DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-14-26 Baltimore, Maryland 21244-1850



Disabled & Elderly Health Programs Group

May 28, 2015

Monica Coury, Assistant Director Arizona Health Care Cost Containment System 801 E. Jefferson, MD#4200 Phoenix, Arizona 85034

Dear Ms. Coury,

We have reviewed Arizona (AZ) State Plan Amendment (SPA) 15-001 received in the San Francisco Regional Office on March 5, 2015. In this SPA, the state proposes to amend the state plan to include supplemental rebates for drugs. The state requests approval for the Arizona Health Care Cost Containment System (AHCCCS) to initiate a single state supplemental rebate program for prescribed and physician-administered drugs dispensed and/or administered to AHCCCS Fee-For-Service and Medicaid Managed Care beneficiaries.

Because we believe that the state has demonstrated that this amendment complies with all applicable requirements, we are pleased to inform you that consistent with the regulations at 42 CFR 430.20, AZ SPA 15-001 is approved, effective January 1, 2015. Please note that this authorization extends only to the supplemental rebate agreement (SRA) submitted to the Centers for Medicare & Medicaid Services (CMS) on March 5, 2015. If revisions are subsequently made to the SRA, a new SPA and required documents should be submitted to CMS for review and authorization.

A copy of the CMS-179 form as well as the pages approved for incorporation into the AZ state plan will be forwarded to you by the San Francisco Regional Office. If you have any questions regarding this SPA approval please contact LT Emeka Egwim, PharmD, at (410) 786-1092.

Sincerely,

/s/

John M. Coster, PhD, RPh Director Division of Pharmacy

cc: Hye Sun Lee, Acting ARA, Seattle Regional Office Suzanna Berman, RPh, Director of Pharmacy Brian Zolynas, San Francisco Regional Office

CENTERS FOR MEDICARE AND MEDICAID SERVICES	April 1	OMB NO. 0938-0193
TRANSMITTAL AND NOTICE OF APPROVAL OF	1. TRANSMITTAL NUMBER:	2. STATE
STATE PLAN MATERIAL	15-001	Arizona
FOR: Centers for Medicare and Medicaid Services	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 AME 6. FEDERAL STATUTE/REGULATION CITATION:	NDMENT (Separate Transmittal for each 7. FEDERAL BUDGET IMPACT:	amendment)
0. FEDERAL STATUTE/REGULATION CITATION.	7. FEDERAL BUDGET IMFACT.	
1927(b)	FFY 15: (\$5,242,600) FFY 16: (\$7,111,600)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable):	
Page 74d Exhibit 12 to Att. 3.1-A, page 9 Exhibit 12(a) to Att. 3.1-A, page 9	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		
12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO:	
Mark	Monica Coury 801 E. Jefferson, MD#4200	
13. TYPED NAME:	Phoenix, Arizona 85034	
Monica Coury	_	
14. TITLE: Assistant Director		
15. DATE SUBMITTED: March 5, 2015		
FOR REGIONAL OFFICE USE ONLY		
17. DATE RECEIVED; March 5, 2015	18. DATE APPROVED: May 28, 2015	A Company of the Comp
PLAN APPROVED – ON		
19. EFFECTIVE DATE OF APPROVED MATERIAL: January 1, 2015	20. SIGNATURE OF REGIONAL OFFICIAL:	
21. TYPED NAME: Hye Sun Lee	22. TITLE: Acting Associate Regional Administrator	
23. REMARKS:		

Revision: HCFA-PM-93-3

(MB)

OMB No.

April 1993

State/Territory:

Arizona

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

Hospitals which dispense covered J. 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)

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

1903(m)(2)(A)

- AHCCCS will participate in the drug rebate L. program for its managed care program.
- AHCCCS will contract with pharmaceutical manufacturers and collect supplemental drug rebates for the fee-for-service program. The State Supplemental Rebate Agreement was submitted to CMS on March 5, 2015.
- AHCCCS will contract with pharmaceutical N. manufacturers and collect supplemental drug rebates for its managed care program. The State Supplemental Rebate Agreement was submitted to CMS on March 5, 2015.

TN No. 15-001

Approval Date May 28, 2015 Effective Date January 1, 2015 Supersedes TN No. 10-007

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.

TN No. <u>15-001</u> Supersedes TN No. 14-010

Approval Date: May 28, 2015 Effective Date: January 1, 2015

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.

TN No. <u>15-001</u> Supersedes TN No. 10-007

Approval Date: May 28, 2015 Effective Date: January 1, 2015