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State/Territory Name: North Carolina

State Plan Amendment (SPA) #: 20-0015

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

December 17, 2020

Mr. Dave Richard
Deputy Secretary, North Carolina Medicaid
Division of Health Benefits
NC Department of Health and Human Services
1985 Umstead Drive
2501 Mail Service Center
Raleigh, North Carolina 27699-2501

Dear Mr. Richard:

The CMS Division of Pharmacy team has reviewed North Carolina's State Plan Amendment (SPA) 20-0015 received in the CMS Medicaid & CHIP Operations Group on September 25, 2020. This SPA proposes to add the provider's gross amount due (GAD) to the reimbursement hierarchy for covered outpatient drugs. This SPA also proposes to implement a new reimbursement methodology for Indian Health Services/Indian Tribal pharmacy facilities based on the OMB encounter rate, as well as adding a delivery payment for drugs delivery by mail, courier, or person-to-person.

In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. We believe that there is evidence regarding the sufficiency of North Carolina's pharmacy provider network at this time to approve SPA 20-0015. Specifically, North Carolina has reported to CMS that 2,640 of the state's 2,792 licensed in-state retail pharmacies are enrolled in North Carolina's Medicaid program. With a 94 percent participation rate, we can infer that North Carolina's beneficiaries will have access to pharmacy services at least to the extent available to the general population since Medicaid requires that beneficiaries be provided access to all covered outpatient drugs of participating drug manufacturers with a rebate agreement through a broad pharmacy network. In contrast, commercial insurers often have more limited drug formularies and a more limited pharmacy network.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0015 is approved with an effective date of September 1, 2020. We are attaching a copy of the signed, updated CMS-179 form, as well as the pages approved for incorporation into North Carolina's state plan.

If you have any questions regarding this amendment, please contact Charlotte Amponsah at (410) 786-1092 or charlotte.amponsah@cms.hhs.gov.

Sincerely,

[redacted] Digitally signed by John M. Coster -S
Date: 2020.12.17 12:55:15 -05'00'

Director
Division of Pharmacy

cc: Charles Friedrich, CMS, Medicaid & CHIP Operations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE 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: 20-0015

2. STATE: NC

3. PROGRAM IDENTIFICATION:
TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
September 1, 2020.

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:

CMS 2345-FC and 42 CFR 447.502

7. FEDERAL BUDGET IMPACT:
a. FFY 2020 $183.05
b. FFY 2021 $2.196.606
c. FFY 2022 $2.196.606

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 4.19-B, Section 12 Pages 1, 1a, 1a.1, 1a.2, 1a.2a, 1b.

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 4.19-B, Section 5, Page 1g & Section 12 Pages 1, 1a, 1a.1, 1a.2, 1b.
.

10. SUBJECT OF AMENDMENT:

Pharmacy POS SPA

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: Secretary

12. SIGNATURE OF STATE AGENCY OFFICIAL:
[redacted]

13. TYPED NAME:
Mandy Cohen, MD, MPH

14. TITLE:
Secretary

15. DATE SUBMITTED: 9/15/2020

16. RETURN TO:

Office of the Secretary
Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-20014

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 9/25/2020

18. DATE APPROVED: 12/17/2020

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 09/01/2020

20. SIGNATURE OF REGIONAL OFFICIAL:
[redacted]
Digitally signed by John M. Coster -S
Date: 2020.12.17 12:55:59 -05'00'

21. TYPED NAME: JOHN COSTER

22. TITLE: DIRECTOR, DIVISION OF PHARMACY

23. REMARKS:

FORM HCFA-179 (07-92)

FORM APPROVED
OMB NO. 0938-0193

MEDICAL ASSISTANCE
State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. **Covered outpatient drugs (COD)**

a.

- Legend and Non-legend drugs
- Drugs not Dispensed by a Retail Community Pharmacy, Long Term Care Pharmacy
- Specialty Drugs not Dispensed by a Retail Community Pharmacy and Dispensed Primarily through the Mail
- Payment for Drug Purchased Outside of the 340B Program by Covered Entities

Reimbursement for the above drugs dispensed to covered beneficiaries shall not exceed the federal upper limit defined as the lowest of:

1. The Actual Acquisition Cost (AAC) plus a professional dispensing fee;
2. The provider's usual and customary charge (U&C) to the general public;
3 The provider's gross amount due (GAD (430-DU) = Total price claimed from all sources: sum of 'Ingredient Cost Submitted' (409-D9), 'Dispensing Fee Submitted' (412-DC), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Incentive Amount Submitted' (438-E3), 'Other Amount Claimed' (480-H9), or
4. The amount established by the State of North Carolina to determine the upper payment limit plus a professional dispensing fee.

In compliance with 42 Code of Federal Regulations 447.512 and 447.514, reimbursement for drugs subject to Federal Upper Limits (FULs) may not exceed FULs in the aggregate.

A professional dispensing fee will not be paid for covered outpatient drugs refilled in the same month, whether it is the same drug or generic equivalent drug, except for blood clotting factor / hemophilia drugs.

For blood clotting factor / hemophilia drugs reimbursement and professional dispensing fee see Section 12, Page 1a.1.

Multiple Source Drugs – North Carolina has implemented a State determined list of multiple source drugs. All drugs on this list are reimbursed at limits set by-the State unless the provider writes in their own handwriting, brand name drug is "medically necessary".

MEDICAL ASSISTANCE
State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. **Covered outpatient drugs (COD)**

b. **North Carolina Actual Acquisition Cost (AAC) For Covered Outpatient Drugs:**

Effective January 1, 2016, North Carolina will base brand and generic drug ingredient pricing on the actual acquisition cost (AAC). The National Average Drug Acquisition Cost (NADAC) pricing will be used for AAC when available. If NADAC is unavailable, then the AAC will be defined as Wholesale Acquisition Cost (WAC).

c. **Professional Dispensing Fee (PDF):**

The professional dispensing fee is paid to pharmacy providers for the initial dispensing and excludes refills within the same month for the same drug or generic equivalent.

The professional dispensing fee is $3.98 for non-preferred brand drugs.

For blood clotting factor / hemophilia drugs professional dispensing fees see Section 12, Page 1a.1.

The generic and preferred brand professional dispensing fee will be based on an enrolled pharmacy's preferred brand and generic drugs during the previous quarter, as documented in the Medicaid Management Information System (MMIS). Based on the previous quarterly volume of an enrolled pharmacy, as documented in MMIS, the total number of generics and preferred brands is divided by the total number of prescriptions billed.

Preferred brand drugs are brand drugs whose net cost to the State after consideration of all rebates is less than the cost of the generic equivalent.

The generic and preferred brand professional dispensing fee will be as follows:

- 85% or more claims per quarter - $13.00
- Less than 85% claims per quarter - $7.88

MEDICAL ASSISTANCE
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PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. **Covered outpatient drugs (COD)**

d. Payment for Clotting Factor / Hemophilia Drugs from Specialty Pharmacies, Hemophilia Treatment Centers (HTC), Centers of Excellence or any other pharmacy provider:

Reimbursement for blood clotting factor / hemophilia drugs purchased through the 340B program and dispensed by specialty pharmacies, hemophilia treatment centers (HTC), Centers of Excellence or any other pharmacy provider will be reimbursed at the lesser of the following:

1) The 340B state maximum allowable cost, plus a per unit professional dispensing fee;
2) The provider's usual and customary charge (U&C) to the general public or their submitted charge plus a per unit professional dispensing fee, or
3) The provider's gross amount due (GAD (430-DU) = Total price claimed from all sources: sum of 'Ingredient Cost Submitted' (409-D9), 'Dispensing Fee Submitted' (412-DC), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Incentive Amount Submitted' (438-E3), 'Other Amount Claimed' (480-H9).

Reimbursement for blood clotting factor / hemophilia drugs purchased outside of the 340B program and dispensed by specialty pharmacies, hemophilia treatment centers (HTC), Centers of Excellence or any other pharmacy provider will be reimbursed at the lesser of the following:

1) The state maximum allowable cost, plus a per unit professional dispensing fee;
2) The provider's usual and customary charge (U&C) to the general public or their submitted charge plus a per unit professional dispensing fee, or
3) The provider's gross amount due (GAD (430-DU) = Total price claimed from all sources: sum of 'Ingredient Cost Submitted' (409-D9), 'Dispensing Fee Submitted' (412-DC), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Incentive Amount Submitted' (438-E3), 'Other Amount Claimed' (480-H9).

The above reimbursement methodology stated in Section 12.d is only applicable to pharmacy claims.
For procedure coded professional / medical drug claims see Section 12, Page 2.

The per unit professional dispensing fee for all units dispensed will be $.04/unit for HTC pharmacies and $.025/unit for all other pharmacies.

Blood clotting factors / hemophilia drugs per unit professional dispensing fees shall be established by a blood clotting factor / hemophilia dispensing fee survey.

e. Payment for 340B Purchased Drugs Dispensed by a Covered Entity, a Contract Pharmacy Under Contract with a 340B Covered Entity, or an Indian Health Service, Tribal or Urban Indian Pharmacy:

Reimbursement for 340B purchased drugs dispensed by 340B covered entities, contract pharmacies under contract with a 340B covered entity, and Indian health service, tribal, or urban Indian pharmacies will be reimbursed at no more than their 340B acquisition cost plus the professional dispensing fee as defined on Attachment 4.19-B, Section 12, Page 1a, Section c.

12. **Covered outpatient drugs (COD)**

f. Reimbursement for drugs purchased through the Federal Supply Schedule will be reimbursed no more than the Federal Supply Schedule acquisition cost plus a professional dispensing fee, unless the reimbursement for covered outpatient drugs is made through a bundled charge or all-inclusive encounter rate.

g. Reimbursement for drugs purchased at Nominal Price (outside of 340B or FSS) will be reimbursed no more than the Nominal Price acquisition cost plus a professional dispensing fee.

h. Covered outpatient drugs dispensed or delivered by *Indian health care provider* (means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603) will be reimbursed at OMB encounter rates.

OMB encounter rates will be paid for pharmacy encounter, as follows:

1. For Medicaid covered outpatient drugs dispensed or delivered to all patients seen by the I/T/U pharmacy providers;

2. Covered outpatient drugs dispensed or delivered by I/T/U facilities as authorized by Public Law 93-638 Agreement ("I/T/U facilities") will be reimbursed at the OMB encounter rates;

   I/T/U facilities will receive one OMB encounter payment for each covered outpatient ~~prescription~~ drug filled or refilled; for a maximum of two (2) OMB encounter payments, per beneficiary, per day, per facility.

   Non-covered under the OMB encounter rates:

   I. Specialty and high cost for covered outpatient drugs with acquisition costs greater than $1,000. These covered outpatient drugs will continue to be reimbursed at the lesser of the fee for service (FFS) unit price or the actual acquisition costs (AAC), plus a professional dispensing fee (PDF);

   II. Eyeglasses, prosthetic devices, hearing aids, diabetic testing equipment and supplies;

   III. Drugs dispensed to beneficiaries assigned to the Health Choice or the Family Planning waiver benefit plans.

3. Encounter is defined as a prescription, whether the prescription is for a single drug or compound drugs. No more than one OMB encounter rate payment is made per covered outpatient drug filled whether the prescription is for a single ingredient drug or a compound drug;

4. There will be no limit on the number of prescriptions filled per patient per day by an I/T/U facility, but an I/T/U facility will receive no more than two (2) OMB encounter payments per day per patient per facility for prescriptions filled or refilled, and these payments shall constitute payment in full for all covered outpatient drugs dispensed for the patient on that day;

MEDICAL ASSISTANCE
State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. **Covered outpatient drugs (COD)**

h. (Continue)

5. The applicable encounter rate will be determined by the date of service submitted on the pharmacy claim; date of service is defined as the date the covered outpatient drug is dispensed.

6. I/T/U facilities receiving an all-inclusive OMB encounter payment for a covered outpatient drug filled or refilled shall not be eligible to receive professional dispensing fees, delivery fees, ingredient costs and any costs associated with drug counseling or medication therapy management (MTM).

i. Investigational drugs are not covered.

j. Reimbursement for drugs delivery by mail, courier or person to person delivery will be established as follows:

$1.50 for mail or courier
$3.00 for person to person

Delivery payment will be for a single claim, once per day per beneficiary per pharmacy, unless the reimbursement for covered outpatient drugs is made through a bundled charge or all-inclusive encounter rate.

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MEDICAL ASSISTANCE
State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. Physician Administered Drug Program (PADP):

The agency's fee schedule rates for physician administered drugs were set as of January 1, 2015 and are effective for services provided on or after that date.

New physician administered drugs are reimbursed at the Average Sales Price (ASP) plus six percent (6%) to follow Medicare pricing. If there is no ASP value available from Medicare, fees shall be established based on the lower of vendor specific National Drug Code (NDC) Average Wholesale Price (AWP) less ten percent (10%) pricing as determined using lowest generic product NDC, lowest brand product NDC or a reasonable value compared to other physician drugs currently on North Carolina's physician drug program list.

Per approved Section 12, page 1a.1 d. effective April 1, 2017, procedure coded professional or medical drug claims for blood clotting factor / hemophilia drugs shall be reimbursed based on the State Maximum Allowable Cost (SMAC).

Effective July 1, 2017, physician administered vaccines are reimbursed at the Wholesale Acquisition Cost plus three percent (3%).

Effective July 1, 2017, physician administered contraceptive drugs are reimbursed at the Wholesale Acquisition Cost (WAC) plus six percent (6%).

Except as otherwise noted in the plan, State developed fee schedule rates are the same for both governmental and private providers of the physician drug program and the fee schedule and any annual/periodic adjustments to the fee schedules are published on the NC Division of Health Benefits Website.

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State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. Dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in disease of the eye or by an optometrist.

~~c.~~ Orthotic and Prosthetic Devices

Payment for each claim for prosthetic/orthotic devices will be equal to the lower of the supplier's usual and customary billed charges or the maximum fee established for each item. The maximum fees are set at the Medicaid fee schedule in effect on July 1, 2012. All rates are published on the website at https://medicaid.ncdhhs.gov/providers/fee-schedules. If a Medicare fee cannot be obtained for a particular item, the fee will be based on estimates of reasonable costs and updated each January 1 by the forecasted percentage increase in prices for the devices.

When devices are provided by state or local government agencies, reimbursement will not exceed the cost of the device.

State Plan Under Title XIX of the Social Security Act
Medical Assistance Program
State: North Carolina

Payments for Medical and Remedial Care and Services

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

Eyeglasses.

Fees paid to dispensing providers are negotiated fees established by the State agency based on industry charges.

Except as otherwise noted in the plan, state developed fee schedule rates are the same for both governmental and private providers of Orthotic and Prosthetic Devices the fee schedule and any annual/periodic adjustments to the fee schedule are published in https://medicaid.ncdhhs.gov/providers/fee-schedules. The agency's fee schedule rate was set as of the and is effective for services provided on or after that date. All rates are January 1, 2014 published on the agency's website.

Payment for materials is made to a contractor(s) in accordance with 42 CFR 431.54(d).