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State/Territory Name: North Carolina

State Plan Amendment (SPA) #: 22-0033

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

January 25, 2023

Dave Richard
Deputy Secretary
Office of the Deputy Secretary
Department of Health and Human Services
Division of Health Benefits
2501 Mail Service Center
Raleigh, NC 27699-20014

Dear Dave Richard:

The CMS Division of Pharmacy has reviewed North Carolina's State Plan Amendment (SPA) 22-0033 received in the CMS Medicaid & CHIP Operations Group on October 31, 2022. This SPA proposes to change the professional dispensing fee to a flat rate of $10.24 and to revise certain state Point of Sale reimbursement policies.

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 22-0033. Specifically, North Carolina has reported to CMS that 2014 of the state's 2701 licensed in-state retail pharmacies are enrolled in North Carolina's Medicaid program. With a 74 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 22-0033 is approved with an effective date of December 1, 2022.

We are attaching a copy of the signed CMS-179 form, as well as the page approved for incorporation into North Carolina's state plan. If you have any questions regarding this amendment, please contact Charlotte Hammond at (410) 786-1092 or charlotte.hammond@cms.hhs.gov.

Sincerely,

[redacted]

Mickey Morgan
Acting Deputy Director
Division of Pharmacy

cc: Betty Staton, North Carolina State Plan and Amendments Manager

DocuSign Envelope ID: 31D5873B-2658-4822-A359-979F0421BAA4
DEPARTMENT OF HEALTH ANDHUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 22-0033

2. STATE: NC

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

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
December 01, 2022

5. FEDERAL STATUTE/REGULATION CITATION
CMS 2345-FC and 42 CFR 447.502

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 23 $ (358,907)
b. FFY 24 $ (416,093)

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 4.19-B, Section 12, Pages 1, 1a, 1a.1, 1a.2, 1a.2a and Page 2

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Attachment 4.19-B, Section 12, Pages 1, 1a, 1a.1, 1a.2, 1a.2a and Page 2

9. SUBJECT OF AMENDMENT
North Carolina Pharmacy Point of Sale (POS) and Physician Administered Drug Program (PADP)

10. 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: Deputy Secretary

11. [redacted] AGENCY OFFICIAL

12. TYPED NAME
Dave Richard

13. TITLE
Deputy Secretary

14. DATE SUBMITTED
10/10/22 | 4:54 AM PDT

15. RETURN TO
Office of the Deputy Secretary
Department of Health and Human Services
NC Medicaid
Division of Health Benefits
2501 Mail Service Center
Raleigh, NC 27699-20014

FOR CMS USE ONLY

16. DATE RECEIVED
10/31/2022

17. DATE APPROVED
1/25/2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
December 1, 2022

19. SIGNATURE OF APPROVING OFFICIAL
[redacted]

20. TYPED NAME OF APPROVING OFFICIAL
Mickey Morgan

21. TITLE OF APPROVING OFFICIAL
Acting Deputy Director

22. REMARKS

Instructions on Back

MEDICAL ASSISTANCE
State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. **Covered Outpatient Drugs (COD)**

a. COD include the following:

- Legend and Non-legend drugs
- Drugs 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.

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
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PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. **Covered Outpatient Drugs (COD)**

b. **North Carolina Actual Acquisition Cost (AAC) For COD:**

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 PDF of $10.24 is paid each time a COD is dispensed.

The professional dispensing fee is determined by the Cost of Dispensing study conducted on behalf of the North Carolina Department of Health and Human Services, Division of Health Benefits.

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

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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 COD 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. COD 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 the OMB encounter rates.

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

1. For Medicaid COD dispensed or delivered to all patients seen by the I/T/U pharmacy providers.

2. COD 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 **COD** 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 total calculated allowable amount (CAA) greater than $1,000. These COD 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), as defined on Attachment 4.19-B, Section 12, Page 1a.
   II. Eyeglasses, prosthetic devices, hearing aids, diabetic testing supplies & equipment.
   III. Drugs dispensed to beneficiaries assigned to the Health Choice or the Family Planning waiver benefit plans.
   IV. Drugs free of charge and vaccines
   V. Emergency supply dispensation: lock-in emergency supply, behavioral emergency supply, 3-day/72hrs emergency supply.
   VI. Drug mailing or delivery fees, drug counseling or medication therapy management and Professional Dispensing Fees.
   VII. 340B purchased drugs.
   VIII. Medicare Part-B and Part-D Drugs.

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 COD filled whether the prescription is for a single ingredient drug or a compound drug.

MEDICAL ASSISTANCE
State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

12. **Covered Outpatient Drugs (COD)**

h. (Continue)

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 OMB encounter payments shall constitute payment in full for all COD dispensed for the patient on that day.

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 COD is dispensed.

6. I/T/U facilities receiving an all-inclusive OMB encounter payment for a COD 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).

7. A drug included in the OMB encounter rate payment, and for which the I/T/U pharmacies receive payment, is not eligible for rebate through the Medicaid Drug Rebate Program, as it does not meet the definition of a "covered outpatient drug" at section 1927(k)(2) and (3) of the Social Security Act, as it must be a direct reimbursement for the drug, and it cannot be reimbursed as part of a bundled or all-inclusive rate payment.

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 COD is made through a bundled charge or all-inclusive encounter rate.

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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) 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 lesser of the State Maximum Allowable Cost (SMAC) or the billed amount.

Effective July 1, 2017, physician administered Long-Acting Reversible Contraceptive (LARC) non-340B drugs are reimbursed based on the lesser of the Wholesale Acquisition Cost (WAC) plus six percent (6%) or the billed amount.

Effective December 1st, 2022, physician administered LARCs, acquired utilizing the 340B program, will be calculated based on 340B ceiling price plus six percent (6%) and will be reimbursed based on the lesser of 106% 340B ceiling price or the billed amount. If 340B ceiling price is not available, then 340B LARC shall be reimbursed based on the 340B Actual Acquisition Cost 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.