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SUBJECT:	Notice of Changes to Billing Requirements for Drugs Administered in Outpatient Clinical
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TO:	Stakeholders
DATE:	April 6, 2012 (Revised 9/10/2012)

Effective July 1, 2012, AHCCCS is implementing new billing requirements for drugs administered in outpatient clinical settings. These requirements are in accordance with and support of the Federal Deficit Reduction Act of 2005, which mandates that all providers submit the National Drug Code (NDC) on all claims with procedure codes for physician-administered drugs in outpatient clinical settings. These services are currently represented on submitted claims by the use of the Healthcare Common Procedure Coding System (HCPCS) codes.

Background

The Deficit Reduction Act of 2005 (DRA) included new provisions regarding State collection of data for the purpose of collecting Medicaid drug rebates from drug manufacturers for physician-administered drugs. Section 6002 of the DRA adds section 1927(a)(7) to the Social Security Act to *require* States to collect rebates on physician-administered drugs. In order for Federal Financial Participation (FFP) to be available for these drugs, the State must provide collection and submission of utilization data in order to secure rebates. Since there are often several NDCs linked to a single HCPCS code, the Centers for Medicare and Medicaid Services (CMS) deem that the use of NDC numbers is critical to correctly identify the drug and manufacturer in order to invoice and collect the rebates.

NDC Definition

The National Drug Code (NDC) is the number which identifies a drug. The NDC number consists of 11 digits in a 5-4-2 format. The first 5 digits identify the labeler code representing the manufacturer of the drug and are assigned by the Food and Drug Administration (FDA). The next 4 digits identify the specific drug product and are assigned by the manufacturer. The last 2 digits define the product package size and are also assigned by the manufacturer. Some packages will display less than 11 digits, but leading "0's" can be assumed and need to be used when billing. For example:

XXXX-XXXX-XX = 0XXXX-XXXX-XX XXXX-XXX-XX = XXXX-0XXX-XX XXXX-XXXX-X = XXXXX-XXX-0X

The NDC is found on the drug container, i.e. vial, bottle, tube. The NDC submitted to the AHCCCS FFS Program and/or MCO Contractors must be the actual NDC number on the package or container from which the medication was administered. Claims may *not* be submitted for one manufacturer when a different manufacturer's product was administered. It is considered a fraudulent billing practice to bill using an NDC other than the one assigned to the drug administered.

When submitting a Medicaid claim for administering a drug, providers must submit the 11-digit NDC without dashes or spaces between the numbers. Claims submitted with NDCs in any other configuration may fail.

Providers of "physician-administered" drugs

Providers of "physician-administered" drugs include any AHCCCS registered provider whose license and scope of practice permits the administration of drugs, such as a medical doctor (MD), doctor of osteopathic medicine (DO), nurse practitioner (NP), physician assistant (PA), ambulatory surgery centers (ASCs), hospital outpatient clinic/services and skilled nursing facilities (SNFs).

Exception: IHS /tribally operated 638 facilities reimbursed at the federally the published all-inclusive rate.

HCPCS codes that will require the NDC information on the claim submission

Drugs billed using HCPCS codes include:

- A, C, J, Q and S codes as applicable.
- "Not otherwise classified" (NOC) and "Not otherwise specified" (NOS) drug codes (e.g., J3490, J9999, and C9399).
- CPT codes, 90281-90399 for immune globulins
- CPT Codes 90476-90749 for vaccines and toxoids

In order to comply with this mandate, contractors and providers **must** do the following, effective for the dates of service on or after July 1, 2012:

- Providers **must** submit a valid 11-digit NDC when billing a HCPCS drug or CPT procedure code as defined above.
- The qualifier "N4" must be entered in front of the 11-digit NDC. The NDC will be submitted on the same detail line as the CPT/HCPCS drug procedure code in the pink shaded area.

Revenue Center Codes affected

To support the NDC claims submission requirements, the following Revenue Center Codes may require a CPT or HCPCS code for administration of the drug and reporting of the specific NDC and quantity:

- 0250-259
- 0262
- 0263
- 0331
- 0332
- 0335
- 0634-0637

NDC quantity to be billed and claims elements required

NDC units are based on the numeric quantity administered to the patient and the unit of measurement. The actual metric decimal quantity administered and the unit of measurement is required for billing. If reporting a fraction, use a decimal point. The units of measurement codes are as follows:

- NDC of the drug administered as described above
- NDC Unit of Measure
 - \circ **F2** = International Unit
 - **GR** = Gram usually for products such as ointments, creams, inhalers, or bulk This unit of measure is typically used in the retail pharmacy setting.
 - \circ ML = Milliliter for drugs that come in vials which are in liquid form
 - \circ UN = Unit (each) for unit of use preparations, generally those that must be reconstituted prior to administration.
- Quantity administered equals number of NDC units

Note: Providers must also continue to submit Revenue Codes, HCPCS codes and related service units in addition to the required NDC information.

HCPCS to NDC quantity conversion examples:

HCPCS	NDC	Quantity Conversion				
J9305	00002762301	HCPCS code is per 10mg and the product comes as a dry powder inject				
		500mg.				
		NDC units are "each vial"				
		Dose was 100 mg, for example				
		HCPCS quantity = 10 and the NDC quantity = $100/500 = 0.2$				
		Enter: N400002762301 UN0.2 on the CMS-1500.				
J3110	00002897101	HCPCS code is for 10mcg and the product comes as 250mcg/ml				
		NDC units are ml				
		Dose was 750mcg				
		HCPCS quantity = 75 and the NDC quantity = 3				
		Enter: N400002897101 ML3 on the CMS-1500.				
J1745	57894003001	HCPCS code is for 10mg and product comes as 100mg powder for injection.				
		NDC units are "each vial"				
		Dose was 200mg				
		HCPCS quantity = $20 (20 \times 10 \text{mg}) = 200 \text{mg}$ and the NDC quantity is 2. This				
		is true even if the dry powder was reconstituted to 20ml.				
		Enter: N457894003001 UN2 on the CMS-1500.				

Note: Payment is based on the quantity of J code units administered.

Paper Billing Instructions

Beginning with dates of service on or after 7/1/2012, all institutional (UB04/837I) and professional (CMS-1500/837P) claims must include the following information:

- NDC and unit of measurement for the drug billed, and
- HCPCS/CPT code and units of service for the drug billed, and
- The actual metric decimal quantity administered.

UB04 Claim Form

To report the NDC on the UB04 claim form, enter the following information into the Form Locator 43 (Revenue Code Description):

- The NDC Qualifier of N4 in the first 2 positions on the left side of the field.
- The NDC 11-digit numeric code, without hyphens.
- The NDC Unit of Measurement Qualifier (as listed above)
- The NDC quantity, administered amount, with up to three decimal places (i.e., 1234.456). Any unused spaces are left blank.

The information in the Revenue Description field is 24 characters in length and is entered without delimiters, such as commas or hyphens.

Form Locator 44 (HCPCS/Rate/HIPPS code): Enter the corresponding HCPCS code associated with the • NDC.

Γ	42. REV. CD.	43. DESCRIPTION	44. HCPCS/RATES	46. SERV. UNITS
1	0250	N400074115278 ML10	J1642	2.00
2				
3				

Form Locator 46 (Serv Units/HCPCS Units): Enter the number of HCPCS units administered.

CMS-1500 Claim Form

To report the NDC on the CMS-1500 claim form, enter the following information:

- In Field 24A of the CMS-1500 Form in the shaded area, enter the NDC Qualifier of N4 in the first 2 positions, followed by the 11-digit NDC (no dashes or spaces) and then a space and the NDC Units of Measure Qualifier, followed by the NDC Quantity. All should be left justified in the pink shaded area above the Date of Service.
- The billed units in column G (Days or Units) should reflect the HCPCS units and not the NDC units. • Billing should not be based off the units of the NDC. Billing based on the NDC units may result in underpayment to the provider.

Example of CMS1500 Paper Claims

24.	А					В	С	D	
DAT	DATE(S) OF SERVICE					Place		PROCEDURE,	SERVICES, OR SUPPLIES
From					of	EMG	(Explain Unusual Circumstances)		
MM	DD	YY	MM	DD	Y	Service		CPT/HCPCS	MODIFIER
					Y				
N400	N400074115278 ML10								
07	01	12	07	01	12	11		J1642	

Note: Submission of multiple NDCs per HCPCS is not allowed.

Electronic Billing Instructions

837 Claims Submission for NDC:

837 Drug Identification					
Loop	Segment	Field Name	Requirement		
2410	LIN02	Prod/Serv ID Qualifier	A value of "N4" is expected.		
2410	LIN03	Prod/Service ID	An 11-digit NDC number is expected and will be mapped to the CPDNDC Prod/Service ID.		
2410/2400	CTP04/ SV104	Quantity	The quantity is expected and will be mapped to CPDNDC quantity. If the unit price on segment CTP03 is different than the unit price on the SV102, then map CTP04; otherwise map SV104.		
2410/2400	CTP05/ SV103	Composite Unit of Measure	The composite unit of measure is expected and will be mapped to CPDNDC composite unit of measure. If the unit price on segment CTP03 is different than the unit price on the SV203, then map CTP04; otherwise map SV103.		

Note: Submission of multiple NDCs per HCPCS is <u>not</u> allowed.

Remittance Advice if NDC is Submitted Incorrectly

If the NDC billing information is missing or invalid, claims may fail. AHCCCS FFS Providers and MCO Contractors will have to resubmit the claim(s) with the required NDC information and/or correct number of units within the time allowed for potential payment.

For Your Information:

- Vendor software submitters please check with your vendor to ensure your software will be able to capture the criteria necessary to submit the 837 with the required NDC information.
- Revised CMS 1500 paper, 837 and on-line billing guidelines will be posted to the AHCCCS website shortly after the release of this notice.
- Training will be provided to FFS providers and MCO staff prior to 7/1/2012 as needed.

If you have any questions or need additional clarification regarding this notice please email:

AHCCCSNDCData@azahcccs.gov.