NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Health Benefits

ROY COOPER • Governor
Kody Kinsley • Secretary
DAVE RICHARD • Deputy Secretary, NC Medicaid

SIGNATURE REQUEST MEMORANDUM

TO: Dave Richard, Deputy Secretary DS DR

FROM: Cecilia Williams, SPA Coordinator

RE: State Plan Amendment

Title XIX, Social Security Act
Transmittal #2022-0033

Purpose
Attached for your review and signature is a Medicaid State Plan amendment, summarized below, and submitted on October 05, 2022, with a due date of October 12, 2022.

Clearance
This amendment has been reviewed for both accuracy and completeness by:

Cecilia Williams, Betty J. Staton, Emma Sandoe, Melanie Bush, Lotta Crabtree, Adam Levinson and Dave Richard.

Background and Summary of Request
It is recommended that you sign the State Plan Amendment submission per Centers for Medicare and Medicaid Services (CMS) protocol as head of the Single State Agency administering the Medicaid program.

This state plan change is to revise the North Carolina Pharmacy Point of Sale (POS) and Physician Administered Drug Program (PADP) reimbursement policies and titles to:

- Change the Pharmacy POS reimbursement methodology to a flat professional dispensing fee (PDF)
- Remove the rule allowing only one PDF per member, per drug, per pharmacy, per month.
- Implement a new PADP reimbursement methodology for 340B Long-Acting Reversible Contraceptives (LARCs), which will be priced at 340B ceiling price plus six percent (6%) and will be reimbursed based on the lesser of 106% 340B ceiling price or the billed amount. When there is no 340B ceiling price available, 340B LARCs will be reimbursed based on the 340B Actual Acquisition Cost plus six percent (6%).
- Align reimbursement with system pricing logics.

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Your approval of this State Plan Amendment is requested. If you have any questions or concerns, please contact me or Cecilia Williams at (919) 270-2530.

MEDICAL ASSISTANCE
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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".

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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 is paid each time a COD is dispensed.

PDFs will not be paid for emergency or 72hr supply fills.

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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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.

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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.

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

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