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In This Issue...

NPI Update for Pharmacy Providers

Update: Active Pharmaceutical Ingredients and Excipients

Process for Returning Unused Mirena Units

**Upcoming Policy Implementation: Off Label Antipsychotic Monitoring in Children
through Age 17**

Changes to the N.C. Medicaid Preferred Drug List

Pharmacies Participating in the 340b Program

Provider Quality Assurance Questionnaire

Provider Billing of Patients Who Are Medicaid Recipients

Changes in Drug Rebate Manufacturers

NPI Update for Pharmacy Providers

Effective immediately, pharmacy providers should start submitting the prescriber NPI on all prescriptions. The DEA number should no longer be submitted.

The NC Medicaid HIPAA Companion Guide Specifications for NCPCP 5.1 will be updated with the following information:

Field #	Field Name	Format	Field/Type	Field Length	NC Medicaid Specifications
466-EZ	Prescriber ID Qualifier	NCPD P V5.1	A/N	2	01 = National Provider Identifier (NPI)

Update: Active Pharmaceutical Ingredients and Excipients

CMS has provided clarification regarding the inclusion of active pharmaceutical ingredients (APIs) and excipients in the Medicaid Drug Rebate system. An API is a bulk drug substance, which is defined by the Food and Drug Administration (FDA) as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product. APIs do not meet the definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). In addition, excipient products used in compounds are non-drug products.

Certain APIs and excipients previously identified as ineligible for coverage under the N.C. Medicaid Outpatient Pharmacy program as of January 1, 2011, are now covered. In addition to this change, additional products have been identified for coverage removal. The list of identified API and excipient NDCs can be found on the Policy & Reimbursement's Spotlight web page on the CMS website at http://www.cms.gov/Reimbursement/02_Spotlight.asp#TopOfPage.

Process for Returning Unused Mirena Units

DMA is working with Bayer HealthCare to develop a process for providers to return unused Mirena units that have been billed to North Carolina Medicaid. This new process will allow Medicaid to receive credit for Mirena units that have not been used by recipients. Updates regarding this process will be available on DMA's Outpatient Pharmacy Program web page at <http://www.ncdhhs.gov/dma/pharmacy/>.

Upcoming Policy Implementation: Off Label Antipsychotic Monitoring in Children through Age 17

The use of antipsychotic medications by children is an issue confronting parents, other caregivers, healthcare professionals, and related organized healthcare agencies across the United States. The use of antipsychotic medications in children and adolescent populations is not as well studied as in adults. It is recognized that many antipsychotic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. Of increasing concern, children and adolescents appear to be at similar or greater risk than adults for a variety of significant side effects related to the use of antipsychotic medications.

Due to well documented safety considerations and limited efficacy information on the use of antipsychotic agents in children, DMA developed a policy titled *Off Label Antipsychotic Monitoring in Children through Age 17*. The policy creates an opportunity to gather information about antipsychotic prescribing trends within the child and adolescent Medicaid population of North Carolina.

DMA in partnership with North Carolina Community Care networks and AccessCare will implement a registry for providers to document the use of antipsychotic therapy in Medicaid-eligible individuals 0 through 17 years of age. This registry is supported by an advisory panel consisting of child psychiatrist representatives from North Carolina's four medical universities. The registry named **A+KIDS** (Antipsychotics-Keeping It Documented for Safety) encourages the use of appropriate baseline and follow-up monitoring parameters to facilitate the safe and effective use of antipsychotics in this population.

Objectives of the **A+KIDS** registry include improving the use of evidence-based safety monitoring for patients for whom an antipsychotic agent is prescribed, reduction of antipsychotic polypharmacy, and reduction of cases in which the FDA maximum dose is exceeded. Data elements collected within the registry reflect a generally accepted monitoring profile for the safety and efficacy follow-up of the prescribed antipsychotic pharmacotherapy. The requirement of safety monitoring documentation in the registry by the prescriber occurs when:

- The antipsychotic is prescribed for an indication that is not approved by the federal FDA.
- The antipsychotic is prescribed at a higher dosage than approved for a specific indication by the federal FDA.
- The prescribed antipsychotic will result in the concomitant use of two or more antipsychotic agents.

Implementation of the registry requirement will be done in phases according to the age of the recipient for whom the antipsychotic is prescribed. Phase one will apply to children who are Medicaid-eligible and 12 years of age or younger. The subsequent phase for the 13 through 17 age group will occur under the same guidelines. The launch for phase one is targeted for April 2011. Providers will receive notification of the official implementation date for each age group. A widespread training effort about the registry is slated to start in March 2011. Community Care of North Carolina and AccessCare will provide the training and education. Providers are directed to the **A+KIDS** website (<http://www.documentforsafety.org>) registration web page to register as an **A+KIDS** provider to enable access to the online registry or to learn more about this initiative. Registration is scheduled to begin the first week of March.

Changes to the N.C. Medicaid Preferred Drug List

N.C. Medicaid will implement changes to the N.C. Medicaid Preferred Drug List (PDL) on **March 7, 2011**. These changes will complete the final phase of the September 15, 2010, implementation of the PDL. The following drug classes were reviewed with changes made to the preferred and non-preferred statuses: multiple sclerosis, growth hormones, ulcerative colitis, electrolyte depleters, psoriasis, and self-administered rheumatoid arthritis agents. Agents for gout and opioid dependence were re-reviewed in order to make updates to reflect recent changes in the drug classes.

The changes are the result of the clinical reviews completed at the January 28, 2011 Preferred Drug List panel meeting and represent specialty drug classes that required a more lengthy review process. The revised PDL as well as PDL updates can be accessed from DMA's Outpatient Pharmacy Program web page at <http://www.ncdhhs.gov/dma/pharmacy/>.

Pharmacies Participating in the 340b Program

If your pharmacy is eligible to participate in 340b, you must submit a request to participate to the Office of Pharmacy Affairs (OPA) with your Medicaid billing information and the appropriate form. The website is <http://www.hrsa.gov/opa/introduction.htm> and the form is listed at the following link: <ftp://ftp.hrsa.gov/bphc/pdf/opa/PrgmReg.pdf/>.

It is very important that OPA have information that is accurate and up to date, particularly the covered entity's exact name and street address. It is the responsibility of each covered entity to contact the OPA with any changes.

While the entity is eligible to participate in the program by virtue of its status, it must notify the OPA of its intention to participate by completing and submitting the appropriate registration form. Once the OPA receives this information, the entity will be eligible to receive pharmaceuticals at the 340B discounted price at the beginning of the next calendar quarter. The quarterly deadlines for data submission to OPA are December 1 for the quarter beginning January 1; March 1 for the quarter beginning April 1; June 1 for the quarter beginning July 1; and September 1 for the quarter beginning October 1. It is the entity's responsibility to tell its wholesaler or manufacturer that it is registered for 340B discount prices when it places an order. If you have any questions regarding this program, please call the HRSA Pharmacy Services Support Center at 1-800-628-6297.

It is also important that you notify N.C. Medicaid of your intent to participate. While the presence of the Medicaid provider number on OPA's database indicates eligibility to participate, the exact quarter of purchasing is required in order to ensure that the state coordinates the exclusion of claims for rebate processing. Please contact Sharon Greeson with the HP Pharmacy Department at 1-800-688-6696 and notify her of your intent to start participating.

Any provider purchasing drugs through the 340b program is required to bill Medicaid the actual acquisition cost plus the dispensing fee (unless they are keeping a separate stock for Medicaid). This is reviewed through a post payment review and overbillings are subject to recoupment

Provider Quality Assurance Questionnaire

In March 2011, DMA's Provider Services Section will begin publishing a series of quality assurance (QA) questionnaires. The QA questionnaire is intended only for DMA's enrolled Medicaid providers. All enrolled providers are encouraged to complete the March 2011 QA questionnaire (available from DMA's website at <http://www.ncdhhs.gov/dma/provider/>). Results obtained from the questionnaire will be kept confidential. Completed questionnaires may be submitted by e-mail to ncdma.providerqasurvey@lists.ncmail.net or by fax to 919-715-8548.

Provider Billing of Patients Who Are Medicaid Recipients

Accepting a Medicaid Recipient

In accordance with 10A NCAC 22J.0106, a provider may choose whether to accept a patient as a Medicaid patient. However, Medicaid providers must be consistent with their policies and procedures when accepting or refusing Medicaid recipients. Providers may not discriminate against a Medicaid recipients based on the recipient's race, religion, national origin, color, or handicap.

Agreeing to provide services to a Medicaid recipient and submission of a claim to the N.C. Medicaid Program for payment constitutes agreement to accept the Medicaid payment (in addition to any authorized copayment or third-party payment) as payment in full.

A provider may refuse to accept a Medicaid recipient and bill the recipient as private pay only if the provider informs the recipient prior to rendering the service, either orally or in writing, that the service will not be billed to Medicaid and that the recipient will be responsible for payment.

Billing the Recipient

Providers may not bill a recipient for

- the difference between the provider's charges and the Medicaid payment in addition to co-payment and third-party payment.
- any service covered by the Medicaid program unless the provider has specifically informed the recipient that Medicaid will not be billed, and the recipient understands and agrees to accept liability for payment.
- any service covered by the Medicaid program for which the provider is denied payment because the provider failed to follow program regulations including, but not limited to, errors on claims, late submission, lack of prior approval, failure to bill third-party resources, etc.
- any service for which the provider is denied payment due to a National Correct Coding Initiative edit.

When a non-covered service is requested by a recipient, the provider must inform the recipient either orally or in writing that the requested service is not covered under the Medicaid program and will, therefore, be the financial responsibility of the recipient. This must be done prior to rendering the service.

A provider may also bill a Medicaid recipient for the following:

- Payments for services that are made to the recipient and not the provider by either commercial insurance or Medicare.

- Services not covered by Medicare if the recipient has Medicare-AID (MQB-Q) coverage
- Allowable Medicaid deductibles or copayments*.
- Unduplicated prescriptions in excess of 11 per month unless recipient is locked in to their pharmacy of record*.
- Visits in excess of the legislative annual visit limit for provider visits for the state fiscal year (July 1–June 30)*. (See <http://www.ncdhhs.gov/dma/provider/AnnualVisitLimit.htm> for information on the annual visit limit.)
- The recipient’s loss of eligibility for Medicaid as defined in 10A NCAC 21B.
- Part D copay.

*Under federal EPSDT law, some limits and restrictions do not apply to recipients under the age of 21. Refer to DMA’s website at <http://www.ncdhhs.gov/dma/epsdt/> for information.

Changes in Drug Rebate Manufacturers

The following changes have been made in manufacturers with Drug Rebate Agreements. It is listed by manufacturer’s code, which are the first five digits of the NDC.

Addition

The following labeler has entered into a Drug Rebate Agreement and has joined the rebate program effective on the date indicated below:

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
43376	Zogenix, Inc	01/31/2011

Voluntarily Terminated Labelers

The following labelers have requested voluntary termination effective April 1, 2011:

International Medication Systems LTD	(Labeler 00548)
Boudreaux’s Butt Past	(Labeler 62103)

Checkwrite Schedule

February 01, 2011	March 03, 2011	April 05, 2011
February 08, 2011	March 08, 2011	April 12, 2011
February 15, 2011	March 15, 2011	April 21, 2011
February 24, 2011	March 24, 2011	

Electronic Cut-Off Schedule

January 27, 2011	February 24, 2011	March 31, 2011
February 03, 2011	March 03, 2011	April 07, 2011
February 10, 2011	March 10, 2011	April 14, 2011
February 17, 2011	March 17, 2011	

Electronic claims must be transmitted and completed by 5:00 p.m. on the cut-off date to be included in the next checkwrite. Any claims transmitted after 5:00 p.m. will be processed on the second checkwrite following the transmission date. POS Claims must be transmitted and completed by 12:00 midnight on the day of the electronic cut-off date to be included in the next checkwrite.

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