Guam - Medicaid Drug Rebate Program (MDRP)

1115 Waiver Demonstration Application

Table of Contents

SECTION I. NARRATIVE SUMMARY OF THE 1115 WAIVER DEMONSTRATION

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

As stated on the Centers for Medicare & Medicaid Services (CMS) Medicaid site: The Medicaid Drug Rebate Program (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 Social Security Act.

The MDRP is designed to offset overall costs of prescription drugs under the Medicaid Program by requiring drug manufacturer 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. Guam Medicaid currently has two (2) Federally Qualified Health Centers (FQHC) that participate under the Section 340B Drug Pricing Program: The Northern Regional Health Center (NRHC) and The Southern Regional Health Center (SRHC). 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 mentioned above.

On February 1, 2016, 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). 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" allows Territories to participate in the Medicaid Drug Rebate Program (MDRP). Additionally, we indicated in the "Covered Outpatient Drug" final 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).

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 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, Guam will be required to participate in the MDRP effective January 1, 2023. However, Guam is allowed to use the 1115 waiver authority to elect not to participate in the MDRP.

B. Application Request and Rationale for Proposed 1115 Waiver Demonstration

The CMS final rule (CMS-2345-FC) allows the territories to "opt out under…section 1902(j) of the Act." It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act that requires Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP).

Historically, the Guam Medicaid funding has been limited under the Section 1108 annual block grant, and further limited by the established 55-45% FMAP. These limitations created an environment where the Guam Medicaid Program experienced hesitancy on the part of health care providers on island in participating in the program. The funding increases provided by the Patient Protection and Affordable Care Act (Obamacare) provided a temporary increase in funding, and recent legislation has further provided additional temporary funding and FMAP increases. These increases have helped the Guam Medicaid Program expand services and encouraged provider participation resulting in better recipient access to services that exist today.

Although the Medicaid Drug Rebate Program (MDRP) will offset costs of prescription drugs under the Guam Medicaid Program, the Territory has identified potential negative impacts for pharmacy providers which may ultimately affect the program's ability to maintain its existing provider network of on-island pharmacies essential for program participants to have adequate access to pharmacy services, and create added labor intensive program costs that may outweigh the benefits of participation in the MDRP.

The island Medicaid pharmacy providers often face challenges in obtaining supplies because of the remoteness of Guam's location relative to supply chains. This often times creates challenges in the form of accepting higher wholesale pricing from distributors when purchasing pharmaceutical drugs, and paying for higher shipping costs because of the need to transport these supplies via air freight due to their inability to stockpile medication when considering drug expiration dates relative to expected sales and supply needs which often causes inventory or availability issues. This often times translates to more expensive costs that is requested as reimbursement for the sale of these medications to program recipients.

Additionally, due to the relatively insignificant total purchase amounts made through pharmaceutical distributors in comparison to the larger pharmacy chains in the mainland U.S., the island pharmacy providers are unable to negotiate for best prices or favorable shipping terms in obtaining medication supplies. Guam's participation in the MDRP would place added pressures on the island Medicaid pharmacy providers because it would require them to carry all drugs of a participating manufacturer, and for the program to cover them under Medicaid. Currently, almost all drug manufacturers are participating in the MDRP.

Guam Medicaid has managed to control the costs of Pharmacy expenditures because it currently controls their drug formulary which list covered medication under the program. However, participation in the MDRP would require that we cover all drugs of participating manufacturers, and essentially cover all drugs if the waiver application is not approved. This would be a substantial cost to Guam Medicaid. The current drug pricing for the program's drug formulary is set at the Lowest Wholesale Price (LWP) under Redbook when the formulary is released in January of each calendar year. The program feels that during this waiver demonstration, they would be able to maintain substantial cost savings for their pharmacy expenditures by maintaining a 16% expenditure limitation for this category relative to the total expenditures, and will attempt to assess this standard in comparison with other state Medicaid programs that are under the MDRP.

Under this MDRP 1115 Waiver Demonstration application, the program will be able to continue to maintain control of drug coverage, and properly assess island pharmacy impacts, which is important

because of potential drug inventory issues faced by the on-island pharmacies due to our remoteness relative to mainland pharmaceutical supply lines. This waiver may prove to be more of a cost savings when compared to potentially having to cover all drugs of manufacturers that enter into a rebate under the MDRP and due to additional labor-intensive costs associated with participation in the MDRP.

C. Demonstration Goals

The overall goal of the demonstration is to assure the network capacity of on-island pharmacy providers remains consistent with the existing capacity prior to an implementation mandated for program participation in the MDRP in order to provide adequate recipient access to pharmacy services, and to allow time to properly assess potential adverse effects of participation in the MDRP on our island pharmacy providers, program recipients, and additional administrative program costs related to the management of the MDRP that would possibly outweigh any rebate savings.

NOTE: The demonstration only applies to on-island pharmacy services authorized by the Guam Medicaid State Plan.

The 1115 Demonstration application requests to waive participation in the Medicaid Drug Rebate Program (MDRP) as it will be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP) than the rebate savings it provides, and may potentially impact provider (pharmacy) participation.

D. Demonstration Population

This demonstration will affect all Guam Medicaid State Plan Beneficiaries who utilize Medicaid authorized On-Island Pharmacy Providers.

E. Eligibility

There are no changes to beneficiary eligibility.

F. Medicaid Delivery System and Covered Benefits

The Territory does not propose any changes to the Medicaid health care delivery system; demonstration enrollees will continue to receive services through the Territory's fee-for-service delivery system. Demonstration enrollees will also continue to receive benefits through the Alternative Benefit Plan; the Territory does not propose any changes to benefits for any Medicaid enrollees.

II. HYPOTHESIS AND QUESTIONS

The focus of the evaluation will be to elaborate on the unique pricing and geographical challenges of On-Island Pharmacies due to limited supply chains available in obtaining Covered Outpatient Drugs (COD), and how Guam's participation on the MDRP would affect their current status as Pharmacy providers for the program. Additionally, it will attempt to evaluate the possible MDRP cost savings for the Guam Medicaid program in comparison with the identified potential negative impacts for pharmacy providers which may ultimately affect the program's ability to maintain existing provider networks of on-island pharmacies essential for program participant's adequate access for pharmacy services as well as assess additional labor intensive, administrative costs for the program in participating in the MDRP.

A. Hypothesis and Questions

Hypothesis: Guam Medicaid's participation in the MDRP would adversely affect the On-Island Pharmacies by creating an unreasonable requirement for them to carry all of a participating manufacturer's COD such that it would be difficult for them to maintain adequate inventory, and to continue as providers on the Medicaid program. Additionally, it

would be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP), and these costs would outweigh the rebate savings MDRP would provide.

Questions:

1. What are the existing supply chains (Pharmaceutical Distributors) available to On-Island Pharmacies due to Guam's geographical location?
2. What current limitations do On-Island Pharmacies have in dealing with existing supply chains when ordering CODs for dispensing to Medicaid recipients?
3. How would Guam Medicaid's participation in the MDRP affect the On-Island Pharmacy Providers decision to continue as a provider on the Medicaid program?
4. Would the cost reduction for pharmacy expenditures outweigh the adverse effects of creating inadequate participant access to On-Island Pharmacy Services?
5. What other costs would be involved in Guam Medicaid's participation in the MDRP, and would these costs outweigh the benefit of the rebate savings to its pharmacy expenditures.

In light of the statutory MDRP directive, Guam Medicaid is seeking a waiver exempting them from the requirement to participate in the drug rebate program. Guam is requesting that the exemption from participating in the MDRP be effective from January 1, 2023 - December 31, 2027.

B. Financial Data

1. Historical Enrollment and Expenditures

Guam Medicaid program's historical enrollment figures for fiscal years 2016 to present and corresponding program year total program expenditures and pharmacy expenditures with projections for FY2022 through FY2027.

Figure 1. Guam Medicaid Program Historical and Projected - Enrollment and Expenditures Data

Fiscal Year	Enrollment	Total Expenditures	Pharmacy Expenditure	Pharmacy Expenditures %	Pharmacy Expenditures Per Recipient
FY2016	43673	$95,382,705	$23,597,926	24.74%	540
FY2017	43476	$108,609,905	$22,251,392	20.49%	512
FY2018	43600	$110,876,286	$13,945,932	12.58%	320
FY2019	43671	$149,037,981	$21,950,084	14.73%	503
FY2020	43238	$157,256,853	$19,570,466	12.44%	453
FY2021	45692	$123,971,992	$19,821,809	15.99%	434
FY2022	43892	$124,189,287	$20,189,602	16.26%	460
FY2023	43990	$124,445,463	$20,234,832	16.26%	460
FY2024	44089	$124,724,257	$20,280,164	16.26%	460
FY2025	44187	$125,003,676	$20,325,598	16.26%	460
FY2026	44286	$125,283,721	$20,371,133	16.26%	460
FY2027	44386	$125,564,394	$20,416,770	16.26%	460

*Projected Data

Note: In Guam's review/analysis of previous FY data, it appears that the data may be skewed due to program numbers being affected by PHE and it's social and financial impacts on the island community.

FY2022 data was projected by averaging the amounts from the six (6) previous years. The program data projections for FY2023 through FY2027 was determined by taking an average increase for data that shows a linear growth for FY2017 through FY2019.

C. Pharmacy Provider Participation

Current Program Year – Pharmacy Provider Data

FY2022: 23 - On-Island Pharmacy Providers;

2 - FQHC Pharmacy Providers;

7 - Off-Island Pharmacy Providers

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 pharmacy surveys.

A. Evaluation Design

Qualitative methods will be employed to evaluate:

* The possible adverse effects to On-Island Pharmacy Providers should Guam participate in the MDRP;
* Current limitations for On-Island Pharmacies with existing supply chains when ordering CODs for dispensing to Medicaid recipients; and
* How Guam Medicaid's Participation on the MDRP would affect their provider status on the Medicaid program.

Pharmacy surveys will be used for qualitative/quantitative methods.

Quantitative methods will be used to evaluate MDRP rebate savings relative to average program savings nationwide, and the following anticipated program costs for implementation of the MDRP (42 CFR 447.511).

* Cost Benefit Analysis to evaluate potential cost savings provided on the MDRP in relation to potential increases in administrative costs to the program due to requirements for contractual services to administer the tracking and reporting of the data for NDCs to the participating drug manufacturers to include an additional State Agency FTE position to be responsible for the MDRP requirements as a whole.
* Guam's assessment of the following Costs associated with participation in the MDRP
    1. Cost of contractor to process claims electronically and invoice manufacturer rebates. (Review of small fee-for-service state, to determine costs for claims processing and invoicing via contractor (e.g., Magellan or Change Healthcare Vendors for minimum cost required to invoice manufacturers, run dispute resolution, and collect money etc.).
    2. Costs involved in developing MDRP Participating Manufacturers NDC Drug Formulary Listing and evaluation of feasibility of developing procedures to prior authorize (PA) drugs to ensure the drugs are from participating manufacturers. (Assess cost and additional labor involved in this procedure).
* Guam's assessment of costs for Integrating Physician Administered drugs into rebate processes (42 CFR 447.520)

  Cost associated with invoicing all outpatient drugs administered in a clinical setting or emergency department. Provider training regarding HCPCS coding system in these settings for claims to reference National Drug Code (NDC) or assess costs to perform a crosswalk from the HCPCS to the NDC. (Capture additional work and support needed to integrate these claims into the invoicing process for rebates).
* Guam's assessment of the Costs associated with requiring Guam to use actual acquisition cost (AAC) + dispensing fee methodology (42 CFR 447.512)

  Cost to pay AAC, if MDRP implemented, requiring Guam to survey its pharmacies regarding their acquisition costs in order to determine if using AWP is close to the pharmacies'

acquisition costs and therefore can be used as a basis for reimbursement. A survey would also need to be done to ascertain dispensing fee costs of your pharmacies. (Estimates: Possible cost of $50,000 -100,000 for the acquisition cost survey and another $50,000-100,000 to do cost of dispensing fee as needed. (RFQs to assess survey costs).

* Assessment of the Drug Utilization Review (DUR) – 1927(g) and 42 CFR 456.703

  1. RFQ to assess costs to contract a Provider Benefits Manager (PBM), to conduct Prospective Drug Utilization Review processes (PRO-DUR). All PBMs offer PRO-DUR as part of the claims processing, but need to ascertain any additional costs related to those services.

  2. Assess feasibility to work with UPIC West, Qlarant in conducting required Retrospective Drug Utilization Reviews (RETRO-DUR). Guam currently working with CMS contractor as part of program integrity reviews to fight fraud, waste and abuse. (Assess any additional cost).

* Assessment and cost breakdown of FTE staff required to be responsible for performing duties related to the Medicaid drug rebate system (Medicaid Drug Product, or MDP) Assess cost associated for a state employee at a minimum of 1/2 of an FTE on Guam's Medicaid staff. (Employee to act as point person for all activities regarding the Medicaid drug benefit to include rebate and Drug Utilization Review, and managing the MDRP contract).

* Assessment Note: Guam/CMS to determine a possible evaluation component for assessing health outcomes to review possible data set for evaluation in developing a metrix measurement for health outcomes and its relationship with provider accessibility (Pharmacy - prescription drug benefits).

B. Data Sources

The demonstration evaluation will rely on data in the Guam Medicaid Management Information System (MMIS) otherwise known as PHPro which does Fee-for Service based claims processing. Use of financial program data will be limited to final paid status claims. HHS/CMS, MDRP Participating Manufacturer Rebate data, and other available State Medicaid Enrollment and Expenditure data reported to CMS.

SECTION IV. COMPLIANCE WITH PUBLIC NOTICE PROCESS

Public Notice:

***Publication in the Guam Daily Post, June 20, 2022 (See attached)**

*Posting on the Government of Guam, Department of Administration-Public Notice Site (Public Notices - Public Notices Portal - Government of Guam)

*Posting on the Department of Public Health and Social Services, Division of Public Welfare, Bureau of Health Care Financing Administration, Guam Medicaid site (http://dphss.guam.gov/category/press-releases-en/)

Public Hearings:

1. June 27, 2022 – Guam Legislative Information Hearing (1-3:00 p.m. CHST) (https://youtube.com/c/GuamLegislatureMedia, (58119) Joint Public Hearing - Speaker Therese M. Terlaje - June 27, 2022 1pm - YouTube)
2. July 8, 2022 – DPHSS In-Person and Virtual (Zoom) Information Hearing (Governor's Conference Room, Ricardo J. Bordallo Complex, 513 West Marine Corps Drive Hagatna, Guam 96910, 1-3:00 p.m. CHST)

30 day comment period: June 20, 2022 to July 28, 2022

Public Comments: Guam received some questions during the first public hearing regarding the benefits of the MDRP for the Medicaid participants from some of the senators in attendance, and will use this feedback as we analyze and assess positive and negative impacts of participating in the MDRP. Additional comments were received from a few of the Medicaid Program Pharmacist through emails and a written testimony in support of Guam's 1115 waiver application, and will utilize these comments in their evaluation design to address these issues and concerns.

1115 Waiver Demonstration Application submitted on **August 5, 2022** (Link to copy of application available at https://www.dphss.gov...)

SECTION V. STATE CONTACT AND SIGNATURE

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Telephone Number: (671) 300-7340
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Authorizing Official:

Authorizing Official (Signature): [redacted] AUG 05 2022

Arthur U. San Agustin, MHR, Director
Department of Public Health and Social Services

Date: August 5, 2022

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DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
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AMENDED PUBLIC NOTICE

GUAM MEDICAID – MEDICAID DRUG REBATE PROGRAM (MDRP) SECTION 1115 WAIVER DEMONSTRATION APPLICATION

Public Notice – July 1, 2022
The Guam Medicaid Program, administered under the Department of Public Health and Social Services (DPHSS), Division of Public Welfare is providing public notice of its intent to:

(1) submit to the Centers for Medicare and Medicaid Services (CMS), on or before August 1, 2022, a written 1115 Demonstration application to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program (MDRP); and

(2) hold public hearings to receive comments on the 1115 Waiver Demonstration application.

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

I. Program Description
A. Overview

As stated on the Centers for Medicare & Medicaid Services (CMS) Medicaid site: The Medicaid Drug Rebate Program (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 Social Security Act.

The MDRP is designed to offset overall costs of prescription drugs under the Medicaid Program by requiring drug manufacturer 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. Guam Medicaid currently has two (2) Federally Qualified Health Centers (FQHC)

that participate under the Section 340B Drug Pricing Program: The Northern Regional Health Center (NRHC) and The Southern Regional Health Center (SRHC). 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 mentioned above.

On February 1, 2016, 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). 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" allows Territories to participate in the Medicaid Drug Rebate Program (MDRP). Additionally, we indicated in the "Covered Outpatient Drug" final 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).

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 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, Guam will be required to participate in the MDRP effective January 1, 2023. However, Guam is allowed to use the 1115 waiver authority to elect not to participate in the MDRP.

In light of the statutory MDRP directive, Guam Medicaid is seeking a waiver exempting them from the requirement to participate in the drug rebate program. Guam is requesting that the exemption from participating in the MDRP be effective from January 1, 2023 - December 31, 2027.

B. Summary of 1115 Waiver Demonstration Application Request

The CMS final rule (CMS-2345-FC) allows the territories to "opt out under...section 1902(j) of the Act." It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act that requires Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP).

Historically, the Guam Medicaid funding has been limited under the Section 1108 annual block grant, and further limited by the established 55-45% FMAP. These limitations created an environment where the Guam Medicaid Program experienced hesitancy on the part of health care providers on island in participating in the program. The funding increases provided by the Patient Protection and Affordable Care Act (Obamacare) provided a temporary increase in funding, and recent legislation has further provided additional temporary funding and FMAP increases. These increases have helped the Guam Medicaid Program expand services and encouraged provider participation resulting in better recipient access to services that exist today.

Although the Medicaid Drug Rebate Program (MDRP) will offset costs of prescription drugs under the Guam Medicaid Program, the Territory has identified potential negative impacts for pharmacy providers which may ultimately affect the program's ability to maintain its existing provider network of on-island pharmacies essential for program participants to have adequate access to pharmacy services, and create added labor intensive program costs that may outweigh the benefits of participation in the MDRP.

The island Medicaid pharmacy providers often face challenges in obtaining supplies because of the remoteness of Guam's location relative to supply chains. This often times creates challenges in the form of accepting higher wholesale pricing from distributors when purchasing pharmaceutical drugs, and paying for higher shipping costs because of the need to transport these supplies via air freight due to their inability to stockpile medication when considering drug expiration dates relative to expected sales and supply needs which often causes inventory or availability issues. This often times translates to more expensive costs that is requested as reimbursement for the sale of these medications to program recipients.

Additionally, due to the relatively insignificant total purchase amounts made through pharmaceutical distributors in comparison to the larger pharmacy chains in the mainland U.S., the island pharmacy providers are unable to negotiate for best prices or favorable shipping terms in obtaining medication supplies. Guam's participation in the MDRP would place added pressures on the island Medicaid pharmacy providers because it would require them to carry all covered outpatient drugs (COD) of a participating manufacturer, and for the program to cover these CODs under Medicaid. Currently, almost all drug manufacturers are participating in the MDRP.

Guam Medicaid has managed to control the costs of Pharmacy expenditures because it currently controls their drug formulary which list covered medication under the program. However, participation in the MDRP would require that we cover all drugs of participating manufacturers, and essentially cover all COD drugs if the waiver application is not approved. This would be a substantial cost increase to Guam Medicaid. The current drug pricing for the program's drug formulary is set at the Lowest Wholesale Price (LWP) listed on Redbook at the time the formulary is released in January of each calendar year. The program feels that during this waiver demonstration, they would be able to maintain substantial cost savings for their pharmacy expenditures by maintaining a relatively low expenditure rate for its pharmacy expense relative to total expenditures, and the approval of the 1115 waiver will allow the program a period of time to assess this standard in comparison with other state Medicaid programs that receive rebates under the MDRP.

Under this MDRP 1115 Waiver Demonstration application, the program will be able to continue to maintain control of its drug formulary and the covered outpatient drug (COD) coverage, and allow more time for the program to properly assess island pharmacy impacts, which is important because of potential drug inventory issues faced by the on-island pharmacies as previously mentioned due to our remoteness relative to mainland pharmaceutical supply lines. This waiver may prove to be more of a cost savings for Guam Medicaid when compared to potentially having to cover all drugs of manufacturers that enter into a rebate under the MDRP and create additional administrative burdens and costs due to additional labor-intensive costs for implementation activities associated with the implementation and participation in the MDRP.

C. Eligibility Requirements

The 1115 Demonstration application requests to waive participation in the Medicaid Drug Rebate Program (MDRP) as it will affect the on-island pharmacy provider participation on the program which will affect adequate access for the program participants described in the chart below.

Eligibility Group Name	Social Security Act and CFR Citations	Income Level
Guam Medicaid Program New Adult Group (MAPNEG), Elderly and Disabled	Social Security Act 1396(a)(10)(A)(i)(VIII) 42 C.F.R. 435.119	New adult group, Elderly and Disabled group with income 0-138 percent LPL

D. Health Care Delivery System and Benefits

This MDRP 1115 Waiver Demonstration Application is seeking to waive the programs participation in the MDRP and does not propose any changes to the Medicaid health care delivery system; Guam Medicaid enrollees will continue to receive services through the Territory's fee-for-service delivery system. MAPNEG Program enrollees will also continue to receive benefits through the Alternative Benefit Plan; the Territory does not propose any changes to benefits for any program enrollees.

E. Cost Sharing

Cost sharing will not be affected under this 1115 Waiver Demonstration request.

II. Goals and Objectives

The overall goal of the demonstration is to assure the network capacity of on-island pharmacy providers remains consistent with the existing capacity prior to an implementation mandated for program participation in the MDRP in order to provide adequate recipient access to pharmacy services, and to allow time to properly assess potential adverse effects of participation in the MDRP on our island pharmacy providers, program recipients, and to assess additional administrative program costs related to the management of the MDRP that would possibly outweigh any rebate savings.

NOTE: The demonstration applies to all pharmacy services for authorized providers under the Guam Medicaid State Plan that dispense covered outpatient drugs (COD).

The 1115 Demonstration application requests to waive participation in the Medicaid Drug Rebate Program (MDRP) as it will be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP) than the rebate savings it provides, and may potentially impact provider (pharmacy) participation.

III. Enrollment Projections and Annual Expenditures

Guam Medicaid program's historical enrollment figures for fiscal years 2016 to present and corresponding program year total program expenditures and pharmacy expenditures with projections for FY2022 through FY2027.

Figure 1. Guam Medicaid Program Historical and Projected - Enrollment and Expenditures Data

Fiscal Year	Enrollment	Total Expenditures	Pharmacy Expenditure	Pharmacy Expenditures %	Pharmacy Expenditures Per Recipient
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*Projected Data

Note: In Guam's review/analysis of previous FY data, it appears that the data may be skewed due to program numbers being affected by PHE and it's social and financial impacts on the island community.

FY2022 data was projected by averaging the amounts from the six (6) previous years. The program data projections for FY2023 through FY2027 was determined by taking an average increase for data that shows a linear growth for FY2017 through FY2019.

IV. Waiver Expenditure Authorities

The CMS final rule (CMS-2345-FC) allows the territories to "opt out under…section 1902(j) of the Act." It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act that requires Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP).

V. Demonstration Hypotheses and Evaluation Parameters

Hypothesis: Guam Medicaid's participation in the MDRP would adversely affect the On-Island Pharmacies by creating an unreasonable requirement for them to carry all of a participating manufacturer's COD such that it would be difficult for them to maintain adequate inventory, and to continue as providers on the Medicaid program. Additionally, it would be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP), and these costs would outweigh the rebate savings MDRP would provide.

Qualitative methods will be employed to evaluate:

* The possible adverse effects to On-Island Pharmacy Providers should Guam participate in the MDRP;

* Current limitations for On-Island Pharmacies with existing supply chains when ordering CODs for dispensing to Medicaid recipients; and

* How Guam Medicaid's Participation on the MDRP would affect pharmacy provider status on the Medicaid program.

Pharmacy surveys will be used for qualitative/quantitative methods.

Quantitative methods will be used to evaluate MDRP rebate savings relative to average program savings nationwide, and the following anticipated program costs for implementation of the MDRP (42 CFR 447.511).

* Cost Benefit Analysis to evaluate potential cost savings provided on the MDRP in relation to potential increases in administrative costs to the program due to requirements for contractual services to administer the tracking and reporting of the data for NDCs to the participating drug manufacturers to include an additional State Agency FTE position to be responsible for the MDRP requirements as a whole.

* Guam's assessment of the following Costs associated with participation in the MDRP

1. Cost of contractor to process claims electronically and invoice manufacturer rebates. (Review of small fee-for-service state, to determine costs for claims processing and invoicing via contractor (e.g., Magellan or Change Healthcare Vendors for minimum cost required to invoice manufacturers, run dispute resolution, and collect money etc.).

2. Costs involved in developing MDRP Participating Manufacturers NDC Drug Formulary Listing and evaluation of feasibility of developing procedures to prior authorize (PA) drugs to ensure the drugs are from participating manufacturers. (Assess cost and additional labor involved in this procedure).

* Guam's assessment of costs for Integrating Physician Administered drugs into rebate processes (42 CFR 447.520)

Cost associated with invoicing all outpatient drugs administered in a clinical setting or emergency department. Provider training regarding HCPCS coding system in these settings for claims to reference National Drug Code (NDC) or assess costs to perform a crosswalk from the HCPCS to the NDC. (Capture additional work and support needed to integrate these claims into the invoicing process for rebates).

* Guam's assessment of the Costs associated with requiring Guam to use actual acquisition cost (AAC) + dispensing fee methodology (42 CFR 447.512)

Cost to pay AAC, if MDRP implemented, requiring Guam to survey its pharmacies regarding their acquisition costs in order to determine if using AWP is close to the pharmacies' acquisition costs and therefore can be used as a basis for reimbursement. A survey would also need to be done to ascertain dispensing fee costs of your pharmacies. (Estimates: Possible cost of $50,000 -100,000 for the acquisition cost survey and another $50,000-100,000 to do cost of dispensing fee as needed. (RFQs to assess survey costs).

* Assessment of the Drug Utilization Review (DUR) – 1927(g) and 42 CFR 456.703
1. RFQ to assess costs to contract a Provider Benefits Manager (PBM), to conduct Prospective Drug Utilization Review processes (PRO-DUR). All PBMs offer PRO-DUR as part of the claims processing, but need to ascertain any additional costs related to those services.
2. Assess feasibility to work with UPIC West, Qlarant in conducting required Retrospective Drug Utilization Reviews (RETRO-DUR). Guam currently working with CMS contractor as part of program integrity reviews to fight fraud, waste and abuse. (Assess any additional cost).

* Assessment and cost breakdown of FTE staff required to be responsible for performing duties related to the Medicaid drug rebate system (Medicaid Drug Product, or MDP) Assess cost

associated for a state employee at a minimum of 1/2 of an FTE on Guam's Medicaid staff. (Employee to act as point person for all activities regarding the Medicaid drug benefit to include rebate and Drug Utilization Review, and managing the MDRP contract).

* Assessment Note: Guam will work with CMS to determine an evaluation component for assessing health outcomes to review possible data set for evaluation in developing a **measurement metrix** for health outcomes and its relationship with provider accessibility (Pharmacy - prescription drug benefits).

VI. Public Review and Comment Process

The complete version of the application and copy of this full notice will be available for public review at the Government of Guam Public Notice Website (Public Notices - Public Notices Portal - Government of Guam) or the Department of Public Health, Division of Public Welfare, Bureau of Health Care Administration website (http://dphss.guam.gov/category/press-releases-en/).

Paper copies are available to be picked up in person at the Guam Department of Public Health & Social Services, Bureau of Health Care Financing Administration, Guam Medicaid/MIP Program Management Office located at 130 University Drive, Room #5 Castle Mall Building, Mangilao, Guam 96913.

Two public meetings will be held regarding the Demonstration application:

(1) Public hearing on Monday, June 27, 2022 from 1:00 p.m. to 3:00 p.m. CHST (Guam Congress Building, Public Hearing Room, 163 Chalan Santo Papa, Hagåtña, Guam 96910). This hearing will be broadcast on GTA TV Channel 21, Docomo Channel 117/112.4, and livestream on https://www.youtube.com/c/GuamLegislatureMedia.

(2) In-Person/Virtual (Zoom) Public hearing on Friday, July 8, 2022 from 1:00 p.m. to 3:00 p.m. CHST. DPHSS In-Person and Virtual (Zoom) Information Hearing. (Governor's Conference Room, Ricardo J. Bordallo Complex, 513 West Marine Corps Drive, Hagatna, Guam 96910, 1:00 p.m. to 3:00 p.m. CHST). Public comments can be made by phone on the day of the hearing by calling the following number: (671) 473-1165.

Zoom Hearing Registration link can be obtained by emailing Jeffrey San Nicolas at Jeffrey.sannicolas@dphss.guam.gov or at the following site: http://dphss.guam.gov/category/press-releases-en/.

Public comments may be submitted until 11:59 PM (CHST) on July 24, 2022. Hard copy questions or public comments may be addressed to: Guam Medicaid – MDRP 1115 Waiver Demonstration, Department of Public Health & Social Services, BHCFA, 155 Hesler Place, Hagatna, Guam 96910, or by telephone to (671) 735-7470, or by electronic mail to michael.gallo@dphss.guam.gov. Please note that comments will continue to be accepted after August 1, 2022, but Guam Medicaid may not be able to consider those comments prior to the initial submission of the 1115 Waiver Demonstration application to CMS.

After Guam 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.

Copies of this notice are available at the Government of Guam, Department of Public Health and Social Services website at http://dphss.guam.gov/category/press-releases-en/ for public review. Additional information concerning this action is available by calling the Guam Medicaid Program at (671) 735-7470/75 or upon request at the address cited below.

Guam Department of Public Health & Social Services, Bureau of Health Care Financing Administration, Guam Medicaid/MIP Program, Management Office located at 130 University Drive, Room #5 Castle Mall Building, Mangilao, Guam 96913.

[redacted]**N AGUSTIN, MHR**
Director

NKorea may be behind $100M crypto hack

SEOUL (Reuters) – North Korean hackers are most likely behind an attack last week that stole as much as $100 million in cryptocurrency from a U.S. company, three digital investigative firms have concluded.

The crypto assets were stolen June 23 from Horizon Bridge, a service operated by the Harmony blockchain that allows assets to be transferred to other blockchains.

Since then, activity by the hackers suggests they may be linked to North Korea, which experts say is among the most prolific cyber attackers. U.N. sanctions monitors says Pyongyang uses the stolen funds to support its nuclear and missile programs.

The style of attack and high velocity of structured payments to a mixer - used to obscure the origin of funds - is similar to previous attacks that were attributed to North Korea-linked actors, Chainalysis, a blockchain firm working with Harmony to investigate the attack, said on Twitter on Tuesday.

That conclusion was echoed by other investigators.

"Preliminarily this looks like a North Korean hack, based on transaction behavior," said Nick Carlsen, a former FBI analyst who now investigates North Korea's cryptocurrency heists for TRM Labs, a U.S.-based firm.

There are strong indications that North Korea's Lazarus Group may be responsible for this theft, based on the nature of the hack and the subsequent laundering of the stolen funds, another firm, Elliptic, said in a report on Thursday.

"The thief is attempting to break the transaction trail back to the original theft," the report said. "This makes it easier to cash out the funds at an exchange."

Sole surviving attacker in 2015 Paris terrorism rampage convicted

(The Washington Post) – The lone surviving member of a group that carried out a 2015 rampage across Paris was found guilty Wednesday of all charges, including murder and terrorism, and sentenced to life in prison, bringing the biggest criminal trial in modern French history to an end.

The court found that Salah Abdeslam played a key role among the men who deployed explosives and assault rifles as they targeted the Bataclan concert venue, a national stadium, and several restaurants and cafes on the night of Nov. 13, 2015, killing 130 people and injuring hundreds. The Islamic State later claimed responsibility for the bloodshed, France's worst terrorist attacks since World War II.

While public attention during the 10-month trial focused on Abdeslam, a Belgian-born French citizen, 19 other suspected perpetrators and accomplices also were charged. Five are presumed dead, and one is imprisoned in Turkey.

Nineteen of the 20 defendants were found guilty of all charges on Wednesday, but their sentences were not immediately announced.

The court sentenced Abdeslam to the harshest form of a life-in-prison sentence under French law, an extremely rare punishment that will make parole almost impossible. It was not immediately clear whether he would appeal.

Marcos vows to boost grains output to prevent food crisis

MANILA (Reuters) - Philippine President Ferdinand Marcos Jr. vowed Monday to do what it takes to boost his country's rice and corn production, seeking to reduce reliance on imports and avoid being hit hard by a food crisis now looming across the world.

Marcos, who was sworn in as president last week and has appointed himself agriculture minister, said the Philippines - the world's second-biggest rice importer - was now at a disadvantage over its food supply.

"When we look around the world, everyone is preparing for it," Marcos said during a meeting with senior agriculture officials, referring to the food crisis.

"So we should really pay close attention to what we can do."

Marcos comes to power at a critical time, with inflation at its highest in more than three years and as the world faces a tightening food supply, resulting from the conflict between major cereals exporters Russia and Ukraine.

A transcript of the meeting provided by the presidential office mentioned no specific remedial measures or targets, but Marcos said the government would ensure affordability of food prices.

To ensure long-term food sufficiency and affordability, Marcos reiterated a campaign promise to "reconstruct our value chain," within his six-year term, to lessen dependence on food imports.

INAUGURATION: *Ferdinand Marcos Jr. waves to the audience after taking his oath as the 17th president of the Philippines during the inauguration ceremony in Manila on June 30. Eloisa Lopez/Reuters*

He also sought a review of a 2019 rice tariffication law, which opened the Philippine door wider to imports by removing the annual quota on purchases and limiting the government's role in rice trade to ensuring supply during emergencies.

US ambassador urges China to stop spreading Russian 'lies'

(Bloomberg) - The U.S. ambassador to China called on the Foreign Ministry in Beijing to stop spreading Russia's "lies," in an unusually direct and public rebuke by the top American diplomat in the country.

Ambassador Nicholas Burns made the "request" in response to a question at a government-backed forum Monday about what China could do to resolve the crisis over Russia's invasion of Ukraine. Burns reiterated President Joe Biden's call for Beijing to avoid helping Moscow carry out the war, before pivoting to a simmering point of contention between the world's two largest economies.

"I would hope that Chinese foreign ministry spokespersons would stop accusing NATO of starting this war. That's Russian propaganda," Burns told the World Peace Forum organized by Tsinghua University. "I hope Foreign Ministry spokespersons would also stop telling lies about American bioweapons labs, which do not exist in Ukraine.

"These all came from Russia. Unfortunately, this has been picked up by the Chinese," Burns added.

While China has said it doesn't support the war and urged talks to end the fighting, top officials and state media have repeatedly blamed the U.S. for provoking Russia by allowing the North Atlantic Treaty Organization's expansion. Diplomats including Foreign Ministry spokespeople Hua Chunying and Zhao Lijian have also used official platforms to amplify Russian-backed conspiracy theories that the U.S. was producing biological weapons in Ukraine.

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…umas' …w professor …owing his opinion

Charles D. Stake is a retired federal attorney who lives in Barrigada, Guam.

Office of the Speaker
THERESE M. TERLAJE
I Mina'trentai Sais na Liheslaturan Guåhan | 36th Guam Legislature
Committee on Health, Land, Justice and Culture

July 27, 2022

The Honorable Tina Rose Muña Barnes
Chairperson, Committee on Rules
I Mina'trentai Sais na Liheslaturan Guåhan
163 Chalan Santo Papa
Hagåtña, Guam, 96910

VIA: The Honorable Amanda L. Shelton, Acting COR Chairperson

SUBJECT: Committee Report on the Committee on Health & Bureau of Health Care Financing Administration Division, Department of Public Health & Social Services Joint Public Hearing- Informational Briefing by the DPHSS Guam Medicaid Program on the Guam Medicaid Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation.

Hafa Adai Chairperson Shelton:

Transmitted herewith is the Committee Report on the Committee on Health & Bureau of Health Care Financing Administration Division, Department of Public Health & Social Services Joint Public Hearing- Informational Briefing by the DPHSS Guam Medicaid Program on the Guam Medicaid Drug Rebate Program (MDRP) 1115 Waiver Demonstration Presentation held on June 22, 2022.

Sincerely,

[redacted]

Guam Congress Building, 163 Chalan Santo Papa, Hagåtña, Guam 96910
Tel: (671) 472-3586 | Fax: (671) 969-3590 | Email: senatorterlajeguam@gmail.com | www.senatorterlaje.com
**For transmittal of official Messages & Communications to the Guam Legislature to be distributed to all Senators, please send to: speaker@guamlegislature.org*

Office of the Speaker
THERESE M. TERLAJE
I Mina'trentai Sais na Liheslaturan Guåhan | 36th Guam Legislature
Committee on Health, Land, Justice and Culture

COMMITTEE REPORT

JOINT PUBLIC HEARING-

Committee Report on the Committee on Health & Bureau of Health Care Financing Administration Division, Department of Public Health & Social Services Joint Public Hearing- **Informational Briefing by the DPHSS Guam Medicaid Program on the Guam Medicaid Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation.**

By Therese M. Terlaje

Guam Congress Building, 163 Chalan Santo Papa, Hagåtña, Guam 96910
Tel: (671) 472-3586 | Fax: (671) 969-3590 | Email: senatorterlajeguam@gmail.com | www.senatorterlaje.com
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Gmail Speaker Therese M. Terlaje <senatorterlajeguam@gmail.com>

FIRST NOTICE of Joint Public Hearing – Monday, June 27, 2022, beginning at 1:00 PM

1 message

Speaker Therese M. Terlaje <senatorterlajeguam@gmail.com> Mon, Jun 20, 2022 at 3:26 PM
To: phnotice@guamlegislature.org
Cc: Audio / Video <av@guamlegislature.org>, Tom Unsiog <sgtarms@guamlegislature.org>, Guam MIS <mis@guamlegislature.org>
Bcc: mindy@postguam.com, The Post Editor in Chief <editor@postguam.com>, haidee@postguam.com, John Oconnor <john@postguam.com>, reporters@postguam.com, rlimtiaco@guampdn.com, Rindraty Limtiaco <slimtiaco@guampdn.com>, Guam PDN <news@guampdn.com>, Jerick Sablan <jpsablan@guampdn.com>, life@guampdn.com, dmgeorge@guampdn.com, Mar-Vic Cagurangan <publisher@pacificislandtimes.com>, Pacific Island Times <pacificislandtimes@gmail.com>, Maureen Maratita <publisher@glimpsesofguam.com>, bryan@mvariety.com, emmanuel@mvariety.com, mabuhaynews@yahoo.com, editor@saipantribune.com, Bruce Hill <pacificjournalist@gmail.com>, Jason Salas <jason@kuam.com>, Sabrina Salas Matanane <sabrina@kuam.com>, Nestor Licanto <nestor@kuam.com>, reporters@kuam.com, K57 <news@k57.com>, Patti Rodriguez <parroyo@spbguam.com>, pattiontheradio@yahoo.com, Sorensen Pacific Broadcasting <news@spbguam.com>, raygibsonshow@gmail.com, manasilva626@yahoo.com, KISH <kstokish@gmail.com>, Manuel Cruz <cruzma812@gmail.com>, Troy Torres <troy@kanditnews.com>, Maria Louella Losinio <louella.losinio@gmail.com>, "Mayors' Council of Guam - Admin." <mcogadmin@teleguam.net>, "Mayor Paul M. McDonald" <mayor.mcdonald671@gmail.com>, agatmayor@yahoo.com, agatvice.chrisfejeran@yahoo.com, "Mayor Frankie A. Salas" <asanmainamayor@gmail.com>, June Blas <mayorbarrigada@gmail.com>, Jessie Bautista <jessie.bautista007@gmail.com>, Jessy Gogue <ocp.mayor@gmail.com>, MELISSA SAVARES <melissa.savares@gmail.com>, "Vice Mayor Peter John S. Benavente" <onedededo@gmail.com>, hagatnamayor@hotmail.com, Mayor Anthony Chargualaf <inalahanmayor@gmail.com>, Allan Ungacta <mayorallan.ungacta@yahoo.com>, Vice Mayor Kevin AN Delgado <mangilao.vicemayor@gmail.com>, mayorernestc@yahoo.com, mtmmayorpaco17@gmail.com, Jesse Alig <jesse.alig@pitiguam.com>, Dale Alvarez <daleealvarez@gmail.com>, Robert Hofmann <guammayor@gmail.com>, rudy iriarte <rudyiriarte@gmail.com>, Mayor Taitague <talofofomayor@gmail.com>, "Mayor Louise C. Rivera" <Mayorlcrivera.tatuha@gmail.com>, "Vice Mayor Albert M. Toves" <atoves.tatuha@gmail.com>, Umatac Mayor <umatacmo@gmail.com>, "Mayor Anthony P. Sanchez" <ymayortony@gmail.com>, "Vice Mayor Loreto V. Leones" <lloretoleones@gmail.com>, "Mayor Bill A. Quenga" <yonamayor2020@gmail.com>, jolene@postguam.com, Phil Leon Guerrero <phil@postguam.com>, Gerry Partido <gerrypartido@gmail.com>, gerry@spbguam.com, Damen Borja <damen@spbguam.com>, tlamorena@gmail.com, jsantotoma@guampdn.com, "Taitano, Joseph" <JTaitano@guampdn.com>, "Arthur U. San Agustin" <arthur.sanagustin@dphss.guam.gov>, "Laureal B. Villagomez" <Laureal.Villagomez@dphss.guam.gov>, "Theresa L. Arcangel" <theresa.arcangel@dphss.guam.gov>, "Terry G. Aguon" <Terry.Aguon@dphss.guam.gov>, Laurent Duenas <Laurent.duenas@dphss.guam.gov>, Chris Malafunkshun Barnett <chrisbarnett671@gmail.com>, "San Nicolas, Michael" <michael.sannicolas@mail.house.gov>, "Michael Q. Gallo" <Michael.Gallo@dphss.guam.gov>, erri Gumataotao <TERESITA.Gumataotao@dphss.guam.gov>, "Jeffrey A. San Nicolas" <Jeffrey.SanNicolas@dphss.guam.gov>, Janet Cruz <Janet.Cruz@dphss.guam.gov>, "Carlos B. Pangelinan" <Carlos.Pangelinan@dphss.guam.gov>, Rachelle Paulino <Rachelle.Paulino@dphss.guam.gov>, Annabelle Estrada <Annabelle.Estrada@dphss.guam.gov>, [redacted]@gmail.com, "Grino, Rose" <rose.grino@fhphealth.com>, [redacted]@mail.mil, usn.guam.navhospgu.list.ubo-external@mail.mil, wilma.RAMOS@medpharmusa.com, [redacted]@yahoo.com, megadrugpharmacy01@gmail.com, accounting@mdwholesaleguam.com, jfisher@mdwholesaleguam.com, rx2@teleguam.net, harmondrugs@aol.com, sgarcia@adventistclinic.com, tsiguenza@adventistclinic.com, mvega@guamsda.com, michelle.deloso@dphss.guam.gov, sandra.leynes@dphss.guam.gov, [redacted]@yahoo.com, [redacted]@yahoo.com, jessabeln@paylessmarkets.com, [redacted]@yahoo.com, jackiep@paylessmarkets.com, sdagana@paylessmarkets.com, sdyigo@paylessmarkets.com, tania.ramos@medpharmusa.net, compharm@ite.net, community_pharmacy@yahoo.com, Marilyn Aflague <marilyn.aflague@gbhwc.guam.gov>, ceciliaa@paylessmarkets.com, mary.chargualaf@medpharmusa.net,

communitypharmacy2@yahoo.com, BusinessOffice.Mailbox@grmc.gu, MEDS2@expressrx.us, [redacted]@hotmail.com, ed.manuel@m3dpropacific.com, maryjean.cabildo@dphss.guam.gov, jean@simplyrxguam.com, [redacted]@gmail.com, linda.kizer@walgreens.com, marina-mahoney@nc-hs.com, thoffman@rxpartnersmgt.com, FMCRxPayerRelationa@fmc-na.com

June 20, 2022

MEMORANDUM

To: All Senators, Stakeholders and Media

From: Speaker Therese M. Terlaje, Chairperson

Subject: **FIRST NOTICE** of Joint Public Hearing – Monday, June 27, 2022, beginning at 1:00 PM

Buenas yan Håfa Adai,

Please be advised that the Committee on Health, Land, Justice, and Culture in conjunction with the Department of Public Health & Social Services, Bureau of Health Care Financing Administration Division will convene a joint public hearing, on **Monday, June 22, 2022, beginning at 1:00 PM** in the Guam Congress Building, Public Hearing Room, for the following agenda item:

· **Guam Medicaid – Medicaid Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation** -The Guam Medicaid Program, administered under the Department of Public Health and Social Services (DPHSS), Division of Public Welfare will conduct a Public Hearing notifying island residents, program recipients & providers, and all other stakeholders of its intent to submit to the Centers for Medicare and Medicaid Services (CMS), on or before August 1, 2022, a written 1115 Demonstration application which will request to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program (MDRP) and to receive comments on the proposed MDRP 1115 Waiver Demonstration application.

The CMS final rule (CMS-2345-FC) allows the territories to "opt out under…section 1902(j) of the Act." It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54), which requires state compliance with applicable requirements of section 1927 requiring Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP) by January 2023.

This 1115 waiver demonstration project will allow for a period for the Guam Medicaid Program to conduct a demonstration study on the potential adverse effects of participation in the MDRP on our island pharmacy providers and program recipients. The 1115 Waivers are generally approved by CMS for an initial five (5) year period and can be extended.

Presentation By: Michael Q. Gallo, Program Coordinator, Guam Medicaid Program

Guam Medicaid Recipients, Pharmacy Providers, and other Stakeholders are invited to provide oral or written testimony. Written testimony may be submitted via email to michael.gallo@dphss.guam.gov or jeffrey.sannicolas@dphss.guam.gov. or hand delivered to Guam Medicaid Program, #130 University Drive, Suite 5 Castle Mall Building, Mangilao, Guam 96913.

All hearings broadcast on GTA TV Channel 21, Docomo Channel 117/112.4, and livestream on https://www.youtube.com/c/GuamLegislatureMedia. In compliance with the Americans with Disabilities Act, Individuals needing special accommodations can contact the Office of Speaker Therese M. Terlaje.

Office of Speaker Therese M. Terlaje
Committee on Health, Land, Justice and Culture
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FIRST NOTICE OF PUBLIC HEARING- TUESDAY, JUNE 27, 2022 AT 1PM_TMT.pdf
367K

Office of the Speaker
THERESE M. TERLAJE
I Mina'trentai Sais na Liheslaturan Guåhan | 36th Guam Legislature
Committee on Health, Land, Justice and Culture

June 20, 2022

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- **Guam Medicaid – Medicaid Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation** (30 minutes)

  The Guam Medicaid Program, administered under the Department of Public Health and Social Services (DPHSS), Division of Public Welfare will conduct a Public Hearing notifying island residents, program recipients & providers, and all other stakeholders of its intent to submit to the Centers for Medicare and Medicaid Services (CMS), on or before August 1, 2022, a written 1115 Demonstration application which will request to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program (MDRP) and to receive comments on the proposed MDRP 1115 Waiver Demonstration application.

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As nuke test looms, NKorea reports intestinal epidemic

By Michelle Ye Hee Lee and Min Joo Kim
The Washington Post

TOKYO - As South Korean and U.S. officials repeated their warnings this week about a potential North Korean nuclear test, Pyongyang announced it is fighting a new intestinal epidemic that comes as the country grapples with drought, COVID and ongoing food and cash shortages from its border lockdown.

During his visit to Washington this week, South Korean Foreign Minister Park Jin echoed U.S. assessments that North Korea apparently has completed preparations for its seventh nuclear test, which would sharply raise the stakes in the diplomatic standoff between Washington and Pyongyang. Park said he believes North Korean leader Kim Jong Un is waiting for the time to make his "political decision."

New satellite images released this week by the Washington-based Center for Strategic and International Studies showed that refurbishment work at the Punggye-ri nuclear testing facility, which has been taking place over the past four months, appeared to be complete.

PYONGYANG: *A sign depicting a scene of medical products transportation is displayed along an empty street, amid growing fears over the spread of COVID-19, in Pyongyang, North Korea, in this photo released on May 23. Kyodo via Reuters*

Pyongyang has held an unprecedented volley of missile tests as it rapidly expands and diversifies its weapons program. It tested an estimated 31 ballistic missiles this year - surpassing its annual record in just six months and despite U.N. Security Council resolutions prohibiting such tests. All the while, North Korea remains in a strict COVID border closure, even for its largest trading partner, neighboring China. Park, speaking at a news conference with U.S. Secretary of State Antony Blinken this week, warned North Korea against further isolating itself.

"I think that North Korea is at a crossroads now. It can go ahead with its nuclear test and isolate itself, or it can make a right decision and return to the diplomacy and the dialogue. I hope North Korea can make the latter choice instead of continuing on a dangerous course of action," Park said.

The Korea Institute for Defense Analyses, which is affiliated with the South Korean Defense Ministry, estimated North Korea has spent as much as 2% of its gross domestic product this year - between $400 million and $650 million - on its missile tests.

Meanwhile, North Korea's Central News Agency reported Thursday on an outbreak of the "acute enteric epidemic," without naming the disease or giving a caseload. The term enteric refers to the gastrointestinal tract, and observers said the disease could be an intestinal illness like typhoid and cholera.

The announcement, though concerning, does not necessarily indicate a worsening public health crisis, according to Ahn Kyung-su, from the Seoul-based research center dprkhealth.org.

Waterborne diseases like cholera and typhoid were rampant in North Korea before the announcement of the country's first coronavirus infection. Ahn said the outbreak of intestinal disease is not an uncommon situation given the country's poor health and sanitary conditions.

"The recent state media reports about the outbreak could be a politically motivated one to demonstrate leader Kim Jong Un's efforts for his people," Ahn said.

North Korean state media reported that Kim is distributing medical aid as part of "his noble outlook on devoted service for the people's well-being."

Still, the outbreak probably complicates matters for the regime, which is already fighting a coronavirus outbreak amid growing economic woes and a chronic shortage of vaccines and medicines.

South Korea's Unification Ministry said Thursday that it is willing to help North Korea battle the new outbreak. But Pyongyang has not responded to offers of coronavirus aid from South Korea and the United States and is unlikely to change course with countries the regime considers national security threats.

North Korea has asked for freight train service with China to be restored amid its shortage of food and medical supplies, Japan's Asahi Shimbun reported this week, citing Chinese sources. It was the latest sign of North Korea's growing dependence on Beijing, which has drawn Pyongyang closer amid rising U.S.-China competition.

Kim reported from Seoul.

Gmail Speaker Therese M. Terlaje <senatorterlajeguam@gmail.com>

SECOND NOTICE of Joint Public Hearing – Monday, June 27, 2022, beginning at 1:00 PM

4 messages

Speaker Therese M. Terlaje <senatorterlajeguam@gmail.com> Fri, Jun 24, 2022 at 2:23 PM
To: phnotice@guamlegislature.org
Cc: Audio / Video <av@guamlegislature.org>, Tom Unsiog <sgtarms@guamlegislature.org>, Guam MIS <mis@guamlegislature.org>
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June 24, 2022

MEMORANDUM

To: All Senators, Stakeholders and Media

From: Speaker Therese M. Terlaje, Chairperson

Subject: **SECOND NOTICE of Joint Public Hearing – Monday, June 27, 2022, beginning at 1:00 PM**

Buenas yan Håfa Adai,

Please be advised that the Committee on Health, Land, Justice, and Culture in conjunction with the Department of Public Health & Social Services, Bureau of Health Care Financing Administration Division will convene a joint public hearing, on **Monday, June 27, 2022, beginning at 1:00 PM** in the Guam Congress Building, Public Hearing Room, for the following agenda item:

- **Guam Medicaid – Medicaid Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation**

The Guam Medicaid Program, administered under the Department of Public Health and Social Services (DPHSS), Division of Public Welfare will conduct a Public Hearing notifying island residents, program recipients & providers, and all other stakeholders of its intent to submit to the Centers for Medicare and Medicaid Services (CMS), on or before August 1, 2022, a written 1115 Demonstration application which will request to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program (MDRP) and to receive comments on the proposed MDRP 1115 Waiver Demonstration application.

The CMS final rule (CMS-2345-FC) allows the territories to "opt out under…section 1902(j) of the Act." It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54), which requires state compliance with applicable requirements of section 1927 requiring Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP) by January 2023.

This 1115 waiver demonstration project will allow for a period for the Guam Medicaid Program to conduct a demonstration study on the potential adverse effects of participation in the MDRP on our island pharmacy providers and program recipients. The 1115 Waivers are generally approved by CMS for an initial five (5) year period and can be extended.

Presentation By: Michael Q. Gallo, Program Coordinator, Guam Medicaid Program

Guam Medicaid Recipients, Pharmacy Providers, and other Stakeholders are invited to provide oral or written testimony. Written testimony may be submitted via email to michael.gallo@dphss.guam.gov or jeffrey.sannicolas@dphss.guam.gov. or hand delivered to Guam Medicaid Program, #130 University Drive, Suite 5 Castle Mall Building, Mangilao, Guam 96913.

All hearings broadcast on GTA TV Channel 21, Docomo Channel 117/112.4, and livestream on https://www.youtube.com/c/GuamLegislatureMedia. In compliance with the Americans with Disabilities Act, Individuals needing special accommodations can contact the Office of Speaker Therese M. Terlaje.

Office of Speaker Therese M. Terlaje
Committee on Health, Land, Justice and Culture
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36th Guam Legislature
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SECOND NOTICE OF PUBLIC HEARING- TUESDAY, JUNE 27, 2022 AT 1PM_TMT.pdf
369K

Michael Q Gallo <Michael.Gallo@dphss.guam.gov> Mon, Jun 27, 2022 at 3:52 AM
To: "Speaker Therese M. Terlaje" <senatorterlajeguam@gmail.com>
Cc: Terri Gumataotao <TERESITA.Gumataotao@dphss.guam.gov>, "Jeffrey A. San Nicolas" <Jeffrey.SanNicolas@dphss.guam.gov>, Janet Cruz <Janet.Cruz@dphss.guam.gov>, "Carlos B. Pangelinan" <Carlos.Pangelinan@dphss.guam.gov>, Rachelle Paulino <Rachelle.Paulino@dphss.guam.gov>, "June S. Perez" <June.Perez@dphss.guam.gov>

Hello Charissa,

Office of the Speaker
THERESE M. TERLAJE
I Mina'trentai Sais na Liheslaturan Guåhan | 36th Guam Legislature
Committee on Health, Land, Justice and Culture

June 24, 2022

MEMORANDUM

To: All Senators, Stakeholders and Media

From: Speaker Therese M. Terlaje, Chairperso [redacted]

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compliance with applicable requirements of section 1927 requiring Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP) by January 2023.

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COVID-19 numbers got "scary," but still fall short of surge

While new COVID-19 cases have increased and hospitalization numbers have crept up slightly, they continue to fall short of the "triggers" that signal another surge.

Guam's test positivity was "skyrocketing" and the seven-day average was about 16%, said Vince Campo, Department of Public Health and Social Services surveillance branch director. Additionally, the seven-day case average "almost hit 100," which he said was "scary" for DPHSS. He reported a seven-day average of 88.3.

This week, however, he said the positivity rates have dropped to about 9% or 10% and, while case numbers have been at 100-plus for the past week or so, Thursday's Joint Information Center report showed 75 new COVID-19 cases from 864 tests administered Wednesday.

During the weekly press conference held Thursday morning, Campo shared the three triggers that would indicate another COVID-19 surge:

- Seven-day average of 100 cases per day.
- 20 COVID-19 hospitalizations.
- 10 COVID-19 patients in the intensive care unit.

Campo said hospitalizations are a "bright side" of the weekly reports. He said Guam continues to see "consistent numbers" hovering at about six to eight patients a day.

"We are not seeing too many hospitalized," he said, adding that even ICU numbers have been very small.

According to the JIC's Thursday report, there were eight hospitalizations: five at Guam Memorial Hospital; two at Guam Regional Medical City; and one at U.S. Naval Hospital Guam. GMH has one COVID-19 ICU patient.

Campo and Dr. Robert Leon Guerrero, DPHSS interim medical officer, continued to encourage residents, particularly those with comorbidities or who are elderly, to continue to wear their masks, wash their hands, and watch their distances from other people - a triad of COVID-19 prevention tips known as the 3 Ws.

(Daily Post Staff)

Bank of Guam's Marati to retire

Jacqueline A. Marati

Jacqueline A. Marati, Bank of Guam senior vice president and chief corporate social responsibility officer, is retiring after 23 years with the bank, Bank of Guam stated in a press release.

Marati, who first joined the bank's Corporate Banking Group in 1999, held the position of special assistant to then-bank president Tony Leon Guerrero before moving to other divisions of the bank including marketing, human resources, communication and public relations.

"Over her career with Bank of Guam, Jackie has made a genuine impact on how the bank has grown and developed our community outreach, sustainability and financial empowerment efforts," said Joaquin P. L.G. Cook, president and CEO.

"We are grateful for the work she has done, but most importantly the relationships she has established and nurtured within the organization and in the community. We know Jackie's commitment to excellence in social responsibility and sustainability is steadfast and that her journey is far from over. The board of directors, management, staff and we, her Bank of Guam familia, wish her the very best in her next chapters."

For the last few years, Marati has overseen the Bank's Communications and Corporate Social Responsibility efforts. Fueled by her passion to give back to the island communities served by the bank, she has led several international award-winning Bank of Guam projects: the Bank's Year in Review, Annual Calendar and Founder's Day of Giving, the bank stated in the release.

(Daily Post Staff)

GPA mobile app getting updates

The Guam Power Authority announced Friday the GPWA mobile phone application is scheduled for updates July 1.

The updates will address application bug fixes, improve application stability and allow compatibility with newer devices, GPA stated in a press release.

As the updates are being implemented, the application will remain fully operational, according to GPA. The updates will be available for download only from the Apple and Google Play App Stores, GPA stated.

(Daily Post Staff)

NOTICE OF JOINT PUBLIC HEARING- MONDAY, JUNE 27, 2022 AT 1:00PM

NOTICE OF JOINT PUBLIC HEARING- MONDAY, JUNE 27, 2022 AT 1:00PM

Public Hearing

Posted on: 06/20/2022 12:19 PM

Posted by: Charissa Manibusan, Charissa Manibusan, Committee Director

Department(s): GUAM LEGISLATURE (/notices?department_id=92)

Division(s): OFFICE OF SPEAKER THERESE M. TERLAJE (/notices?division_id=259)

Notice Topic(s): PUBLIC HEARING (/notices?topic_id=74)

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June 20, 2022

MEMORANDUM

To: All Senators, Stakeholders and Media

From: Speaker Therese M. Terlaje, Chairperson

Subject: **NOTICE** of Join Public Hearing – Monday, June 27, 2022, beginning at 1:00 PM

Buenas yan Håfa Adai,

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· **Guam Medicaid – Medicaid Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation** (30 minutes)

The Guam Medicaid Program, administered under the Department of Public Health and Social Services (DPHSS), Division of Public Welfare will conduct a Public Hearing notifying island residents, program recipients & providers, and all other stakeholders of its intent to submit to the Centers for Medicare and Medicaid Services (CMS), on or before August 1, 2022, a written 1115 Demonstration application which will request to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program (MDRP) and to receive comments on the proposed MDRP 1115 Waiver Demonstration application.

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Presentation By: Michael Q. Gallo, Program Coordinator, Guam Medicaid Program

Guam Medicaid Recipients, Pharmacy Providers, and other Stakeholders are invited to provide oral or written testimony. Written testimony may be submitted via email to **michael.gallo@dphss.guam.gov (mailto:michael.gallo@dphss.guam.gov)** or **jeffrey.sannicolas@dphss.guam.gov (mailto:jeffrey.sannicolas@dphss.guam.gov)**. or hand delivered to Guam Medicaid Program, #130 University Drive, Suite 5 Castle Mall Building, Mangilao, Guam 96913.

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Committee on Health, Land, Justice and Culture

Joint Public Hearing- 36th Guam Legislature Committee on Health & the Bureau of Health Care Financing Administration Division, Department of Public Health, and Social Services

Monday, June 27, 2022, beginning at 1:00 PM

AGENDA

- Informational Briefing by the DPHSS Guam Medicaid Program on the Guam Medicaid Drug Rebate Program (MDRP) 1115 Waiver Demonstration Presentation

    - The Guam Medicaid Program, administered under the Department of Public Health and Social Services (DPHSS), Division of Public Welfare will conduct a Public Hearing notifying island residents, program recipients & providers, and all other stakeholders of its intent to submit to the Centers for Medicare and Medicaid Services (CMS), on or before August 1, 2022, a written 1115 Demonstration application which will request to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program (MDRP) and to receive comments on the proposed MDRP 1115 Waiver Demonstration application.

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I Mina'trentai Sais na Liheslaturan Guåhan | 36th Guam Legislature

Office of Speaker Therese M. Terlaje

Committee on Health, Land, Justice and Culture

Date: MONDAY, JUNE 27, 2022 **Time:** 1:00PM

JOINT PUBLIC HEARING- Informational Briefing by the Department of Public Health & Social Services
GUAM MEDICAID PROGRAM– Medicaid Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation

	NAME	ADDRESS	CONTACT NO.	E-MAIL	Type of Testimony		Support	
					WRITTEN	ORAL	Yes	No
1	Gault, Michael		[redacted]					
2	Jeffry SanNicks		[redacted]				✓	
3	Janet Cruz		[redacted]				✓	
4	Charles Pangelinan		[redacted]				✓	
5	Dennis G. Rodriguez, Jr.	Gov's office	[redacted]					
6								
7								
8								
9								
10								

Guam Medicaid Program

MEDICAID DRUG REBATE PROGRAM 1115 WAIVER DEMONSTRATION

Presented By: Michael Gallo, Program Coordinator

Introduction

The Guam Medicaid Program is conducting this public hearing to inform the Public, Program Recipients, Medicaid Pharmacy Providers, and all other Stakeholders of its intent to submit to the Centers for Medicare and Medicaid services (CMS), an 1115 Demonstration Application on or before August 1, 2022, requesting to waive the Federal Mandate for Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP) and to receive comments on the proposed 1115 Waiver Demonstration Application.

Discussion Points

I. MEDICAID DRUG REBATE PROGRAM (MDRP)
II. 1115 WAIVER DEMONSTRATIONS
III. GUAM MEDICAID PRESCRIPTION DRUG BENEFIT
IV. MDRP IMPLEMENTATION – 1115 WAIVER ASSESSMENT AREAS/EVALUATION DESIGN

I. Medicaid Drug Rebate Program (MDRP)

The Medicaid Drug Rebate Program (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 states cover prescription drugs under the MDRP, which is authorized by Section 1927 of the Social Security Act.

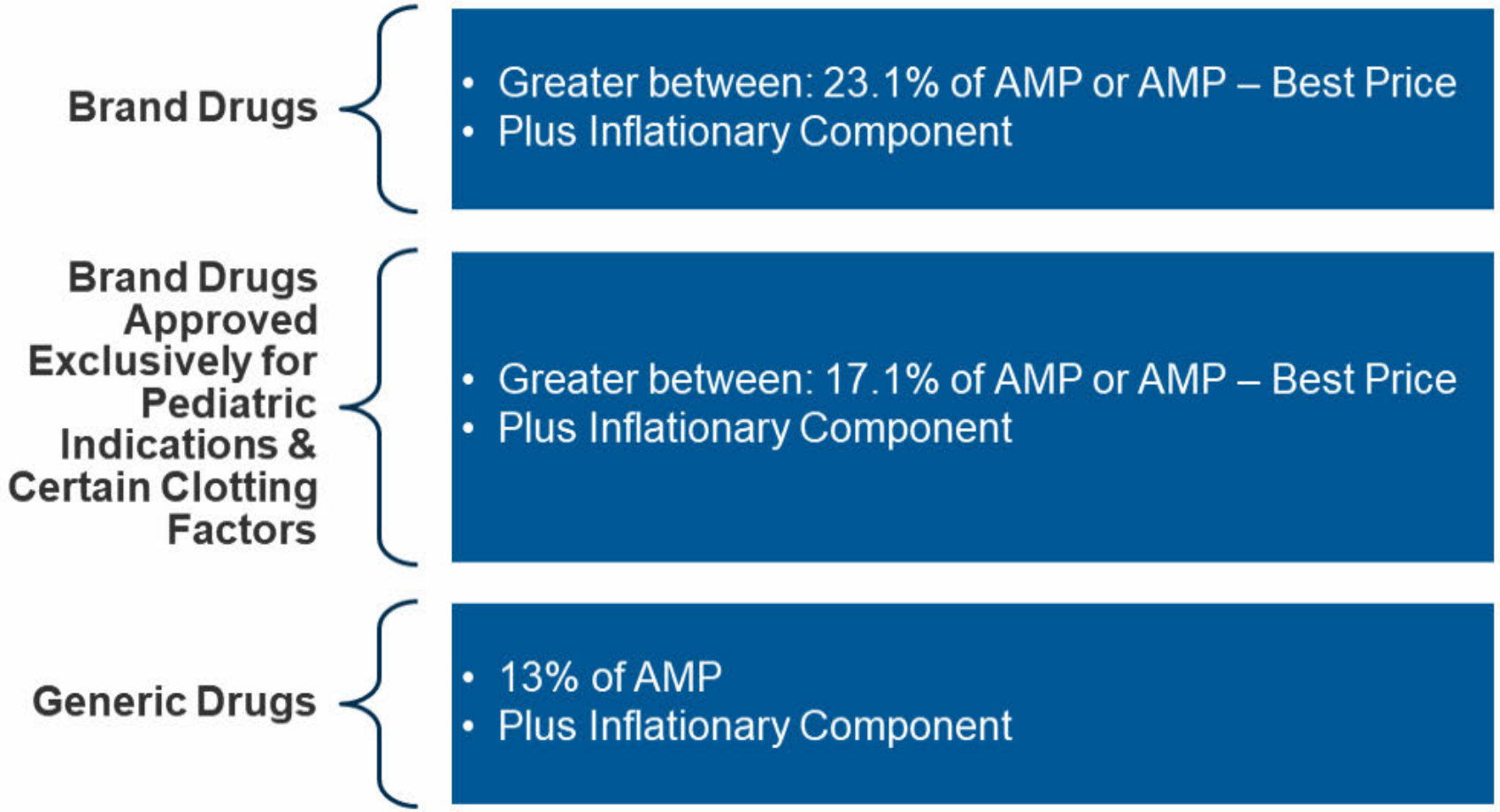
I. Medicaid Drug Rebate Program (MDRP)

- The MDRP is designed to offset overall costs of prescription drugs under the Medicaid Program by requiring drug manufacturer 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 all of the manufacturer's covered outpatient drugs (COD).

- 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 based on the FMAP.

Figure 1

Medicaid Statutory Rebate Amounts



NOTE: AMP is average manufacturer price.
SOURCE: 42 U.S.C. 1396r-8 (c)

I. Medicaid Drug Rebate Program (MDRP)

On February 1, 2016, 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). 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" allows Territories to participate in the Medicaid Drug Rebate Program (MDRP).

*This "Covered Outpatient Drug" final rule allows Territories to use existing waiver authority under Title XIX of the Social Security Act to elect not to participate in the MDRP (1115 Waiver Demonstration).

I. Medicaid Drug Rebate Program (MDRP)

On November 19, 2021, CMS issued "Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States". This rule delayed for 9 months the April 1, 2022 effective date of inclusion of the U.S. territories in the amended regulatory definitions of "States" and "United States" for purposes of the Medicaid Drug Rebate Program (MDRP), adopted in the interim final rule with comment period entitled, "Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States", published in the November 25, 2019 Federal Register to January 1, 2023.

II. 1115 Waiver Demonstration

Under section 1115(a) of the Act, CMS, operating under the Secretary's delegated authority, may authorize a state to conduct experimental, pilot, or demonstration projects that, in the judgment of the Secretary, are likely to assist in promoting the objectives of title XIX of the Act. The Secretary (1) may, under section 1115(a)(1), waive provisions in section 1902 of the Act.

An 1115 waiver is an experimental, pilot, or demonstration project that promotes the objectives of Medicaid and CHIP. The waiver tests a hypothesis and states must develop an evaluation design to test it. 1115 Waivers must be budget neutral meaning the waiver will not increase federal Medicaid expenditures. The waiver is usually approved by CMS for an initial 5 year period and can be extended.

II. 1115 Waiver Demonstration

1115 Waiver Public Notice Process:

* CMS requires a 30 day state public notice and comment period for 1115 applications.

* Two public hearings must be held at least 20 days prior to submission of an 1115 application. Public notice information including the notice/comment process and a copy of application must be posted page or must be linked to from the main page.

*State public notice requirements are found in 42 CFR 431.408.

*CMS will conduct a 30 day federal public notice process within 15 days of receiving the application.

II. 1115 Waiver Demonstration

1115 Waiver Monitoring and Compliance: * State must perform periodic review of the implementation of the waiver. Within 6 months of the implementation date the state must hold a public forum to solicit comments on the progress of the waiver. A public forum must be held annually thereafter. Requirements regarding this are found in 42 CFR 431.420.

1115 Waiver Reporting Requirements: * The state must submit a draft annual report to CMS. The draft report must be published on their website. CMS will provide the state comments. The state must publish the final report on its website. Requirements regarding the report are found in 42 CFR 431.428.

II. 1115 Waiver Demonstration

Guam Medicaid – MDRP 1115 Waiver Demonstration

HYPOTHESIS:

Guam Medicaid's participation in the MDRP could adversely affect On-Island Pharmacy Providers by creating an unreasonable requirement for them to carry all of the MDRP participating manufacturer's COD such that it would be difficult for them to maintain adequate inventory, and this may be prohibitive for them to continue as providers on the Medicaid program. Additionally, it would be more costly and labor intensive due to required administrative costs for the program to participate in the MDRP, and these costs would outweigh the rebate savings the MDRP would provide.

III. Guam Medicaid Drug Prescription Benefit

* Closed drug formulary (Guam Medicaid controls formulary listing)

*Brand medication not allowed – unless requested/documented as medically necessary

*Pricing established in January of each calendar year based on lowest wholesale price (LWP) listed on Red Book (IBM Micromedex) – Online Subscription for drug medication price listing that is updated daily excluding weekends and holidays

Note: These control measures have allowed the program to maintain relatively low expenditures for their drug prescription benefits.

III. Guam Medicaid Prescription Drug Benefit

Current On-Island Pharmacy Challenges - Difficulty in obtaining supplies due to the remoteness of Guam's location relative to supply chains (This often times creates challenges in the form of accepting higher wholesale pricing from distributors when purchasing pharmaceutical drugs, and paying for higher shipping costs). This often times translates to more expensive costs requested as reimbursement for the sale of CODs to program recipients.

Guam's participation in the MDRP would place added pressures on the island Medicaid pharmacy providers and may prove more costly because it would require them to carry all CODs of participating MDRP manufacturers, and for the program to cover them. Note: Currently, almost all drug manufacturers are participating in the MDRP.

III. Guam Medicaid Prescription Drug Benefit

Current On-Island Pharmacy Challenges - Difficulty in obtaining supplies due to the remoteness of Guam's location relative to supply chains (This often times creates challenges in the form of accepting higher wholesale pricing from distributors when purchasing pharmaceutical drugs, and paying for higher shipping costs). This often times translates to more expensive costs requested as reimbursement for the sale of CODs to program recipients.

Guam's participation in the MDRP would place added pressures on the island Medicaid pharmacy providers and may prove more costly because it would require them to carry all CODs of participating manufacturers on the MDRP, and for the program to cover them. Note: Currently, almost all drug manufacturers are participating in the MDRP.

IV. MDRP Implementation – 1115 Waiver Demonstration

Assessment Questions/Evaluation design:

1. What are the existing supply chains (Pharmaceutical Distributors) available to On-Island Pharmacies?

2. What current limitations do On-Island Pharmacies have in dealing with existing supply chains when ordering CODs for MDRP participating manufacturers?

3. How would Guam Medicaid's participation in the MDRP affect On-Island Pharmacy Providers decision to continue as a provider on the Medicaid program?

IV. MDRP Implementation – 1115 Waiver Demonstration

Assessment Questions/Evaluation design: (Continued)

4. Would the cost reduction for pharmacy expenditures outweigh the adverse effects of creating potential inadequate participant access to On-Island Pharmacy Services?

5. What other costs would be involved in Guam Medicaid's participation in the MDRP, and would these costs outweigh the benefit of the rebate savings to its pharmacy expenditures.

Note: CMS is currently working with the Guam Medicaid Program to develop the Evaluation Design for the 1115 Waiver Demonstration and will be published on the Guam Medicaid website when finalized.

Discussion Points Review

* MEDICAID DRUG REBATE PROGRAM (MDRP)

* 1115 WAIVER DEMONSTRATIONS

* GUAM MEDICAID PRESCRIPTION DRUG BENEFIT

* MDRP IMPLEMENTATION – 1115 WAIVER ASSESSMENT AREAS/EVALUATION DESIGN

Thank You
For Your Attention

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PUBLIC NOTICE

GUAM MEDICAID – MEDICAID DRUG REBATE PROGRAM (MDRP) SECTION 1115 WAIVER DEMONSTRATION APPLICATION

Public Notice – June 24, 2022
The Guam Medicaid Program, administered under the Department of Public Health and Social Services (DPHSS), Division of Public Welfare is providing public notice of its intent to:

(1) submit to the Centers for Medicare and Medicaid Services (CMS), on or before August 1, 2022, a written 1115 Demonstration application to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program (MDRP); and

(2) hold public hearings to receive comments on the 1115 Waiver Demonstration application.

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

I. Program Description
A. Overview

As stated on the Centers for Medicare & Medicaid Services (CMS) Medicaid site: The Medicaid Drug Rebate Program (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 Social Security Act.

The MDRP is designed to offset overall costs of prescription drugs under the Medicaid Program by requiring drug manufacturer 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. Guam Medicaid currently has two (2) Federally Qualified Health Centers (FQHC)

that participate under the Section 340B Drug Pricing Program: The Northern Regional Health Center (NRHC) and The Southern Regional Health Center (SRHC). 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 mentioned above.

On February 1, 2016, 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). 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" allows Territories to participate in the Medicaid Drug Rebate Program (MDRP). Additionally, we indicated in the "Covered Outpatient Drug" final 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).

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 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, Guam will be required to participate in the MDRP effective January 1, 2023. However, Guam is allowed to use the 1115 waiver authority to elect not to participate in the MDRP.

In light of the statutory MDRP directive, Guam Medicaid is seeking a waiver exempting them from the requirement to participate in the drug rebate program. Guam is requesting that the exemption from participating in the MDRP be effective from January 1, 2023 - December 31, 2027.

B. Summary of 1115 Waiver Demonstration Application Request

The CMS final rule (CMS-2345-FC) allows the territories to "opt out under...section 1902(j) of the Act." It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act that requires Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP).

Historically, the Guam Medicaid funding has been limited under the Section 1108 annual block grant, and further limited by the established 55-45% FMAP. These limitations created an environment where the Guam Medicaid Program experienced hesitancy on the part of health care providers on island in participating in the program. The funding increases provided by the Patient Protection and Affordable Care Act (Obamacare) provided a temporary increase in funding, and recent legislation has further provided additional temporary funding and FMAP increases. These increases have helped the Guam Medicaid Program expand services and encouraged provider participation resulting in better recipient access to services that exist today.

Although the Medicaid Drug Rebate Program (MDRP) will offset costs of prescription drugs under the Guam Medicaid Program, the Territory has identified potential negative impacts for pharmacy providers which may ultimately affect the program's ability to maintain its existing provider network of on-island pharmacies essential for program participants to have adequate access to pharmacy services, and create added labor intensive program costs that may outweigh the benefits of participation in the MDRP.

The island Medicaid pharmacy providers often face challenges in obtaining supplies because of the remoteness of Guam's location relative to supply chains. This often times creates challenges in the form of accepting higher wholesale pricing from distributors when purchasing pharmaceutical drugs, and paying for higher shipping costs because of the need to transport these supplies via air freight due to their inability to stockpile medication when considering drug expiration dates relative to expected sales and supply needs which often causes inventory or availability issues. This often times translates to more expensive costs that is requested as reimbursement for the sale of these medications to program recipients.

Additionally, due to the relatively insignificant total purchase amounts made through pharmaceutical distributors in comparison to the larger pharmacy chains in the mainland U.S., the island pharmacy providers are unable to negotiate for best prices or favorable shipping terms in obtaining medication supplies. Guam's participation in the MDRP would place added pressures on the island Medicaid pharmacy providers because it would require them to carry all covered outpatient drugs (COD) of a participating manufacturer, and for the program to cover these CODs under Medicaid. Currently, almost all drug manufacturers are participating in the MDRP.

Guam Medicaid has managed to control the costs of Pharmacy expenditures because it currently controls their drug formulary which list covered medication under the program. However, participation in the MDRP would require that we cover all drugs of participating manufacturers, and essentially cover all COD drugs if the waiver application is not approved. This would be a substantial cost increase to Guam Medicaid. The current drug pricing for the program's drug formulary is set at the Lowest Wholesale Price (LWP) listed on Redbook at the time the formulary is released in January of each calendar year. The program feels that during this waiver demonstration, they would be able to maintain substantial cost savings for their pharmacy expenditures by maintaining a relatively low expenditure rate for its pharmacy expense relative to total expenditures, and the approval of the 1115 waiver will allow the program a period of time to assess this standard in comparison with other state Medicaid programs that receive rebates under the MDRP.

Under this MDRP 1115 Waiver Demonstration application, the program will be able to continue to maintain control of its drug formulary and the covered outpatient drug (COD) coverage, and allow more time for the program to properly assess island pharmacy impacts, which is important because of potential drug inventory issues faced by the on-island pharmacies as previously mentioned due to our remoteness relative to mainland pharmaceutical supply lines. This waiver may prove to be more of a cost savings for Guam Medicaid when compared to potentially having to cover all drugs of manufacturers that enter into a rebate under the MDRP and create additional administrative burdens and costs due to additional labor-intensive costs for implementation activities associated with the implementation and participation in the MDRP.

C. Eligibility Requirements

The 1115 Demonstration application requests to waive participation in the Medicaid Drug Rebate Program (MDRP) as it will affect the on-island pharmacy provider participation on the program which will affect adequate access for the program participants described in the chart below.

Eligibility Group Name	Social Security Act and CFR Citations	Income Level
Guam Medicaid Program New Adult Group (MAPNEG), Elderly and Disabled	Social Security Act 1396(a)(10)(A)(i)(VIII) 42 C.F.R. 435.119	New adult group, Elderly and Disabled group with income 0-138 percent LPL

D. Health Care Delivery System and Benefits

This MDRP 1115 Waiver Demonstration Application is seeking to waive the programs participation in the MDRP and does not propose any changes to the Medicaid health care delivery system; Guam Medicaid enrollees will continue to receive services through the Territory's fee-for-service delivery system. MAPNEG Program enrollees will also continue to receive benefits through the Alternative Benefit Plan; the Territory does not propose any changes to benefits for any program enrollees.

E. Cost Sharing

Cost sharing will not be affected under this 1115 Waiver Demonstration request.

II. Goals and Objectives

The overall goal of the demonstration is to assure the network capacity of on-island pharmacy providers remains consistent with the existing capacity prior to an implementation mandated for program participation in the MDRP in order to provide adequate recipient access to pharmacy services, and to allow time to properly assess potential adverse effects of participation in the MDRP on our island pharmacy providers, program recipients, and to assess additional administrative program costs related to the management of the MDRP that would possibly outweigh any rebate savings.

NOTE: The demonstration applies to all pharmacy services for authorized providers under the Guam Medicaid State Plan that dispense covered outpatient drugs (COD).

The 1115 Demonstration application requests to waive participation in the Medicaid Drug Rebate Program (MDRP) as it will be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP) than the rebate savings it provides, and may potentially impact provider (pharmacy) participation.

III. Enrollment Projections and Annual Expenditures

Guam Medicaid program's historical enrollment figures for fiscal years 2016 to present and corresponding program year total program expenditures and pharmacy expenditures with projections for FY2022 through FY2027.

Figure 1. Guam Medicaid Program Historical and Projected - Enrollment and Expenditures Data

Fiscal Year	Enrollment	Total Expenditures	Pharmacy Expenditure	Pharmacy Expenditures %	Pharmacy Expenditures Per Recipient
FY2016	43673	$95,382,705	$23,597,926	24.74%	540
FY2017	43476	$108,609,905	$22,251,392	20.49%	512
FY2018	43600	$110,876,286	$13,945,932	12.58%	320
FY2019	43671	$149,037,981	$21,950,084	14.73%	503
FY2020	43238	$157,256,853	$19,570,466	12.44%	453
FY2021	45692	$123,971,992	$19,821,809	15.99%	434
FY2022	43892	$124,189,287	$20,189,602	16.26%	460
FY2023	43990	$124,445,463	$20,234,832	16.26%	460
FY2024	44089	$124,724,257	$20,280,164	16.26%	460
FY2025	44187	$125,003,676	$20,325,598	16.26%	460
FY2026	44286	$125,283,721	$20,371,133	16.26%	460
FY2027	44386	$125,564,394	$20,416,770	16.26%	460

*Projected Data

Note: In Guam's review/analysis of previous FY data, it appears that the data may be skewed due to program numbers being affected by PHE and it's social and financial impacts on the island community.

FY2022 data was projected by averaging the amounts from the six (6) previous years. The program data projections for FY2023 through FY2027 was determined by taking an average increase for data that shows a linear growth for FY2017 through FY2019.

IV. Waiver Expenditure Authorities

The CMS final rule (CMS-2345-FC) allows the territories to "opt out under…section 1902(j) of the Act." It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act that requires Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP).

V. Demonstration Hypotheses and Evaluation Parameters

Hypothesis: Guam Medicaid's participation in the MDRP would adversely affect the On-Island Pharmacies by creating an unreasonable requirement for them to carry all of a participating manufacturer's COD such that it would be difficult for them to maintain adequate inventory, and to continue as providers on the Medicaid program. Additionally, it would be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP), and these costs would outweigh the rebate savings MDRP would provide.

Qualitative methods will be employed to evaluate:

* The possible adverse effects to On-Island Pharmacy Providers should Guam participate in the MDRP;

* Current limitations for On-Island Pharmacies with existing supply chains when ordering CODs for dispensing to Medicaid recipients; and

* How Guam Medicaid's Participation on the MDRP would affect pharmacy provider status on the Medicaid program.

Pharmacy surveys will be used for qualitative/quantitative methods.

Quantitative methods will be used to evaluate MDRP rebate savings relative to average program savings nationwide, and the following anticipated program costs for implementation of the MDRP (42 CFR 447.511).

* Cost Benefit Analysis to evaluate potential cost savings provided on the MDRP in relation to potential increases in administrative costs to the program due to requirements for contractual services to administer the tracking and reporting of the data for NDCs to the participating drug manufacturers to include an additional State Agency FTE position to be responsible for the MDRP requirements as a whole.

* Guam's assessment of the following Costs associated with participation in the MDRP

1. Cost of contractor to process claims electronically and invoice manufacturer rebates. (Review of small fee-for-service state, to determine costs for claims processing and invoicing via contractor (e.g., Magellan or Change Healthcare Vendors for minimum cost required to invoice manufacturers, run dispute resolution, and collect money etc.).
2. Costs involved in developing MDRP Participating Manufacturers NDC Drug Formulary Listing and evaluation of feasibility of developing procedures to prior authorize (PA) drugs to ensure the drugs are from participating manufacturers. (Assess cost and additional labor involved in this procedure).

* Guam's assessment of costs for Integrating Physician Administered drugs into rebate processes (42 CFR 447.520)

Cost associated with invoicing all outpatient drugs administered in a clinical setting or emergency department. Provider training regarding HCPCS coding system in these settings for claims to reference National Drug Code (NDC) or assess costs to perform a crosswalk from the HCPCS to the NDC. (Capture additional work and support needed to integrate these claims into the invoicing process for rebates).

* Guam's assessment of the Costs associated with requiring Guam to use actual acquisition cost (AAC) + dispensing fee methodology (42 CFR 447.512)

Cost to pay AAC, if MDRP implemented, requiring Guam to survey its pharmacies regarding their acquisition costs in order to determine if using AWP is close to the pharmacies' acquisition costs and therefore can be used as a basis for reimbursement. A survey would also need to be done to ascertain dispensing fee costs of your pharmacies. (Estimates: Possible cost of $50,000 -100,000 for the acquisition cost survey and another $50,000 - 100,000 to do cost of dispensing fee as needed. (RFQs to assess survey costs).

* Assessment of the Drug Utilization Review (DUR) – 1927(g) and 42 CFR 456.703
1. RFQ to assess costs to contract a Provider Benefits Manager (PBM), to conduct Prospective Drug Utilization Review processes (PRO-DUR). All PBMs offer PRO-DUR as part of the claims processing, but need to ascertain any additional costs related to those services.
2. Assess feasibility to work with UPIC West, Qlarant in conducting required Retrospective Drug Utilization Reviews (RETRO-DUR). Guam currently working with CMS contractor as part of program integrity reviews to fight fraud, waste and abuse. (Assess any additional cost).

* Assessment and cost breakdown of FTE staff required to be responsible for performing duties related to the Medicaid drug rebate system (Medicaid Drug Product, or MDP) Assess cost

associated for a state employee at a minimum of 1/2 of an FTE on Guam's Medicaid staff. (Employee to act as point person for all activities regarding the Medicaid drug benefit to include rebate and Drug Utilization Review, and managing the MDRP contract).

VI. Public Review and Comment Process

The complete version of the application and copy of this full notice will be available for public review at the Government of Guam Public Notice Website (Public Notices - Public Notices Portal - Government of Guam) or the Department of Public Health, Division of Public Welfare, Bureau of Health Care Administration website (http://dphss.guam.gov/category/press-releases-en/).

Paper copies are available to be picked up in person at the Guam Department of Public Health & Social Services, Bureau of Health Care Financing Administration, Guam Medicaid/MIP Program Management Office located at 130 University Drive, Room #5 Castle Mall Building, Mangilao, Guam 96913.

Two public meetings will be held regarding the Demonstration application:

(1) Public hearing on Monday, June 27, 2022 from 1:00 p.m. to 3:00 p.m. CHST (Guam Congress Building, Public Hearing Room, 163 Chalan Santo Papa, Hagåtña, Guam 96910). This hearing will be broadcast on GTA TV Channel 21, Docomo Channel 117/112.4, and livestream on https://www.youtube.com/c/GuamLegislatureMedia

(2) Virtual Public hearing on Tuesday, July 5, 2022 from 1:00 p.m. to 3:00 p.m. CHST. (Department of Public Health and Social Services, Division of Public Welfare, Bureau of Health Care Financing Administration, Guam Medicaid Program)

Zoom Hearing Registration link can be obtained by emailing Jeffrey San Nicolas at Jeffrey.sannicolas@dphss.guam.gov or at the following site: http://dphss.guam.gov/category/press-releases-en/.

Public comments may be submitted until 11:59 PM (CHST) on July 24, 2022. Hard copy questions or public comments may be addressed to: Guam Medicaid – MDRP 1115 Waiver Demonstration, Department of Public Health & Social Services, BHCFA, 155 Hesler Place, Hagatna, Guam 96910, or by telephone to (671) 735-7470, or by electronic mail to michael.gallo@dphss.guam.gov. Please note that comments will continue to be accepted after August 1, 2022, but Guam Medicaid may not be able to consider those comments prior to the initial submission of the 1115 Waiver Demonstration application to CMS.

After Guam 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.

Copies of this notice are available at the Government of Guam, Department of Public Health and Social Services website at http://dphss.guam.gov/category/press-releases-en/ for public review. Additional information concerning this action is available upon request at the address cited below.

Guam Department of Public Health & Social Services, Bureau of Health Care Financing Administration, Guam Medicaid/MIP Program Management Office located at 130 University Drive, Room #5 Castle Mall Building, Mangilao, Guam 96913.

[redacted] SAN AGUSTIN, MHR
Director

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.400, add paragraph (c) to read as follows:

§ 117.400 Indiana Harbor Canal.

* * * * *

(c) The Indianapolis Boulevard Bridge, mile 2.59, at East Chicago, shall open on signal if at least twelve hours' notice is given.

M.J. Johnston.

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2021–25268 Filed 11–18–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2482–F2]

RIN 0938–AT82

Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States

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

ACTION: Final rule.

SUMMARY: This final rule will delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to a value based purchasing (VBP) arrangement, of the final rule entitled, ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'', published in the December 31, 2020 **Federal Register** to July 1, 2022. This final rule will also delay for 9 months the April 1, 2022 effective date of inclusion (hereinafter referred to as the inclusion date) of the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) in the amended regulatory definitions of ''States'' and ''United States'' for purposes of the Medicaid Drug Rebate Program (MDRP), adopted in the interim final rule with comment period entitled, ''Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States'', published in the November 25, 2019 **Federal Register** to January 1, 2023. We requested public comment on the proposed delays of the applicable effective date and inclusion date and discuss the comments received in this final rule.

DATES: These regulations are effective on December 20, 2021.

FOR FURTHER INFORMATION CONTACT: Christine Hinds, (410) 786–4578.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of Proposed Delays in Effective and Inclusion Dates of Certain Regulation Provisions

In the ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements: Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States'' proposed rule that published in the May 28, 2021 **Federal Register** (86 FR 28742) (hereinafter referred to as the proposed rule), CMS made two proposals. First, CMS proposed to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the final rule entitled, ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' (85 FR 87000) (hereinafter referred to as the December 31, 2020 final rule), for 6 months to July 1, 2022. Second, CMS proposed to delay the April 1, 2022, inclusion date in the amended regulatory definitions of ''States'' and ''United States'', adopted in the interim final rule with comment period entitled ''Medicaid Program; Covered Outpatient Drugs; Further Delay of Inclusion of Territories in Definitions of States and United States'' (84 FR 64783), for 2 years until April 1, 2024, or in the alternative, to a date earlier than April 1, 2024, but not before January 1, 2023 based on public comments.

B. Proposed Delay of Effective Date of Amendatory Instruction 10.a.

The December 31, 2020 final rule advanced CMS' efforts to support state flexibility to enter into innovative value-based purchasing (VBP) arrangements with drug manufacturers for new and innovative, and often costly therapies, such as gene therapies, and codified new approaches required by section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018) and the existing Medicaid DUR program to improve the clinical use of opioids and reduce the potential for abuse in Medicaid patients. In addition, it codified in regulation several changes made in recent legislation and clarified other provisions of regulations relating to the Medicaid Drug Rebate Program (MDRP).

The regulations included in the December 31, 2020 final rule went into effect on March 1, 2021, except for certain amendatory instructions, including instruction 10.a., which is effective on January 1, 2022. In the proposed rule, we proposed to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the December 31, 2020 final rule on manufacturer reporting of multiple best prices connected to a VBP arrangement, to July 1, 2022, and sought public comment on the proposed delay. As discussed in the proposed rule, we believed a delay of 6 months is warranted to assure that stakeholders have the ability to implement the new VBP policy in a manner that assures patient access and quality of care are protected. We sought public comments on this proposed delay in the effective date, including the impact of this delay on affected beneficiaries. The primary reason for the original delay, and the proposed delay, was to provide more time for CMS, states, and manufacturers to make the complex system changes necessary to implement the new best price and VBP program, and assure patient access and quality of care, given the current need to devote resources to the public health emergency (PHE) relating to COVID–19 that has been in effect, and will likely remain in effect at least through 2021. On April 21, 2021, the Secretary of Health and Human Services (the Secretary) renewed the PHE initially declared on January 31,

2020, to continue giving CMS programs (including Medicaid) flexibility to support beneficiaries during the COVID–19 pandemic. This PHE was most recently renewed on October 15, 2021. In response to the PHE, CMS put in place its own pandemic plan (*https://www.cms.gov/files/document/covid-pandemic-plan.pdf*) to address the needs of its stakeholders, as well as the beneficiaries of its various programs including Medicaid. As part of that plan, CMS provided that it may approve waivers, amendments, and flexibilities for U.S. states, including the District of Columbia, and U.S. territories to allow Medicaid and CHIP programs to adapt their operations as necessary to respond to the pandemic. The pandemic plan also provided that it may make adjustments to the agency's value-based payment initiatives to allow health providers, healthcare facilities, Medicare Advantage and Part D plans, and States to focus on providing needed care to beneficiaries. In addition to the flexibilities granted to states under the PHE, the President signed into law on March 11, 2021, the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) to address the health care and economic needs of the country during the pandemic. This law is one of the most significant expansions of Medicaid since enactment of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), and includes several new mandatory benefit requirements on states that will take time to implement.

We acknowledged in the December 31, 2020 final rule that the changes to the reporting of multiple best prices by manufacturers under the MDRP (a VBP policy) adopted under the amendatory instruction 10.a would require additional time to provide operational guidance and complex system changes to implement. Thus, we delayed the effective date of the VBP provision until January 1, 2022. States that opt to participate in VBP models offered by manufacturers under the multiple best price approach must ensure that beneficiaries have appropriate access to care under such arrangements by developing systems and methods to track beneficiaries and their outcomes, retrieving and evaluating the patient-specific outcomes data, and securing the cooperation of providers and beneficiaries to enter into some of the more complex outcome-based arrangements offered by the manufacturers. Thus, there will be requirements on states to develop significant capabilities to build an infrastructure that will be able to implement VBP.

We also noted that we want to be sure that our own technology infrastructure will be ready to receive multiple VBP offers from manufacturers that will report them to CMS, and subsequently report them to states. We developed a new Medicaid Drug Program (MDP) system. This MDP system will replace CMS' current legacy system with certain aspects of the system expected to be transitioned in the summer of 2022. However, because of other events that have transpired since the regulation was published on December 31, 2020, we explained in the proposed rule that we did not believe that certain aspects of the system necessary for states and manufacturers to operationalize the VBP multiple best price program would be transitioned at that time, making a January 1, 2022 effective date infeasible. We also noted that we believed that it is important to have a technically up-to-date system that is ready to support the data requirements necessary for states and manufacturers to operationalize the VBP multiple best price program. When the proposed rule was issued, we were concerned we could have a delay with operationalizing that part of the MDP system, which could mean we would not have the necessary CMS components in place by later this year to implement the program by January 1, 2022, and believed July 1, 2022, to be a more realistic target date. As noted in the proposed rule, the demands on researching, producing, and distributing COVID–19 drug treatments and vaccines have likely diverted some manufacturer financial and human resources from developing and implementing system changes that would be required to enter multiple best price offers in the MDP system.

We also stated that in the proposed rule that we understand that there was interest among patient and consumer groups, states, and manufacturers in the new multiple best price policy, and that we were committed to implementing the VBP multiple best price policy in a manner that assures that Medicaid beneficiaries have access to medications and therapies that are appropriately administered and monitored. However, we remain concerned that there are several challenges the states, providers, and manufacturers are facing during the PHE. These included those resulting from the passage of the ARP, including those relating to implementing expanded eligibility and mandatory benefit requirements under Medicaid (as described below). In summary, states, providers and manufacturers, as well as CMS, will need additional time to operationalize the multiple best prices policy under amendatory instruction 10.a.

Therefore, given the possible delay in the MDP system and the recent developments around the PHE and ARP, we explained in the proposed rule that we believe more time is critical to permit CMS and our partners—states, providers, and manufacturers—to successfully implement the multiple best prices approach so that Medicaid patients benefit from these programs to full extent possible.

Specifically, CMS and all the parties involved with the multiple best prices policies will want to make sure Medicaid patients receive the drug therapies under the VBP approach that are prescribed for them in a timely manner; that the VBP program does not create unnecessary barriers or requirements on the patient to access the drug; that they receive appropriately scheduled doses of a therapy if the patient treatment under the VBP arrangement is based on multiple doses; and that patient outcomes are tracked so that optimal patient care is provided; and, the states can obtain any additional discounts due to them from manufacturers under the VBP arrangement. We also believe it is in the best interest of the Medicaid program and Medicaid beneficiaries, in particular, that states prioritize the Medicaid eligibility and benefit requirements under the ARP (for example, expanded optional Medicaid coverage for postpartum women, expansion of COVID–19 testing and treatment services, and expansion of vaccine administration to limited benefit groups), resulting from enactment of the ARP to address beneficiary needs during the COVID–19 pandemic. Therefore, we proposed a delay to the effective date for amendatory instruction 10.a. (the multiple best price approach) of 6 months (effective July 1, 2022). By allowing more time to address the needs of Medicaid beneficiaries during the PHE, states, CMS, providers, and manufacturers will also have more time to put in place appropriate beneficiary protections as part of the multiple best price approach. Again, by delaying the effective date of the amendment permitting multiple best price reporting for 6 months, the amendatory instruction 10.a would be effective beginning July 1, 2022. In the proposed rule, CMS also stated it expects to issue additional guidance before that time on operational and policy aspects of the new VBP program, including specifications relating to beneficiary protections.

C. Proposed Delay of Inclusion Date of U.S. Territories in Amended Regulatory Definitions of ''States'' and ''United States''

The Covered Outpatient Drug (COD) final rule, published in the February 1, 2016 **Federal Register** (81 FR 5170), amended the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) for the purposes of the MDRP with a delayed effective date of 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 MDRP 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 Social Security Act (the Act). Puerto Rico, the Virgin Islands, and Guam may use waiver authority under section 1115 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 change to the definition of ''States'' and ''United States'' under the COD final rule to include the territories would also impact the quarterly calculation of average manufacturer price (AMP) and best price by manufacturers. That is, the change requires manufacturers 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 AMP and best price. It 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'' take effect, regardless of whether the U.S. territories seek to waive participation in the MDRP.

Once the COD final rule became effective, CMS began discussions with the territories regarding their participation in the MDRP. Based on those discussions, it became evident that interested territories would not be ready to participate in the MDRP by April 1, 2017. Stakeholders also reiterated the concerns in the comments to the COD final rule (81 FR 5224) that drug manufacturers will likely need to increase drug prices paid by U.S. territory Medicaid programs once the territories are included in the definitions of ''States'' and ''United States'' to avoid setting a new, lower best price. That is because if prices for drugs in the territories are lower than those in the states, then those prices could become the Medicaid best price for that drug in the entire Medicaid program. The manufacturers may then increase their drug prices in the territories to avoid this outcome, and an increase in drug prices in the territories could result in an increase in territory Medicaid drug spending without the offsetting benefit of receiving Medicaid rebates. Furthermore, the increase in Medicaid drug spending could adversely impact the availability of drugs to patients in the territories because of their Medicaid funding cap.

As a result of these initial and subsequent discussions on preparedness, the potential for increased Medicaid drug prices in certain territories, and later, due to additional impacts of natural disasters in several of the territories, CMS issued two interim final rules with comment period (IFC) to further delay the effective date for including the U.S. territories in the regulatory definitions of ''States'' and ''United States'' for purposes of the MDRP. The first, the ''Medicaid Program; Covered Outpatient Drug; Delay in Change in Definitions of States and United States'' IFC, was issued on November 15, 2016, amending the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories beginning April 1, 2020, rather than to April 1, 2017 (81 FR 80003). The second, the ''Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States'' IFC, was published on November 25, 2019, and further delayed the inclusion date for amending the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories to April 1, 2022, rather than April 1, 2020 (84 FR 64783).

For similar reasons, in addition to ensuring continued beneficiary access and quality of care protections, we proposed to amend 42 CFR 447.502 to delay the April 1, 2022 inclusion date for the amended regulatory definitions of ''States'' and ''United States'' to April 1, 2024, and sought public comment on the proposed delay. In the alternative, we proposed to finalize an earlier inclusion date, but no earlier than January 1, 2023, based on public comments received. We explained in the proposed rule that we believe an additional delay of 2 years may be warranted because it would allow the territories to focus their human and financial resources on ensuring the health and well-being of their beneficiaries during this PHE, rather than having to divert those resources to the development of systems required to participate in the MDRP, which can take several years to implement from start to finish, and sought public comments on the proposal.

As discussed in the proposed rule, we believe that in light of the pandemic and the resource demands stemming from the PHE (including those established under the ARP) on the Medicaid program and its beneficiaries, it is imperative that the territories prioritize the Medicaid eligibility and mandatory benefit requirements brought about by the ARP to address beneficiary needs during the COVID–19. Therefore, we believe that a further delay in the inclusion date of the U.S. territories in the regulatory definitions of ''States'' and ''United States'' is warranted and proposed an inclusion date beginning April 1, 2024. In the alternative, we proposed to finalize an inclusion date that may be earlier than April 1, 2024, but not before January 1, 2023, based on public comments received.

We explained in the proposed rule that by delaying the inclusion date to April 1, 2024, or in the alternative, a date earlier than April 1, 2024, but not before January 1, 2023, we are allowing the territories additional time to develop needed systems and policy changes, to avoid unintended increases in drug costs and access concerns. The needed 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.

The proposed delay in inclusion date would also benefit those territories that choose not to participate in the MDRP, which would be required to use human and financial resources that are currently focused on responding to the PHE to complete the section 1115 and section 1902(j) waiver applications that are required to waive out of MDRP participation should the current April 1, 2022 date remain in effect.

Moreover, as explained in the proposed rule, should the amended regulatory definitions of ''States'' and ''United States'' go into effect on April 1, 2022, all manufacturers' sales to the territories and prices paid will be included in the AMP and best price calculations at that time, regardless of whether the territory is participating in the MDRP. As discussed in the COD final rule (81 FR 5224), we heard from various stakeholders who stated concerns that drug manufacturers would likely be prompted to increase drug

prices, including prices paid by the U.S. territory Medicaid programs, once the territories are included in the definitions of ''States'' and ''United States.'' This is because, as currently drafted, section 1927 of the Act requires that eligible sales of drugs within the United States be included in the drug manufacturers calculation of AMP and best price. The inclusion of these prices in AMP and best price could result in the 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 affect territories because of their Medicaid funding cap. As noted previously in the proposed rule, that could result in an increase in drug prices in the territories, making drugs less affordable, and making it more difficult for the territories to address their own public health needs during the PHE. We believe this provides further rationale for delaying the effective date of the inclusion of the territories in the regulatory definitions of ''States'' and ''United States.'' It will ensure that during this PHE, which has the potential to extend into 2022, those territories that opt to waive participation from the MDRP will not face the additional financial burdens associated with increased Medicaid drug costs from drug manufacturers increasing drug prices to the territories.

We proposed a new inclusion date of April 1, 2024, for the amended regulatory definitions of ''States'' and ''United States'' to include the U.S. territories for purposes of the MDRP. In the alternative, we proposed to finalize an inclusion date that may be earlier than April 1, 2024, but before January 1, 2023, based on public comments received. We specifically requested comments on whether April 1, 2024, or an earlier inclusion date, but not earlier than January 1, 2023, would be more appropriate for the amended regulatory definitions. More specifically, we requested public comments that will assist us in understanding all relevant concerns related to establishing a new inclusion date, including whether territories are ready to participate in the MDRP, and whether CMS is able to execute appropriate and necessary waivers for territories that do not want to participate. In any case, manufacturers would be required to include their sales to the territories in their AMP and best price calculations based on the inclusion date finalized in a final rule, which we proposed to be April 1, 2024, or possibly earlier, but no earlier than January 1, 2023 based on public comments.

II. Response to Public Comments and Provisions of the Final Rule

In response to the proposed rule, we received 29 public comments.

A. Delay of Effective Date of Amendatory Instruction 10.a. (§ 447.505(a))

The following is a summary of the comments received and our responses on proposed delay of effective date of amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to value based purchasing (VBP) arrangements.

Comment: Several commenters supported the proposal to delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a. of the December 31, 2020 final rule, which addresses the reporting by manufacturers of multiple best prices connected to a VBP arrangement. These commenters supported the proposed delay because of both the time as well as the state and federal resources that have been taken up by the emergence of the pandemic, implementation of Medicaid expansion under the ARP, and the focus on development, production, and distribution of vaccination efforts related to controlling the spread of the COVID–19 virus. Some commenters indicated that they do not believe that states, providers, and CMS have the infrastructure in place at this time to be able to track the necessary data related to health outcomes to properly implement VBP arrangements. They believe that the proposed delay will allow for some of this work (for example, work associated with pandemic efforts and infrastructure work to collect adequate patient data with appropriate privacy protections) to be finished without compromising care for those who need it in the interim. The commenters also noted that the proposed delay will allow CMS, states, and manufacturers time to develop and test the new MDP system, and allow CMS to develop operational guidance to facilitate multiple best price reporting.

Response: We appreciate the support of the proposed delay of the effective date of amendatory instruction 10.a. to July 1, 2022, and continue to believe that the proposed delay is necessary for CMS, manufacturers, states, and providers to engage in the work necessary to facilitate the multiple best price reporting approach. As commenters noted, we are implementing a new MDP system and, as part of that new system, will include the necessary changes to address multiple best price reporting. The additional 6 months will give us time to upgrade our new MDP system to collect multiple best prices, as well as explore and test these changes with the manufacturers and states that have been anxious to commit to the multiple best price approach. We will also use this time to issue operational guidance for states and manufacturers on reporting and accessing the multiple best price information in the MDP system.

For commenters' concerns regarding infrastructure and data collection, while we plan to provide general operational guidance, we do not plan to issue guidance on how to operationalize, evaluate, or monitor *specific* VBP arrangements as each arrangement will have its own set of specific facts and circumstances associated with the arrangement, such as the drug, the anticipated outcomes, and population included in the arrangement. A ''one size fits all'' approach to operationalizing a VBP arrangement is not possible because of the many different arrangements on the marketplace (85 FR 87018).

Comment: A few commenters urged CMS to effectuate the multiple best price reporting option as established in the final rule, but no later than the proposed delay in effective date of July 1, 2022. Several commenters, while agreeing with the proposed delay, continue to believe that the multiple best price reporting flexibility is essential to ensuring that patients benefit from VBP arrangements. One commenter in particular was disappointed that CMS was considering the proposed 6 month delay in effective date, but understood that putting in place the necessary systems and modifications for a seamless adoption of this new program is challenging. This commenter encouraged CMS to work diligently to ensure the proposed effective date of July 1, 2022 was achievable. Another commenter indicated that any further delay in effective date, beyond the 6 months proposed, will result in substantial negative repercussions for patient access to therapies that address significant unmet need, especially for Medicaid beneficiaries, and therefore, should be a one-time delay.

Response: This delay rule allows states additional time to ensure patient access by Medicaid beneficiaries to certain higher cost therapies. We will continue to assess system readiness for states, manufacturers and CMS to ensure the reporting by manufacturers of multiple best prices connected to a VBP arrangement can be effectuated in

the timeframe established in this delay rule, and we may consider further delays in future rulemaking if systems are not ready.

Comment: Several commenters provided input as to how CMS, states, and manufacturers should utilize the time associated with the proposed 6 month delay in effective date. One commenter encouraged CMS to utilize the proposed 6 month delay to issue subregulatory guidance regarding whether an arrangement would qualify as a VBP arrangement if a State Medicaid Agency is not able to access the same type of patient and outcomes data utilized in the commercial contract that resulted in the multiple best price. In other words, the commenter questioned if the state and the manufacturer will be allowed to modify the commercial sector agreement to better fit the Medicaid population, and how manufacturers will report multiple best prices when multiple commercial and/or state agencies enter into similar contracts but have different outcomes, resulting in different rebates and multiple best prices.

Response: We appreciate the commenters' recommendations for how CMS, states, and manufacturers should utilize the time associated with the proposed 6 month delay in effective date; however, these comments and recommendations are outside of the scope of this rulemaking. We note, however, that CMS plans to provide further operational guidance for states and manufacturers in the near future regarding the implementation of the multiple best price reporting.

Comment: A few commenters requested that CMS take this additional time to consult with Medicaid agencies and other stakeholders to ensure the necessary systems and technology needed to facilitate the collection and reporting of patient clinical outcomes are in place. The commenters further commented that CMS should encourage and incentivize consistency (for example, standard data reporting requirements) in these systems across states.

Response: We agree with the commenters, and as noted in the December 31, 2020 final rule, we plan to develop operational guidance regarding the final policy permitting multiple best price reporting. To that end, we have been available to manufacturers, states, and other stakeholders to discuss what is needed in MDP systems to effectuate the reporting of multiple best prices and intend to issue operational guidance associated with the MDP system changes. We expect to also provide states with guidance regarding existing Medicaid access and beneficiary protections when engaging in VBP arrangements.

With respect to the standardization of reporting systems across states, we understand that such systems would benefit states, patients, and manufacturers, as it would facilitate implementation of VBP programs, and avoid duplication of efforts. Since the MDP systems operated by CMS will not be collecting patient-specific or outcomes data associated with VBP arrangements, we will not be encouraging or providing incentives to standardized data collection reporting associated with VBP arrangements as part of the MDP system. However, we expect that states, working with their supplemental rebate contractors or other VBP vendors, as well as manufacturers, will attempt to create standardized reporting templates and formats that may become industry standards over time.

Comment: A few commenters indicated their appreciation of CMS' December 31, 2020 final rule to enhance flexibility in creating VBP arrangements; however, the commenters do not believe a 6 month delay in the effective date allows CMS sufficient time to adequately address the operational complexities and other legal hurdles (giving examples such as the federal Anti-Kickback Statute or Medicare Part B requirements) that impede adoption of VBP arrangements in a timely fashion. Therefore, the commenters stated that to leverage the full benefit of VBP arrangements, additional flexibilities and clarity are needed that cannot be provided via subregulatory guidance and urged CMS to withdraw the December 31, 2020 final rule and issue a revised proposed rule, or reopen the December 31, 2020 final rule for further public comment. A commenter indicated that while they appreciate CMS' interest in and effort to modernize the MDRP to support innovation that advances high value, patient-centered care through VBP arrangements, the final VBP multiple best price policy lacks clarity and does not consider a full range of operational hurdles. The commenter also indicated that the changes to the MDRP alone are not sufficient to reduce current barriers to VBP arrangements in the commercial market, and therefore, CMS must address the Anti-Kickback Statute (AKS), impact to Average Sales Price (ASP), and other government price reporting barriers to realize the full potential of VBP arrangements.

Another commenter expressed concerns regarding how the final rule on VBP arrangements could be gamed by manufacturers. The commenter suggested and encouraged CMS withdraw the December 31, 2020 final regulation, prohibit manufacturers from reporting multiple best prices, limit outcomes-based arrangements under a bundled approach, and clarify requirements regarding stacking discounts. The commenter expressed concern that CMS' VBP regulations, as finalized in the December 31, 2020 final rule, are not related to the Medicaid program and instead are designed to encourage specific types of contracting in the commercial market. This commenter suggested that the VBP regulations change Medicaid program requirements to achieve a goal outside of the Medicaid program and asserted that it is not appropriate to harm the Medicaid program to promote commercial contracting flexibility.

Response: The proposed rule only proposed a delay in effective date related to the VBP multiple best price reporting policy finalized in the December 31, 2020 final rule. The underlying policy itself was not a subject of the proposed rule open to public comment. Thus, comments related to the underlying policy are outside the scope of this rulemaking. At this time, we believe the 6 month delay beyond the initial delay in inclusion date from the COD final rule will be adequate for manufacturers to provide the data necessary to report multiple best prices in MDP system. Any other legal requirements that manufacturers may be subject to, such as the federal anti-kickback statute or Medicare Part B requirements, are outside of the scope of this rulemaking. However, we do intend to issue additional guidance on the interaction between VBP and Medicare Part B ASP calculations.

Comment: Some commenters continue to request additional clarity on whether, and to what extent, new VBP arrangements run afoul of the federal anti-kickback statute. The commenters indicate that CMS should work to remove barriers imposed by AKS that limit or prevent adoption of VBP arrangements.

Response: While we appreciate the comments received, these issues are outside the scope of this rulemaking. As noted above, the underlying policy regarding VBP arrangements was not a subject of the proposed rule open to public comment. Rather, the proposed rule specifically proposed a 6 month delay to the effective date for the policy permitting manufacturers to report multiple best prices related to a VBP arrangement. Questions regarding these

issues should be directed to the Office of the Inspector General (OIG).

Comment: A couple of commenters reiterated their comments provided on the ''Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' proposed rule that appeared in the June 19, 2020 **Federal Register** (85 FR 37256), including comments regarding the drug utilization review requirements.

Response: The DUR requirements set forth in the December 31, 2020 final rule were not a subject of this proposed rule and were not impacted by the proposed delay.

After consideration of the comments received regarding the proposed delay to amendatory instruction 10.a. of the December 31, 2020 final rule, we are finalizing the proposed July 1, 2022 effective date.

B. Delay of Inclusion Date of U.S. Territories in Amended Regulatory Definitions of ''States'' and ''United States'' (§ 447.502)

The following is a summary of the comments received and our responses on the proposed delay of the inclusion date for the U.S. territories in the definition of ''States'' and ''United States'' at § 447.502 to April 1, 2024, or, alternatively, a date that is earlier than April 1, 2024, but not before January 1, 2023 based on public comments received.

Comment: Several commenters supported the proposed delay of the April 1, 2022 inclusion date to April 1, 2024, or, alternatively, to a date earlier than April 1, 2024, but not before January 1, 2023 based on public comments. These commenters supported the proposed delay because of the territories' current need to focus on the PHE relating to COVID–19 and the time needed to prepare for the technology infrastructure changes necessary to support participation in the MDRP. The commenters also noted concern that manufacturers may increase their drug prices in the territories as a result of their participation in the MDRP. One commenter specifically noted concern as to whether the territories would be capable of participating in the MDRP prior to April 1, 2024.

Another commenter supported the proposed delay, given the various programs and processes that a state has to put in place to effectively and efficiently participate in the MDRP, such as establishing a drug manufacturer rebate billing mechanism, a state drug utilization reporting mechanism, a process to assure that all drugs of a manufacturer that sign a rebate agreement with the Secretary of HHS are covered, a dispute resolution process, and a Drug Utilization Review (DUR) program.

Another commenter supported a proposed delay of the April 1, 2022 inclusion date and suggested October 1, 2023 as an alternative inclusion date. The commenter stated that an October 1, 2023 inclusion date would provide an additional eighteen months beyond April 1, 2022 before the territories are included in the amended regulatory definitions of ''States'' and ''United States'', and believed that an October 1, 2023 inclusion date is justified because some interested territories have requested more time to prepare for MDRP participation and suggested potential policy changes to address increases in drug prices. In addition, the commenter indicated that the territories and manufacturers will need this additional time because their resources continue to be diverted to the COVID–19 pandemic response.

Another commenter found it difficult to envision territories having the infrastructure or funding in place to fully transition to the MDRP given the PHE. The commenter also noted that even if a territory was prepared to make this transition, the providers, including hospitals and others across the healthcare marketplace that prescribe and provide prescription drugs, would need to update their systems, resulting in significant confusion and patient access barriers. The commenter believed further guidance is necessary to prepare the territories for this transition, as well as the providers of care within those programs. The commenter restated these reasons for prior delays in implementing this requirement as rationale for reversing the 2016 COD final rule including territories in the definition of ''States'' and ''United States.''

Other commenters indicated that they did not support the proposed delay because one territory in particular, Puerto Rico, has made significant efforts to prepare for participation in the program. The commenter indicated that the proposed delay would be financially harmful to that territory because it has already written a request for proposal (RFP) to procure a vendor to manage participation in the MDRP, which has an expected launch date of July 1, 2022, and a delay would result in the need for multiple modifications to the territory's RFP. The commenter also noted that the territory has undertaken a significant amount of budgeting and financial forecasting as part of their efforts, which indicated that there would be a financial loss as a result of unrealized federal rebates for both brand and generic drugs if there is a delay beyond the territory's FY 2023, which runs from July 2022 through June 2023.

Response: In proposing this delay, and in finalizing a new inclusion date of January 1, 2023, we considered all public comments received, the needs of all the stakeholders, including territories and manufacturers, while considering the impact that the delay could have on access to necessary and affordable medications for the citizens of the territories, both those that would and would not participate in MDRP.

To balance the willingness of territories that want to participate, while accommodating the time to prepare waivers for those that do not, we have determined that the January 1, 2023 date, which falls within the scope of the alternative proposal, is appropriate.

Based on the information available to us at this time, we believe that of the five territories, only two will make efforts to participate in MDRP, regardless of the ultimate inclusion date, and the others will require additional time to request the applicable waivers. Of the two territories that we anticipate will make efforts to participate in MDRP, only one (Puerto Rico) has definitively indicated that they are ready and will be able to participate in MDRP as early as July 1, 2022, while the other (U.S. Virgin Islands) has previously expressed interest, but may or may not have decided whether to participate by January 1, 2023.

Those territories that do not participate will need time to prepare to waive out of the program through the appropriate Medicaid waiver mechanism.

To accommodate the resource needs of the territories during the PHE, we believe a January 1, 2023 inclusion date gives Puerto Rico the ability to participate sooner than the April 1, 2024 inclusion date, while giving the other territories a firm deadline to make a final decision to participate or waive out of the program. The timeline also recognizes the work done to date by Puerto Rico to prepare to participate in the program. Therefore, the new inclusion date for U.S. Territories in the amended regulatory definitions of ''States'' and ''United States'' for purpose of the Medicaid Drug Rebate Program will be January 1, 2023, which is the earliest new inclusion date that we could have finalized given our proposals in the proposed regulation.

We note the suggestion for a delayed inclusion date of October 1, 2023 made by one of the commenters in light of the additional time needed and requested by some territories. we believe that further delay beyond January 1, 2023 negatively impacts the progress Puerto Rico has made to prepare to participate in the program (for example, Puerto Rico has already invested significantly in consulting costs and begun the request for proposal process for a system contractor). For example, Puerto Rico has indicated it could be ready to participate in the MDRP as early as July 1, 2022, and therefore, an effective date of October 1, 2023 would push back MDRP participation by over a year from that date for the territory that has the overwhelming majority of drug spending, and which stands to benefit most from participation in MDRP.

As for the commenter's request for additional guidance, the delay can be used to help any territory that plans on participating in the program more time to prepare its beneficiaries, pharmacies, and providers. That is because participation in the MDRP will increase the availability of medications that are available in participating territories, but the territories can also use various utilization management techniques, and providers and patients may need time to be educated on how these programs will work. Moreover, a territory participating in MDRP may need technical help from us on reporting its state drug utilization data, and, for example, assuring that all its physician administered drug claims also include National Drug Code (NDC) numbers. Like our state partners, we are available to guide territories that want to participate in MDRP to assure beneficiary access to drugs, as well as to properly invoice participating manufacturers for federal rebates.

Comment: A few commenters noted their general opposition to the expansion of the MDRP beyond the 50 states and DC to include the territories. One commenter remarked that at most, CMS should limit the expansion to only requiring that rebates be paid by the manufacturers to the territories, but not require manufacturers to include sales to the territories in calculation of their AMP or determination of their Best Price because of the enormous burden and compliance concerns that such an expansion would pose on the manufacturer.

A couple of commenters, while supporting the proposed delay of the participation of the territories in the MDRP to April 1, 2024, were still concerned with the decision to include the territories in the definition of ''States'' and ''United States'' in the first place, and urged CMS to address their prior comments requesting the agency to reverse its decision to add the territories to the Medicaid rebate program.

Response: We note that the definitions of ''States'' and ''United States'' at § 447.502 were amended to include the U.S. territories for purposes of the MDRP in the COD final rule with a delayed inclusion date. We did not propose to change the underlying policy, only to delay the inclusion date. As such, comments requesting that we revisit the underlying policy are outside the scope of this rulemaking.

After consideration of the comments received regarding the proposed delay of inclusion date for the U.S. territories in the definitions of ''States'' and ''United States'' at § 447.502, we are finalizing an inclusion date of January 1, 2023.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2021.

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—PAYMENT FOR SERVICES

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

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

■ 2. Amend § 447.502 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 January 1, 2023, 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 January 1, 2023, 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.

* * * * *

■ 3. Effective July 1, 2022, in paragraph (a), by revising the definition of ''Best price'' to read as follows:

§ 447.505 Determination of best price.

(a) * * *

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement.

* * * * *

Dated: November 4, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–25009 Filed 11–17–21; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 211115–0231]

RIN 0648–BK56

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Biennial Specifications; 2021–2022 and 2022–2023 Specifications for Pacific Mackerel

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS is implementing allowable catch levels including an overfishing limit, an allowable biological catch, and an annual catch limit for Pacific mackerel in the U.S. exclusive economic zone off the West Coast (California, Oregon and Washington) for the fishing seasons 2021–2022 and 2022–2023. This rule is finalized pursuant to the Coastal Pelagic Species Fishery Management Plan. The

1115 Waivers: A Brief Overview

Introduction

An 1115 waiver is an experimental, pilot, or demonstration project that promotes the objectives of Medicaid and CHIP. The waiver tests a hypothesis and states must develop an evaluation design to test it. 1115 Waivers must be budget neutral meaning the waiver will not increase federal Medicaid expenditures. An 1115 is generally approved by CMS for an initial 5 year period and can be extended.

Application

States can develop their own application or use a CMS template, which includes the following categories:

- Description of the program
- Eligibility criteria
- Benefits and cost sharing requirements
- Delivery system and payment rates
- Implementation date and approach
- Financing and budget neutrality
- Proposed waivers and expenditure authorities
- Public notice and public hearing information

Prior to submission states may consult with CMS or submit a pre-application concept paper to CMS. Applications must be submitted both electronically and as a printed document. Applications will be approved no sooner than 45 days after notice of receipt of a completed application.

Public Notice Process

CMS requires a 30 day state public notice and comment period for 1115 applications. This includes a detailed public notice and an abbreviated public notice. Two public hearings must be held at least 20 days prior to submission of an 1115 application. Public notice information including the state's notice/comment process and a copy of application must be posted on the state agency's main website page or must be linked to from the main page. Additionally, the state must use an email list to notify interested parties as well as conduct tribal consultation. State public notice requirements are found in 42 CFR 431.408. CMS will conduct a 30 day federal public notice process within 15 days of receiving the application.

Monitoring and Compliance

State must perform periodic review of the implementation of the waiver. Within 6 months of the implementation date the state must hold a public forum to solicit comments on the progress of the waiver. A public forum must be held annually thereafter. Requirements regarding this are found in 42 CFR 431.420.

Reporting Requirements

The state must submit a draft annual report to the CMS. The draft report must be published on the state's website. CMS will provide the state comments. The state must publish the final report on its website. Requirements regarding the report are found in 42 CFR 431.428.

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Displaying title 42, up to date as of 4/25/2022. Title 42 was last amended 4/14/2022.

Title 42 - Public Health
Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter C - Medical Assistance Programs
Part 431 - State Organization and General Administration
Subpart G - Section 1115 Demonstrations

EDITORIAL NOTE ON PART 431

Editorial Note: Nomenclature changes to part 431 appear at 75 FR 48852, Aug. 11, 2010.

§ 431.420 Monitoring and compliance.

(a) ***General.***

(1) Any provision of the Social Security Act that is not expressly waived by CMS in its approval of the demonstration project are not waived, and States may not stop compliance with any of these provisions not expressly waived. Waivers may be limited in scope to the extent necessary to achieve a particular purpose or to the extent of a particular regulatory requirement implementing the statutory provision.

(2) States must comply with the terms and conditions of the agreement between the Secretary and the State to implement a State demonstration project.

(b) ***Implementation reviews.***

(1) The terms and conditions will provide that the State will perform periodic reviews of the implementation of the demonstration.

(2) CMS will review documented complaints that a State is failing to comply with requirements specified in the special terms and conditions and implementing waivers of any approved demonstration.

(3) CMS will promptly share with the State complaints that CMS has received and will also provide notification of any applicable monitoring and compliance issues.

(c) ***Post award.*** Within 6 months after the implementation date of the demonstration and annually thereafter, the State must hold a public forum -

(1) To solicit comments on the progress of a demonstration project.

(2) At which members of the public have an opportunity to provide comments and in such time as to include a summary of the forum in the quarterly report associated with the quarter in which the forum was held, as well as in its annual report to CMS.

(3) The public forum to solicit feedback on the progress of a demonstration project must occur using one of the following:

(i) A Medical Care Advisory Committee that operates in accordance with § 431.412 of this subpart.

(ii) A commission or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about the demonstration's progress.

(iii) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(4) [Reserved]

(d) ***Terminations and suspensions.***

(1) The Secretary may suspend or terminate a demonstration in whole or in part, any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the demonstration project.

(2) The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes.

(3) The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.

(e) ***Closeout costs.*** When a demonstration is terminated, suspended, or if waivers or expenditure authority are withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination of the demonstration or expenditure authority, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) ***Federal evaluators.***

(1) The State must fully cooperate with CMS or an independent evaluator selected by CMS to undertake an independent evaluation of any component of the demonstration.

(2) The State must submit all requested data and information to CMS or the independent evaluator.

Displaying title 42, up to date as of 4/25/2022. Title 42 was last amended 4/14/2022.

Title 42 - Public Health
Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter C - Medical Assistance Programs
Part 431 - State Organization and General Administration
Subpart G - Section 1115 Demonstrations

EDITORIAL NOTE ON PART 431

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§ 431.428 Reporting requirements.

(a) ***Annual reports.*** The State must submit an annual report to CMS documenting all of the following:

(1) Any policy or administrative difficulties in the operation of the demonstration.

(2) The status of the health care delivery system under the demonstration with respect to issues and/or complaints identified by beneficiaries.

(3) The impact of the demonstration in providing insurance coverage to beneficiaries and uninsured populations.

(4) Outcomes of care, quality of care, cost of care and access to care for demonstration populations.

(5) The results of beneficiary satisfaction surveys, if conducted during the reporting year, grievances and appeals.

(6) The existence or results of any audits, investigations or lawsuits that impact the demonstration.

(7) The financial performance of the demonstration.

(8) The status of the evaluation and information regarding progress in achieving demonstration evaluation criteria.

(9) Any State legislative developments that may impact the demonstration.

(10) The results/impact of any demonstration programmatic area defined by CMS that is unique to the demonstration design or evaluation hypothesis.

(11) A summary of the annual post-award public forum, including all public comments received regarding the progress of the demonstration project.

(b) ***Submitting and publishing annual reports.*** States must submit a draft annual report to CMS no later than 90 days after the end of each demonstration year, or as specified in the demonstration's STCs. The State must publish its draft annual report on its public Web site within 30 days of submission to CMS.

(1) Within 60 days of receipt of comments from CMS, the State must submit to CMS the final annual report for the demonstration year.

(2) The final annual report is to be published on the State's public Web site within 30 days of approval by CMS.

Office of the Speaker
THERESE M. TERLAJE
I Mina'trentai Sais na Liheslaturan Guåhan | 36th Guam Legislature
Committee on Health, Land, Justice and Culture

I. OVERVIEW

The Committee on Health, Land, Justice, and Culture in conjunction with the Bureau of Health Care Financing Administration Division, Department of Public Health and Social Services convened a Joint Public Hearing on the Informational Briefing by the DPHSS Guam Medicaid Program- Guam Drug Rebate Program (MDRP), 1115 Waiver Demonstration Presentation on Monday, June 27, 2022, at 1:00 PM in *I Liheslatura*'s Public Hearing Room.

Public Notice Requirements

In compliance with Open Government law, notices for this Joint Public Hearing were published in the Guam Daily Post and posted to the Government of Guam Public Notice Portal on **Monday, June 20, 2022,** (5-Day Notice), and again on **Friday, June 24, 2022** (48-Hour Notice). The Joint Public Hearing was livestreamed on the Guam Legislature's YouTube Channel. Public Notices were also disseminated via email to all senators and all main media broadcasting outlets.

Senators Present

Speaker Therese M. Terlaje, Chairperson
Senator Sabina F. Perez, Vice Chairperson on Health, Land, and Culture
Senator Telena Nelson, Vice Chairperson on Justice
Senator Christopher M. Duenas, Committee Member
Senator Telo T. Taitague, Committee Member
Senator Joanne M. Brown, Committee Member
Senator V. Anthony Ada

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**For transmittal of official Messages & Communications to the Guam Legislature to be distributed to all Senators, please send to: speaker@guamlegislature.org*

Appearing before the Committee

Michael Gallo, Program Coordinator, Guam Medicaid Program, Department of Public Health & Social Services (DPHSS)
Jeffrey San Nicolas, Medicaid, and Medically Indigent Program (MIP) Program Management Analyst, DPHSS
Janet Cruz, Medicaid, and MIP Program Management Analyst, DPHSS
Carlos Pangelinan, State Office, Division of Public Welfare, DPHSS
Rachelle Paulino, State Office, Division of Public Welfare, DPHSS Former Senator Dennis Rodriguez, Chief Advisor on Healthcare, Governor's Office

II. SUMMARY OF TESTIMONY & DISCUSSION

The Joint Public Hearing was Called-to-Order at **1:02 PM.**

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: *Håfa Adai* and welcome everyone. The Committee on Health, Land, Justice and Culture is now called to order. Today is Monday, June 27th, 2022, and the time is 1:02 PM. In compliance with the Open Government Law, notices for this joint public hearing were published in the Guam Daily Post on Monday, June 20, and again on Friday, June 24, 2022, and posted to the Government of Guam public notice portal and live streamed via the Guam Legislature's YouTube channel. Notices were also disseminated via email to all senators and all main media broadcasting outlets. Individuals testifying, please first state your name for record keeping purposes and wait to be recognized by the chair.

So, today's hearing is a joint public hearing between the Guam Legislature and the Department of Public Health and Social Services. It's being held as part of a requirement by the Center for Medicaid Services or CMS that

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Public Health hold two public hearings at least 20 days prior to submission of a section 1115 application. So today on our agenda is number one, an informational presentation on the Guam Medicaid Drug Rebate Program, the MDRP. The 1115 waiver demonstration application by the Guam Medicaid program administered under the Department of Public Health and Social Services and number two, the Guam Medicaid Program intends to submit to the Centers for Medicare and Medicaid services on or before August 1st, 2022, a written 1115 demonstration application, which will request to waive the mandate for the Guam Medicaid Program to participate in the Medicaid Drug Rebate Program, the MDRP, and to receive comments on the proposed MDRP 1115 waiver demonstration application. Number three, the CMS final rule, CMS 2345 FC allows the territories to opt out under section 1902j of the act. It is through this waiver authority that the Guam Medicaid program is electing to apply under section 1115A1 of the Act to waive section 1902A54 which requires state compliance with applicable requirements of section 1927, requiring Guam Medicaid to participate in the Medicaid Drug Rebate Program, MDRP by January 2023. This 1115 waiver demonstration project will allow for a period for the Guam Medicaid Program to conduct a demonstration study on the potential adverse effects of participation in the MDRP on our island pharmacy providers and program recipients. The 1115 waivers are generally approved by the CMS for an initial five-year period and can be extended.

So again, welcome to representatives from the Department of Public Health and Social Services and of course, I want to thank my colleagues for being here today. We have our majority leader, Senator Telena Nelson, we have our minority leader Senator Chris Duenas and Senator Telo Taitague. *Si yu'os ma'åse'* colleagues for being with me here today. Alright, I'm going to call on the program coordinator for the Guam Medicaid Program, Mr.

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Michael Gallo. If you could please introduce your team and then, you can begin. I understand that you have a PowerPoint presentation. I think we've put that up on MIS but I've also given copies to the senators, just FYI and let me just recognize Senator Tony Ada also for being here today. *Si yu'os ma'åse'* Senator. Alright so, Mr. Gallo, if you could just, again, state your position and who's with you here today.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Good afternoon, everyone. My name is Michael Gallo. I'm a program coordinator with the Public Health Medicaid Program. With me today, towards my right is Jeff San Nicolas. He's a management analyst with the Medicaid program MIP. Ms. Janet Cruz immediately to my right. She is also a management analyst working with the Medicaid and MIP program. To my left we have Carlos Pangelinan, and he is working with the state office under the Division of Public Welfare and Ms. Rachelle Paulino and she also works with the state office for the Division of Public Welfare.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you. You may proceed.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Okay. I wanted to first, thank you Speaker Terlaje for assisting us in presenting this information to the public. We definitely want to also thank Senator Nelson, Senator Ada, Taitague and Senator Duenas for attending the hearing as well. We can go ahead and go to the presentation. So, what we're doing today is, we're presenting information with regards to the Medicaid Drug Rebate Program, and this was brought up because of a legislative role that was passed requiring the program to participate in MDRP, Medicaid Drug Rebate Program by January of 2023.

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However, the legislation that included the territories for participation in the Medicaid Drug Rebate Program also provided for an 1115 waiver demonstration which would allow us to opt out for a period of time and so next slide please.

So, the Guam Medicaid Program is conducting this hearing to inform the public, our program recipients, Medicaid pharmacies, providers, and other stakeholders of our intent to submit to CMS, the Centers for Medicare and Medicaid Services, this 1115 demonstration application by August 1st of 2022. This will request the program to be waived from the federal mandate to participate in the Medicaid Drug Rebate Program. During this time, we would also receive comments on our waiver demonstration so that we could submit this as additional information on the application to CMS.

Next slide please. So, we're going to go over four main discussion points in today's hearing. The first being the explanation of the Medicaid Drug Rebate Program. The mandate that was created because of a final role legislation. The second discussion point we would be covering would be the 1115 waiver demonstration. In speaking with a lot of people that have shown interest in these types of waiver demonstrations, there's been some confusion on what exactly an 1115 waiver is. So, we'll attempt to define what that is and how it's normally used and some of the requirements in order for it to get approved. The third thing we wanted to kind of go over was because the Medicaid Drug Rebate Program would affect the Guam Medicaid prescription drug benefit to our existing participants and the mentality was that in participating in this MDRP it would provide a cost savings. We wanted to go over what we currently do for that benefit under the program and the measures that we're currently using to maintain our cost so that doesn't inflate. The final area that we're going to be discussing will be talking about the Medicaid Drug Rebate Program. In our initial

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assessment of implementation there was some areas that were concerning and so hence the 1115 waiver assessment. We'll go into further explanation about the 1115 waiver assessment and the evaluation that will be conducted during this period of time that we're requesting CMS to waive our participation in MDRP.

Next slide please. So, the first area that we wanted to cover was the Medicaid Drug Rebate Program and to explain a little bit about what this is. The program includes CMS, state Medicaid agencies and drug manufacturers. This agreement that would be arranged under the MDRP would help to offset the federal and state costs of outpatient prescription drugs dispensed to our Medicaid participants. Although the prescription benefit is not a mandated benefit, it's something that all states do cover under the Medicaid program.

Next slide please. So, we wanted to explain a little bit more again about what the Medicaid Drug Rebate Program is. So, this program offsets cost of prescription drugs by requiring drug manufacturers to enter into an agreement with the Secretary of Health and Human Services in exchange for the Medicaid program, covering all the manufacturers covered outpatient drugs or CODs. So, manufacturers are responsible for paying rebates on those drugs that are paid and dispensed under the Medicaid plan. The rebates are paid by the manufacturers on a quarterly basis and that rebate goes to the states, but it's shared between both the states and the federal government based on the FMAP.

Next slide, please. We wanted to just briefly go over how that rebate structure is set up in the MDRP and if you take a look at the three categories, there are brand drugs. Brand drugs approved exclusively for pediatric indications and certain clotting factors and then generic drugs. So

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each of these categories, they have a formula that determines a percentage of what's called the average manufacturer price. So, normally the formula would be the average manufacturer price minus the best price given to wholesalers or drug distributors or 23.1% of AMP, which is whichever is greater. Plus, there's an inflationary component that's also added to that as well. So that's how the rebates are formulated.

Next slide please. So, what we wanted to cover here under this section was to share with you the first legislative action that provided for the inclusion of territories. So, on February 1st, 2006, there was a final rule that amended what was stated under the Medicaid Drug Rebate Program that all states would participate. Now initially states only referred to actual states and not territories. So, this final rule actually initially amended the language to include territories under the definition of states for the MDRP. It also created the provision for the 1115 waiver demonstration to opt out.

Next slide please. So why are we here today? Well, here in this slide, we can see that on November 19th, 2021, there was another final rule that mandated the territories under the inclusion of MDRP with the definition of states to include the territories to participate by January 1st, 2023.

Next slide please. So that brings us to our next topic of discussion, which is the 1115 waiver demonstration. So, under section 1115 of the Act, CMS may authorize the state to conduct experimental pilot or demonstration projects that in the judgment of the Secretary are likely to assist in promoting objectives of the Act. So, the Secretary may under section 1115 waiver provisions in section 1902 of the Act and that's what we're requesting that the Secretary approves our 1115 waiver demonstration to temporarily waive our requirement to participate in the Medicaid Drug Rebate Program so that we can assess how participation will actually affect

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both our participants, the pharmacy providers on island, and our actual program costs. So just to be clear in the slide, it points out that although waiver is included in the language there for the 1115, it's actually an experimental pilot or demonstration project. So, it's basically a study. We wanted to apply for this to study how it would affect it. So, some of the things that we needed to be aware of with the 1115 waivers is that it must be budget neutral. So, that means that if it's approved, it would not cost the federal government more than if it didn't exist. So, budget neutral.

Next slide please. So, in honor of this 1115 waiver demonstration to be approved, there are several requirements with regards to public notice that we need to meet. So, CMS requires a 30-day state public notice and comment period for this 1115 waiver. We need to conduct two public hearings at least 20 days prior to submission of the 1115 application, public notice information including the notice comment process and the copy of the application needs to be posted on our site and some of the components of our application are still a work in progress. We've been working with CMS to develop the evaluation design portion of the 1115 waiver, and I'll go through that a little bit more in one of the other slides. Now, when we submit the application to CMS, there's also a requirement for them to do a 30-day federal public notice within 15 days of receiving our application. So, there are timelines that we're trying to meet in order to get this approved before the January 1, 2023, implementation deadline.

Next slide please. Now two other areas of requirement would be the monitoring and compliance of the 1115 waiver. So, if it's approved, we have to do periodic reviews of the implementation of the waiver six months after it's implemented. We also have to have a public forum to solicit additional comments on the progress of the waiver and a public forum must be held annually thereafter. Now, as mentioned the 1115

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waiver demonstrations are usually approved for a five-year period and that's what we're currently looking at. Now that doesn't mean that once they do approve it, that it'll be for the entire five years. It'll be assessed based on the reports that are submitted annually and based on our findings. So, the other requirement is a reporting requirement. So, we need to submit a draft annual report to CMS, and it must be published on our department website. We also have to publish a final report after receiving comments back from CMS. Okay.

Next slide please. Okay. So there are different components to this 1115 waiver demonstration. As I mentioned, it's actually a request for a study and so in this study, there's a hypothesis that needs to be presented and this is the hypothesis that we came up with at first glance when we looked at the requirements of the MDRP. So, Guam's Medicaid's participation in MDRP could adversely affect on-island pharmacy providers by creating an unreasonable requirement for them to carry all of the MDRP participating manufacturers, COD such that it would be difficult for them to maintain adequate inventory. We wouldn't be able to pay for any medication that wasn't covered under a manufacturer that was in a MDRP agreement with us. So, this inventory requirement may be prohibitive for them to continue as providers on the Medicaid Program. Additionally, it would be more costly and labor intensive due to required administrative costs for the program to participate in the MDRP and these costs would outweigh the rebate savings the MDRP would provide. So, there's an additional administrative cost. We would have to hire a contractor to track all the medication that was dispensed and come up with a quarterly report that would have to be submitted to the drug manufacturers in order for us to get the rebate. We don't have a grasp yet of what those costs would be, but that's what this request for the 1115 waiver would allow us to do the study to see what those costs would involve.

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SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Mr. Gallo, what is COD?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Those are covered. I'm sorry. It's not cost. It's covered outpatient drugs.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Covered outpatient drugs. Okay. So, this hypothesis is the crux of what you're submitting to them. This is the study you want them to conduct.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: This is the study that we will be conducting.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Oh okay. You will be conducting.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes. That's correct.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: To hold off while you conduct this study.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Right. So, the covered outpatient drugs is actually their entire line of drug formulary that the manufacturers produce.

Next slide please. So, this third area, the Guam Medicaid Drug Prescription Benefit. We wanted to discuss some of the measures that we take currently

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under the program to minimize our cost in this area. So currently the Guam Medicaid Program has a closed drug formulary. So, we're able to control the types of drugs that can be administered under the program or dispensed. We don't normally allow for brand medication unless requested, documented and medically necessary. Additionally, the pricing established is established in January of each calendar year, based on the lowest wholesale price listed on red book. Now, red book is a listing online subscription for drug medication price, and it's updated on a daily basis. So, these control measures have historically allowed the Medicaid program to maintain a relatively low expenditure for our drug prescriptions. I believe the average that we were looking at was maybe in the neighborhood of 17, 18% of total costs for the program. And medication for the Medicaid program is probably one of the higher areas that you see costs.

Next slide please. So, at first glance during our initial assessment one of the things that we had identified that currently the island pharmacies face challenges. They have a difficulty in obtaining supplies due to our remoteness here in the Pacific relative to the supply chains. Now, oftentimes the drug wholesalers or medication wholesalers are not negotiating with our local pharmacies. So, they pay whatever the drug distributors list is the cost for the medication and on top of that, they additionally would pay the cost of air freight. So, this is one of the things that our local pharmacy providers had mentioned to us, and you know, these added costs create a hardship and a burden for them, and we had initially come up with the impression that having them cover all or carry all CODS for manufacturers under the MDRP would create a hardship or additional burden on them. Now, the additional burden, one of the things that we were concerned about was that it may be too costly for them to continue on the program, which may cause them to drop from

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participation and would create our participation access problems where our Medicaid participants or recipients wouldn't be able to receive their medication through on-island pharmacies.

Next slide please. Okay. So, this next area of discussion talks about the MDRP implementation and some of the things that in our evaluation design we would want to look at and so we came up with some questions and these were the areas that we would base the evaluation design around and collect data to prove the hypothesis. So, the first question, what are the existing supply chains? Pharmaceutical distributor available to on island pharmacies. Secondly was what current limitations do on-island pharmacies have in dealing with existing supply chains when ordering COD for MDRP participating manufacturers. Third area: how would Guam Medicaid participation in the MDRP affect on-island pharmacy provider's decision to continue as a provider on the Medicaid Program. Now, some of these assessments wouldn't be in actually gathering data. That third area would probably have to do a survey to see what the pharmacies' thoughts on the matter would be and then try and assess that way.

Next slide, please. So, these last two areas that we thought of trying to do the assessment and including this in our valuation design was for these two questions, would the cost reduction for pharmacy expenditures outweigh the adverse effects of creating potential inadequate participation access to on-island pharmacy services and then lastly, what other costs would be involved in Guam Medicaid's participation in the MDRP and would these costs outweigh the benefit of the rebate savings to its pharmacy expenditures. Now at first glance, again, when we did an assessment, it appeared that the MDRP program is a complicated program. So, we would probably need to have an additional full-time employee just to manage that particular aspect of the program. There are other areas we

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would have to contract with a vendor that would be able to track all the dispensing of medication, both in the pharmacies and in the hospital settings, so that we would be able to report that back to the manufacturers and obtain the rebate. Now we don't have a grasp yet of what those costs would be, but we were currently looking at reaching out to the U.S. Virgin Islands since they're similar in size to our program and see what their costs are as they try to implement the MDRP and use some of their data to do our assessment. So, the last note again, it's just to be open that we're currently working with a Guam Medicaid Program or with CMS to develop our evaluation design for the 1115 waiver. As soon as that's completed, we have several zoom meetings set up but again, as soon as that's completed, that will be published on the website.

Next slide please. So, in conclusion, we've discussed the four points here. We've discussed the Medicaid Drug Rebate Program and the mandate that the Guam Medicaid Program now participate in this Drug Rebate Program by January 1st, 2023, because of that and using the 1115 waiver demonstration we're going to opt to request for a period of time to do a study to assess. We also went over some of the control measures that we used to limit our expenses with prescription drug benefits and then lastly, we covered some implementation challenges, with starting the MDRP and how those areas will be included in our evaluation design as we work with CFS to finalize that. Next slide, please. So, that concludes the information briefing that I have. Did you have any questions?

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you, Mr. Gallo. I'd like to recognize in addition to the senators present that I announced earlier, the presence of the vice chair of the Committee on Health Senator Sabina Perez, also Senator Joanne Brown, and also, we have with us today in our audience former Senator Dennis Rodriguez, who is

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currently the governor's Chief Advisor on Healthcare. That was announced recently. Yeah, if I could start with a couple questions. One is how long are you going to request a waiver for, in other words, how long is this study going to take?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Well, normally when the 1115 waiver demonstrations are submitted, they're usually approved for a five-year period but again, that may continue for the entire five years. There is that reporting component that we would have to meet on an annual basis. There's also a quarterly report that needs to be submitted to CMS as well.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: So, the questions that you've listed, I know you're working with CMS to finalize this design, but the question that you've listed, they don't seem like they would take that long to answer to me, but I'm not sure and so I just wanted to note also for the record that we invited the Guam Board of Examiners for Pharmacy, and we asked the Department of Public Health to invite all pharmacies on Guam to this hearing. So, they were notified.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. Do you think it would take that long?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: The Medicaid Drug Rebate Program has quite a bit of requirements in order for us to implement it. We don't have a comfortable grasp yet on what that would entail the cost involved and so this 1115

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waiver demonstration application was just a way for us to gain additional time. We're looking at January 1st, 2023.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. So, if you gain additional time five years, what happens during the five years to reimbursement? Is there any reimbursement or is there none?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: No, if we don't participate in the MDRP there's no rebates that would. However, the rebate during the study, we wanted to assess whether the additional costs to the program outweighs the rebates that we would receive based on our current control measures. Yeah.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. All right. Did anyone else on the panel want to add anything before I open it up to questions from the senators? Alright then. Senator Nelson.

SENATOR TELENA CRUZ NELSON: Thank you, Madam Speaker. Good afternoon.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Good afternoon, ma'am.

SENATOR TELENA CRUZ NELSON: So, the bottom-line up front is that you're going to request a waiver. It's already been decided that you're going to move forward to request the waiver. Is that correct?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: We're working towards submitting an application. We're trying to meet all these timelines. So, hopefully we'll be able to meet the

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timelines to submit the application, whether it'll be approved. That again would have to be determined by CMS.

SENATOR TELENA CRUZ NELSON: Okay and during that time if the waiver request does get approved, you're going to do an analysis on your hypothesis that you represented. Is that correct?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes ma'am.

SENATOR TELENA CRUZ NELSON: Okay. What is the impact to the people that would partake in this program? If you did not request the waiver.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: The impact for the recipients would be minimal. We would still cover, well, let me take that back. The Medicaid Drug Rebate Program would open up our drug formulary, which means participating in the Medicaid Drug Rebate Program would open up our drug formulary. Our drug formulary is our covered medication. Currently, we don't allow for brand medication. We don't allow for a lot of different things. So, we're able to control costs that way. If we were to participate, we would cover everything that the manufacturers produced and so there would be a rebate, but would that rebate cover the additional costs and that's what we're trying to assess.

SENATOR TELENA CRUZ NELSON: And who pays the initial cost?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: The program would have to bear the initial cost.

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SENATOR TELENA CRUZ NELSON: The Medicaid Program.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct. Yes.

SENATOR TELENA CRUZ NELSON: That's currently at 85% reimbursement rate. Is that the same program you're talking about? Where would the funding come from to pay for the initial cost specifically?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. So currently we're the FMAP.

SENATOR TELENA CRUZ NELSON: The FMAP?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: The FMAP would be. It's currently at 83%. 83% with PHC. It's an additional 6.2. So, it's currently at 89.2.

SENATOR TELENA CRUZ NELSON: 89.2. So, that's a good FMAP because in previous years we had 55%, right? Correct?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct. However, we don't know what's going to happen after September 30. That FMAP may go back to what it originally was, which is 45/55.

SENATOR TELENA CRUZ NELSON: Okay but isn't it a good thing to open up the formulary for the people and for the government to help them pay for their medication? I mean, the issue with COVID 19 is that we saw that our healthcare was greatly hindered. We did not put enough emphasis

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in the previous years towards our healthcare and we saw that as a result globally, we saw people die. We saw a shortage in nurses. We saw a shortage in hospital staff. We saw a shortage of doctors. We saw a shortage of medical necessities. We saw a shortage of medicine in general, so wouldn't it be a good thing for us to move forward with this MDRP and give the government take care of the people in this sense, help them with their medicine. Shouldn't we refocus our efforts towards healthcare and really do it and commit ourselves to this?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I think that offering more medication to our recipients would make sense that it would be more beneficial, but covering all brand medications, versus generic medications. I'm not sure if the cost difference would.

SENATOR TELENA CRUZ NELSON: Right. But if the doctor prescribed me Acetaminophen over Tylenol through the Medicaid Program, is that patient going to be given Tylenol or is that patient going to be given Acetaminophen?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Well, currently, even though we don't allow for brand medication, we do allow for it if it's medically necessary.

SENATOR TELENA CRUZ NELSON: Okay. But if the doctor prescribed a patient Acetaminophen and the MDRP, the Medicaid Drug Prescription Benefit. I'm sorry, what is it? Yeah, the Medicaid Drug Rebate Program. You said that it's going to open up the formulary and so if the doctor prescribed me Acetaminophen over Tylenol, I would still get dispersed Acetaminophen. Right? If I'm a part of this Medicaid program or is the

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pharmacy going to say, okay, they prescribed you Acetaminophen we're going to give you the brand name, Tylenol.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: It's whatever the physician will prescribe.

SENATOR TELENA CRUZ NELSON: Okay. So just because we opened the brand formulary, and we say that this program is going to allow also for brand names not just generic, a name medicine, that that's not always the case that they're going to get the brand name medicine. Is that correct?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct.

SENATOR TELENA CRUZ NELSON: So, back to my question again, don't you think that this would be good for the people if we can participate rather than request for a waiver, if it gives them more options and the government absorbs this kind of cost. It's just a simple reprioritization, right, of where our priorities will be at the legislature. Right. So, wouldn't you be advocating for that instead?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I think, my experience with the federal programs is that we have to be fiscally responsible. We have to create a benefit program that would benefit the majority of people with limited resources and so again the study, it's not to stop us from participating, it's to allow us time to assess at this point, it's hard for me to make that.

SENATOR TELENA CRUZ NELSON: The waiver will delay the implementation of the program. Is that correct?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct.

SENATOR TELENA CRUZ NELSON: And you stated that it's going to delay the implementation. The waiver can last as long as five years, is that correct?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: It may last, but it could last only for a quarter.

SENATOR TELENA CRUZ NELSON: Okay. But it's uncertain, right?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: It would be up to CMS.

SENATOR TELENA CRUZ NELSON: So, don't you think then why don't we provide this kind of program to the people who are in most need and still conduct the study at the same time? There's nothing that stops us from doing the assessment while we're within the program. There's a timeline for opting out. So as long as we meet that timeline, we can request the waiver then.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: If we don't act now that window's going to close. We won't be able to request for the waiver.

SENATOR TELENA CRUZ NELSON: Okay. So, it's August 1st, 2022.

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MICHAEL GALLO, PROGRAM COORDINATOR, DPHSS MEDICAID PROGRAM: Right.

SENATOR TELENA CRUZ NELSON: And then you learned about this waiver in. Is it on November 25th, 2019? I mean, yeah, that's right. Is that the date? You know, it would've been easier if we had a timeline and then you listed all the critical events leading up to the rebate program.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, the November 2021 final rule, that set the date for January 1st, 2023. So, in November of 2021 the program knew that it had to implement the MDRP.

SENATOR TELENA CRUZ NELSON: Okay but when were you first alerted about this?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I could get the information. I've only been with the program since December of 2019. So, I could get that information to you and provide it.

SENATOR TELENA CRUZ NELSON: Wow. Okay. It says here in the presentation that it says on February 1st, 2016, that was when the Medicaid Drug Rebate Program started and then the delay date for provision relating to manufacture reporting of multiple best prices connected to a value-based purchasing arrangement was on November 19th, 2021. The rule was delayed for nine months to April 1st, 2022, and you came in December, right? You came in just December 2021?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: No, December 2019.
SENATOR TELENA CRUZ NELSON: 2019. So, this should have been within your time, right that you noticed that there was a …

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: November 2021, I think you stated for the record, right?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. Unfortunately, it wasn't my purview. I wasn't responsible for this particular.

SENATOR TELENA CRUZ NELSON: So, seven months later we're having the hearing. Roughly seven months. Yeah. I'm not convinced that this waiver is acting in the best interest of the people. I'm not convinced at all, especially with the presentation. It seems like we're acting for something else and the questions that I do have really have to deal with the hypothesis that you stated and even if you ask for a waiver within three months, for three months you said it can be done as quick as a quarter. It just makes me question why didn't we do this sooner? In November 2021. Why didn't we ask sooner if we thought it was only going to take a quarter to do this analysis? So, is it within your authority that you are going to send this waiver request forward? Is that your authority?

MICHAEL GALLO, PROGRAM COORDINATOR, DPHSS MEDICAID PROGRAM: No. I'm just assigned to work on this project.

SENATOR TELENA CRUZ NELSON: Who authorizes that?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, the administrator would make the decision to submit that.

SENATOR TELENA CRUZ NELSON: And who's the administrator.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Our current administrator is Teresita Gumataotao for the Bureau of Healthcare Financing Administration.

SENATOR TELENA CRUZ NELSON: Okay. Madam Speaker, you know, I'm just concerned that we're moving forward with a proposed waiver. We don't have all the answers and perhaps the waiver was to find the answers, but there was more than enough time to collect the analysis seven months later and I'm not convinced that this waiver is going to benefit the people at all. That's all I have and, you know, thank you for your work. Thank you for the presentation.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: You're welcome.

SENATOR TELENA CRUZ NELSON: It's really just a concern of how this is going to impact the people and it seems like it's going to take something away rather than give them something and if it's something that we could do at the Legislature to reprioritize how we spend our money and to reprioritize how we move going forward, then I would think that you would be here advocating to participate in this program, and we need to afford more money to adjust for the rebate and rather than requesting a waiver to do an analysis.

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I understand that. Let me give you an example of some of the things that we've had to deal with. We've had Medicaid participants that have gone to a physician. The physician, I'm not sure if they're operating under their, own interest or other interest but they would prescribe a brand drug medication and so for instance, the difference between the brand drug will be $50 a pill versus 5 cents a pill and they're reasoning behind wanting the brand drug medication is because it's a soft chew and the participant is having difficulty chewing and swallowing. However, in speaking to other physicians, they're also able to crush the medication and dissolve it. So, in order to provide cost savings and provide benefits to more people, rather than paying $50 for a 30-pill prescription we'd rather pay the 5 cents per pill for 30 pills and not harm or hinder the health benefits of the participant in any way.

SENATOR TELENA CRUZ NELSON: So, I caught in that explanation that in order to give more medication to more benefits to more people. Yeah. So, are you saying that you're not going to be able to give more benefits to people if we participate in this new program?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I'm not sure. I can't say that, but I'm just giving you an example of some of the issues that we face so that we have to make a determination whether or not.

SENATOR TELENA CRUZ NELSON: Yeah. Is there a cap on how many patients Medicaid can cover? Is there a cap on the amount spent per patient?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: No, it's just based on what we have and what our local FMAP can provide.

SENATOR TELENA CRUZ NELSON: Right and how do you get what you have as far as revenue? How do you get what you have?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Well, of course that's given by the federal grantor and then matched by our local.

SENATOR TELENA CRUZ NELSON: Matched by local funds.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct.

SENATOR TELENA CRUZ NELSON: And how do you get those local funds? Through the Legislature's appropriation. So, when the statement is said that there's a concern that we will not be able to provide individuals with the benefits, but if there's no cap on the benefits and there's no cap on how many patients we can provide the service to, and you receive your revenue from federal grants and from appropriation from the Legislature, then it would be the Legislature's job to ensure that the appropriation is supplemented. So, we can still cover the people that qualify and not put a cap on the program. Is that correct?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct.

SENATOR TELENA CRUZ NELSON: Okay. Thank you, Madam Speaker.

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SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you. Anyone want to add? Mr. Pangelinan.

CARLOS PANGELINAN, DPHSS: I'd just like to add that, you know, with respect to what Mike had said cost and the ability or the availability of a formulary listing is not the only consideration. You also have to consider whether or not because there are other requirements and Mike had explained already that this would then require the providers to carry all of the outpatient drugs. I think the thing here is we just don't know.

SENATOR TELENA CRUZ NELSON: So why is that a problem?

CARLOS PANGELINAN, DPHSS: Well, we don't know what the impact would be.

SENATOR TELENA CRUZ NELSON: So, it looks like you're acting in the best interests of the provider and not the patients.

CARLOS PANGELINAN, DPHSS: No, no, no, no, no. It's not in trying to act on behalf of the provider. It's making sure that the drugs are going to be available. Now if a provider is required to provide things that they can't afford, then why would they then participate in the program to begin with? I mean, that's just the only consideration that, you know, you should also think about. So yeah, that's all I wanted to add.

SENATOR TELENA CRUZ NELSON: So how much does the initial cost cover? Is there a formula for that?

CARLOS PANGELINAN, DPHSS: Yeah, I don't understand.

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SENATOR TELENA CRUZ NELSON: You said that the government or the program covers the initial cost. So, how much is the initial cost?

CARLOS PANGELINAN, DPHSS: It would be the cost of medication.

SENATOR TELENA CRUZ NELSON: Overall. Right? Is it overall, do they have to pay a co-payment?

CARLOS PANGELINAN, DPHSS: We don't currently have co-payment.

SENATOR TELENA CRUZ NELSON: Okay. So how does that lead into what …

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, maybe what Carlos is trying to explain is that because our pharmacies are unable to create large inventories because of their limited resources. If we require them to carry Pfizer's entire line of medication, to include all their brand medication, as well as generic. That may create a hardship for them because if the physician prescribes Pfizer, whatever it is and they don't have it, then they try and give him another medication that they have in inventory. We won't pay for it. We won't be able to pay for it under the MDRP.
SENATOR TELENA CRUZ NELSON: You won't be able to pay for it.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Correct.

SENATOR TELENA CRUZ NELSON: Who's we?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: It's not a contract, it's a medication under MDRP.

SENATOR TELENA CRUZ NELSON: I think also then we should take a look at the revenue flow chart, because now you're saying we won't be able to pay for it, but earlier we talked about that the government covers it and the federal program. So, as far as the medication piece to participate in this program.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. So, we wouldn't be able to pay for a medication that wasn't under the contracted manufacturer. So, if all the pharmacy had in stock was a non-contracted manufacturer medication, and that's all they had to fill the prescription with, the program couldn't pay for it because it's not under the MDRP program.

SENATOR TELENA CRUZ NELSON: So, is there a list of what is acceptable and not?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: There is a list of all the manufacturers that are participating on the program, and then there are thousands of NBCs on there, tens of thousands.

SENATOR TELENA CRUZ NELSON: That do not participate as part of the program?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: No, that would be included on their COD. So, there's a lot of variables that we're trying to assess and hence the need for additional time.

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SENATOR TELENA CRUZ NELSON: How are other states and territories impacted? Have you observed or done any research there?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Well, the other states and some of the other territories under a different type of regulations, so some of them are faced with the issues that we have. Obviously supply chains for a Walgreens out in California is different from Mega Drugs out here. They can't negotiate for the best price because the amount of medication that they order on a weekly basis, even a monthly basis is significant for a lot of these wholesale distributors. You know, $50,000 worth of medication versus, you know, 5 million sales for Walgreen, they have no bargaining power. So, they just accept the cost of whatever the wholeseller is going to sell it to them and then they have to tack on additional costs for shipping. So, we want to consider both the participants as well as the providers because without the providers, we have no program.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you.

SENATOR TELENA CRUZ NELSON: Can I still ask questions, or you want me to, okay. I'll pause my questions.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: We'll come back to you. Senator Taitague.

SENATOR TELO T. TAITAGUE: Thank you, Madam chair and good afternoon, everyone who's here today. Thank you so much for being here. I just want to go back to this whole nemesis of the 1115 waiver. I went online of course because it's the first time I've ever heard of it. So, I went online

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and started reading about it and if I'm not mistaken, Mike, what we're here today is to discuss, is this considered the first public hearing that is required for you to go through this process?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct.

SENATOR TELO T. TAITAGUE: Okay, so this is public hearing number one.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct.

SENATOR TELO T. TAITAGUE: And then you're going to have a public hearing number two.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes.

SENATOR TELO T. TAITAGUE: Correct and then after that when do you have to submit your findings once you've calculated everything and put it together, do you have one more public hearing to present the findings? Because I know the pharmacies here on this island are going to want to chime in on this. We want to hear from them in fact.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, we have the second hearing that we've tentatively scheduled for, well, not tentatively, but we're shooting for July 5th at 1:00 PM and it would be via zoom. It would be departmental hearing. We would send out notice to the providers, publish for the public to view that

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and what we envision is emailing to receive the invitation for the zoom link.

SENATOR TELO T. TAITAGUE: Very good. Yeah. So that will be number two, right? Because it says that you're required to. Once that's completed, you finished that public hearing, you have a timeline to submit to the Center, right?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes, we do.

SENATOR TELO T. TAITAGUE: And that date is what, when you submit?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: We're shooting for August 1st. That deadline may or may not be met just because we're behind. Yeah. We've been pushing this and so I see the window to submit this application. We don't know if that's still open. We have a call with them this week and we're going to assess where we're at.

SENATOR TELO T. TAITAGUE: So, you're going to be allowed by the federal side to give you an additional time to comply with the information, the application, because according to the website, it's an application that you have to fill out, right and go through the process.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: That's correct. So, we have to submit it to them by a certain time that gives them enough time to review because they also have a public comment requirement where they have to publish it and so we've been

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working with them based on this June hearing timelines and then submission, gather the public comment with for 30 days, submit the application by August 1st and then keep moving forward in order to meet that January 2023 timeframe for implementation. Again, I'm not sure.

SENATOR TELO T. TAITAGUE: Is that January 23rd, 2023, or January 23?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: January 1st, 2023.

SENATOR TELO T. TAITAGUE: Carlos, would this affect the hospital? I don't know why I'm affiliating you with Guam Memorial.

CARLOS PANGELINAN, DPHSS: Because I used to work there.

SENATOR TELO T. TAITAGUE: Okay. That's probably why. Okay. They have a pharmacy there at the hospital.

CARLOS PANGELINAN, DPHSS: They don't have an outpatient pharmacy.

SENATOR TELO T. TAITAGUE: Do you think it'll affect if let's say this waiver is produced?

CARLOS PANGELINAN, DPHSS: I'm not absolutely sure, but I would venture to think that it wouldn't because they don't have an outpatient pharmacy. Their drugs are usually for the inpatient.

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SENATOR TELO T. TAITAGUE: Okay. Do you think Mike, that this would, cause some type of, well, I guess everybody contributing one to avoid any high cost to medication by all bringing in at one time, like bulk with all these pharmacies coming together to try and find a way to make it cost efficient because we know this is supposed to help.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I had thought of possibility them forming co-op to order in bulk but even at that with the amounts, you know, based on our small population, these major distributors and I believe there are a few that operate on island that do distribute, Amerisource, Bergen. I don't recall the other names right now but they're like number one, number two, number three in the nation and so they deal with Walgreens, they deal with CVS.
SENATOR TELO T. TAITAGUE: We're just not that big.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. Like mom-and-pop stores trying to compete with Costco.

SENATOR TELO T. TAITAGUE: So, my question then Mike to you is why even go after this waiver?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Well, what we really wanted to assess to make sure that we're not rushing to participate in something that the federal government has set, but hasn't considered how this affects us because of our remoteness from supply chains and so rather than doing injustice to both the providers or recipients, we really wanted to take time to see how this is going to impact the program.

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SENATOR TELO T. TAITAGUE: Assess it, right? Okay. That explains it and I appreciate it. The last question I have well we talked about pharmacies and the impact, but we will know that I guess when we have that public hearing. The second public hearing when we invite everybody to come to the table and kind of see where we're at that point, but it's not like we're required to do this waiver at all. I mean, it's an option that's given to all the territories now, which has not been able to do it and like you said, it's not mandated at all. It just gives us that door opening but if it's not conducive to Guam and it costs us more, I'm sure we're going to make those changes. Other than that, you, Jeff, Janet, Carlos and of course, Rachelle thank you so much for being here and providing, and I look forward to that second public hearing because that's where we're going to really see the numbers. So, I appreciate it. Thank you, Madam chair.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you, Senator. Yeah. So, the second public hearing, just to clarify, is one that will be held by Public Health. It's a requirement of Public Health before they submit their application to have two public hearings and submit input from everybody, stakeholders. Correct. So, we've joined together with them today so that their public hearing will be broadly broadcast, and we've invited all the providers on island, all pharmacists, all of the pharmacy board we've even asked that Medicaid recipients are welcome as well and I'm sure that that invitation will also be extended by public health for the next public hearing. Okay. So, Senator Duenas.

SENATOR CHRISTOPHER M. DUENAS: *Si yu'os ma'åse'* Madam Chair, Mike and to the team that's joined us on the panel. Thank you for being here. A lot of the technical questions were asked, so I wanted to go back to the study. What is the timeline on that and what do you expect to gain from that timeline?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Timeline as far as the study conduct? We do have a requirement for quarterly reports, semi-annual reports and an annual report. As we gather information, we're going to actively try to determine if we can get data for certain areas. The cost for a contractor to do the billing for the Medicaid Drug Rebate Program. Again, we're going to reach out to the U.S. Virgin Islands. One of the difficulties that we have with our program, is that we don't have the IT specialists here on the island and so we oftentimes have to go to state side contractors and a lot of times they don't want to deal with us because our participant numbers are so small that it's not a money maker for them.

SENATOR CHRISTOPHER M. DUENAS: Yeah, and that's I guess that's what I was driving at because it seems to me that in order to arrive at the evaluation and to arrive at whether or not you have a conclusion on the cost benefit analysis, you know, that's what you're going to need is kind of that technical comparison and that, you know, that data because rather than otherwise, you may just end up in the end within an analysis that doesn't provide.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Fortunately, as I mentioned the U.S. Virgin Islands, they have a similar population of recipients. They're much closer to the mainland. So, as far as contractors willing to travel to their location, as opposed to come out to Guam that's going to play into the factor for cost, I imagine but we're going to use that as a jump off base point for what the cost would be for us to contract for that particular service.

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SENATOR CHRISTOPHER M. DUENAS: Okay. I guess my final thought too would be, I think I caught this during the presentation is you're not locked into the five years, even if you were approved.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: No, if we had assessed that after, you know, a few months of studying this, that it's more advantageous to be on the program, then definitely that's the direction we would want to go. Again, at this point we just don't know. So rather than act hastily and create more problems than the benefit is going to us, we'd like to do a better assessment.

SENATOR CHRISTOPHER M. DUENAS: Yeah, and that's for the benefit of our public that's watching, right and this body jointly joining with you for the broadness of getting the word out. I think that's our comfort level at this point. Then we can walk away from the table saying, you know, look, the folks from public health are here. They're evaluating a program in terms of what we could avail to but you know, we're not looking at locking or committing ourself to something that in the final analysis with all the information studies and everything. We've been able to ascertain whether or not we get a full blown contractor or not and base ourself on what anecdotal stuff we put together. We wouldn't be locked into saying, oh my God, we're stuck with this for five years now because yeah, we went down this road. So, I just wanted to maybe see if I was on the right track to kind of give our people a bit more comfort level. So, I'm going to continue to listen. Sounds fascinating. I hope that we get the participation from the pharmaceutical companies in your next round, or maybe they'll send you something in writing but certainly I think that cannot be a missing link. I think that has to be information that will be vital to your final analysis, but that's all I have for now, Madam Speaker. Thank you for this opportunity.

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SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you, Senator. Senator Ada.

SENATOR V. ANTHONY ADA: Thank you, Madam Chair, Madam Speaker. Mr. Gallo, thank you and to everyone here thank you for being here today. I think a question I have is has any round table discussions or any discussions at all been happening with the pharmacies as to this program that you guys were looking at considering?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: We haven't had an opportunity to do a round table discussion with them, but I have reached out to the pharmacies for Payless, Mega Drugs and had discussions with them as far as the challenges that they currently have with the supply chains and dealing with these major distributors for the pharmaceutical manufacturers.

SENATOR V. ANTHONY ADA: And were they able to get back to you or?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: They had just mentioned some of the challenges like what was pointed out with regards to not being able to negotiate a price when they open up the price listing for medication. It's whatever is there that's your price and we don't negotiate with you because you can't meet our quota for discount and on top of that, you have to pay for shipping, air freight.

SENATOR V. ANTHONY ADA: Yeah. I mean, my concern is when we get to the second hearing, right and that those pharmacies that do participate, those that don't participate, they may come back and say, well,

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we never knew about this. We were never notified and things like that. So, I'm just trying to see how far out and why did you go with notifying, you know, while the participants or possible participants into the program?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, I'm also the supervisor for the claim section for the Medicaid program and I have six supervisors that deal with pharmacy providers. So, prior to this hearing, we made sure to speak to my supervisors to assure that the pharmacies that they're assigned to are notified of the hearing so that they can provide their input because we definitely want to make decisions based on a total understanding of what's going on.

SENATOR V. ANTHONY ADA: Yeah, definitely because you know, the impact that it could have on either the recipients of the medication or the participants, the pharmacies, right. Like you said, does the benefit outweigh the risk or the cost of the program and I hope that on the next hearing that we'll be able to get more input and those especially from the pharmacies and the public at large to see what they come up with but thank you for the presentation. I think it was very well put together. Hopefully we get more information, and we look forward to hearing onto the next hearing. Thank you, Madam Chair.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON Thank you, Senator. Senator Perez.

SENATOR SABINA F. PEREZ: Thank you, Madam Speaker. So just a couple questions. If you can unpack this concept of budget neutral, what would that entail because looking over the presentation, it talks about how the rebate program would require drug manufacturers to provide the

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rebate. So how does that apply to Guam? Is it the pharmaceutical company itself or the manufacturer of the drug?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Okay. So, the Medicaid Drug Rebate Program is a contract between the drug manufacturers that want to participate, and they would contract with HHS. We would enter into a contract with the pharmaceutical manufacturers and then we would supply them on a quarterly basis. All the medication that was dispensed by NBC National Drug Code, which drug code is assigned to each medication that's made regardless of manufacturer. So, we would collect all that data, send it to them. They would use that information to calculate based on the formula. So, the formula was the average wholesale price minus best price. So, for brand medication, it would be the average manufacturer price minus best price, or 23.1% of the average manufacturer price, whichever is greater and then they would also include an inflationary component and that calculation would be by drug, by NDC and so it's just rows and rows of data that we would have to report and then they would calculate, send us the rebate based on what we paid under the program for those particular NDCs that they manufacture. We would get that rebate and then we would split it with CMS based on the FMAP.

SENATOR SABINA F. PEREZ: So, you know, we've never done this program before. Right. So, we don't have a baseline and so how do we determine what budget neutral is?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Well, budget neutral right now, it would mean that we're not requesting for additional monies to conduct this study or just using the existing funding to do our analysis. So, we're not going to hire an extra

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person to conduct the study under the 1115 waiver application. We would just have to do it in house. The assessment would have to be done based on our current resources.

SENATOR SABINA F. PEREZ: Okay. Just for clarification. So, the rebate comes from the manufacturer not from our pharmaceutical on-island?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: No. The pharmacies, the only reason why the pharmacies are involved is because they purchase the medication through a wholesaler that distributes for a manufacturer.

SENATOR SABINA F. PEREZ: Okay. So, I guess the question is how do you determine budget neutral? Right. Coming from our perspective. That still needs to be clarified. I don't have a good sense.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah, so if we were to submit our application and tell CMS that we need to hire three more people in order to conduct our study, then that's not budget neutral. Right. Because we're incurring additional costs. So, if the waiver was approved, would it cost additional money to CMS? And right now, the answer would be no. If they allow us the additional time, it's not costing them additional money.

SENATOR SABINA F. PEREZ: Yeah. I think you know, one of the benefits of the program perhaps I think my colleagues have intimated is the access to lots of different drugs. Right. But then, you know, I think maybe perhaps. Are you rethinking your hypothesis? Is there a way to rethink that hypothesis because I think it's important to be able to balance the needs of the community in addition to the cost issue?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: As we gather more information, it has changed our viewpoint to some extent, on whether our hypothesis needs to be changed. Still in the process of discussing that with CMS and our current management team. I mean, this project is complicated and to the extent that it has a lot of different components that need to be assessed and so it's not something that can be analyzed in a month or that type of thing. As we look at all the different components that's required under the MDRP, what is that going to require of the program's resources in order to implement that and that's what we're trying to answer.

SENATOR SABINA F. PEREZ: I think the drugs are the largest cost, right. You know, I think that's going to be something to think about. You know, I concur with my colleagues that you know, we do have to look at the interest of the public in regard to access to drugs, especially perhaps the newer drugs, you know, with our high rates of cancer, other elements that our communities are experiencing. I think that's important to look at. Access is important but we also have to look at the cost too as well, obviously. So, I feel like the hypothesis needs to be readjusted.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I guess the only issue that I have again, is going back to creating an additional burden on the pharmacies. So, if the program requirements are so burdensome that it's not beneficial for a pharmacy to say, oh yeah, okay. I'll provide medication for your program recipients, but you're requiring me to carry all of this medication. I can't do it and so you're telling me that if I have something in inventory and I can dispense it because it's a comparable medication. If I dispense it, you're not going to pay me. So those are the things that we're trying to assess as well as

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whether or not the additional expansion of the medication is going to be beneficial as well and as we look at the program, we definitely don't want to withhold benefits or successful health outcomes for our recipients. That's not the purpose of what we're trying to do with the 1115 waiver. It's not to nickel and dime the program, it's really just to ensure that as we move forward towards either implementing it or not implementing it, that we're looking at how it affects everyone.

SENATOR SABINA F. PEREZ: Thank you for that point. Yeah, I do look forward to the next public hearing but perhaps we can have a targeted approach with the hypothesis so that wherever the drugs, you know, which drugs are needed here, perhaps allow that but you know, have a more targeted approach I think is what's necessary. So yeah, no further questions. Thank you, Madam Chair.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you, Senator. Senator Brown.

SENATOR JOANNE M. BROWN: Thank you very much, Madam Speaker. You know, and so we see the issues and intricacies with regards to some of these federal programs that sometimes get so complicated that the desired objective doesn't get received by the public and I'm sure we all agree. We would want to maximize the opportunity for our people to participate and receive the needed medication because certainly not everyone has the luxury of affording all the medication, especially as you get older that you're being prescribed by your doctor. So, I think we recognize that. Just so the public and we don't get the impression, you know, that this is a slow, winding down process. I know you have August 1st, is that your deadline to confirm whether or not Guam will participate in the program or is it simply your application time and then they

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determine if you're going to participate or not. Do they review that and say, yes, we're going to include you or not? What happens there?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. So, based on our discussions with CMS, we've come up with an August 1st deadline to submit in order for them to give them enough time for their processes to go through their approval so that it'll be in place by January 1st, 2023. As I mentioned, we've missed a few time frames that we were looking at initially. So, we need to reassess with them whether we're going to be able to accomplish this.

SENATOR JOANNE M. BROWN: Is it simply an application process on our part or do they get to review it to determine whether we get to participate or not? What's the next step after this timeline if you determine we're submitting? Do they get to say yay or nay, or is it automatic because you apply for the program or where are we with that?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, it's a requirement for the publication, the comment period. So, the requirement is 20 days prior to submission, we've had to complete the two public hearings and so we've completed one, we have an additional one to go. So, 20 days prior to submission, so we're pushing into July now we need to have it submitted by August. Additionally, we need to complete a 30-day comment period from the date of publication of our public notice and so we did publish on the department's website for the public hearing. We are in the process of trying to put that on the DOA site that's under the open government bill that requires.

SENATOR JOANNE M. BROWN: Yeah. Just to let you know DOA's website in and of itself, doesn't meet the public notice requirements. So be

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mindful of that. You need to publish it and you want to maximize the opportunity for people in the public to see this, right. So, I hope you're publishing in the paper. I mean, I know the Speaker does make the effort to publish all our hearings in the paper, but please make sure you do that for your own zoom meeting so that at least you maximize that opportunity, but just online, just not accommodate that requirement for public notices. Again, just to get back to my question, is this something that once you, I understand you very clearly outlined the process and procedures you're undertaking to meet these requirements. I'm just asking, once you do that is automatic participation or they still get to review and determine whether or not Guam gets to participate or not?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: They review whether or not they're going to approve our application.

SENATOR JOANNE M. BROWN: Okay. So, there's still an approval process after you submit it. It's not an automatic reply and we're participating.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, they may see our application and say no, this is not going to work. We're not going to give you the waiver. You need to participate come January 1st, 2023.

SENATOR JOANNE M. BROWN: With regards to our pharmacist, private pharmacist. Is it optional for them if they want to participate or not?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: They have to be a Medicaid provider. So, all our program providers enter into a provider agreement with the program. Yeah. So those are the ones we're concerned about.

SENATOR JOANNE M. BROWN: And do you have pharmacists now that are part of this program or is this a whole new program?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: No, we do. The prescription benefit is a benefit that the Medicaid program offers, and we do have pharmacy providers that offer Medicaid.

SENATOR JOANNE M. BROWN: Okay but is it optional for them? Do all pharmacists are required to participate or again, for private pharmacists? Is it optional? Should they choose to participate or not? Like you have some doctors. Some doctors won't take certain programs. So, I just want to clarify because I'm not aware.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. So, the provider agreement, the way it usually works is a pharmacy would say, hey, we want to be on the program or at times we also try to encourage providers that are new and that we approach them and say, hey, we have this program. Would you like to be a provider? And then we would enter into the agreement with them.

SENATOR JOANNE M. BROWN: Okay is it optional just to clarify and simple English? Optional or not?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah, nobody's required to participate.

SENATOR JOANNE M. BROWN: Okay, it's optional if they choose to participate.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: We don't force pharmacies. We can't.

SENATOR JOANNE M. BROWN: So, right now, how many pharmacists on Guam do we have and how many participate in any type of federal program like this? Just out of curiosity. I don't think they're here. Right? Hopefully they'll participate in your hearing that you have scheduled in a couple of weeks to get some feedback.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: We have quite a few. I don't have that exact number, but if you'd like I can provide a list.

SENATOR JOANNE M. BROWN: It would be helpful to the committee to know, okay. I mean, if we have, you know, 15 pharmacists and we have seven participating and also for, you know, helpful for the public as well because I mean, I'm sure, especially the elderly in our community that are challenged and you know, need medication. I'm sure it's a frustration, but at the same time in order to operate, and I do appreciate the fact that you're going through this process. I mean, everyone can, you know, slam the table and demand we want this done. As long as it's, you know, being completed in a reasonable period to make sure it's actually beneficial because if it's too cumbersome and then we can't get the medication we need anyway then where are we with regards to our community?

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah, I think for years we've had some difficulty with getting providers because we've had limited budgets. From 2016 forward, it looks like we've had some inflow of additional funding and so the medical providers on island want to be a provider under the program and so we've seen some increase because of the additional funding but yeah, in the past it's been difficult. They don't want to, or they'll participate in Medicaid, but they don't want to participate in MIP, so it's been challenging in the past, but it's gotten better because of the additional funding that we currently have.

SENATOR JOANNE M. BROWN: And so, what will you get besides the medication in this process? Does the federal government subsidize anything further for Guam in this case or is it just simply providing access to the medication through these pharmacies should they participate? Let's just sum it up in simple terms, because I'll tell you the last hour for me and most people would be like, it's boring this very boring listening to them at the legislature today. Nothing exciting about this subject but the bottom line is trying to get this medication that these drug manufacturing companies have agreed with the federal government. They've ventured into an agreement. They're going to give these medications at a certain cost that's more affordable. We are assuming and that's why this type of program exists, and we want to see if this is going to work on Guam and that about sums it up, at least in my mind what we're engaging here this afternoon of this discussion.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Okay. So, the Medicaid Drug Rebate Program works is the rebate would be provided by the manufacturer to the states and they're

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doing that because they've contracted with CMS or HHS to be part of the program where the Medicaid programs in each state when they enter into this agreement, they cover all the manufacturer's medication. So, whatever they produce out there, if a physician writes a script for it, if it's medically necessary, the program will pay for it and so they calculate all of those payments that the Medicaid state agencies pay for the recipients for the manufacturer's drug, and they use that number to calculate the rebate. So, if I can use an analogy, it's kind of similar to the WIC, right? Where they contract for formula and so for every Similac that the WIC program dispenses under the program. The manufacturer will give them an X amount of dollars for each can or bottle of formula that sells because it's beneficial for them because when they're on the program, more of their product is sold. So overall they have an increase in their sales but then to offset that for our costs, they give us the rebate.

SENATOR JOANNE M. BROWN: My last question, because you brought up because we're a smaller community, there's some disadvantages of scale because we are a smaller community versus CVS and you know, San Diego or whatever. Is that anything that could be looked at for Guam to inquire about or something our Congressional rep can look at with regards to that formulation so that smaller jurisdictions are not at a disadvantage in participating at the best price for this medication versus larger communities that of course, because of the scale yeah. You know, are able to have it more readily accessible and at an affordable price.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah, it would be nice if there was some type of federal program that would create that additional savings or subsidy for communities like us. I don't know if that's possible and how they would

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create that to create an incentive for the manufacturers to want to participate. Big businesses, you know, they're profit driven.

SENATOR JOANNE M. BOWN: But I think federal policy. I mean, as there are other benefits for disadvantageous locations, according to population, you know, our income levels, things like that that have been put in place for other federal programs. I mean, it's just something that probably, since you, and I think it's a very good point that you brought to light about that issue, because we're just assuming everything's equal throughout the system, but because of our location, our smaller population. We're not able to take advantage of obviously the large volume that makes it more accessible for other jurisdictions. So, I'm just pointing that out. Thank you very much for responding to my questions. Thank you very much Madam Speaker for the opportunity to ask these questions.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you, Senator Brown. I had promised Senator Nelson to come back to her if she's in the building but in the meanwhile, I'm going to ask a couple more questions if you could clarify. The FMAP rate right now, 89% that we are getting from federal dollars to cover Medicaid. That's the money we're talking about using to pay for medicine, right? So, whether we pay brand medicine versus generic medicine, currently your office is covering generic medicine only unless there's a medical need for the brand and that is so that we can use that same money to cover more patients or perhaps more medicine. Is that right?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Right. So, because of the additional funding, we've looked at ways to increase benefits, not just for individual recipients on the program, but to make it more accessible to larger households with larger incomes.

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We've increased the income guidelines. We've included COFA over the past. I think that's in 2021 and so we've looked at ways to use the funding to cover more of the population and so it's not just trying to hold onto the money because at the end of the fiscal year, we definitely don't want to give money back and I know it's always been a struggle for the Legislature to appropriate enough for us to fully match.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Yes. We have not appropriated enough to fully match in last fiscal year or even the proposal for this upcoming fiscal year, if we get this type of matching. Right. So, and we want to do that, but yeah. So, would you say it's fair to say, I mean, well, what is the purpose of using generics then? Is it for that purpose that you're describing in order to extend this Medicaid program to more eligible people?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. I mean, it's to be fiscally responsible. The generic medication, I'm not aware that it creates negative health outcomes for people that use it.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: So, it's more affordable and we can use the money for additional things if we can buy medicine at more affordable rates.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. We increase our benefits like eyeglasses and so those things we've looked at expanding, and then we have durable medical equipment, some cardiac implants. So, we've included that and that's expanded some of the benefits.

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SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. So, have any pharmacists objected so far to this application for a waiver?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Not that I'm aware of.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Have any doctors or pharmacists objected to your current Medicaid drug formulary with generics only unless there's a medical reason?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: We have had some instances where a physician, maybe not on-island has recommended a brand medication for the purposes that I had mentioned earlier because the patient was having difficulty swallowing, but then it was found that those other medications can be ground to be dissolved in liquid to use and with that particular instance that physician worked for a provider that wanted to recommend medication that was produced by another company under the provider.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: All right. So, it was for their benefit. I see. How many incidents like that?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Those are few. I mean, there are constant requests for brand medication, and we do give it.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. So, you are granting requests for brand medication when the physicians request it for particular purposes. Alright and under this reimbursement program, that's

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the same. It depends on what the physician prescribes you said earlier. Right?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: It would be different in the sense that it would be open to every drug that the participating manufacturer had in their line. All the participating manufacturers.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. I want you to clarify that. So, you said the pharmacies would be required to purchase all medicines made by that manufacturer, any manufacturer in the program or all manufacturers in the program. So, you used one example, Pfizer. A pharmacy company on Guam would have to purchase all medications made by Pfizer if they wanted to participate in this program and the other drug companies.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes. So, I guess the way that it would work, and we were hoping that we could get some of the pharmacies to come in and provide input, but I would imagine that it would be based on their usage. So, the types of medication that they dispense on a monthly basis, I would imagine that they would determine what the monthly need is and if we were on the program, look at those participating manufacturers and then try and order enough from the different manufacturers for a particular type of medication to sustain their current prescription. You know, so it's like supplying as you need it, but not over ordering because you don't get reimbursed if you buy the medication and it expires, then you just throw it away. That's a loss to them. Okay.

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SPEAKER THERESE M. TERLAJE, CHAIRPERSON: So, if you order meds and it expires, you don't get reimbursed. If it never gets prescribed after you've ordered it, you don't get reimbursed. Right and are there some that are just not covered by CMS although they're manufactured by Pfizer, for example, that they would never get reimbursed for.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: So, if they're on the MDRP, the manufacturer was then their entire line of CODs would be covered. So, it would be a challenge, I think for a pharmacy to try and figure out what medication to order. I wouldn't know how they would determine who to order from the quantities, the types, based on even their current prescription listing because they're prescribing current medication I imagine.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: But what is the harm in the pharmacy getting some, but not the rest and saying to the patient and to you, we don't have that currently in stock, so you have to go somewhere else. So, they only order what they're comfortable ordering. What are the implications of that? Is that against the rules?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: It wouldn't be against the rules, but the participant wouldn't get medication for one, I guess because there wouldn't be anybody that they could go to, to get it.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Yeah. Isn't that the current case on Guam right now, there's some certain meds you can only get from one pharmacy. That's my understanding or at least for certain periods when the rest are.

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MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I haven't personally come across that situation, but I know again, because of their limitation, that's probably the case that at times the supply chain it won't come in and then they won't have it for a week or two, and then they would have to come back another time. The prescriptions are good for a year, but then that would be that the recipient would go a week or two without their medication, which probably is not good for healthy outcomes.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Alright. Is there such a thing as, so you apply for the waiver, you might get a five-year waiver. Is there such a thing as a permanent opting out. So, eventually Guam will be included in this program and pharmacies have to prepare for that.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yeah. We would need to request for an extension in order for it to continue and again, even though it's normally approved for five years, it doesn't mean that it's going to be approved for five years.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. Yeah. We're looking at spending on how CMS judges, how long it should take you to get these questions answered, right? It's like a cost benefit analysis but in the end, even if it's not beneficial, let's say, or we might lose pharmacists. You're saying we might still have to implement it unless we get another waiver from CMS for another period of time.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Right.

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SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay and yeah, I was just going to suggest to you for your next hearing to please notify the doctors so that they can weigh in. For me, if the doctors are not pounding down your doors for a brand name medicine, then we're okay. If they're saying that is urgently needed and it's being rejected too easily, right by Public Health, we need this program. So that all medicines that we can prescribe, all medicines are in the range of what we can prescribe pretty much is what we're trying to tell them. I don't know. I'd just like to hear from them what their input is in addition to the pharmacies and what impact this would have on them.

I want to thank you. I know it's not the most exciting topic, but it's very important for when we're talking about patient care and so I would like to just, if you could describe it in terms of patient care, right? So, they get options. Of course, of which medicine they're going to get under this program and their medicines already covered under the program. We're giving them and if the doctors want to try additional medicines, those will be covered under this program if we get under the rebate program and for now, they can still be covered by any type of brand name medicine if the doctor justifies that. Okay. Well, that sounds great to me. As long as the doctors are aware of that, and the pharmacies bring this medicine to Guam. Sometimes they don't bring it at all and it's just not available at all. Right. Okay. All right. Senator Rodriguez, is there anything you'd like to add? Senator Taitague, a question.

SENATOR TELO T. TAITAGUE: It's just a suggestion if I may. Mike, when you contact the pharmacies that are on island way before the public hearing, if you can provide them the guidelines and exactly what it entails, instead of just saying, hey, we're coming for a 1115 waiver, and then, you know, show up. It's important to get them well versed and well-schooled.

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So, when they do come to the public hearing, they understand exactly what this will entail. So, I'd appreciate it if you can do that beforehand, before the public hearing. Just school them, what this 1115 would really do for them. Okay.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes ma'am.

SENATOR TELO T. TAITAGUE: That's all. Thank you.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: I also want to acknowledge what you said earlier about how it was difficult to get Medicaid providers, medical providers for a time there in Guam because of slow payments or, you know, from Medicaid to the providers. I think it was payments and now we are in a good situation where it's much more attractive to providers to cover Medicaid patients. So that's great. I want to thank you for the work in that regard, and we don't want to go backwards with our pharmacies where right now we have pharmacies who aren't providers, and we don't want to create a situation where they are going to opt out of the program. Right. That's your goal in doing this cost benefit analysis.

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Yes, ma'am. That was our concern.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Okay. Thank you and so, Senator Rodriguez.

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FORMER SENATOR DENNIS RODRIGUEZ, CHIEF ADVISOR ON HEALTHCARE, GOVERNOR'S OFFICE: *Håfa Adai* and good afternoon, Madam speaker and senators. Thank you very much for allowing me to just chime in. I want to thank the public health folks for being here and you know, from the governor's office, we're going to provide the support and assistance that's needed to move this forward and just want to assure you that this government would never jeopardize our patients receiving any type of medication, whether it's covered under the Guam formulary, the prescription formulary that we currently have, or if we do have to implement this Medicaid prescription rebate program and so I think you know, what they're trying to do would also give us an opportunity to, you know, look at as the governor has her initiative of getting our Gov Guam health insurance into some sort of self-funded program at one point in time, and perhaps looping that into a Medicaid program and also the vision of expanding our Medicaid program to at least up to 300% of the Guam Federal Poverty Level, which I I believe right now it's at 200 or 138, right?

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: Currently it's 138 local poverty level.

FORMER SENATOR DENNIS RODRIGUEZ, CHIEF ADVISOR ON HEALTHCARE, GOVERNOR'S OFFICE: Yes and so as we move to increase that to get more people eligible, this timeframe that if CMS does approve this waiver would give us that opportunity to, you know, make that determination as you know, that pharmaceuticals is one of the biggest costs in the delivery of healthcare and so we're hoping that's something that could be considered as we move forward as well.

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SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Thank you. Senator Rodriguez, what do we need in order to increase it to 300%? Is that just a determination, like a rulemaking or is it going to be something more than that or in addition to the state plan?

FORMER SENATOR DENNIS RODRIGUEZ, CHIEF ADVISOR ON HEALTHCARE, GOVERNOR'S OFFICE: Yeah. First of all, of course is to make the determination, what does increasing it to 300% mean? And what does that mean financially and if that, if we're able to afford that. If there is the will of our government to support that type of expenditure, we're watching very closely the FMAP formula changing after December and so we're hoping to be able to develop a plan that we can also take to the federal government, aside from this section 1115 waiver, perhaps a separate type of application that would give us the opportunity to expand a new program under Medicaid and so that's why, you know, it was something for us to be able to be here and support them, with this section 1115 waiver is because that's part of the process as you know, this legislature has passed several years ago and expanding the Medicaid program and part of that is pursuing a section 1115 waiver.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: All right. From 138% to 300%, what is necessary for that?

FORMER SENATOR DENNIS RODRIGUEZ, CHIEF ADVISOR ON HEALTHCARE, GOVERNOR'S OFFICE: We've been working with public health so Carlos can.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Sure. Mr. Pangelinan.

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CARLOS PANGELINAN, DPHSS: We would have to ascertain how many people we would have to include in the program, additional people and when we've studied that and we find out how many, then we can project a cost. We're not at that stage yet where we know it but if I could, may I bring up one point because with respect to Senator Perez's concern. I've been with the department for almost a year, and I'd just like to say that there are many different ways. Well, there's several different ways of changing the benefits and in the time that I've been here in the last year, there have been probably a dozen or so or half a dozen or so state plan amendments, the vast majority have always been to expand. So, I just didn't want to leave this room, giving the impression that, because we don't want to participate in this drug rebate program, that that's all we ever really, you know, we're just looking for ways to not participate in these federal expansion programs but yeah, we talk about expanding all the time. Uh, just a couple weeks ago, we were looking at a wellness benefit, which we don't have currently.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: All right and is it an amendment to the state plan that's required for the 138 to the 300%?

CARLOS PANGELINAN, DPHSS: I'm not sure. That's something that our team here…

MICHAEL GALLO, PROGRAM COORDINATOR, GUAM MEDICAID PROGRAM: I'm sorry if I could interject, it would probably be a state plan amendment.

SPEAKER THERESE M. TERLAJE, CHAIRPERSON: Alright. Okay. Thank you. Alright. Anything else, if not, then thank you and good luck on your next public hearing. I hope that the pharmacies are responsive to that,

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and I will shout it out as much as I can, but there being no additional individuals to present further testimony, this joint public hearing is now adjourned. Guam Medicaid recipients, pharmacy providers, and stakeholders can watch the proceedings on Guam Legislature's YouTube channel, and they are invited to submit written testimony via email to Mr. Michael Gallo, Program coordinator with the Guam Medicaid program at Michael.gallo@dphss.gov or to Mr. Jeffrey San Nicolas at Jeffrey.sannicholas@dphss.guam.gov or by hand delivery to the Guam Medicaid Program, number 130, University Drive, Suite 5, Castle Mall Building Mangilao, Guam 96913.

Si yu'os ma'åse' to all of you from public health and to the governor's office as well and to my colleagues. Thank you very much for your interest and participation in this hearing. So, we are now adjourned. The time is 2:55 PM. *Si yu'os ma'åse'.*

The Joint Public Hearing was adjourned at **2:55 PM.**

III. FINDINGS & RECOMMENDATIONS

The Committee on Health conducted this joint public hearing regarding the Medicaid Drug Rebate Program (MDRP) in conjunction with the Guam Department of Public Health and Social Services (DPHSS). Guam is required to begin participating in the Medicaid Drug Rebate Program on January 1, 2023, per federal mandate. The MDRP program would offset the cost of prescription drugs by requiring drug manufacturers to enter into an agreement with the Secretary of Health and Human Services in exchange for the Medicaid program, covering all the manufacturers covered outpatient drugs. Manufacturers are responsible for paying rebates on those drugs that are paid and dispensed under the Medicaid plan. The

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rebates are paid by the manufacturers on a quarterly basis and that rebate goes to the states, but it's shared between both the states and the federal government based on the FMAP.

The Department of Public Health and Social Services would like to apply for a waiver to the federal mandate to participate in the Medicaid Drug Rebate Program and intends to submit the waiver application by August 1, 2022. The 1115 waiver demonstration application would allow for DPHSS to conduct a demonstration study on the potential adverse effects of participation in the MDRP on the island's pharmacy providers and program recipients. DPHSS would like to test their hypothesis that Guam's Medicaid's participation in MDRP could adversely affect the on-island pharmacy providers by creating an unreasonable requirement for them to carry all of the MDRP participating manufacturers covered outpatient drugs such that it would be difficult for them to maintain adequate inventory. According to Program Director Michael Gallo, the evaluation design and data to be collected will be based on the following questions:

- What are the existing supply chains, pharmaceutical distributors available on the island?
- What current limitations do on-island pharmacies have in dealing with existing supply chains when ordering COD for MDRP participating manufacturers?
- How would Guam Medicaid participants in the MDRP affect on-island pharmacy provider's decisions to continue as a provider on the Medicaid Program?

According to Program Director Gallo, in his communications with pharmacy providers, concerns were expressed on their inability to negotiate or bargain with wholesale distributors for best prices because the amount of medication

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that they order on a weekly and monthly basis do not meet wholesale quotas for discounts. Providers generally accept the wholesaler costs, in addition to shipping costs. There is also a concern that Guam wouldn't be able to pay for any medication that wasn't covered under a manufacturer that was in a MDRP agreement. Hence, the inventory requirement may be prohibitive for pharmacies to continue as providers in the Guam Medicaid Program.

Additionally, it may be more costly and labor intensive due to required administrative costs for the Guam Medicaid program to participate in the MDRP. There is a concern that these costs would outweigh the rebate savings the MDRP would provide. DPHSS would like to request a waiver from the MDRP to study all of the potential impacts of implementing the MDRP.

It is a requirement by the Centers for Medicare and Medicaid (CMS) that Guam's Public Health department hold two public hearings at least 20 days prior to submission of a section 1115 application which requests a waiver from the Medicaid Drug Rebate Program and receive comments on the proposed MDRP 1115 waiver demonstration application. The 1115 waivers are generally approved by the CMS for an initial five-year period and can be extended.

In addition to public hearing notices published in a newspaper of general circulation and on the Guam Public Notice online portal five (5) days and forty-eight (48) hours prior to the joint public hearing, to enlist feedback from the general public, the Committee invited the Guam Board of Examiners for Pharmacy and asked the Department of Public Health to invite all pharmacies on Guam to the hearing. None were present to provide oral testimony.

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During the hearing, questions and concerns were raised by members of the Committee on Health regarding the delaying of the implementation of the Medicaid Drug Rebate Program and if it is in the best interest of the patients to request a waiver at this time. Members asked if DPHSS could have conducted the study regarding the potential impacts of the MDRP earlier or if the entire 5-year waiver period is necessary to conduct the study. Recommendations were also made by Committee Chairperson Terlaje to acquire the feedback of physicians, in addition to Guam Medicaid Recipients, Pharmacy Providers, and other Stakeholders.

A second public hearing regarding the Medicaid Drug Rebate Program was organized and scheduled by the Department of Public Health and Social Services to be conducted on July 5, 2022.

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AND

MARITIME TRANSPORTATION

June 27, 2022

Transmitted Via Email:
michael.gallo@dphss.guam.gov

Michael Gallo
Program Coordinator, Guam Medicaid Program
Guam Department of Public Health and Social Services

SUBJECT: Letter of Request – MDRP

Dear Mr. Gallo,

Buenas yan Håfa Adai! During today's public hearing relative to the Guam Medicaid – Medicaid Rebate Program (MDRP) 1115 Waiver Demonstration Presentation, the concern shared with the legislature is that "Guam Medicaid's participation in the MDRP could adversely affect On-Island Pharmacy Providers by creating an unreasonable requirement for them to carry all of the MDRP participating manufacturer's COD such that it would be difficult for them to maintain adequate inventory, and this may be prohibitive for them to continue as providers on the Medicaid program."

Please provide the official document and citation that would require Guam's participating pharmacies to provide all the MDRP participating manufacturer's covered outpatient drugs in their inventories for our records.

If your office requires any assistance or accommodations that can be provided by our office or the 36th Guam Legislature, please let us know. Should you have any questions or concerns, you may contact my office at senatortcnelson@guamlegislature.org or (671) 989-7696.

Senseramente,

[redacted]

Senator Telena Cruz Nelson
36th Guam Legislature

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RE: Letter of Request – Medicaid Drug Rebate Program (MDRP)

Dear Senator Nelson,

Håfa Adai! Thank you for attending the joint legislative public hearing regarding the Guam Medicaid Program's, Medicaid Drug Rebate Program (MDRP) - 1115 Waiver Demonstration Presentation that was conducted on June 27, 2022.

On November 19, 2021, the CMS Interim Final Rule mandated Guam Medicaid program to participate in the MDRP effective January 1, 2023. However, Guam Medicaid program is submitting this MDRP 1115 Waiver Demonstration to be exempt from participation on the effective date, and allowing Guam Medicaid program to assess the feasibility and adverse effect to our On-Island Pharmacy Providers by creating an unreasonable requirement for them to carry all of the MDRP participating manufacturer's COD such that it would be difficult for them to maintain adequate inventory, and this may be prohibitive for them to continue as providers on the Medicaid program.

I apologize for the delay in providing the official documentation and citation that requires Guam's participating pharmacies to provide all the MDRP participating manufacturer's covered outpatient drugs in their inventories. In communicating your request with Ms. Barbara Prehmus, our CMS Medicaid Program Specialist with the Division of Program Operations-West, and Ms. Christine Hinds, Technical Director, Division of Pharmacy, CMCS, CMS, they both indicated that Social Security Act §1927 (42 U.S.C. 1396r-8) (d)(4)(B) provides this stipulation for covering all CODs under the MDRP. Attached is a PDF copy, and the following is an excerpt:

Social Security Act §1927

Compilation of Social Security Laws §1927. PAYMENT FOR COVERED OUTPATIENT DRUGS. Sec. 1927.[42 U.S.C. 1396r–8] Requirement for Rebate Agreement.—In general.— In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in ...

If you have any questions, please contact Ms. Teresita C. Gumataotao, Bureau of Health Care Financing Administration Administrator, by email at teresita.gumataotao@dphss.guam.gov or telephone at (671) 300-7340.

Sinceramente.

AR[redacted]N AGUSTIN, MHR
DPHSS Director

PAYMENT FOR COVERED OUTPATIENT DRUGS[296]

SEC. 1927. [42 U.S.C. 1396r–8] (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992[297]) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) EFFECTIVE DATE.—Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section[298], such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act[299] with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph[300].

(B) COVERED ENTITY DEFINED.—In this subsection, the term "covered entity" means an entity described in section 340B(a)(4) of the Public Health Service Act

(C) ESTABLISHMENT OF ALTERNATIVE MECHANISM TO ENSURE AGAINST DUPLICATE DISCOUNTS OR REBATES.—If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act within 12 months of the date of the enactment of such section[301], the following requirements shall apply:

determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) USE OF NDC CODES.—Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) HARDSHIP WAIVER.—The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) TERMS OF REBATE AGREEMENT.—

(1) PERIODIC REBATES.—

(A) IN GENERAL.—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved , including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs.

(B) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter, including amounts received by a State under subsection (c)(4),[305] shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

(C) SPECIAL RULE FOR OTHER DRUGS.—

(i) IN GENERAL.—In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1903(a) in the manner specified in clause (ii), in an amount equal to the product of—

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

(ii) MANNER OF PAYMENT REDUCTION.—The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State under this title to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1903(d)(2). Such a disallowance is not subject to a reconsideration under section 1116(d).

(2) STATE PROVISION OF INFORMATION.—

(A) STATE RESPONSIBILITY.—Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the

outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(C)[309] PENALTIES.—

(i) FAILURE TO PROVIDE TIMELY INFORMATION.—In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) FALSE INFORMATION.—Any manufacturer with an agreement under this section that knowingly provides false information, including information related to drug pricing, drug product information, and data related to drug pricing or drug product information,[310] is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a), (b), (f)(3), and (f)(4)[311]) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(iii)MISCLASSIFIED DRUG PRODUCT OR MISREPORTED INFORMATION.—

(I) IN GENERAL.—Any manufacturer with an agreement under this section that knowingly (as defined in section 1003.110 of title 42, Code of Federal Regulations (or any successor regulation)) misclassifies a covered outpatient drug, such as by knowingly submitting incorrect drug product information, is subject to a civil money penalty for each covered outpatient drug that is misclassified in an amount not to exceed 2 times the amount of the difference between—

(aa) the total amount of rebates that the manufacturer paid with respect to the drug to all States for all rebate periods during which the drug was misclassified; and

(bb) the total amount of rebates that the manufacturer would have been required to pay, as determined by the Secretary using drug product information provided by the manufacturer, with respect to the drug to all States for all rebate periods during which the drug was misclassified if the drug had been correctly classified.

(II) OTHER PENALTIES AND RECOVERY OF UNDERPAID REBATES.—The civil money penalties described in subclause (I) are in addition to other penalties as may be prescribed by law and any other recovery of the underlying underpayment for rebates due under this section or the terms of the rebate agreement as determined by the Secretary.

(iv) INCREASING OVERSIGHT AND ENFORCEMENT.—Each year the Secretary shall retain, in addition to any amount retained by the Secretary to recoup investigation and litigation costs related to the enforcement of the civil money penalties under this subparagraph and subsection (c)(4)(B)(ii)(III), an amount equal to 25 percent of the total amount of civil money penalties collected under this subparagraph and subsection (c)(4)(B)(ii)(III) for the year, and such retained amount shall be available to the Secretary, without further appropriation and until expended, for activities related to the oversight and enforcement of this section and agreements under this section, including—

(I) improving drug data reporting systems;

(II) evaluating and ensuring manufacturer compliance with rebate obligations; and

(III) oversight and enforcement related to ensuring that manufacturers accurately and fully report drug information, including data related to drug classification.

(A) IN GENERAL.—Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) RANGE OF REBATES REQUIRED.—

(i) MINIMUM REBATE PERCENTAGE.—For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995 and before January 1, 2010, is 15.1 percent; and

(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent.

(ii) TEMPORARY LIMITATION ON MAXIMUM REBATE AMOUNT.—In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(iii) MINIMUM REBATE PERCENTAGE FOR CERTAIN DRUGS.—

(I) IN GENERAL.—In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

(II) DRUG DESCRIBED.—For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

(aa) A clotting factor for which a separate furnishing payment is made under section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.

(C) BEST PRICE DEFINED.—For purposes of this section—

(i) IN GENERAL.—The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug, and Cosmetic Act[314]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code[315], the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act[316]);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(ii) FACTORS.—The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) NONAPPLICATION.—Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code.

(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 300a-6 of this title.

(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1900, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(C)[319]TREATMENT OF NEW FORMULATIONS.—

(i) IN GENERAL.—In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for a rebate period with respect to such drug under this subsection shall be the greater of the amount described in clause (ii) for such drug or the amount described in clause (iii) for such drug.

(ii) AMOUNT 1.— For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the amount computed under subparagraph (A) and, as applicable, subparagraph (B) for such drug and rebate period.

(iii) AMOUNT 2.— For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the product of—

(I) the average manufacturer price for the rebate period of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

(II) the highest additional rebate (calculated as a percentage of average manufacturer price) under this paragraph for the rebate period for any strength of the

(I) by substituting "the applicable quarter" for "the calendar quarter beginning July 1, 1990"; and

(II) by substituting "the last month in such applicable quarter" for "September 1990".

(iv) APPLICABLE QUARTER DEFINED.— In this subsection, the term "applicable quarter" means, with respect to a drug described in clause (iii), the fifth full calendar quarter after which the drug is marketed as a drug other than a single source drug or an innovator multiple source drug.

(4)[323]RECOVERY OF UNPAID REBATE AMOUNTS DUE TO MISCLASSIFICATION OF COVERED OUTPATIENT DRUGS.—

(A) IN GENERAL.—If the Secretary determines that a manufacturer with an agreement under this section paid a lower per-unit rebate amount to a State for a rebate period as a result of the misclassification by the manufacturer of a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made) than the per-unit rebate amount that the manufacturer would have paid to the State if the drug had been correctly classified, the manufacturer shall pay to the State an amount equal to the product of—

(i) the difference between—

(I) the per-unit rebate amount paid to the State for the period; and

(II) the per-unit rebate amount that the manufacturer would have paid to the State for the period, as determined by the Secretary, if the drug had been correctly classified; and

(ii) the total units of the drug paid for under the State plan in the period.

(B)AUTHORITY TO CORRECT MISCLASSIFICATIONS.—

(i) IN GENERAL.—If the Secretary determines that a manufacturer with an agreement under this section has misclassified a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made), the Secretary shall notify the manufacturer of the misclassification and require the manufacturer to correct the misclassification in a timely manner.

(ii) ENFORCEMENT.—If, after receiving notice of a misclassification from the Secretary under clause (i), a manufacturer fails to correct the misclassification by such time as the Secretary shall require, until the manufacturer makes such correction, the Secretary may do any or all of the following:

(I) Correct the misclassification, using drug product information provided by the manufacturer, on behalf of the manufacturer.

(II) Suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's national rebate agreement, and exclude the misclassified drug from Federal financial participation in accordance with section 1903(i)(10)(E).

(III) Impose a civil money penalty (which shall be in addition to any other recovery or penalty which may be available under this section or any other provision of law) for each rebate period during which the drug is misclassified not to exceed an amount equal to the product of—

(aa) the total number of units of each dosage form and strength of such misclassified drug paid for under any State plan during such a rebate period; and

(bb) 23.1 percent of the average manufacturer price for the dosage form and strength of such misclassified drug.

(C)REPORTING AND TRANSPARENCY.—

(i) IN GENERAL.—The Secretary shall submit a report to Congress on at least an annual basis that includes information on the covered outpatient drugs that have been identified as misclassified, any steps taken to reclassify such drugs, the actions the Secretary has taken to ensure the payment of any rebate amounts which were unpaid as a result of such misclassification, and a disclosure of expenditures from the fund created in subsection (b)

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act[325] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS.—A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

(7)[326] NON-EXCLUDABLE DRUGS.—The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines

(e) TREATMENT OF PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations[327], in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) SPECIAL RULE.—If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

means for providing access to each State agency designated under section 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title of the retail survey price determined under this paragraph.

(2) ANNUAL STATE REPORT.—Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this title for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) ANNUAL STATE PERFORMANCE RANKINGS.—

(A) COMPARATIVE ANALYSIS.—The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

(B) AVAILABILITY OF INFORMATION.—The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) DRUG USE REVIEW.—

(1) IN GENERAL.—

(A) In order to meet the requirement of section 1902(a)(54)[328], a State shall provide[329] for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization[330] among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 483.60 of title 42, Code of Federal Regulations[331].

(2) DESCRIPTION OF PROGRAM.—Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) PROSPECTIVE DRUG REVIEW.—

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-

(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) STATE DRUG USE REVIEW BOARD.—

(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 ***[334] licensed and actively practicing pharmacists.

(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in[335] (2)(B).

(ii) Application of standards as defined in section (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) ELECTRONIC CLAIMS MANAGEMENT.—

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—

(i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy[337]

(V)[338] discounts provided by manufacturers under section 1860D–14A.

(ii) INCLUSION OF OTHER DISCOUNTS AND PAYMENTS.—Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

(C) EXCLUSION OF 505(C) DRUGS.—[339]In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail community pharmacies.

(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (4)[340]), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act[341] or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations[342]) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act[343]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

Evaluations"),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the United States during the period.

(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term "innovator multiple source drug" means a multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration, unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation)).[349]

(iii) NONINNOVATOR MULTIPLE SOURCE DRUG.—The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) SINGLE SOURCE DRUG.—The term "single source drug" means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4), which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation)). Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration.[350]

(B) EXCEPTION.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) DEFINITIONS.—For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(8) REBATE PERIOD.—The term "rebate period" means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) STATE AGENCY.—The term "State agency" means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.

(10) RETAIL COMMUNITY PHARMACY.—The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(11) WHOLESALER.—[351]The term "wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

[296] See Vol. II, P.L. 110-275, §203), with respect to pharmacy reimbursement under Medicaid.

[297] November 4, 1992 [P.L. 102-585;106 Stat. 4943].

[329] P.L. 115–271, §1004(b) struck ", by not later than January 1, 1993,". Effective for drug use reviews conducted on or after January 1, 2020.

[330] P.L. 115–271, §1004(b), inserted "excessive utilization" after "gross overuse,"; struck "or inappropriate or medically unnecessary care" and inserted "inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization". Effective for drug use reviews conducted on or after January 1, 2020.

[331] See Vol. II, 42 CFR. 483.60.

[332] P.L. 115–271, §1004(b), inserted "excessive utilization" after "gross overuse,"; struck "or inappropriate or medically unnecessary care" and inserted "inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization". Effective for drug use reviews conducted on or after October 1, 2020.

[333] As in original. Probably should be "paragraph".

[334] As in original.

[335] As in original. Probably should be "paragraph".

[336] As in original. Probably should be "of".

[337] As in original; no ending punctuation.

[338]

[339] P.L. 116–59, §1603(a), in the header, struck "Inclusion" and inserted "Exclusion"; struck "a new drug application" and inserted "the manufacturer's new drug application"; and struck "inclusive" and inserted "exclusive". Effective on the first day of the first fiscal quarter that begins after the date of enactment, which was September 27, 2019.

[340] P.L. 116–16, §6(c)(1), struck "paragraph (5)" and inserted "paragraph (4)". Effective for covered outpatient drugs supplied by manufacturers under section 1927 agreements on or after April 18, 2019.

[341] See Vol. II, P.L. 75-717, §§505 and 507.

[342] See Vol. II, Code of Federal Regulations, 21 CFR 310.6.

[343] See Vol. II, P.L. 75-717.

[344] As in original. probably should be "biological product".

[345] P.L. 75-717; 52 Stat. 1040.

[346] P.L. 116–16, §6(c)(A), struck "an original new drug application" and inserted "a new drug application" each place it appeared. Effective for covered outpatient drugs supplied by manufacturers under section 1927 agreements on or after April 18, 2019.

[347] P.L. 116–16, §6(c)(2)(B), struck "(not including any drug described in paragraph (5))" and inserting ", including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),". Effective for covered outpatient drugs supplied by manufacturers under section 1927 agreements on or after April 18, 2019.

[348] As in original. Probably should be followed by "is".

[349] P.L. 116–16, §6(c)(2)(C)(i), struck "was originally marketed" and inserted "is marketed"; and inserted ", unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation))". Effective for covered outpatient drugs supplied by manufacturers under section 1927 agreements on or after April 18, 2019.

[350] P.L. 116–16, §6(c)(2)(D), inserted ", including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4)," after "covered outpatient drug"; inserted "unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation))"; and inserted "Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration." Effective for covered outpatient drugs supplied by manufacturers under section 1927 agreements on or after April 18, 2019.

[351] P.L. 116–59, §1603(b), struck "manufacturers," and "manufacturer's and" from the list. Effective on the first day of the first fiscal quarter that begins after the date of enactment, which was September 27, 2019.

Fw: Medicaid Drug Rebate Program

Michael Q Gallo <Michael.Gallo@dphss.guam.gov>

Fri 7/1/2022 6:37 PM

To: Jeremy Mariano <jmariano@megadrugguam.com>
Cc: Jeffrey A. San Nicolas <Jeffrey.SanNicolas@dphss.guam.gov>;Janet Cruz <Janet.Cruz@dphss.guam.gov>;Terri Gumataotao <TERESITA.Gumataotao@dphss.guam.gov>;Rachelle Paulino <Rachelle.Paulino@dphss.guam.gov>;Carlos B. Pangelinan <Carlos.Pangelinan@dphss.guam.gov>;Theresa L. Arcangel <Theresa.Arcangel@dphss.guam.gov>

Hello Mr. Mariano,

A copy of our public notice regarding our MDRP 1115 Waiver Demonstration which has more information on this action can be found on our website at http://dphss.guam.gov/category/press-releases-en/. There is also a link to a copy of our draft application for this 1115 waiver that you can review. Additionally, you can view the YouTube video for the legislative informational hearing that was conducted on Monday (6/27/20222).

We are greatly appreciative of your viewpoints that you presented, and would encourage you to attend the next hearing at the Governor's Conference Room next week Friday (7/8/2022) at 1:00 p.m. I would be happy to discuss the challenges that the MDRP would pose for the pharmacy providers as I understand them. Please feel free to give me a call at (671) 483-7264 anytime that is convenient for you.

Mike

Michael Q. Gallo
Program Coordinator,
Medicaid/MIP Programs, Bureau of Health Care Financing Administration,
Division of Public Welfare, Department of Public Health and Social Services
155 Hesler Place, Hagatna, Guam 96910
Tel: (671) 735-7470 Fax: (671) 735-7476 Cell: (671) 483-7264

From: Jeremy Mariano <jmariano@megadrugguam.com>
Sent: Friday, July 1, 2022 2:45 PM
To: Michael Q Gallo <Michael.Gallo@dphss.guam.gov>
Subject: Medicaid Drug Rebate Program

Dear Mr. Gallo,

I'm sorry I missed your call. Please send me a message on a best time to hop on a call with you.

Thank you for your presentation at the public hearing. I understand the difficulties in explaining the issue to the public and I appreciate your work in doing so. Pricing drugs is probably one of the most complex endeavors in the health care system and is difficult to completely understand even if we work in the field.

I'm not comfortable submitting a written testimony right now as I do not have a decent grasp on the Medicaid Drug Rebate Program and what it entails for all of us.
However, I want to bring these points as questions and concerns to you:
1.) In your presentation, it was noted that almost ALL drug manufacturers participate in the MDRP. How would that practically change what medications would be covered by Medicaid?
Would only drugs made by manufacturers participating in MDRP be covered? If yes, I think this is where we might encounter availability and supply problems, especially to drugs limited to only a few manufacturers that may not be in MDRP. However, it might be a non-issue if almost all drug manufacturers are part of the program.
2.) In my view, pharmacies and Guam Medicaid should have an idea of what the formulary would be if Guam was to sign up for MDRP. Will it be limiting coverage to drugs made by manufacturers participating in the MDRP *only*? Or will the formulary be similar to today and that some drugs would just be eligible for rebates on Guam Medicaid's end (i.e. a cherry on top of the cake) but all other drugs still have the possibility of being covered and not just get a rebate from the manufacturer. After all of that, we should find out if the MDRP would be more limiting or restrictive if access is the main issue.
I can give you examples on how this is happening on the private insurance side and on how it can be bad in terms of access for patients.
3.) From the Guam Medicaid office's perspective, I think your top concerns are the implementation and compliance specifics with the program on your side. Another issue to consider is will those rebates outweigh any of the implementation costs down the line. Maybe this needs to be more of an emphasis on the next public hearing as I think it would be easier to understand as this stresses the need for the waiver and the studies.
4.) I do think that CMS created this possibility of a waiver in anticipation that territories would encounter all of these aforementioned supply problems and implementation concerns. Are these waivers renewable if it is in the best interest of Guam's Medicaid program?

5.) Lastly, please see the following excerpts from CMS on 11/19/2021 found in the Federal Register that you may be aware of already but might still find useful https://www.federalregister.gov/documents/2021/11/19/2021-25009/medicaid-program-delay-of-effective-date-for-provision-relating-to-manufacturer-reporting-of:

- the development of systems required to participate in the MDRP, which can take several years to implement from start to finish
- we are allowing the territories additional time to develop needed systems and policy changes, to avoid unintended increases in drug costs and access concerns. The needed 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.
- The proposed delay in inclusion date would also benefit those territories that choose not to participate in the MDRP, which would be required to use human and financial resources that are currently focused on responding to the Public Health Emergency to complete the section 1115 and section 1902(j) waiver applications that are required to waive out of MDRP participation

Thank you for reading my comments and questions.

Kind regards,

Jeremy Mariano, Pharm.D.
Compliance Officer

Mega Drug

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Written Testimony

Michael Q Gallo <Michael.Gallo@dphss.guam.gov>

Thu 7/7/2022 7:55 PM

To: Cheryl Marimla <cheryl.marimla@medpharmusa.net>
Cc: Terri Gumataotao <TERESITA.Gumataotao@dphss.guam.gov>;Janet Cruz <Janet.Cruz@dphss.guam.gov>;Jeffrey A. San Nicolas <Jeffrey.SanNicolas@dphss.guam.gov>;Carlos B. Pangelinan <Carlos.Pangelinan@dphss.guam.gov>;Rachelle Paulino <Rachelle.Paulino@dphss.guam.gov>;Speaker Therese M. Terlaje <senatorterlajeguam@gmail.com>;Dennis.rodriguez@guam.gov <Dennis.rodriguez@guam.gov>;Arthur U. San Agustin <Arthur.SanAgustin@dphss.guam.gov>;Laurent Duenas <Laurent.Duenas@dphss.guam.gov>;Terry G. Aguon <Terry.Aguon@dphss.guam.gov>
Bcc: Dhan Dobert Barrido <Dhan.Barrido@dphss.guam.gov>;Evelyn G. Tordecilla <Evelyn.Tordecilla@dphss.guam.gov>;Julito Martinez <Julito.Martinez@dphss.guam.gov>;Kristine Endrina <Kristine.Endrina@dphss.guam.gov>;Melanie Carrie <Melanie.Carrie@dphss.guam.gov>;Mildred D.C. Galon <Mildred.Galon@dphss.guam.gov>;Renee Carpela <Renee.Carpela@dphss.guam.gov>

1 attachments (179 KB)

20220707183603.pdf;

Hafa Adai Ms. Marimla,

Thank you for providing your comments regarding the MDRP 1115 Demonstration Waiver. We greatly appreciate the time you have taken to both attend the legislative hearing on June 27, 2022, and to prepare these comments regarding the challenges that you continue to face in providing this valuable service to our Medicaid program recipients.

We will use this information as we move forward in assessing the impacts of the MDRP, and try to improve our program processes so that we continue to be fiscally responsible of program funds, and at the same time be reasonable in the compensation structure to our pharmacy providers that provide this much needed service for our Medicaid recipients.

Although, we acknowledge your submission, and our receipt of these comments via email. We encourage you to attend the hearing tomorrow via Zoom if you are unable to attend in person so that this can be presented to the general public in order for others to better understand your challenges, and the prudence in our actions to request for this 1115 Waiver to better assess the MDRP impacts on the Medicaid Program. You also have the option to provide these comments telephonically during the hearing by calling the following number: (671) 473-1165.

Thank you ounce again for your invaluable insights regarding this issue which helps us to better understand how the MDRP will impact you as a Medicaid provider, and the services to our program recipients!

Mike

From: Cheryl Marimla <cheryl.marimla@medpharmusa.net>
Sent: Thursday, July 7, 2022 6:37 PM
To: Michael Q Gallo <Michael.Gallo@dphss.guam.gov>
Subject: Written Testimony

Good evening Mr. Gallo,

Please see attached written testimony from the pharmacists in our company.

Thank you and regards,

Cheryl O. Marimla, R.Ph.
Pharmacy Operations and Compliance Manager

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