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State/Territory Name: Ohio

State Plan Amendment (SPA) #: 17-023

This file contains the following documents in the order listed:

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

September 26, 2017

Ms. Barbara R. Sears
State Medicaid Director
Ohio Department of Medicaid
P.O. Box 182709
Columbus, OH 43218

Dear Ms. Sears:

We have reviewed Ohio's State Plan Amendment (SPA) 17-023 received in the Chicago Regional Office on June 29, 2017. This SPA proposes to bring Ohio into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

SPA 17-023 establishes reimbursement rates for covered outpatient drugs using an actual acquisition cost methodology and implements a tiered professional dispensing fee, fewer than 49,999 prescriptions per year is $13.64, between 50,000 and 74,999 prescriptions is $10.80 per year, between 75,000 and 99,999 prescriptions per year is $9.51, and 100,000 or more prescriptions per year is $8.30. This SPA also includes reimbursement rates for 340B drugs, federal supply schedule drugs, and drugs purchased at a nominal price. The state provided data and studies to demonstrate that the acquisition cost methodology and pharmacy dispensing fees being paid are sufficient to assure that Ohio's beneficiaries will have access to pharmacy services at least to the extent as the general population. In addition, this SPA proposes to update the drugs which it may exclude from coverage or otherwise restrict in order to comply with the requirements of the 21st Century Cures Act.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-023 is approved with an effective date of April 1, 2017. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Ohio's state plan will be forwarded by the Chicago Regional Office. If you have any questions regarding this amendment, please contact Yolonda Williams at (410) 786-6618 or yolonda.williams@cms.hhs.gov.

Sincerely,

/s/

Meagan T. Khau
Deputy Director
Division of Pharmacy

CC: Ruth Hughes, ARA, CMS, Chicago Regional Office
Carolyn Humphrey, Ohio Department of Medicaid

Department of Health & Human Services
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601-5519

September 26, 2017

Barbara R. Sears, Director
Ohio Department of Medicaid
P.O. Box 182709
50 West Town Street, Suite 400
Columbus, Ohio 43218

ATTN: Sarah Curtin, SPA Coordinator

RE: Companion Approval Transmittal Number (TN) 17-023

Dear Ms. Sears:

This letter is being sent as a companion to our approval of the Ohio State Plan Transmittal Notice (TN) 17-023 that implements pharmacy pricing changes to comply with the actual acquisition cost and professional dispensing fee requirements of the Covered Outpatient Drug Rule, and to implement Section 5008 of the 21 Century Cures Act to remove references to agents when used for cosmetic purposes or hair growth. The changes in this state plan amendment (SPA) are effective on April 1, 2017.

Because we review the entire pharmacy services and payment section of the state plan, we reviewed the provider-administered pharmaceuticals section which is part of the benefit in the Code of Federal Regulations (CFR) at 42 CFR §440.120(a). We identified concerns with language in, Item 12-a. on page 4 of 4 that was not in compliance with 42 CFR §430.10 that requires a comprehensive written document showing that the methodology is understandable, clear, unambiguous and auditable. Because the provider-administered pharmaceuticals language was not submitted with TN 17-023, we require the state to submit a SPA to revise this page. Since the state is not changing the payment methodology, we do not need a new public notice as our request clarifies existing state plan language so that it comports with 42 CFR 430.10. Please make the following changes to Attachment 4.19-B, Item 12-a. Page 4 of 4:

1. Remove the following sentence identified by the cross-out edit from the first paragraph. Because the provider-administered pharmaceutical is the lesser of the submitted charge or a payment that follows a methodology described in the ordered list numbered a-e, the rate is not fixed at November 1, 2015 pricing.

   All maximum payment amounts are published on the agency's website at medicaid.ohio.gov/PROVIDERS/FeeScheduleandRates.aspx. ~~The agency's vaccines, toxoids, and other provider-administered pharmaceuticals fee schedule was set as of November 1, 2015, and is effective for services provided on or after that date.~~ Except as otherwise noted in the plan, state-developed fee schedules and rates are the same for both governmental and private providers.

2. Update the footer Effective Date to the first day of the quarter in which the State plan amendment is submitted. For example, October 1, 2017 is the earliest next page effective date. An effective date of the page in the footer is sufficient to show the methodology has been approved but removes the ambiguity of a fixed date of fee screens suggested by the November 1, 2015 date.

3. Keeping the methodology for the other provider-administered pharmaceuticals on the page, we request the state move the payment amount for vaccines and toxoids to the physician services payments in Attachment 4.19-B, Item 5a.

4. Delete the Item 12-a (a) sentence that ties the amount of payment to the Ohio Administrative Code. Because the state can change the Ohio Administrative Code without public notice and state plan submission, the methodology is ambiguous.

5. Please confirm that the state determined physician-administered pharmaceuticals payments are sufficient to enlist enough providers to assure access to care and services in Medicaid at least to the extent that care and services are available to the general population in the geographic area and are included in the access monitoring for pharmacy.

The state has 90 days from the date of this letter to respond to this letter. Within that period, the state may submit SPAs to address the inconsistencies or submit a corrective action plan describing in detail how the state will resolve the issues identified above in a timely manner. Failure to respond may result in the initiation of a formal compliance process. During the 90 days, CMS will provide any required technical assistance.

Please contact Yolonda Williams, of my staff, at (410) 786-6618 or via email at Yolonda.williams@cms.hhs.gov if you have any questions.

Sincerely,

/s/

Meagan T. Khau
Deputy Director
Division of Pharmacy

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES	1. TRANSMITTAL NUMBER: **17 - 023**	2. STATE **OHIO**
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE **April 1, 2017**	

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:	7. FEDERAL BUDGET IMPACT: (in thousands)
42 U.S.C. Section 1396r-8 42 C.F.R. Part 447	a. FFY 2017 ($4,297) b. FFY 2018 ($8,657)
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 3.1-A, Item 6-d-4, Page 1 of 1 Attachment 3.1-A, Item 12-a, Page 2 Attachment 3.1-A, Item 12-a, Page 3 Attachment 4.19-B, Item 6-d-(4), Page 1 of 1 Attachment 4.19-B, Item 7-c, Pages 1 and 2 of 2 Attachment 4.19-B, Item 12-a, Pages 1-3 of 4	Attachment 3.1-A, Item 6-d-4, Page 1 of 1 (TN 09-036) Attachment 3.1-A, Item 12, Page 2 of 12 (TN 13-034) ATTACHMENT 3.1-A, ITEM 12, PAGE 2b OF 12 (TN 11-013) Attachment 3.1-A, Item 12-a, Page 2a of 12 (TN 11-001) Attachment 4.19-B, Item 6-d-(4), Page 1 of 1 (TN 13-019) Attachment 4.19-B, Item 7-c, Page 1 and 2 of 2 (TN 16-031) Attachment 4.19-B, Item 12-a, pages 1-3 of 4 (TN 13-019)

10. SUBJECT OF AMENDMENT:

Coverage and Limitations and Payment for Services: Pharmacy: Change to Actual Acquisition Cost and Professional Dispensing Fee

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:
The State Medicaid Director is the Governor's designee

12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]	16. RETURN TO:
13. TYPED NAME: **BARBARA R. SEARS**	**Carolyn Humphrey** **Ohio Department of Medicaid** **P.O. BOX 182709** **Columbus, Ohio 43218**
14. TITLE: **STATE MEDICAID DIRECTOR**	
15. DATE SUBMITTED: June 29, 2017	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED:
June 29, 2017	September 26, 2017
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: April 1, 2017	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
21. TYPED NAME: Ruth A. Hughes	22. TITLE: Associate Regional Administrator

23. REMARKS:

Instructions on Back

FORM CMS-179 (07-92)

6. Medical care and any other type of remedial care recognized under state law, furnished by licensed practitioners within the scope of their practice as defined by state law.

d. Other practitioners' services

(4) Pharmacists' services.

The Department covers the administration of seasonal and pandemic influenza vaccines and the administration of drugs by injection by licensed pharmacists who are practicing within their scope and employed by pharmacies that contract with Ohio Medicaid. Participating pharmacies and pharmacists must meet all requirements set forth by the Ohio Board of Pharmacy.

Provisions related to Medicare Part D Prescription Drug Coverage

Pursuant to Section 1935(d)(1) of the Social Security Act, effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

Pursuant to Sections 1927(d)(2) and 1935(d)(2) of the Social Security Act, the Medicaid agency provides coverage for the following Medicare-excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

The following drugs, which are subject to restriction under Section 1927(d)(2) of the Social Security Act, are covered:

☐ (a) agents when used for anorexia, weight loss, or weight gain
☐ (b) agents when used to promote fertility
☒(c) agents when used for the symptomatic relief of cough and colds
☒(d) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
☒(e) nonprescription drugs (only cough and cold products, anihistamines, antacids, antidiarrheals, stool softeners, laxatives, analgesics, and topical products including acne, antifungals, and corticosteroids)
☐(f) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
☐(g) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

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

a. Prescribed drugs

Selected over-the-counter drugs provided by nursing facilities for their recipient-residents are included in the nursing facility services. Nursing facilities receive a per diem amount that includes payment for selected over-the-counter drugs and are responsible for ensuring that their recipient-residents obtain those drugs. For dates of service on or after 8/1/09, selected over-the-counter drugs are paid for by the nursing facilities and are not eligible for reimbursement on a fee-for-service basis. Reimbursement methodology for nursing facilities is described in Attachment 4.19-D.

Select active pharmaceutical ingredients (APIs) and excipients used in extemporaneously compounded prescriptions are covered when dispensed by a participating pharmacy provider pursuant to a prescription issued by a licensed prescriber following all state and federal laws. A list of the covered APIs and excipients can be found at the following: http://pharmacy.medicaid.ohio.gov/drug-coverage.

Excluded Drug Coverage of Smoking/Tobacco Cessation Products for Pregnant Women

The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) tobacco/smoking cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline.

6. Medical care and any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law.

d. Other practitioners' services

(4) Pharmacists' services.

Providers will be paid an administration fee for the administration of seasonal and pandemic influenza vaccines and the administration of drugs by injection.

The administration fee is the same for both governmental and private providers.

When a provider administers a seasonal or pandemic influenza vaccine or drug by injection in a pharmacy, the administration fee is the lesser of the provider's charge or the Medicaid maximum allowable payment of $19.35. This amount is effective for services provided on or after April 1, 2017.

7. Home health services, continued.

c. Medical supplies, equipment, and appliances suitable for use in the home.

Payment for an enteral nutrition product is the lesser of the submitted charge or an amount based on the Medicaid maximum for the product. The Medicaid maximum is listed on the agency's Durable Medical Equipment payment schedule. Where no Medicaid maximum is specified, payment is 77% of the average wholesale price (AWP).

Payment for blood glucose monitors, test strips, lancets, lancing devices, needles including pen needles, calibration solution/chips, and needle-bearing syringes with a capacity up to three milliliters is the lesser of the submitted charge or the calculated allowable payment. The calculated allowable is the sum of the cost of the supply plus the professional dispensing fee assigned to the provider. The cost of the supply is determined as 100% of the wholesale acquisition cost (WAC); if the WAC cannot be determined, the cost of the supply is 83.33% of the AWP.

Payment for a wheelchair, part, accessory, or related service is determined in the following manner:

For a wheelchair (either a manual wheelchair or a power mobility device) and any related part or accessory, it is the lesser of the submitted charge or a percentage of the amount allowed under fee-for-service Medicare for the jurisdiction that includes Ohio.

For an evaluation and related services, it is the lesser of the submitted charge or a percentage of the amount established by the Medicare Physician Fee Schedule.

For labor provided for a covered repair or covered maintenance, it is the lesser of the submitted charge or a number derived by formula from wage figures reported by the United States Bureau of Labor Statistics and from the federal standard mileage rate.

Maximum payment amounts are listed in the Wheelchair section of the agency's Durable Medical Equipment payment schedule.

For any other service or item, payment is the lesser of the submitted charge or an amount based on the Medicaid maximum for the service or item. The Medicaid maximum is the amount listed on the agency's Durable Medical Equipment payment schedule. Where no Medicaid maximum is specified, payment is 72% of the list price; if no list price is available, it is 147% of the invoice price.

For a covered procedure, service, or supply represented by a new HCPCS procedure code that takes effect at the beginning of a calendar year, the initial maximum payment amount is set at 80% of the Medicare allowed amount.

Medicaid maximum payment amounts are published on the agency's website at medicaid.ohio.gov/PROVIDERS/FeeScheduleandRates.aspx.

The agency's Durable Medical Equipment payment schedule was set as of January 1, 2017, and is effective for services and items provided on or after that date. The agency's Diabetic Testing and Injection Supplies payment schedule (part of the Pharmacy payment schedule) was set as of April 1, 2017, and is effective for services provided on or after that date.

Except as otherwise noted in the plan, state-developed payment schedules and amounts are the same for both governmental and private providers.

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

a. Prescribed drugs

Payment for prescribed drugs meets all reporting requirements and provisions of section 1927 of the Social Security Act. Payment for prescribed drugs will be made based on the various categories as specified below. No supplemental allowance will be authorized for broken-lot charges, prescription delivery charges or state and local sales tax.

A. Payment for the following prescribed drugs will be in accordance with the Actual Acquisition Cost (AAC) definition at 42 CFR 447.512.
   1. Brand name and generic drugs and other drugs/products meeting the definition of covered outpatient drug in 42 CFR 447.502 including covered over-the-counter medications will be paid at ingredient cost based on AAC, plus professional dispensing fee.
      a. AAC is defined as the lesser of:
         - National Average Drug Acquisition Cost (NADAC) plus professional dispensing fee, or
         - The provider's usual and customary charge.
      b. If NADAC is unavailable, AAC is the lesser of:
         - Wholesale Acquisition Cost (WAC+0%) plus professional dispensing fee, or
         - State Maximum Allowable Cost (SMAC) plus professional dispensing fee, or
         - The provider's usual and customary charge

         SMAC means the maximum amount to be paid for an equivalent generic drug group based on an estimate of the statewide AAC.
      c. Professional Dispensing Fees are determined on the basis of surveys conducted of pharmacy operational and overhead costs. The fees are reviewed periodically for reasonableness. A survey of each Medicaid-enrolled pharmacy provider every other year documents prescription volume and determines the tier under which the pharmacy will be paid.
         i. The professional dispensing fee tiers including fees for compounded drugs that are not sterile compound or total parenteral nutrition compound claims are as follows:
            - Less than 49,999 prescriptions per year = $13.64
            - Between 50,000 and 74,999 prescriptions per year = $10.80
            - Between 75,000 and 99,999 prescriptions per year = $9.51
            - 100,000 or more prescriptions per year = $8.30
         ii. Sterile compound claims will receive a dispensing fee of $10 per day supplied, with a maximum dispensing fee of $70 per claim.
         iii. Total parenteral nutrition compound claims will receive a professional dispensing fee of $15 per day supplied, with a maximum dispensing fee of $150 per claim.

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

a. Prescribed drugs (continued)

2. Drugs purchased by 340B covered entities through the federal 340B drug price program will be paid at ingredient cost based on 340B AAC, plus professional dispensing fee.
3. Drugs purchased by 340B covered entities outside of the federal 340B drug price program will be paid at the same AAC methodology used for providers that are not 340B covered entities described in Section A.1.a. through A.1.b. of Item 12-a, page 1, plus the professional dispensing fee assigned as described in Section A.1.c. of Item 12-a, page 1.
4. Drugs acquired through the federal 340B drug price program and dispensed by 340B contract pharmacies are not covered.
5. Drugs acquired through the Federal Supply Schedule (FSS) will be paid at the FSS actual acquisition cost, plus the professional dispensing fee.
6. Drugs acquired at nominal price, (outside of 340B or FSS) will be paid at the actual acquisition cost, plus the professional dispensing fee.

B. Payment for the following prescribed drugs are not required to be paid based on AAC.

1. Federally Qualified Health Centers will be paid for drugs dispensed to patients for use in their personal residence according to the AAC methodology described in Section A. of Item 12-a, pages 1-2, plus the professional dispensing fee.
2. Specialty drugs not dispensed by a retail community pharmacy including drugs dispensed primarily through the mail (but not in institutions or long term care) will be paid at the same AAC calculated allowable methodology described in Section A.1 of Item 12-a, page 1, plus the professional dispensing fee.
3. Clotting factor and other blood products used to treat hemophilia and other blood disorders will be paid at the lesser of:
    - The payment limit shown in the current Medicare part B drug pricing file, minus the furnishing fee assigned by Medicare part B, plus the professional dispensing fee assigned to the provider in Section A.1.c. of Item 12-a, page 1, or
    - The provider's usual and customary charge.

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

a. Prescribed drugs (continued)

4. Drugs dispensed through institutions or long-term care that are not included as part of an inpatient stay will be paid at the same AAC calculated allowable methodology described in Section A.1 of Item 12-a, page 1.
Payment for selected over-the-counter drugs provided by nursing facilities (NFs) for their recipient-residents is included in the nursing facility services. Nursing facilities receive a per diem amount that includes payment for selected over-the-counter drugs and are responsible for ensuring that their recipient-residents obtain those drugs. Payment for selected over-the-counter drugs provided to residents of NFs is included in the facility per diem and is not eligible for reimbursement on a fee-for-service basis. Reimbursement methodology for nursing facilities is described in Attachment 4.19-D.

5. Coverage for investigational drugs is subject to prior authorization and must be determined to be medically necessary. Payment for investigational drugs is the cost actually paid by the provider plus the provider's cost to dispense.

C. Federal Upper Limits (FUL)

1. The aggregate payment of drugs subject to the FUL will not exceed the FUL based on the NADAC for ingredient cost payment for multiple source drugs.
2. Compliance with the FUL in the aggregate will be ensured on an annual basis.