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## **Removal of Active Pharmaceutical Ingredients and Excipients as Covered Outpatient Drugs**

CMS has provided policy clarification regarding the inclusion of active pharmaceutical ingredients (APIs) and excipients in the drug rebate program. 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 [21 CFR § 207.3(a)(4)]. APIs may be included in extemporaneously compounded prescriptions and may serve as the active drug component in a compounded formulation.

In accordance with the foregoing, APIs do not meet the definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). As such, APIs are not subject to the requirements of the Medicaid Drug Rebate (MDR) program. In addition, excipient products used in compounds (e.g., aquaphor, petrolatum, etc) are non-drug products and, as a result, should not be reported to the MDR program.

To the extent possible, CMS has identified the APIs and excipients that are listed in the MDR system. CMS is notifying manufacturers that the National Drug Codes (NDCs) do not qualify as covered outpatient drugs and, as a result, will be deleted from the MDR product file of covered outpatient drugs effective January 1, 2011. CMS will notify all State Medicaid programs regarding the removal of these products. The list of identified API and excipient NDCs can be found on the Policy & Reimbursement's Spotlight Webpage [http://www.cms.gov/Reimbursement/02\\_Spotlight.asp#TopOfPage](http://www.cms.gov/Reimbursement/02_Spotlight.asp#TopOfPage). Please note that this is not a definitive list.

The compounding powders and other products listed on the CMS website will not be rebate eligible effective January 1, 2011 and therefore will no longer be covered in the Medicaid Outpatient Pharmacy Program. However, some of the compounding powders such as hydroxyprogesterone caproate will be covered in other program areas. Additional information will be provided in future updates.

## **End-dated Coverage of Generic Colchicine**

Effective with date of service November 16, 2010, Medicaid end-dated coverage of generic single-ingredient oral colchicine products. Colcrys, the brand-named colchicine, has been changed to a preferred product on the Preferred Drug List and is available without prior authorization. The Food and Drug Administration (FDA) determined that the single-ingredient oral colchicine products are unapproved new drugs and cannot be marketed without appropriate FDA approval.

## **Contact E-Mail Addresses**

All applicants are asked at the time of enrollment to provide a valid e-mail address for the individual or authorized agent who is authorized to receive information or make business decisions on behalf of the applying provider. This e-mail address is used by CSC—the provider enrollment, verification, and credentialing contractor—to communicate important information to

an applicant once the application has been submitted. The e-mail address is entered into a provider's record and may also be used by DMA to communicate important information in a timely manner to providers related to participation with the N.C. Medicaid Program. All communication from the N.C. Medicaid Program is important and should be handled promptly. Providers are reminded that it is important to maintain accurate contact information and to notify CSC when there is a change to the e-mail address on file with Medicaid. Changes should be reported using the Medicaid Provider Change Form. The form can be accessed from the NC Tracks website at <http://www.nctracks.nc.gov/provider/cis.html>.

Questions about your contact e-mail address information may be directed to CSC at the number listed below.

**CSC, 1-866-844-1113**

### **Discontinuation of Focused Risk Management Program**

DMA will discontinue the Focused Risk Management (FORM) program as of December 15, 2010. The FORM review will no longer be required, and pharmacies will no longer receive the professional service fee related to this program. Recipients aged 21 years and older who require more than 11 unduplicated prescriptions each month will continue to be restricted to a single pharmacy through the Recipient Opt-in program.

### **Incomplete Application Final Notice**

As the provider enrollment, verification, and credentialing (EVC) vendor for the N.C. Medicaid Program, CSC processes enrollment applications, enrollment additions, and Medicaid Provider Change Forms. When an EVC credentialing coordinator determines that an application is missing information, the coordinator suspends the application as "Incomplete" and sends a letter to the applicant indicating the information that must be provided in order to complete the application. If the missing information is not provided within 30 days from the date of the letter, CSC sends a system-generated e-mail to the applicant (see below) stating that the application will be voided. Any applicant who feels that he/she has received this notice in error should immediately contact the CSC EVC Call Center at 1-866-844-1113. CSC will promptly investigate and address your concerns.

The following paragraph is excerpted from the e-mail message that CSC sends to an applicant when an application is voided because CSC has not received all of the required information within 30 days.

*After reviewing your application, an EVC Credentialing Coordinator determined that the information provided was incomplete. CSC sent notification to your office via mail and/or e-mail of the necessary corrections to complete your request for enrollment. As of the date of this letter, the records indicate that it has been more than thirty (30) days since CSC notified you of the necessary correction(s), and we have not received a response from you. Therefore, your application will be voided as an inactive, incomplete application for enrollment. There will be instances where the application is completed in processing but the follow-up status of Incomplete was not removed. Please contact CSC for verification and investigation.*

If you have questions regarding the notice, please contact the CSC EVC Call Center (1-866-844-1113) and reference the Enrollment Tracking Number (ETN) indicated in the final notice. Customer service agents are available Monday through Friday, 8:00 a.m. through 5:00 p.m. Eastern Time, at 1-866-844-1113.

## **Update on the N.C. Health Information Technology Plan and Schedule**

### **Background**

On February 17, 2009, President Obama signed the American Recovery and Reinvestment Act of 2009 (Recovery Act), a critical measure to stimulate the economy. Among other provisions, the new law provides major opportunities for the Department of Health and Human Services (DHHS), its partner agencies, and the states to improve the nation's health care through health information technology (HIT) by promoting the meaningful use of electronic health records (EHR) via incentives. The Final Rule outlining the provisions of this program was published in the July 28, 2010, Federal Register. A copy of that rule can be found on DMA's EHR web page (<http://www.ncdhhs.gov/dma/provider/ehr.htm>).

### **Schedule for EHR Incentive Payments**

DMA is creating a system called North Carolina Medicaid Incentive Payment System (NC MIPS) that will accept registration data from providers, perform the processing to verify the eligibility of providers to receive an incentive payment, and calculate the payment amount. Providers will be able to begin registration with NC MIPS beginning January 1, 2011, via a web page linked from DMA's website. On April 1, 2011, NC MIPS will begin processing the actual payments and funds will be sent to those providers who have met the eligibility requirements of the EHR Incentive Payment Program.

### **Additional Information**

Frequently asked questions (FAQs) on the Final Rule are available on DMA's EHR web page. These questions and answers provide an excellent overview of the main provisions of the Medicaid providers EHR Incentive Program. Additional FAQs are also available from CMS (<http://questions.cms.hhs.gov/app/answers/list/p/21,26,1058>).

The CSC EVC Call Center will also answer questions at this toll-free number: 1-866-844-1113.

### **Enrollment Fee Clarification**

As mandated by Session Law 2009-451, beginning September 1, 2009, the N.C. Medicaid Program implemented a \$100 enrollment fee for all new enrollments and at 3-year intervals when providers are re-credentialed.

**APPLICANTS SHOULD NOT SUBMIT PAYMENT WITH THEIR APPLICATION.** Upon receipt of your enrollment application, an invoice will be mailed to you if the fee is owed. An invoice will only be issued if the tax identification number in the enrollment application does not identify the applicant as a currently enrolled Medicaid provider.

Providers are reminded that payment

- is due immediately upon receipt of an invoice for the enrollment fee;
- should be remitted to the address on the invoice and not directly to CSC; and
- is accepted by check or money order made payable to DMA.

Please make every effort to remit payment promptly. Applications will not be processed if payment is not received. If payment is not received within 30 days of the date on the invoice, your application will be voided and you will be required to reapply.

### **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 labelers have entered into a Drug Rebate Agreement and have joined the rebate program effective on the date indicated below:

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
23360	Akorn Strides	11/10/2010
51477	Nesher Pharmaceuticals, Inc	11/09/2010

#### **Voluntarily Terminated Labeler**

The following labeler has requested voluntary termination effective January 1, 2011:

Smith & Nephew, Inc (Labeler 50484)

The following labeler has requested voluntary termination effective April 1, 2011:

Advanced Vision Research (Labeler 58790)

### Checkwrite Schedule

November 02, 2010	December 02, 2010
November 09, 2010	December 07, 2010
November 18, 2010	December 14, 2010
	December 22, 2010

### Electronic Cut-Off Schedule

October 28, 2010	November 24, 2010
November 04, 2010	December 02, 2010
November 10, 2010	December 09, 2010
	December 16, 2010

*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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