DHS (gov.vi) under the "USVI Medicaid Drug Rebate Program" section. The full public notice and template were published on January 09, 2023 and the amended full public notice was published on January 19, 2023. The abbreviated public notice was published on February 14, 2023. A screenshot of the DHS website posting is attached.

Two public hearings were conducted virtually via Microsoft Teams on January 23, 2023 and January 25, 2023. There was only one question received during the hearings to confirm that 340B drugs were part of the cost benefit analysis. Notes of the two public hearings, the hearing PowerPoint presentation, and email notice to pharmacies of Public Hearing are attached.

The Public Comment Period was completed on February 20, 2023. No written or email public comments were received to date.

SECTION V. STATE CONTACT AND SIGNATURE

State Medicaid Director Name: Mr. Gary A. Smith

Telephone Number: 340-642-6278

E-mail Address: Gary.Smith@dhs.vi.gov

Authorizing Official (Typed): Gary A. Smith

Authorizing Official (Signature): [redacted]

Date:

List Of Attachments:

1. Screenshot of Public Notice Posting on DHS Website.
2. Full Public Notice
3. Abbreviated Public Notice
4. Notes From Two Public Hearing
5. PowerPoint Presentation For Hearings
6. Email Notice Of Public Hearings.

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.

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

UNITED STATES VIRGIN ISLANDS DEPARTMENT OF HUMAN SERVICES

PUBLIC NOTICE

February 14, 2023

The Centers for Medicare & Medicaid Services (CMS) published the "Medicaid Program; Covered Outpatient Drug" Final Rule with Comment Period (CMS-2345-FC) in the Federal Register (81 FR 5170). This rule allows inclusion of the territories in the definitions of "States" and "United States" and allows territories to participate in the federal Medicaid Drug Rebate Program (MDRP) effective January 01, 2023. Additionally, CMS indicated that territories are able to use existing waiver authority under Section 1115 of the Social Security Act to elect not to participate in the MDRP.

The USVI is proposing under Section 1115 of the Social Security Act, to conduct an evaluation of whether the USVI Medicaid program should enter into the MDRP, or continue under its current fee-for-service Medicaid drug program. The evaluation will study the impact of the costs and benefits of participation in the MDRP on the USVI Medicaid drug program, its providers, and its beneficiaries in the USVI. The evaluation will compare the costs and benefits of MDRP participation to the current Medicaid drug program and possible modifications of that program without entering into the MDRP.

In compliance with Federal requirements at 42 CFR 431.408, the USVI Department of Human Services is inviting public comment on this proposed evaluation. During the period of this evaluation, there will be no changes to the USVI Medicaid drug program eligibility, benefits, coverage, or reimbursement. Paper copies of the proposed evaluation are available from the USVI Department of Human Services at the following locations:

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

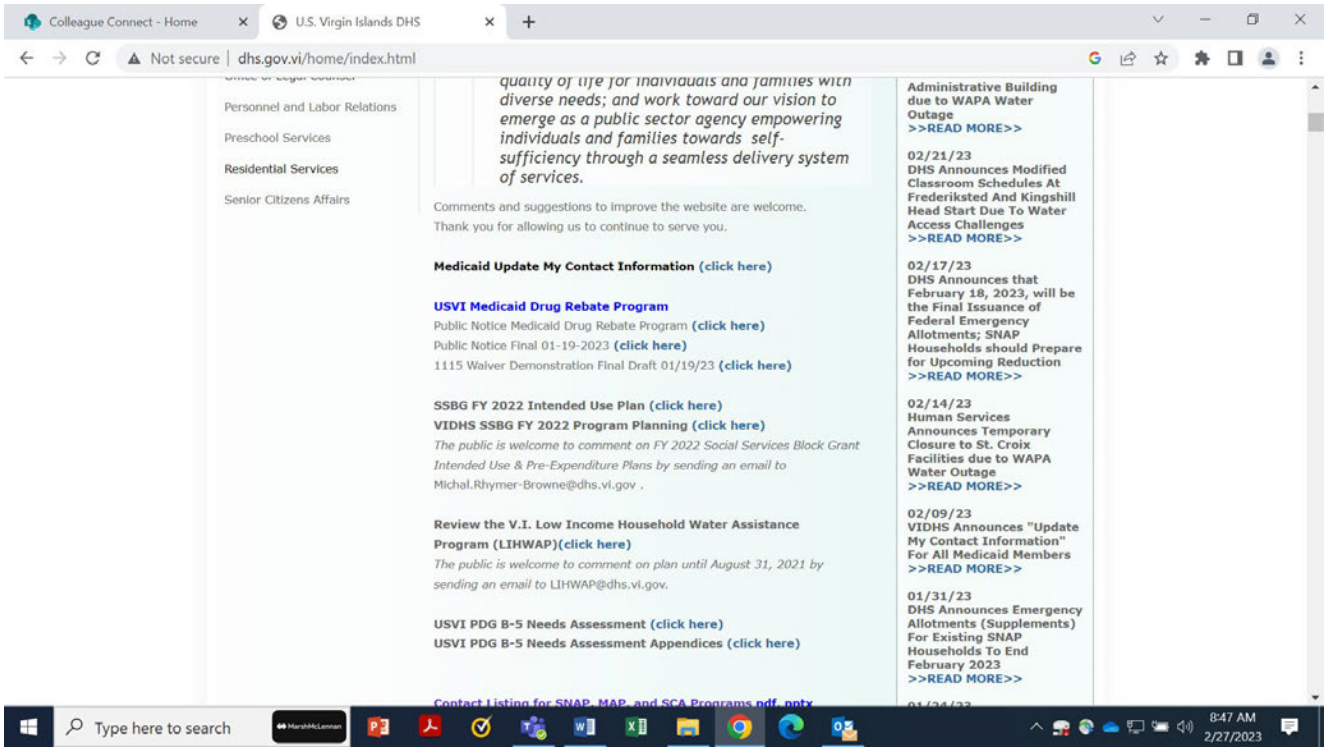
STX: Medicaid Director
#47 Mars Hill Complex
Frederiksted, VI 00840

Copies are also available on the DHS website at http://www.dhs.gov.vi/home/index.html under the Section entitled "USVI Medicaid Drug Rebate Program."

Public written comments are due no later than February 20, 2023. The comments may be submitted to DHS at the addresses noted above or via email at providerrelationsmap@dhs.vi.gov .

In addition, the USVI conducted two virtual public hearings on January 23, 2023 and January 25, 2023. Any questions should be sent to the USVI Medicaid Program Director at the addresses listed above.

http://www.dhs.gov.vi/home/index.html



Meeting Title	1115 Waiver: Public Hearing 1
Date	Monday, January 23, 2023
Time and Location	1 – 2 p.m. ET via Teams
Dial-In Information	Dial: 1-207-352-3680 Meeting ID: 264 970 419 048
Web Conference	URL: Click here to join the meeting Passcode: T6eM6B
Meeting Facilitator	Gary Smith
Note Taker	Savana Gordon
Attendees	**VI Medicaid Commissioner:** Kimberley Causey-Gomez **Medicaid Assistant Commissioner:** Michael Rhymer-Browne **VI:** Gary Smith, Beverly Joseph, Carla Huggins, Karen Virgil, Lydia Magras **SGRX Health:** Ime Ekpenyong, Heather Hage Kosalski, Latecia Jones **Mercer:** Bill Lasowski, Kristin Coyle, David Parrella **BerryDunn:** Dawn Webb, Amber Davis, Savana Gordon
Attachments	**N/A**

Meeting Purpose: To present and answer stakeholder questions about the Virgin Island's 1115 Waiver Application.

Action Items

- **There were no action items established during the public hearing.**

Agenda Items

Item #	Topic and Description	Responsible
1.	Introduction	Gary Smith
2.	Presentation of the 1115 Waiver Medicaid Drug Rebate Program (MDRP)	Bill Lasowski
3.	Question and Answer Portion	Group
4.	Conclusion	Gary Smith

Meeting Notes

Item #	Topic and Description
1.	Introduction • Gary Smith opened the public hearing by welcoming all participants. • Introductions were made from the team to the participants. • Gary said the purpose of this meeting is for pharmacy; however, no members of the pharmacy department were in attendance. • Gary asked if anyone opposed the public hearing from being recorded. There were no objections, and the recording was launched. • Assistant Commissioner Michal Rhymer-Browne said she is looking forward to the public responses to this hearing and how to better utilize the VI's federal funds.
2.	Presentation of the Section 1115 Waiver MDRP • Amber Davis displayed the slide deck. • Bill Lasowski provided information on the brief overview of MDRP and Section 1115 Waiver. • The Centers for Medicare & Medicaid Services (CMS) issued a final regulation that established all territories to be included in the MDRP by January 1, 2023. Territories can submit a Section 1115 Waiver to waive participation in the MDRP, if approved by CMS. • The VI is proposing a Section 1115 Waiver to be exempt from the MDRP until the Territory can determine if the requirements of the MDRP are the right choice for the VI. • Kristin Coyle presented information on the Cost/Benefit Analysis. The Cost/Benefit Analysis will determine if the VI should participate fully in the MDRP or waive participation and continue the current fee-for-service drug program with modifications.
3.	Question and Answer Portion • Gary asked the group for questions. There were no questions asked.
4.	Conclusion • The next public hearing is Wednesday, January 25, 2023. • After the second hearing is held, the public will have until February 20, 2023, to submit any comments on the proposal before the final proposal is submitted to CMS.

Meeting Title	1115 Waiver: Public Hearing 2
Date	Wednesday, January 25, 2023
Time and Location	9 – 10 a.m. ET via Teams
Dial-In Information	Dial: 1-207-352-3680 Meeting ID: 285 682 185 587
Web Conference	URL: Click here to join the meeting Passcode: YsDutV
Meeting Facilitator	Gary Smith
Note Taker	Savana Gordon
Attendees	**United State Virgin Islands (USVI):** Gary Smith, Beverly Joseph, Carla Huggins **Stakeholders:** USVI General Public **USVI Pharmacies:** Shakil Baig (Drug Farm Pharmacy), Kisha Christian (Neighborhood Pharmacy), Jacquelynn Rhymer-George (Frederiksted Health Care) **SGRX Health:** Ime Ekpenyong, Carla Powell, Latecia Jones **Mercer:** Bill Lasowski, Kristin Coyle **BerryDunn:** Dawn Webb, Amber Davis, Savana Gordon
Attachments	**N/A**

Meeting Purpose: To present and answer stakeholder questions about the USVI's 1115 Waiver application.

Action Items

- **There were no action items established during the public hearing.**

Agenda Items

Item #	Topic and Description	Responsible
1.	Introduction	Gary Smith
2.	Presentation of the Section 1115 Waiver Medicaid Drug Rebate Program (MDRP)	Bill Lasowski
3.	Question and Answer Portion	Group
4.	Conclusion	Gary Smith

Meeting Notes

Item #	Topic and Description
1.	Introduction • Gary Smith opened the public hearing by welcoming all participants. • Gary asked if anyone opposed the public hearing being recorded. There were no objections, and the recording was launched. • Introductions were made from the team to the public.
2.	Presentation of the Section 1115 Waiver MDRP • Amber Davis displayed the slide deck. • Bill Lasowski provided a brief overview of MDRP and Section 1115 Waiver. • The Centers for Medicare & Medicaid Services (CMS) issued a final regulation that established all territories have to be included in the MDRP by January 1, 2023. Territories can submit a Section 1115 Waiver to waive participation in the MDRP if approved by CMS. • The USVI is proposing a Section 1115 Waiver to be exempt from the MDRP until the territory can determine if the requirements of the MDRP are the right choice for the USVI. • Kristin Coyle presented information on the cost/benefit analysis. The cost/benefit analysis will determine if the USVI should participate fully in the MDRP or waive participation and continue the current fee-for-service drug program with modifications.
3.	Question and Answer Portion • Gary opened the session to questions. • A question was asked about whether the cost/benefit analysis will include all information regarding the 340B claims and rebate, as it has financial implications that are used to help the underserved community of the USVI. • Kristin confirmed the 340B claims will be included in the cost/benefit analysis. Kristin said the USVI will not be able to collect the rebate under the MDRP due to federal regulation and law; however, providers will receive a higher dispensing fee compared to what is being received at this time. • Kristin said all rebates outside of the MDRP are driven by drug manufacturers contracting. Drug manufacturers typically exclude 340B drugs from their rebates.
4.	Conclusion • When there were no additional questions or comments, Gary closed the meeting, reminding everyone that the public comment period is open until February 20, 2023,

Item #	Topic and Description
	and people can continue to submit questions and comments about the 1115 Waiver before the final proposal is submitted to CMS.

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

USVI Medicaid Program
Section 1115 Public Hearing
Medicaid Drug Rebate Program (MDRP)

St. Thomas 01/23/23 2:00 PM – 3:00 PM (AST)

St. Croix 01/25/23 10:00 AM – 11:00 AM (AST)

Gary A. Smith

Medicaid Director

Agenda

- Introductions & Overview - Gary Smith – Medicaid Director
- MDRP Overview & The Territories - Bill Lasowski – Mercer
- Section 1115 Waiver – Bill Lasowski – Mercer
- Cost Benefit (C/B) Analysis – Kristin Coyle – Mercer
- Public Notice/Meeting Process & Next Steps – Bill Lasowski – Mercer
- Questions & Closing Remarks - Gary Smith – Medicaid Director

MDRP Overview & The Territories

- MDRP Enacted In 1990
- Manufacturers Must Have A Rebate Agreement With CMS To Have Its Drugs Covered Under The Medicaid Program
- In Exchange For Rebates, States Must Cover Their Drugs In Medicaid Program
- Rebates Collected Must Be Shared With The Federal Government
- CMS Calculates The Rebate Amounts
- States Collect The CMS Rebate Amounts And Report Them To CMS To Offset The Original Drug Expenditures

MDRP Overview & The Territories

- States May Also Negotiate Supplemental Rebates Directly With Manufacturers
- States That Participate Must Abide By All Of The Additional Federal Policy, Operational, And Administrative Requirements Of The MDRP
- CMS, States, And The Manufacturers All Have A Part In The Operation And Administration Of The MDRP
- States And DC Have Always Been Required To Participate While Territories Were Exempt
- CMS Began Issuing Proposed Regulations In February 2016 To Include The Option For The Territories To Participate In The MDRP

MDRP Overview & The Territories

- Beginning In November 2016, CMS Issued A Series Of Regulations Delaying This Option For The Territories
- These Delays Were Necessitated Because Of The Longer Timeframes Needed By Manufactures To Address Pricing Determinations And The Territories For Planning, Budgeting, And Developing Necessary Systems
- On November 19, 2021, CMS Issued A Final Regulation Which Established January 01, 2023, As The Final Date For The Territories To Be Included In The MDRP
- Additionally, In That Regulation CMS Provided The Option For The Territories To Waive Participation In The MDRP By Submitting A Section 1115 Waiver & Having That Approved By CMS

Section 1115 Waiver

- The VI Is Proposing A Section 1115 Waiver From CMS To Study The MDRP Requirement
- This Section 1115 Waiver Will Initially Exempt The VI From All Participation In the MDRP
- During The Exemption Period Under The Waiver, The VI Will Continue Its Current Fee-For-Service Medicaid Drug Program
- As A Result, We Do Not Expect Any Impact On Our Medicaid Enrollees, Pharmacy Providers, Covered Prescription Drugs, Or The Overall Operation Of The Current Medicaid Drug Program During This Exemption Period Under The Waiver

Section 1115 Waiver

- On January 09 & 19, 2023, We Published The Full Text Of The Draft Section 1115 Waiver On The Department Of Human Services Website
- The Draft Wavier Contains The Background Detail That We Just Discussed Above
- It Also Indicates The VI Is Asking For A Full Exemption From Complying With The MDRP To Complete A Cost/Benefit (C/B) Analysis
- The C/B Analysis Results Will Be Used To Determine The Financial & Program Viability & Benefits Of Participation In The MDRP Or Fully Waive Participation & Continue The VI Fee-For-Service Drug Program With Modifications

Cost-Benefit Analysis

- The C/B Analysis Will Review Historical VI Medicaid Drug Program Expenditures And Drug Claims Project Costs Under Two Scenarios: 1) With A Waiver (Current Program) And 2) Without A Waiver (MDRP)
- The C/B Analysis Will Assess The Requirements Under The MDRP With Regard To Drug Coverage Limitations, Drug Pricing & Geographical Challenges, Pharmacy Reimbursement Limits & Fees, Pharmacy Network Adequacy, Drug Utilization Review, & Drug Rebate Collections, And Program Administration & Operational Costs

Cost-Benefit Analysis

- The VI Will Then Compare The Additional Costs And Benefits From Its Assessment Of The MDRP On The VI Medicaid Drug Program (Without Waiver) To The Current VI Medicaid Fee-For-Service Drug Program (With Waiver) To Determine Which Approach Would Be The Most Programmatically And Financially Advantageous To The VI Medicaid Program
- We Expect The Results Of The C/B Analysis To Establish Whether The VI Should Participate In The MDRP Or Maintain The Section 1115 Waiver Exemption From The MDRP & Continue The Current VI Medicaid Program With Possible Modifications

Public Notice/Meeting Process & Next Steps

- Prior To Submitting The Final Section 1115 Proposal To CMS, The VI Is Required To Provide Public Notice & Conduct Two Public Hearings
- The Public Notice And Section 1115 Waiver Proposal Were Published On January 09 & 19, 2023 On The DHS Website As Mentioned Earlier
- The Two Public Hearings Are Being Conducted On January 23, 2023 (STT) & January 25, 2023 (STX) Virtually Using Teams.
- The Public Will Have 30 Days (Until February 20, 2023) To Submit Comments On The Waiver Proposal As Provided For In The Public Notice
- VI Will Then Submit The Final Proposal To CMS Along With Any Comments VI Receives And The Notes From The Two Hearings

Public Notice/Meeting Process & Next Steps

- CMS Will Have 15 Days To Confirm Receipt Of The Section 1115 Application
- CMS Will Then Solicit Further Public Comment By Posting The Section 1115 Application On The CMS Website – The Public May Also Comment Through That Process
- CMS Will Also Publish Any Comments Received On Their Website
- Thus, CMS Will Not Typically Issue A Final Decision On The Waiver Proposal Until At Least 45 Days After Receipt By CMS
- CMS May Also Work With The State On Any Necessary Modifications Or Additional Information That May Be Needed

Public Notice/Meeting Process & Next Steps

- The VI Will Provide Periodic Updates To CMS On The Progress Of The C/B Analysis
- Additionally, Within 6 Months Of Implementation (Annually Thereafter) The VI Will Hold A Public Forum On The Progress Of The Waiver
- The VI Will Also Provide An Update On The Results Of The C/B Analysis Upon Its Completion And The Final Decision(s) Made By The Medicaid Program
- As Mentioned Earlier The Public May Provide Written Comments To The VI Medicaid Program Until February 20, 2023, And To CMS On Their Website

Questions & Closing Remarks - Gary Smith – Medicaid Director

- We Are Ready To Take Any Questions You May Have
- Please Indicate In The Teams Chat That You Have A Question And Provide Your Name, Title And Organization So We Can Call On You
- Final Thoughts/Comments

Lasowski, Bill

From: Beverly Joseph <Beverly.Joseph@dhs.vi.gov>
Sent: Monday, January 23, 2023 6:54 PM
To: drugfarmpharmacy@yahoo.com; tradewindsv.i@hotmail.com; pharmacy@mspvt.st.com; chelseadrugstoreredhook@gmail.com; Rx3829@transformco.com; anna@doctorschoicepharmacies.com; vw5101@vitaminworld.com; sophie garcia; Mt. Welcome Pharmacy; Neighborhood Pharmacy
Cc: Gary Smith; Lasowski, Bill
Subject: Public Notice & 1115 Waiver
Attachments: 20230119 USVI MDRP Full Public Notice-Final-Draft-09-19-2022_CMS feedback 9 23 22.docx; 20230119 USVI Medicaid Drug Rebate 1115 Waiver Demonstration Amended Final Draft-Posted_.docx

Good day Everyone,

On behalf of Mr. Gary Smith, DHS Medicaid Director.

We cordially invite you to attend the Public Notice & 1115 Waiver Rebate.

please send a member of your team to join this meeting so you are informed, and all questions will gwt answered.

Teams meeting on Wednesday January 25, 2023. 10:00am-11:00am.

As we discuss the Public Notice & 1115 Waiver.

Microsoft Teams meeting

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MS. BEVERLY JOSEPH

EXPANSION SERVICES COORDINATOR/ PROVIDER RELATIONS/CLAIMS MANAGER

MEDICAID PROGRAM

DEPARTMENT OF HUMAN SERVICES

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WWW.VIMMIS.COM

"WORKING TOGETHER TO MAKE A DIFFERENCE"

REMINDER! ALL MEDICAID MEMBERS FIVE YEARS OF AGE AND OLDER RETURNING TO THE USVI TERRITORY MUST BE TESTED FOR COVID-19 AT LEAST FIVE DAYS BEFORE THEIR TRIP. NEGATIVE RESULTS NEED TO BE UPLOADED TO THE U.S. VIRGIN ISLANDS TRAVEL SCREENING PORTAL. PLEASE VISIT HTTPS://USVITRAVELPORTAL.COM 24 HOURS PRIOR TO TRAVEL TO OBTAIN AN APPROVED GREEN QR CODE. IF YOU HAVE ANY QUESTIONS OR CONCERN, PLEASE CONTACT ME VIA ANY MEDIUM BELOW.