Table of Contents

State/Territory Name: Utah

State Plan Amendment (SPA) #: UT-17-0002

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

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



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

April 12, 2017

Joseph K. Miner Executive Director, Utah Department of Health Post Office Box 141000 Salt Lake City, Utah 84114-1000

Dear Dr. Miner:

We have reviewed the Utah State Plan Amendment (SPA) TN# 17-0002 received in the Denver Regional Office on January 17, 2017. Under this SPA, the state proposes to revise Utah's pharmacy reimbursement methodology to comply with the key provisions of the Covered Outpatient Drug Final Rule with Comment (81 FR 5170) that was published in the Federal Register on February 1, 2016. The rule requires states to pay pharmacies based on the drug ingredient cost, defined as the actual acquisition cost (AAC), plus a professional dispensing fee. We are pleased to inform you that the amendment is approved with an effective date of April 01, 2017.

The Denver Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the Utah Medicaid State Plan. If you have any questions regarding this amendment, please contact Yolonda Williams at (410) 786-6618 or yolonda.williams@cms.hhs.gov.

Sincerely,

Meagan T. Khau Deputy Director Division of Pharmacy

cc: Richard C. Allen, Associate Regional Associate Mandy Strom, Denver Regional Office Craig Devashrayee, Utah Department of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTHCARE FINANCING ADMINISTRATION	FORM APPROVED OMB NO. 0938-0193
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: 2. STATE: 17-0002-UT Utah
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)
TO: REGIONAL ADMINISTRATOR HEALTHCARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE April 1, 2017
	O BE CONSIDERED AS NEW PLAN AMENDMENT
 FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440.120 	 7. FEDERAL BUDGET IMPACT: a. FFY <u>2017</u> \$0 b. FFY <u>2018</u> \$0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
Page 4 of ATTACHMENT 1.2-C; Pages 1, 1a, 1b, and 1c of Attachment #12a within ATTACHMENTS 3.1-A and 3.1-B; Pages 19, 19a, 19a(2), and 19b of ATTACHMENT 4.19-B; Page 22g of ATTACHMENT 4.19-B	Page 4 of ATTACHMENT 1.2-C; Pages 1, 1a, 1b, and 1c of Attachment #12a within ATTACHMENTS 3.1-A and 3.1-B; Pages 19, 19a, 19a(2), and 19b of ATTACHMENT 4.19-B; Page 22g of ATTACHMENT 4.19-B
 10. SUBJECT OF AMENDMENT: Covered Outpatient Drug Rule 11. GOVERNOR'S REVIEW (Check One): GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED 	OTHER, AS SPECIFIED:
12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO:
13. TYPED NAME: Joseph K. Miner, M.D.	Craig Devashrayee, Manager Technical Writing Unit Utah Department of Heath
14. TITLE: Executive Director, Utah Department of Health	PO Box 143102 Salt Lake City, UT 84114-3102
15. DATE SUBMITTED: January 17, 2017	RANNING MARKANISK ANTITIDUS VETTING VETTING OUT TROUGHEN DE SANDANDED STATE AND A ANTITED STATE
16 17. DATE RECEIVED Jamuary 17, 2017	DATE APPROVED April 12, 2017
19 EFFECTIVE DATE OF AFPBOSED MATERIAL	
April 1, 2017 1 YYAED NAME	ARA, EMICHO
Richard C Allen PLAN APPERCVED 4000	

ATTACHMENT 1.2-C Page 4

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State:

UTAH

DIRECTOR'S OFFICE (Continued)

MEDICAL CARE ADVISORY COMMITTEE

The Medical Care Advisory Committee (MCAC) advises the Medicaid agency director on health and medical care services. The committee includes board-certified physicians, health care representatives and other advocacy groups. The agency director appoints members to this committee on a rotating and continuous basis. The committee participates in policy development and program administration to further recipient participation in the Medicaid program. This committee meets monthly to discuss important Medicaid issues and conducts an annual public hearing to discuss the Medicaid fiscal year budget.

DRUG UTILIZATION REVIEW BOARD

The Drug Utilization Review Board (DUR) assesses the proper use of outpatient drugs in the Medicaid program, promotes cost effective drug use, and safeguards against fraud and improper drug utilization. The board is comprised of licensed and actively practicing members in accordance with 42 U.S.C. 1396r-8(g).

T.N. # <u>17-0002</u>

Approval Date <u>4/12/201</u>7

Supersedes T.N. # 07-008

Effective Date 4-1-17

LIMITATIONS

- 1. Outpatient drugs covered under Medicare Prescription Drug Benefit Part D for fullbenefit dual eligible beneficiaries who are defined as individuals who have Medicare and full Medicaid coverage, will not be covered under Medicaid in accordance with SSA 1935(a).
- 2. Drugs excluded under Medicare Part D are not covered for dual eligible recipients, except for certain limited drugs which are provided, in accordance with SSA, Section 1927(d)(2), to other Medicaid recipients including those who are full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit Part D. These drugs are limited to include:
 - a. selected legend cough and cold agents used for symptomatic relief, as listed in the Utah Medicaid Pharmacy Services Provider manual,

b. selected over-the-counter drugs from the following categories:

Antacid liquids and tablets Anti-diarrheal preparations Anti-fungal preparations Antihistamines Contraceptive Drugs Fever reducers and pain relievers (ASA, APAP and NSAIDs) Hydrocortisone Laxatives Anti-Lice preparations Stomach acid reducers

T.N.# ____

17-0002

Approval Date 4/12/2017

Supersedes T.N. # ____11-014____

Effective Date _______

LIMITATIONS

- 3. Drug Efficacy Study Implementation Project Drugs (DESI Drugs) as determined by the FDA to be less-than-effective are not a benefit of the Medicaid program.
- 4. Other drugs and/or categories of drugs as determined by the Utah State Division of Health Care Financing and listed in the Pharmacy Provider Manual are not a benefit of the Medicaid program.
- 5. In accordance with Utah Law 58-17b-606(4), when a multi-source legend drug is available in the generic form, reimbursement for the generic form of the drug will be made unless the treating physician demonstrates a medical necessity for dispensing the non-generic, brand-name legend drug. However, the Department of Health pharmacists may override the generic mandate provisions if a financial benefit will accrue to the state (See Utah Code 58-17b-606).
- 6. The Division maintains a preferred drug list for selected therapeutic drug classes. The therapeutic classes will be selected and a preferred drug or drugs for each therapeutic class implemented at the discretion of the Division.

T.N. # _____

17-0002

Approval Date 4/12/2017

Supersedes T.N. # 14-008

ATTACHMENT 3.1-A Attachment #12a Page 1b

PRESCRIBED DRUG SERVICES

LIMITATIONS

- 7. The State is in compliance with Section 1927 of the Social Security Act. The State will cover drugs of manufacturers participating in the federal rebate program. The State is in compliance with reporting requirements for utilization and restriction to coverage based on the requirements for Section 1927 of the Act. The State has the following policies for the supplemental rebate program for the Medicaid population:
- a. The State maintains, and updates periodically, a version of the rebate entitled 'Supplemental Rebate Agreement between the State and the drug manufacturer for drugs provided to the Medicaid population and the Sovereign States Drug Consortium Addendum to Member States Agreements'.
- b. Pursuant to 42 USC 1396r-8, the State has established a preferred drug list (PDL) with non-preferred drugs identified. The PDL program shall negotiate drug discounts, rebates, or benefits for the Medicaid program.

T.N. # <u>17-0002</u>

Approval Date 4/12/2017

Supersedes T.N. # 07-006

Effective Date 4-1-17

LIMITATIONS

8. CMS has authorized the State of Utah to enter into "The Sovereign States Drug consortium (SSDC)." The SSDC serves as a vehicle that allows the State to pool its data, lives, and resources with other State Medicaid programs desiring supplemental rebates, but the Consortium does not itself contract with the manufacturers. Utah's supplemental rebate agreement will be the version authorized by CMS and as updated periodically.

Participation in the SSDC multi-state rebate agreement will not limit the State's ability to negotiate state-specific supplemental agreements. Utah will contract directly with each manufacturer.

- 9. The Agency may exceed the limitations on existing covered services to the extent allowed by law, if its medical staff determines:
 - a. that the proposed services are medically appropriate; and
 - b. that the proposed services are more cost effective than alternative services.
- 10. The prior authorization process for covered outpatient drugs conforms to section 1927(d)(5)(B) of the Act.

T.N. # _____

17-0002

Approval Date 4/12/2017

Supersedes T.N. # 07-006

LIMITATIONS

- 1. Outpatient drugs covered under Medicare Prescription Drug Benefit Part D for fullbenefit dual eligible beneficiaries who are defined as individuals who have Medicare and full Medicaid coverage, will not be covered under Medicaid in accordance with SSA 1935(a).
- 2. Drugs excluded under Medicare Part D are not covered for dual eligible recipients, except for certain limited drugs which are provided, in accordance with SSA, Section 1927(d)(2), to other Medicaid recipients including those who are full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit Part D. These drugs are limited to include:
 - a. selected legend cough and cold agents used for symptomatic relief, as listed in the Utah Medicaid Pharmacy Services Provider manual,
 - b. selected over-the-counter drugs from the following categories:

Antacid liquids and tablets Anti-diarrheal preparations Anti-fungal preparations Antihistamines Contraceptive Drugs Fever reducers and pain relievers (ASA, APAP and NSAIDs) Hydrocortisone Laxatives Anti-Lice preparations Stomach acid reducers

T.N.#

17-0002

Approval Date 4/12/2017

Supersedes T.N. # ____11-014____

LIMITATIONS

- 3. Drug Efficacy Study Implementation Project Drugs (DESI Drugs) as determined by the FDA to be less-than-effective are not a benefit of the Medicaid program.
- Other drugs and/or categories of drugs as determined by the Utah State Division of Health Care Financing and listed in the Pharmacy Provider Manual are not a benefit of the Medicaid program.
- 5. In accordance with Utah Law 58-17b-606(4), when a multi-source legend drug is available in the generic form, reimbursement for the generic form of the drug will be made unless the treating physician demonstrates a medical necessity for dispensing the non-generic, brand-name legend drug. However, the Department of Health pharmacists may override the generic mandate provisions if a financial benefit will accrue to the state (See Utah Code 58-17b-606).
- 6. The Division maintains a preferred drug list for selected therapeutic drug classes. The therapeutic classes will be selected and a preferred drug or drugs for each therapeutic class implemented at the discretion of the Division.

T.N. # _____

17-0002

Approval Date 4/12/2017

Supersedes T.N. # 14-008

LIMITATIONS

- 7. The State is in compliance with Section 1927 of the Social Security Act. The State will cover drugs of manufacturers participating in the federal rebate program. The State is in compliance with reporting requirements for utilization and restriction to coverage based on the requirements for Section 1927 of the Act. The State has the following policies for the supplemental rebate program for the Medicaid population:
- a. The State maintains, and updates periodically, a version of the rebate entitled 'Supplemental Rebate Agreement between the State and the drug manufacturer for drugs provided to the Medicaid population and the Sovereign States Drug Consortium Addendum to Member States Agreements'.
- b. Pursuant to 42 USC 1396r-8, the State has established a preferred drug list (PDL) with non-preferred drugs identified. The PDL program shall negotiate drug discounts, rebates, or benefits for the Medicaid program.

T.N. # _____ 17-0002

Approval Date 4/12/2017

Supersedes T.N. # ___07-006____

Effective Date 4-1-17

LIMITATIONS

8. CMS has authorized the State of Utah to enter into "The Sovereign States Drug consortium (SSDC)." The SSDC serves as a vehicle that allows the State to pool its data, lives, and resources with other State Medicaid programs desiring supplemental rebates, but the Consortium does not itself contract with the manufacturers. Utah's supplemental rebate agreement will be the version authorized by CMS and as updated periodically.

Participation in the SSDC multi-state rebate agreement will not limit the State's ability to negotiate state-specific supplemental agreements. Utah will contract directly with each manufacturer.

- 9. The Agency may exceed the limitations on existing covered services to the extent allowed by law, if its medical staff determines:
 - a. that the proposed services are medically appropriate; and
 - b. that the proposed services are more cost effective than alternative services.
- 10. The prior authorization process for covered outpatient drugs conforms to section 1927(d)(5)(B) of the Act.

T.N. # _____

Approval Date 4/12/2017

Supersedes T.N. # 07-006

17-0002

S. PRESCRIBED DRUGS

Covered outpatient drugs will be reimbursed based on an established product cost plus a professional dispensing fee. The payment for individual prescriptions shall not exceed the amount billed. The amount billed must be no more than the usual and customary charge (U&C) to the private pay patient. The following methodology is used to establish Medicaid payments:

Effective for claims adjudicated on or after April 1, 2017, except as otherwise stated in this section and in addition to a reasonable professional dispensing fee as applicable, reimbursement for brand and generic covered outpatient drugs will be as follows:

The lesser of the Utah Estimated Acquisition Cost (UEAC), Federal Upper Limit, Utah Maximum Allowable Cost (UMAC), or the Ingredient Cost Submitted.

Federal Upper Limit

The federal upper limit is the maximum allowable ingredient cost reimbursement established by the Federal government (e.g., Centers for Medicare and Medicaid Services (CMS) for selected multiple-source drugs. The aggregate cost of product payment for the drugs on the federal upper limit list will not exceed the aggregate established by the Federal government.

Utah MAC

Utah MAC is the National Average Drug Acquisition Cost (NADAC) published by the Centers for Medicare and Medicaid Services (CMS). If CMS does not publish a NADAC for a covered outpatient drug, the Maximum Allowable Cost reimbursement may be established by the State for selected drugs.

T.N. # _____ 17-0002

Supersedes T.N. # _____16-0010

Approval Date 4/12/2017

Effective Date 4-1-17

42 CFR 440.120

S. PRESCRIBED DRUGS (Continued)

Utah Estimated Acquisition Cost (UEAC)

The Utah EAC is the Wholesale Acquisition Cost (WAC).

Professional Dispensing Fees

The Utah Medicaid professional dispensing fees are as follows:

- 1. \$9.99 for urban pharmacies located in Utah;
- 2. \$10.15 for rural pharmacies located in Utah;
- 3. \$9.99 for pharmacies located in any state other than Utah; and
- 4. \$716.54 for hemophilia clotting factor dispensed by the contracted pharmacy and in accordance with Attachment 4.19-B, Page 22g.

Urban pharmacies are pharmacies physically located in Weber, Davis, Utah and Salt Lake counties.

Drugs Dispensed by IHS/Tribal facilities

Covered outpatient drugs dispensed by an IHS/Tribal facility to an IHS/Tribal member are reimbursed at the encounter rate in accordance with the Utah Medicaid Indian Health Services Provider Manual.

Specialty Drugs and Covered Outpatient Drugs Primarily Dispensed through the Mail

Specialty drugs and covered outpatient drugs primarily dispensed through the mail are reimbursed in the same manner as other covered outpatient drugs in accordance with the reimbursement rules of this section.

T.N. # _____ 17-0002

Supersedes T.N. # ______16-0010

Approval Date <u>4/12/2</u>017

Effective Date ______

S. PRESCRIBED DRUGS (Continued)

Covered Outpatient Drugs Purchased Through the 340B Program

Covered entities that purchase covered outpatient drugs through the 340B program and used the 340B covered outpatient drugs to bill Utah Medicaid are required to submit the 340B acquisition cost on the claim and identify the medications as being purchased through the 340B by using the Submission Clarification Code = '20' or 'UD' modifier.

Payment for covered outpatient drugs purchased through the 340B program will be the lesser of the 340B acquisition cost plus a professional dispensing fee, as applicable, or the billed charges.

Payment for covered outpatient drugs not purchased through the 340B program are to be submitted, and reimbursed, in accordance with the reimbursement rules under this section.

340B covered entities may not utilize contract pharmacies to bill Utah Medicaid unless the covered entity, contract pharmacy, and State Medicaid agency have a written agreement in place to prevent duplicate discounts.

Federal Supply Schedule

Providers that purchase covered outpatient drugs through the Federal Supply Schedule (FSS) and use the covered outpatient drugs to bill Utah Medicaid are required to submit the FSS acquisition cost on the claim, unless the reimbursement is made through a bundled charge or all-inclusive encounter rate.

Payment for covered outpatient drugs purchased through the FSS will be the lesser of the FSS acquisition cost plus a professional dispensing fee, as applicable, or the billed charges.

Payment for covered outpatient drugs not purchased through the FSS are to be submitted, and reimbursed, in accordance with the reimbursement rules of this section.

Nominal Price

Providers that purchase covered outpatient drugs at Nominal Price and use the covered outpatient drug to bill Utah Medicaid are required to submit the acquisition cost on the claim.

Payment for covered outpatient drugs purchased at Nominal Price will be the lesser of the Nominal Price acquisition cost plus a professional dispensing fee, as applicable, or the billed charges.

T.N. # _____ 17-0002

Supersedes T.N. # ___09-001

Approval Date <u>4/12/201</u>7

42 CFR 440.120

S. PRESCRIBED DRUGS (Continued)

Covered Outpatient Drugs not Dispensed by a Retail Community Pharmacy

Covered outpatient drugs not dispensed by a retail community pharmacy are reimbursed in the same manner as other covered outpatient drugs in accordance with the reimbursement rules of this section.

Provider Administered Drugs

Covered provider administered drugs will be reimbursed according to the Average Sale Price (ASP) Drug Pricing File, published quarterly by the Centers for Medicare and Medicaid Services (CMS), for drugs that have an ASP price set by CMS.

Covered provider administered drugs for which CMS does not publish an ASP price will be reimbursed in accordance with the Utah Medicaid fee schedule published on Medicaid's Coverage and Reimbursement Code Look-up Tool.

Hemophilia Drugs

Hemophilia drugs are reimbursed in accordance with the rules of this section and the Hemophilia Disease Management program in Attachment 4.19-B, Page 22g.

Investigational Drugs

Investigational drugs are not covered by Utah Medicaid.

T.N. # _____ 17-0002

Approval Date <u>4/12/2017</u>

Supersedes T.N. # <u>93-002</u>

Effective Date _______

y

DISEASE MANAGEMENT - HEMOPHILIA

Disease management payments will be in accordance with the contracted rates or billed charges, whichever is less. Reimbursement for disease management is fee-for-service and includes the following:

Reimbursement per in-home monthly nurses visit, reimbursed per 15 minute units and capped at 4 units per day. Additional in-home services may be provided on an as needed basis for up to one additional visit per month.

In-home nursing visits will be reimbursed at the lesser of \$30 per 15 minute unit or the billed charges.

Payment for disease management services, reimbursed per month and capped at 1 unit per month, under the plan does not duplicate payments made to public agencies or private entities under other program authorities for this same purpose.

Payment for disease management services will be reimbursed at the lesser of \$631.65 per member per month or the billed charges; however, the initial month a member is serviced by the contract provider the disease management services will be reimbursed at the lesser of \$1,000 per member or the billed charges. The initial month fee is only eligible to be paid once per member.

All Medicaid disease management hemophilia services are paid pursuant to a selective contract authorized through authority in an approved 1915(b)(4) Waiver.

T.N. # _____ 17-0002

Approval Date <u>4/12/201</u>7

Supersedes T.N. # 05-019

Effective Date _______