

## WRITTEN SECTION REPORTS

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# CLINICAL POLICY AND PROGRAMS REPORT

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(REPORT PERIOD APRIL 16, 2016 THROUGH JUNE 3, 2016)

## 1. POLICIES PRESENTED TO THE N.C. PHYSICIAN ADVISORY GROUP (PAG)

The N.C. Physician Advisory Group met on 04/28/16, 05/26/16

The Pharmacy & Therapeutic Committee met on 05/10/16

### **Recommended Policies**

- 1A-41, Office-Based Opioid Treatment - 04/28/16

### **Recommended Pharmacy**

- PA Criteria Entresto (sacubitril/valsartan) - 05/26/16
- PA Criteria Systemic Immunomodulators (add Xeljanz XR) - 05/26/16
- Annual Preferred Drug List (PDL) updates - 05/26/16

### **PAG Administrative Notification**

- 3L, State Plan Personal Care Services - 04/28/16

## 2. POLICIES POSTED FOR PUBLIC COMMENT

- 3K-1, Community Alternatives Program for Children (CAP/C) (Policy Termination) - 04/06/16
- 3K-2, Community Alternatives Program for Disabled Adults and Choice Option (CAP/DA-Choice) (Policy Termination) - 04/06/16
- 3K-3, Community Alternatives Program (CAP) Waiver - 04/06/16
- 3L, State Plan Personal Care Services PCS - 05/03/16

## 3. POLICIES POSTED FOR ADDITIONAL PUBLIC COMMENT

- NONE

## 4. AMENDED OR NEW POLICIES POSTED TO DMA WEBSITE

- 1C-2, Medically Necessary Routine Foot Care - 05/01/16

## BEHAVIORAL HEALTH CLINICAL POLICY REPORT

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### 1. BEHAVIORAL HEALTH CLINICAL POLICY UPDATES:

DHHS sponsored its first Critical Time Intervention approved training April 27-28, 2016 in Greensboro. The next training is June 16-17, 2016 in Durham at Alliance Behavioral Healthcare.

#### **Certified Community Based Health Clinics (CCBHC):**

Section 223 Demonstration Program to Improve Community Mental Health Services of the PAMA ACT was enacted on April 1, 2014. It requires the establishment of a demonstration program to improve community behavioral health services. NC was one of the 24 states who received a one-year planning grant. The CCBHC planning project is a collaborative effort between DMA and the Division of Mental Health, Developmental Disabilities and Substance Abuse Services (DMHDDAS). Of those 24 states, eight will be awarded a two-year demonstration in October 2016. The team is diligently working on the certification process, data collection process, prospective payment system, and stakeholder engagement.

57 total sites, 24 organizations, submitted proposals to participate in the demonstration. The top three rural sites and top four urban sites have been chosen. These sites must complete a community based needs assessment and hold focus groups to determine the specific needs of their community. DHHS will provide technical assistance throughout this process. Once the needs assessments and focus groups are completed a rural and urban review team will visit each site to verify the sites ability to provide the services required by the Substance Abuse and Mental Health Services Administration (SAMHSA). Ultimately, one rural and one urban site will be chosen. DMA is working on finalizing the PPS rate for these sites.

### BEHAVIORAL HEALTH IDD SECTION UPDATES:

#### **Treatment for Autism Spectrum Disorder:**

The Centers for Medicare and Medicaid Services have issued guidance on EPSDT coverage of Autism Spectrum Disorder. It is their expectation that states cover a continuum of services for these individuals. To that end, the North Carolina is exploring options to provide additional services to this population with assistance from Mercer and stakeholder engagement. DMA has requested a special provision to allow for and allocate funding to a State Plan Amendment for Evidence and Research Based Treatment of Autism Spectrum Disorder.

#### **TBI Waiver:**

The North Carolina General Assembly has appropriated \$1,000,000 for fiscal year 2015-2016 and \$2,000,000 for fiscal year 2016-2017 to fund a TBI Medicaid Waiver based on the recommendations from the Joint Legislative Oversight Committee on Health and Human Services. This waiver is currently under review by CMS.

#### **Innovations Waiver:**

A technical amendment to the Innovations waiver to implement resource allocation and add flexibility to service definitions was submitted to CMS in October 2015. The state has responded to formal Requests for Additional Information and the responses have been accepted, and DMA is waiting for CMS approval. DMA has requested the implementation date of the technical amendment be changed to November 1, 2016 to allow adequate time for implementation post approval.

**Home and Community Based Services Rule:**

The state has been working with CMS to develop the final version of the HCBS transition. DMA submitted the request in draft to CMS, and is waiting for CMS comments prior to posting for public comment. Additional information on the HCBS Rule can be found at <http://www.ncdhhs.gov/hcbs/index.html>.

**LME-MCO CONTRACT SECTION UPDATES:**

**External Quality Review:**

CMS requires that states conduct external quality reviews (EQRs) of contracted managed care organizations to analyze aggregate information on quality, timeliness, and access to the health care services that an MCO furnishes to Medicaid recipients. The Carolinas Center for Medical Excellence (CCME) will begin conducting these reviews onsite at each LME-MCO in June 2016.

**LME-MCO Mergers:**

Cardinal Innovations Healthcare Solutions and CenterPoint Human Services are on schedule to complete merger activities by July 1, 2016.

**2. OUTPATIENT PHARMACY**

**Preferred Drug List (PDL) Update Effective April 1, 2016**

After receiving Fast Track Designation and Priority Review, the U.S. Food and Drug Administration (FDA) recently approved NARCAN® (naloxone HCl) 4 mg Nasal Spray, manufactured by Adapt Pharma, for commercial use in the United States. Based on the patient safety benefit of the commercially available naloxone nasal spray which facilitates the safe and immediate administration of naloxone for overdose, NARCAN® Nasal Spray will be move to preferred status in the Opioid Antagonist drug class on the [NC Medicaid PDL NC Medicaid Preferred Drug List \(PDL\)](#) with an effective date of April 1, 2016.

OPIOID ANTAGONIST	
<b>Preferred</b> naloxone ampule / syringe / vial (generic for Narcan®) Narcan® Nasal Spray	<b>Non-Preferred</b> Evzio® Auto-Injector

**Updates to NC Medicaid and Health Choice Clinical Coverage Policy No: 9**

On May 1, 2016, several changes to the Medicaid and Health Choice Clinical Coverage Policy No: 9 will go into effect. Clinical Coverage Policy No: 9 provides guidance for outpatient pharmacy related requirements and processes. The majority of changes are being made in response to legislation or as clarification of the policy. Selected changes are described in further detail below.

**Section 3.2.1 (e) Medicaid Vaccine Coverage in the Pharmacy:**

A new legislative mandate will allow pharmacists to administer vaccinations within the scope of their practice and pharmacies to receive reimbursement for vaccinating NC Medicaid beneficiaries. The addition of vaccinations as a covered service in Policy No. 9 is consistent with this legislative mandate. **This IS NOT programmed in NCTracks at this time.**

### **Section 5.5.1 Medicaid Copayment Requirements:**

Language has been changed in the policy to clarify the expectations around pharmacy procedures for NC Medicaid beneficiaries who are unable to afford co-pays. Many pharmacies are willing to help recipients who find themselves without money for medication co-pays, but based on previous language, many pharmacies expressed concern over the perceived requirement to attempt collection of the co-pay indefinitely.

Medicaid beneficiaries are required to make a \$3.00 copayment for each prescription (unless they are exempt for specific criteria listed in the policy). A pharmacy provider cannot discount or waive a copayment for a Medicaid beneficiary as a business practice. However, if a Medicaid beneficiary is financially unable to pay the copayment, the pharmacy provider cannot deny services to the Medicaid beneficiary. The pharmacy provider must open an account for the beneficiary and collect the amount owed at a later date. All attempts to collect the copay are required to be documented by the pharmacy provider. The pharmacy provider may write off the charges and stop monitoring the claim if the account has not been paid within a certain timeframe that is consistent with the pharmacy's normal accounting practices.

### **Section 5.9.1 Use of NADAC, Generic Dispensing Rate and MAC:**

Per Session Law 2015-241, changes to pharmacy reimbursement have been made as follows:

1. Medications will be paid at the National Average Drug Acquisition Cost (NADAC) or Usual and Customary (U&C) price submitted by the pharmacy if they are less than the NADAC price. NADAC is the Center for Medicare & Medicaid Services, (CMS) survey on drug prices, (<http://medicaid.gov/Medicaid-CHIP-Program-Information/ByTopics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html>). NADAC has two prices, a brand NADAC price for branded products and a generic NADAC price for products that are generic or a brand that has generic equivalents. Brand NADAC prices will be paid for all preferred brands, brands that do not have a generic equivalent, and for brands where the physician indicated 'medically necessary' on the prescription, and the pharmacy submits a DAW1. The generic NADAC prices will be used in all other cases.
2. If a price is not found on NADAC, the product will be priced at the lesser of Wholesale Acquisition Cost (WAC), State Maximum Allowable Cost (SMAC) or U&C.
3. Dispensing fees will increase to \$3.98 for non-preferred brand product listed on the preferred drug list (PDL) or brands not listed on the PDL. Preferred brands and generics will be paid a rate according to the individual pharmacy's generic dispensing rate (GDR). A GDR  $\geq 85\%$  will receive a dispensing fee of \$13.00 and a GDR  $< 85\%$  will receive a dispensing fee of \$7.88.

Both Maximum Allowable Cost (MAC) lists and NADAC are methods pharmacy payers use to estimate drug pricing when deciding on drug reimbursement rates to pharmacies. MAC list price calculations are generally proprietary and differ with each pharmacy benefit manager (each payer). The state's MAC reimbursement is based on application of a percentage factor applied to the lowest priced generic, but may be adjusted based on the cost of other generic products of the same drug. MAC lists are generally not updated as regularly and can be significantly different from actual current drug costs. NADAC is calculated by CMS and is a more transparent drug cost list that is available online to anyone. It is updated weekly using pharmacy invoice prices that surveyed pharmacies voluntarily provide from the prior week. NC Medicaid will use NADAC price for reimbursement if the drug in question is included on the NADAC list. Otherwise the state MAC list will continue to be used. **This IS NOT programmed in NCTracks at this time.**

**Section 5.14 Beneficiary Management Lock-In Period Increased to Two Years:**

In response to Session Law 2015-141, Section 12F.16 (1), the lock-in period has been increased from one year to two years.

All NC Medicaid beneficiaries that meet the criteria for inclusion (not changed) in the Beneficiary Management Lock-In Program, will be restricted to the use of a single prescriber and pharmacy in order to obtain opioid analgesics, benzodiazepines, and certain anxiolytics in order for the claim to pay during the two year lock-in period. **This IS NOT programmed in NCTracks at this time.**

**Immunizations and Vaccinations Provided by Pharmacists**

On May 9, 2016, the Centers for Medicare & Medicaid Services (CMS) notified DMA that our State Plan Amendment (SPA) 16-0003 had been reviewed and was approved with an effective date of January 1, 2016.

North Carolina's approved SPA allows pharmacists to provide covered vaccinations and immunizations (seasonal influenza vaccines, herpes zoster vaccine, hepatitis B vaccine, meningococcal vaccines, tetanus-diphtheria and tetanus and diphtheria toxoid vaccines) to Medicaid and Health Choice beneficiaries within the scope of their practice as legislated by G.S. 90-85.15B. It also allows North Carolina Medicaid to reimburse pharmacies for these covered vaccinations and immunizations when provided by pharmacists.

While CMS approved our SPA with an effective date of January 1, 2016, **this IS NOT programmed in NCTracks at this time.**

# RECIPIENT AND PROVIDER SERVICES REPORT

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## PROVIDER RECREDENTIALING

The Centers for Medicare and Medicaid Services requires that all Medicaid providers are revalidated (recruited) at least every five years. This is to ensure that provider enrollment information is accurate and current. The provider's credentials and qualifications will be evaluated to ensure that they meet professional requirements and are in good standing. The recertification process also includes a criminal background check on all owners and managing relationships associated with the provider record.

Every active NCTracks Provider must be recertified. It is crucial that all providers who receive a recertification notice promptly respond and begin the recertification process. Providers will receive a recertification letter 45 days before their recertification due date. If the provider does not complete the recertification process **within the allotted 45 days, payment will be suspended** until the recertification process is completed. The provider will also receive a termination notice. If the provider does not complete the recertification process within thirty (30) days from payment suspension and termination notice, **participation in the N.C. Medicaid and Health Choice Programs will be terminated**. Providers must submit a re-enrollment application to be reinstated.

## NON-EMERGENCY MEDICAL TRANSPORTATION (NEMT) PROVIDER ENROLLMENT

As required by the Affordable Care Act, any vendor who provides NEMT services must enroll as a Medicaid provider through NCTracks, the Medicaid Management Information System. As enrolled Medicaid providers, vendors will no longer be reimbursed by the County Department of Social Services (DSS). However, they are required to contract with the County DSS. The vendors will bill for transportation services through NCTracks.

The planned implementation date for NEMT vendors to begin submitting claims in NCTracks is Sept. 1, 2016. NEMT vendors started submitting provider enrollment applications through NCTracks on May 2016.

## MEDICAID & HEALTH CHOICE PROVIDER FINGERPRINT-BASED CRIMINAL BACKGROUND CHECKS

In accordance with 42 CFR 455.434(b), providers designated as a "high" categorical risk will soon be required to submit a set of fingerprints to the North Carolina Division of Medical Assistance (DMA) through its enrollment vendor, CSRA, as a part of the federally mandated provider screening process. "High" risk providers are listed under 42 CFR 424.518 (c) and the North Carolina General Statute. 108C-3(g). The requirement for fingerprint based criminal background checks applies to both the "high" risk provider and any person with a 5 percent or more direct or indirect ownership interest in the organization, as those terms are defined in 42 CFR 455.101. Providers will be able to identify all locations in North Carolina where fingerprinting services will be offered.

Providers required to submit fingerprint evidence will be notified in writing of the requirement. A deadline for compliance will be established and the providers who fail to meet the deadline will be denied participation in the NC Medicaid and Health Choice programs. Providers enrolled by Medicare or another State's Medicaid or CHIP program are not required to complete fingerprint based criminal background checks to enroll in NC Medicaid and Health Choice.

**ENROLLMENT OF ATTENDING, RENDERING, ORDERING, PRESCRIBING OR REFERRING PROVIDERS**

Beginning with date of service Feb. 1, 2016, the presence of the National Provider Identifier (NPI) of a non-enrolled ordering, prescribing or referring provider on a N.C. Medicaid or N.C. Health Choice (NCHC) has resulted in a “pay and report edit” appearing on the Remittance Advice (RA). DMA will notify providers when the edit disposition will change from a “pay and report” status to “suspend” status. When the edit is changed to suspend claims, if an attending, rendering, ordering, prescribing or referring provider does not enroll within the 90-day timeframe, the billing provider will receive a denial with an EOB stating that “the attending, rendering, ordering, prescribing or referring provider is not enrolled.” This will permit the billing provider to notify the attending, rendering, ordering, prescribing or referring provider to begin the enrollment process on NCTracks.

Targeted for an August 1, 2016, implementation, will be the requirement of the provider’s NPI as a data element on the claim for the following programs. All providers should note that any NPI entered on a claim will be validated, even if it is not required for that service/claim type.

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