March 5, 2015

Cheryl Young
Division of Medicaid and Children's Health Operations
U.S. Department of Health & Human Services
Centers for Medicare & Medicaid Services
90 Seventh Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

RE: SPA #15-001, Supplemental Drug Rebates

Dear Ms. Young

Enclosed is Arizona SPA #15-001, Supplemental Drug Rebates, which updates the State Plan to include rebates for supplemental drugs, effective January 1, 2015. The purpose of this State Plan Amendment is to request approval for AHCCCS to initiate a State Supplemental Rebate Program, as a Single State, for prescribed and physician-administered drugs dispensed and/or administered to AHCCCS Fee-For-Service and Managed Care Contractors' Medicaid beneficiaries. More information about Arizona's pharmacy program is provided in the attached document entitled "Overview of Arizona's Pharmacy program." In addition, enclosed for your review is the proposed AHCCCS-pharmaceutical manufacturer supplemental rebate contract.

Should you require additional information, do not hesitate to contact Suzi Berman at 602-417-4726.

Sincerely,

Monica H. Coury
Assistant Director
Office of Intergovernmental Relations

Overview of Arizona's Pharmacy program with Proposed Supplemental Rebates

AHCCCS may negotiate with manufacturers for supplemental rebates for prescription drugs that are in addition to those required by Title XIX of the Social Security Act. There is no upper limit on the dollar amounts of the supplemental rebates that may be negotiated. The supplemental rebate may be one factor considered in exempting a prescription drug from prior authorization, however it is secondary to considerations of safety, effectiveness, clinical appropriateness and clinical outcomes of the drug in comparison to other therapeutically interchangeable alternative drugs.

AHCCCS Pharmacy & Therapeutics Committee

AHCCCS currently has a Pharmacy & Therapeutics Committee (P&T) that was appointed by the agency Director and is comprised of practicing pharmacists, physicians and nurses. The purpose of the committee is to advise AHCCCS on medication use, evidence-based clinical practices, clinical studies & outcomes, pharmacoeconomic data, the merits of new drugs and any changes to the AHCCCS Minimum Required Prescription Drug List (MRPDL) including the identification of preferred products.

The P&T Committee conducts drug reviews in the therapeutic categories based on the clinical and therapeutic value of the products in each class. The committee uses research articles, studies various compendia, specialists, and in many cases the AMCP Dossier to review medications.

AHCCCS in conjunction with the P&T Committee, which at a minimum, meets quarterly, established the Minimum Required Prescription Drug List. All AHCCCS Managed Care Contractors and the Fee-For-Service Program must adopt and integrate this drug list and its utilization parameters into their formularies per the AHCCCS Medical Policy 310-V located on the AHCCCS website in the AHCCCS Medical Policy Manual. The Contractors may be less restrictive on their formulary for drugs listed on the MRPDL; however, the Contractor may not add additional utilization management parameters. For example, Contractors are prohibited from adding a prior authorization requirement to a drug listed on the MRPDL that is not currently listed with a prior authorization requirement. The goal of the MRPDL is to uniformly provide clinically appropriate cost-efficient medications to AHCCCS beneficiaries.

Federally Reimbursable Drugs

AHCCCS beneficiaries have access to and coverage for all federally reimbursable medications based on medical necessity. Under AHCCCS's current program, all federally reimbursable drugs are eligible for coverage; those not listed on the AHCCCS MRPDL and/or the FFS or Managed Care Contractors' formularies, may be subject to prior authorization, consistent with Section 1927(d)(5) of the Social Security Act.

Prior Authorization Process

AHCCCS FFS and Managed Care Contractors' pharmacy programs include a prior authorization process to ensure that all drugs remain available to AHCCCS beneficiaries. Prescribing clinicians may submit a prior authorization request for medications not listed on the MRPDL or the FFS/Contractors' Drug List for clinical review. The Contractor and the FFS pharmacy director evaluate prior authorization requests for medical necessity and clinical appropriateness. If the prior authorization process determines there is justification for the prescribing of a federally reimbursable drug not listed on the MRPDL or the FFS/Managed Care Contractors' formularies, the beneficiary will be provided the drug. This prior authorization for the specific drug will remain in place for the duration of the medically necessary requested time period.

Medication Not Listed on the MRPDL or FFS/Managed Care Contractors' Formularies

For AHCCCS beneficiaries currently taking a medication not listed on the MRPDL or the FFS/Contractors' formularies, the prescribing clinician is required to submit a prior authorization that includes the medical necessity justification for continuing the medication. The prior authorization process requires prescribing clinicians to examine the medication therapy of their patients, and make a medical justification for the continuation of the drug not listed on the MRPDL or FFS/Contractors' formularies. In all circumstances, the goal for AHCCCS and its Contractors' is to administer the prior authorization process and ensure that patients have access to medications that are genuinely needed for their care and individual health situations.

Special Needs Populations

The AHCCCS P&T Committee conducts therapeutic drug and class reviews based on the clinical and therapeutic value of the products in each class. The committee uses research articles and compendia that relate to the products under review. The P&T Committee is cognizant of the needs of special populations during the review process, for example, HIV, oncology, Hepatitis C, behavioral health and anticonvulsant drug therapies. AHCCCS will take the special needs of beneficiaries with these complex medical conditions into account in determining the identity and the range of drugs to be available with and without the need to obtain prior authorization.

Sudden Changes in Medication Therapy

The AHCCCS MRPDL is not new and sudden changes in drug therapy are not expected as a result of implementing a supplemental rebate program that provides preferred drug status for certain therapeutic classes. The Committee will evaluate and review utilization data to determine the beneficiary impact when a new preferred drug is chosen. Beneficiaries and prescribing clinicians will be notified in advance of a new preferred product status of a drug to allow prescribing clinicians to either make a therapeutic change or submit a prior authorization for continued use of the non-preferred product.

Supplemental Rebate Information

For the Supplemental Rebate Program, the P&T Committee will meet in open session to allow manufacturers to present on their specific drug and to discuss the evidence-based merits of drugs in a specified therapeutic class. After those deliberations, the Committee will meet in a closed session to discuss the financial aspects of the drug and drug class. In all cases the evidence-based merits of a medication outweigh the financial aspects. The committee will make recommendations to AHCCCS for drugs to be considered for preferred status. AHCCCS will review the recommendations and if in agreement will move forward with the manufacturer contracting process to obtain a supplemental rebate.
The collection of supplemental rebates will not affect capitation rates to AHCCCS Contractors; the collection will also not affect reimbursement rates to pharmacies, IHS/638 facilities or to prescribers for physician-administered medications. In relationship to supplemental rebates, Pharmacies retain 100 percent of the adjudicated prescription claim payments provided to them and they are not obligated to return any portion of the Medicaid payment to AHCCCS, or any other intermediary organization or entity. The Pharmacies will not receive any remuneration or enhanced payments from the receipt of AHCCCS' supplemental rebate payments made under this SPA.

AHCCCS payments for the pharmacy benefit contained in the budget are from an appropriation from the legislature. AHCCCS and its Contractors' Pharmacy Benefit Managers reimburse pharmacies through a standard adjudication and reimbursement process. The reimbursement rates may vary depending on whether the pharmacy is located in a suburban, rural or frontier area of the State of Arizona. The reimbursement methodology is based on reasonable costs to provide medications to AHCCCS beneficiaries.

Currently, the federal rebates are submitted for and collected by Magellan Medicaid Administration (MMA) for the AHCCCS for the Fee-For-Service and Managed Care Contractors' Programs; they will also invoice, collect and report to AHCCCS on all supplemental rebate invoicing and collections for FFS and MCO Contractors' utilization. In 2010, the initial Rebate Vendor RFP included the scope of work for both federal and supplemental rebate programs. The rebate vendor was selected through the use of an open competitive process that was consistent with federal and state procurement standards and requires the vendor to conduct a variety of pharmacy rebate and related functions, including negotiating and managing supplemental rebate agreements. During the procurement process, AHCCCS conducted a thorough evaluation of costs and benefits prior to the selection of MMA as our rebate vendor.

Our current contract with MMA includes coverage for supplemental rebate processing in the same manner as invoicing and collecting the federal rebate. The resulting contract award with MMA does not lock us into a particular mechanism for negotiating and managing such agreements. AHCCCS will negotiate its own supplemental rebates as a stand-alone Single state.

At this time, AHCCCS does not receive any supplemental rebates, however, under the proposed SPA, AHCCCS expects to contract and receive supplemental rebates from drug manufacturers in addition to the federal Medicaid drug rebate. AHCCCS will reduce the Medicaid expenditures under the state plan by the amount of the rebates or revenue received and will also ensure that CMS receives the federal share of the supplemental rebates in accordance with the current FMAP rate to be compliant with Section 1927(b)(1)(B) of the Act.

AHCCCS has never received any goods, services or other benefits for Medicaid covered beneficiaries from the pharmaceutical manufacturers. Under the proposed SPA, AHCCCS will not receive any goods, services or other benefits other than the supplemental rebates. Regardless of whether a medication may or may not require prior authorization, AHCCCS will not request nor accept any goods, services or other benefits other than the supplemental rebates.

It is the intent of the agency to prepare an annual report on the MRPDL, to include compliance statistics as well as savings that have accrued to the state as a result of the implementation of the Supplemental Rebate Program. The federal fiscal impact from implementing the AHCCCS Supplemental Rebate Program is expected to be approximately $5.2 million for FY2014/2015 and $7.1 million for FY2015/2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL **FOR: Centers for Medicare and Medicaid Services**	1. TRANSMITTAL NUMBER: 15-001	2. STATE Arizona
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE AND MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE January 1, 2015	

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

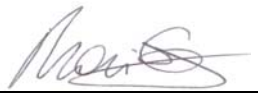
6. FEDERAL STATUTE/REGULATION CITATION: 1927(b)	7. FEDERAL BUDGET IMPACT: FFY 15: $5,242,600 FFY 16: $7,111,600
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Page 74d Exhibit 12 to Att. 3.1-A, page 9 Exhibit 12(a) to Att. 3.1-A, page 9	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Same

10. SUBJECT OF AMENDMENT:

Updates the State Plan to include supplemental drug rebates effective January 1, 2015.

11. GOVERNOR'S REVIEW *(Check One)*:

☒ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: Monica Coury 801 E. Jefferson, MD#4200 Phoenix, Arizona 85034
13. TYPED NAME: Monica Coury	
14. TITLE: Assistant Director	
15. DATE SUBMITTED: March 5, 2015	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED:
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME:	22. TITLE:
23. REMARKS:	

Revision: HCFA-PM-93-3 (MB) OMB No.
April 1993

State/Territory: Arizona

1927(j)(2)
42 CFR 456.703(c)

J. Hospitals which dispense covered outpatient drugs are exempted from the drug utilization review requirements of this section when facilities use drug formulary systems and bill the Medicaid program no more than the hospital's purchasing cost for such covered outpatient drugs.

1927(g)

K. AHCCCS will participate in the drug rebate program for the fee-for-service program.

1903(m)(2)(A)

L. AHCCCS will participate in the drug rebate program for its managed care program.

M. AHCCCS will contract with pharmaceutical manufacturers and collect supplemental drug rebates for the fee-for-service program.

N. AHCCCS will contract with pharmaceutical manufacturers and collect supplemental drug rebates for its managed care program.

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12a. Prescribed drugs.

Medicare Part D drugs are not covered for full benefit dual eligible members, as coverage is provided through Medicare Part D PDPs and MAPDs

Prescription drugs for covered transplantation services shall be provided in accordance with AHCCCS transplantation policies.
AHCCCS only covers over-the-counter medications in place of a covered prescription medication that is clinically appropriate, equally safe and effective, and less costly than the covered prescription medication.

In compliance with Section 1927(b) of the Social Security Act (the Act), the State collects drug rebates and supplemental drug rebates in accordance with established policy for drug rebate and supplemental drug rebate agreements as provided in Exhibit 12(a) to Attachment 3.1-A.

12c. Prosthetic devices.

Prosthetic devices are limited to devices prescribed by a physician or other licensed practitioner to artificially replace missing, deformed or malfunctioning portions of the body and which are medically necessary to the rehabilitation of the member.

Covered prosthetic devices for members age 21 and older do not include hearing aids, cochlear implants, bone anchored hearing aids, percussive vests, microprocessors for controlled joints for the lower limbs in addition to microprocessor-controlled joints for the lower limbs, penile implants, and vacuum devices.

Orthotic devices, which are defined as devices that are prescribed by a physician or other licensed practitioner of the healing arts to support a weak or deformed portion of the body, are not covered except under the following circumstances: Halos to treat cervical fracture instead of surgery; Walking boots instead of surgery or serial casting; Knee orthotics for crutch dependent ambulation instead of a wheelchair.

12d. Eyeglasses.

Eye examinations for prescriptive lenses and the provision of prescriptive lenses under EPSDT services.

Adult services are limited to eyeglasses and contact lenses as the sole prosthetic device after a cataract extraction.

13. Other diagnostic, screening, preventive, and rehabilitative services, i.e., other than those provided elsewhere in the plan.

13a. Diagnostic Services.

Genetic testing is not covered unless the results of the genetic tests are necessary to differentiate between treatment options. Genetic testing is not covered to determine specific diagnoses or syndromes when such determination would not definitively alter the medical treatment of the member.

DRUG REBATE AGREEMENT:
The State is in compliance with Section 1927(b) of the Social Security Act (the Act) to collect rebates. Based on the requirements for Section 1927 of the Act, the State will collect rebates from manufacturers participating in the Medicaid drug Rebate Program. The State has the following policies for drug rebate agreements:

- The drug file permits coverage of participating manufacturers.
- The State is in compliance with reporting requirements for utilization and restrictions to coverage.
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification in accordance with Section 1927(b)(3)(D).
- All drugs invoiced to manufacturers for rebates will comply with the provisions of the National Drug Rebate agreement.
- The State shall remit the Federal Government's share required under the National Drug Rebate Agreement.

SUPPLEMENTAL DRUG REBATE AGREEMENT:
The State is in compliance with Section 1927(b) of the Social Security Act (the Act) to collect supplemental rebates. Based on the requirements for Section 1927 of the Act, the State has the following policies for the supplemental drug rebate program:

- A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid population has been authorized by CMS effective January 1, 2015.
- Supplemental rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.
- The supplemental rebate agreement is applicable only to Medicaid recipients. This includes Medicaid recipients enrolled in a managed care organization. (MCO).

AHCCCS recognizes and assures that it will comply with the confidentiality mandate of Section 1927(b)(3)(D) of the Social Security Act.