ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Program Planning & Development

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OFFICIAL NOTICE

DMS-2007-A-5	**DMS-2007-0-6**	**DMS-2007-HH-2**	**DMS-2007-CA-4**
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DMS-2007-EE-3	**DMS-2007-S-1**	**DMS-2007-Y-2**	
DMS-2007-00-6	**DMS-2007-T1**		

TO: **Health Care Provider – Ambulatory Surgical Centers; Arkansas Department of Health; Certified Nurse-Midwife; Certified Registered Nurse Anesthetist (CRNA); Critical Access Hospital; End-Stage Renal Disease; Family Planning; Federally Qualified Health Center (FQHC); Home Health; Hospital; Independent Radiology; Nurse Practitioner; Oral Surgeon; Pharmacy; Physician; Podiatry; Private Duty Nursing; Prosthetics; Rehabilitative Hospital; Rural Health Clinic (RHC); Transportation**

DATE: **October 24, 2007**

SUBJECT: **Implementation of the Federal Deficit Reduction Act of 2005, Requiring National Drug Codes (NDC) When Billing Drug Procedure Codes**

I. Background

The Federal Deficit Reduction Act of 2005 mandates that Arkansas Medicaid require the submission of National Drug Codes (NDCs) on claims submitted with Health Care Financing Administration Common Procedure Code System, Level II/Current Procedural Terminology, 4th edition (HCPCS/CPT) codes for **drugs** administered. The purpose of this requirement is to assure that the State Medicaid Agencies obtain a rebate from those manufacturers who have signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS).

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid will implement billing protocol per the Federal Deficit Reduction Act of 2005. This official notice will explain changes in policy and billing protocol for providers that submit claims for drug HCPCS/CPT codes.

A. Covered Labelers

Arkansas Medicaid, by statute, will only pay for a drug procedure billed with an NDC when the pharmaceutical labeler of that drug is a covered labeler with Centers for Medicare & Medicaid Services (CMS). A "covered labeler" is a pharmaceutical manufacturer that has entered into a federal rebate agreement with CMS to provide each State a rebate for products reimbursed by Medicaid Programs. A covered labeler is identified by the first 5 digits of the NDC. To assure a product is payable for administration to a Medicaid beneficiary, compare the labeler code (the first 5 digits of the NDC) to the list of covered labelers which is maintained on the Arkansas Medicaid website.

A complete listing of **"Covered Labelers"** is located on the Arkansas Medicaid Web page at www.medicaid.state.ar.us, click on Provider Services, select Prescription Drug information, and then select Covered Labelers. See Diagram 1 for an example of this screen. The effective date is when a manufacturer entered into a rebate agreement with CMS. The *Labeler termination date* indicates that the manufacturer no longer participates in the federal rebate program and therefore the products cannot be reimbursed by Arkansas Medicaid on or after the *termination date*.

Diagram 1

LABELER CODE	LABELER NAME	EFFECTIVE DATE	TERMINATION DATE
00002	ELI LILLY AND COMPANY	1/1/1991	
00003	E.R. SQUIBB & SONS, INC	1/1/1991	
00004	HOFFMANN-LA ROCHE	1/1/1991	
00005	LEDERLE LABORATORIES	1/1/1991	
00006	MERCK & CO., INC.	1/1/1991	
00007	GLAXOSMITHKLINE	1/1/1991	
00008	WYETH LABORATORIES	1/1/1991	
00009	PFIZER, INC.	1/1/1991	
00011	BECTON DICKINSON MICROBIOLOGY SYSTEMS	10/1/1991	7/1/1998
00013	PFIZER, INC.	1/1/1991	

In order for a claim with drug HCPCS/CPT codes to be eligible for payment, the detail date of service must be prior to the *NDC termination date*. The NDC termination date represents the shelf-life expiration date of the last batch produced, as supplied on the Centers for Medicare and Medicaid Services (CMS) quarterly update. The date is supplied to CMS by the drug manufacturer/distributor.

Arkansas Medicaid will deny claim details with drug HCPCS/CPT codes with a detail date of service equal to or greater than the NDC termination date.

When completing a Medicaid claim for administering a drug, indicate the HIPAA standard 11-digit NDC with no dashes or spaces. The 11-digit NDC is comprised of three segments or codes: a 5-digit labeler code, a 4-digit product code and a 2-digit package code. The 10-digit NDC assigned by the FDA printed on the drug package must be changed to the 11-digit format by inserting a leading zero in one of the three segments. Below are examples of the FDA assigned NDC on a package changed to the appropriate 11-digit HIPAA standard format. Diagram 2 displays the labeler code as

five digits with leading zeros; the product code as four digits with leading zeros; the package code as two digits without leading zeros, using the "5-4-2" format.

Diagram 2

00123	0456	78
LABELER CODE (5 digits)	**PRODUCT CODE (4 digits)**	**PACKAGE CODE (2 digits)**

NDCs submitted in any configuration other than the 11 digit format will be rejected/denied. *NDCs billed to Medicaid for payment must use the 11 digit format without dashes or spaces between the numbers.*

See Diagram 3 for sample NDCs as they might appear on drug packaging and the corresponding format which should be used for billing Arkansas Medicaid:

Diagram 3

10-digit FDA NDC on PACKAGE	Required 11-digit NDC (5-4-2) Billing Format
12345 6789 1	1234567890**0**1
1111-2222-33	**0**1111222233
01111 456 71	01111**0**45671

B. Drug Procedure Code (HCPCS/CPT) to NDC Relationship and Billing Principles

HCPCS/CPT codes and any modifiers will continue to be billed per the policy for each procedure code. However, the NDC and NDC quantity of the administered drug is now also required for correct billing of drug HCPC/CPT codes. To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS/CPT codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied. We encourage you to enlist the cooperation of all staff members involved in drug administration to assure collection or notation of the NDC from the actual package used. It is not recommended that billing of NDCs be based on a reference list, as NDCs vary from one labeler to another, from one package size to another, and from one time period to another.

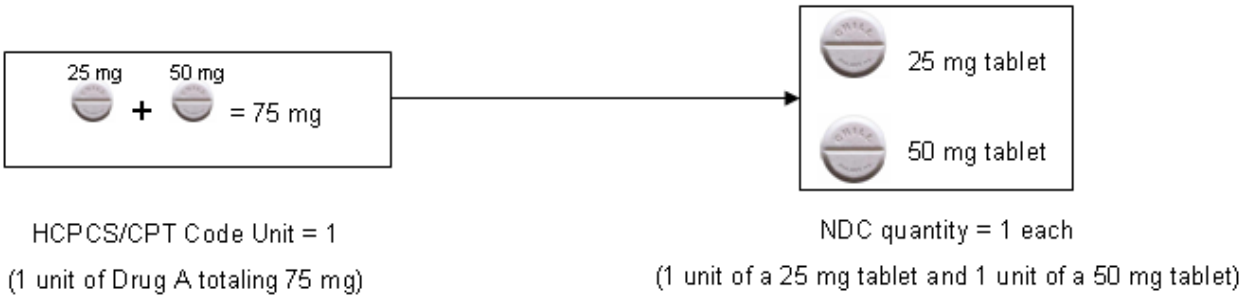
Exception: There is no requirement for an NDC when billing for vaccines.

II. Claims Filing

The HCPCS/CPT codes billing units and the NDC quantity do not always have a one-to-one relationship.

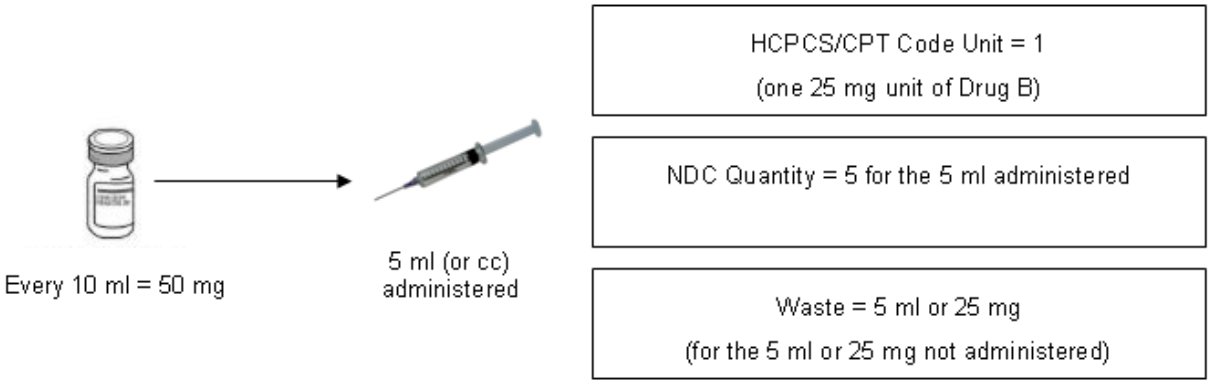
Example 1: The HCPCS/CPT code may specify up to 75 mg of the drug whereas the NDC quantity is typically billed in units, milliliters or grams. If the patient is provided 2 oral tablets, one at 25 mg and one at 50 mg, the HCPCS/CPT code unit would be 1 (1 total of 75 mg) in the example whereas the NDC quantity would be 1 each (1 unit of the 25 mg tablet and 1 unit of the 50 mg tablet). See Diagram 4.

Diagram 4



Example 2: If the drug in the example is an injection of 5 ml (or cc) of a product that was 50 mg per 10 ml of a 10 ml single-use vial, the HCPCS/CPT code unit would be 1 (1 unit of 25 mg) whereas the NDC quantity would be 5 (5 ml). In this example, 5 ml or 25 mg would be documented as wasted. See Diagram 5.

Diagram 5



A. Electronic Claims Filing – 837P (Professional) and 837I (Outpatient)

Electronic claims can be filed with a maximum of 5 NDCs per detail.

Procedure codes that do not require paper billing may be billed electronically. Any procedure codes that have required modifiers in the past will continue to require modifiers.

Arkansas Medicaid will require providers using Provider Electronic Solutions (PES) to use the required NDC format when billing HCPCS/CPT codes for administered drugs.

When billing multiple NDCs, the HCPCS/CPT should reflect the total charges and units of all administered NDCs. The NDC fields should reflect the price and units of each specific NDC, up to a maximum of five NDCs per detail.

1) For 837P professional claims, from the Service 2 tab, in the RX Indicator field, select "Y" to open the RX tab. On the RX tab, enter the NDC, Unit of Measure, Quantity and Price for each NDC.

2) For 837I outpatient claims, from the Service tab, in the RX Indicator field, select "Y" to open the RX tab. On the RX tab, enter the NDC, Unit of Measure, Quantity and Price for each NDC.

If billing electronic claims using vendor software, check with your vendor to ensure your software will be able to capture the criteria necessary to submit these claims. Vendor companion guides are located on the Arkansas Medicaid Web page at https://www.medicaid.state.ar.us/ . Click on Provider, select HIPAA, select Documents for vendors and then select Companion guides.

B. Paper Claims Filing – CMS-1500 and CMS-1450 (UB-04)

Arkansas Medicaid will require providers billing drug HCPCS/CPT codes including covered unlisted drug procedure codes to use the required NDC format.

See Diagram 6 for CMS-1500 and Diagram 7 for CMS-1450 (UB-04).

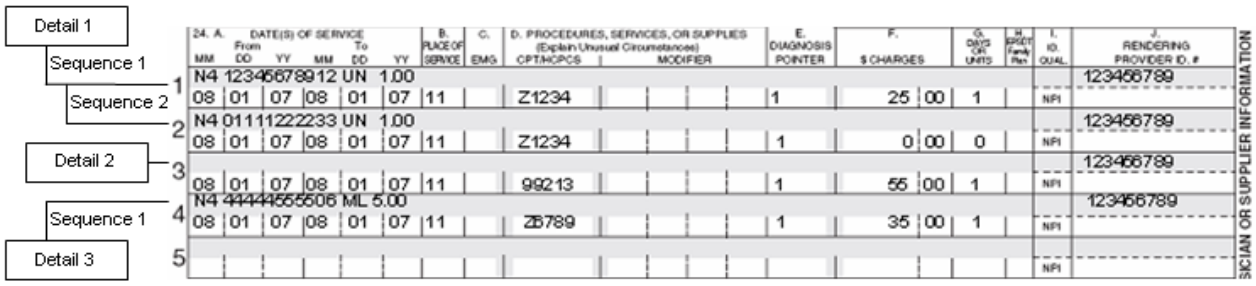
CMS-1500

For professional claims, CMS-1500, list the qualifier of "N4", the 11-digit NDC, the unit of measure qualifier (F2 - International Unit; GR - Gram; ML - Milliliter; UN - Unit), and the number of units of the actual NDC administered in the shaded area above detail field 24A, spaced & arranged exactly as in Diagram 6.

Each NDC, when billed under the same procedure code on the same date of service is defined as a "sequence". When billing a single HCPCS/CPT code with multiple NDCs as detail sequences, the first sequence should reflect the total charges in the detail field 24F and total HCPCS/CPT code units in detail field 24G. Each subsequent sequence number should show zeros in detail fields 24F and 24G. See Detail 1, sequence 2 in Diagram 6.

The quantity of the NDC will be the total number of units billed for each specific NDC. See Diagram 6, first detail, sequences 1 and 2. Detail 2 is a Procedure Code that does not require an NDC. Detail 3, sequence 1 gives an example where only one NDC is associated with the HCPCS/CPT code.

Diagram 6



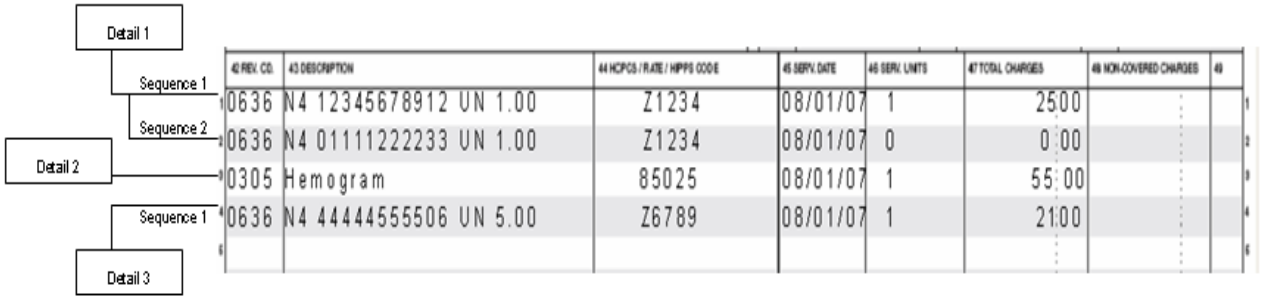
CMS-1450 (UB-04)

For institutional outpatient claims on the UB-04, use the locator field 43 (Description) to list the qualifier of "N4", the 11-digit NDC, the unit of measure qualifier (F2 - International Unit; GR - Gram; ML - Milliliter; UN - Unit), and number of units of the actual NDC administered, spaced & arranged exactly as in Diagram 7.

Each NDC, when billed under the same procedure code on the same date of service is defined as a "sequence". When billing a single HCPCS/CPT code with multiple NDCs as detail sequences, the first sequence should reflect the total charges in the detail locator field 47 and total HCPCS/CPT code units in locator field 46. Each subsequent sequence number should show zeros in locator fields 46 and 47. See Detail 1, sequence 2 in Diagram 7.

The quantity of the NDC will be the total number of units billed for each specific NDC. See Diagram 7, first detail, sequences 1 and 2. Detail 2 is a Procedure Code that does not require an NDC. Detail 3, sequence 1 gives an example where only one NDC is associated with the HCPCS/CPT code.

Diagram 7



Procedure Code/NDC Detail Attachment Form- DMS-664

For drug HCPCS/CPT codes requiring paper billing (i.e., for manual review), complete every field of the DMS-664 "Procedure Code/NDC Detail Attachment Form." Attach this form and any other required documents to your claim when submitting it for processing. See Diagram 8 for an example of the completed form. A copy of form DMS-664 is attached and may be copied for claim submission. Copies of the DMS-664 will not be provided. Section V of the provider manual will be updated to include this form.

Diagram 8

Detail #	Sequence #	NDC											Proc Code /Modifier	Drug Name/Dose/Route	Wasted
1	1	1	2	3	4	5	6	7	8	9	1	2	Z1234	ABC drug/25 MG/Oral	0
1	2	0	1	1	1	1	2	2	2	2	3	3	Z1234	XYZ drug/50 MG/Oral	0
3	1	4	4	4	4	4	5	5	5	5	0	6	Z6789	PRQ drug/5 ML/IV	5 ML

III. Adjustments

Paper adjustments for paid claims filed with NDC numbers will not be accepted. Any original claim will have to be voided and a replacement claim will need to be filed. Providers have the option of adjusting a paper or electronic claim electronically.

IV. Remittance Advices

Only the first sequence in a detail will be displayed on the remittance advice reflecting either the total amount paid or the denial EOB(s) for the detail.

V. Drug Efficacy Study Implementation (DESI) Drugs

The Federal Drug Administration (FDA) reviews the effectiveness of drugs approved between 1938 and 1962 through a program named the Drug Efficacy Study Implementation (DESI) program. Drugs that were approved by the FDA before 1962 were permitted to remain on the market while evidence of their effectiveness was reviewed. If the DESI review indicates a lack of substantial evidence of a drug's effectiveness, the FDA will publish its proposal to withdraw approval of the drug for marketing. In accordance with Section 1903(i)(5) of the Social Security Act, federal funds participation (FFP) is not available for Less than Effective (LTE) drugs or the Identical, Related or Similar (IRS) drugs identified by the FDA and published quarterly by the Centers for Medicare & Medicaid Services

This means that any HCPCS/CPT code will not be payable when linked to any NDC with a DESI indicator. If it is determined that all NDCs linked to a specific HCPCS/CPT are DESI, this is an instance where the procedure code will no longer be payable.

A list of "DESI" drugs with the effective and end dates will be on the Arkansas Medicaid website. From the main page, click "Provider," then select "Prescription Drug Information" and then select "DESI NDCs (non-payable) associated with HCPCS/CPT Codes." See Diagram 9 for an example of the DESI list.

Diagram 9

ARKANSAS MEDICAID

DESI NDCs (non-payable) associated with HCPCS/CPT Codes

For further information -- please contact EDS Pharmacy Help Desk -- 1-800-707-3854

Last Updated 10/15/2007

NDC	DESI Drug Begin Date	Drug Label Name	Drug Manufacturer Name	HCPCS/CPT
00009025302	11/17/2003	DEPO-TESTADIOL VIAL	PHARMACIA/UPJHN	J1060

VI. Record Retention

Each provider must retain all records for five (5) years from the date of service or until all audit questions, dispute or review issues, appeal hearings, investigations or administrative/judicial litigation to which the records may relate are concluded, whichever period is longer.

At times, a manufacturer may question the invoiced amount, which results in a drug rebate dispute. If this occurs, you may be contacted requesting a copy of your office records to include documentation pertaining to the billed HCPCS/CPT code. Requested records may include NDC invoices showing purchase of drugs and documentation showing what drug (name, strength and amount) was administered and on what date, to the beneficiary in question.

Thank you for your participation in the Arkansas Medicaid Program.

If you need this material in an alternative format, such as large print, please contact our Americans with Disabilities Act Coordinator at (501) 682-8323 or (501) 682-6789 (TDD).

If you have questions regarding this notice, please contact the EDS Provider Assistance Center at In-State WATS 1-800-457-4454, or locally and Out-of-State at (501) 376-2211.

*Arkansas Medicaid provider manuals, official notices and remittance advice (RA) messages are available for downloading from the Arkansas Medicaid website: **www.medicaid.state.ar.us**.*

Roy Jeffus, Director

Procedure Code/NDC Detail Attachment Form

This form is an attachment for Arkansas Medicaid paper claims billed with HCPCS or CPT drug procedure codes that require review.

These claims are filed on a CMS-1500 (HCFA-1500) or a CMS-1450 (UB-04).

Recipient Name _____ Recipient ID_____

Provider Name _____ Provider ID_____

Detail #	Sequence #	NDC											Proc Code /Modifier	Drug Name/Dose*/Route	Wasted

Please fill in: The corresponding **detail and sequence** number from the CMS-1500 (HCFA-1500) or a CMS-1450 (UB-04).

- NDC number used
- Procedure code and any modifiers
- Name of drug administered
- *Dosage administered **(consider <u>strength</u> of NDC when recording dose)**
- Route of administration
- Amount of drug wasted

DMS-664(1/08)