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

January 2023 – Final Draft

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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. 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.

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 83% through December 13, 2022. On December 14, 2022, the USVI's FMAP will revert to 55% unless new federal legislation is enacted. 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-FY2025			
FY	**Total**	**Federal**	**VI**

Actuals			
2018	10,841,838	10,253,678	588,160
2019	15,394,900	15,394,900	0
2020	26,236,738	25,648,578	588,160
2021	27,211,312	24,272,492	2,938,820
Totals	79,684,788	75,569,648	4,115,140
Projections			
2022	22,209,492	19,810,868	2,398,625
2023*	25,540,916	21,198,960	4,341,956
2024*	29,372,053	24,378,804	4,993,249
2025*	33,777,861	28,035,625	5,742,236
Totals	110,900,323	93,424,257	17,476,066
*Assumes 83% FMAP Continues			

C. Pharmacy Provider Participation

Current Program Year – Pharmacy Provider Data

2022: 14 On-Island Pharmacy Providers. Drug expenditures have been averaging approximately $18 million per year over the past 4.5 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

[PLACEHOLDER - To be completed after USVI Medicaid's notice and public comment period concludes available at (https://www.dphss.gov...)]

SECTION V. STATE CONTACT AND SIGNATURE

State Medicaid Director Name:

Telephone Number:

E-mail Address:

Authorizing Official (Typed):

Authorizing Official (Signature):

Date: