

PROVIDER BULLETIN

NO. 08-03

January 31, 2008

TO: Physicians, Mid-level Practitioners, and Clinics Administering Medications

FROM: Vivianne M. Chaumont, Director
Division of Medicaid and Long-Term Care
Department of Health and Human Services

RE: **National Drug Code (NDC) Requirements for Physician Administered Medication**

Please share this information with administrative, clinical and billing staff.

Many of you have already been including the NDC's on claims for medications administered in your clinics per the 1/1/2007 claim form completion instructions. To date, NE Medicaid had been able to submit for rebates on "single source" drugs, i.e. drugs for which there is only one NDC for one HCPCS code. However, the federally mandated rebate submission has been expanded to include those drugs that have numerous NDC's for each HCPCS. This bulletin will clarify the "why and what" of the NDC requirement and discuss the necessity of NDC submission.

The Deficit Reduction Act of 2005 (DRA) requires states to collect rebates for physician administered drugs. As a result, states must now collect the 11-digit NDC on all outpatient claims for drugs administered during the course of a patient's clinic visit. Providers are required to submit their claims with the exact NDC that appears on the product administered. The NDC is found on the medication's packaging and must be submitted in the 5digit-4digit-2digit format.

Nebraska Medicaid's coverage and pricing procedures have not changed with regard to medications administered in the clinical setting. Please refer to the provider manuals available online at <http://hhss.ne.gov/reg/t471.htm> for policy guidelines for each program.

Please see the following 'Question and Answer' section for answers to most common questions/concerns. If you have further questions or concerns about this information, please contact Lorelee Novak at (402) 471-9368 regarding the CMS 1500 or 837 P claims or Margaret Booth at (402) 471-9380 regarding UB or 837 I claims.

NDC AND HCPCS FREQUENTLY ASKED QUESTIONS

1. Why do I have to bill with National Drug Codes (NDCs) in addition to Healthcare Common Procedure Coding System (HCPCS) codes?

As previously mentioned, the Deficit Reduction Act of 2005 (DRA) includes provisions regarding state collection of data for the purpose of collecting Medicaid drug rebates from drug manufacturers for physician-administered drugs. States are **required** to collect rebates on physician-administered drugs in order for Federal Financial Participation (FFP) funds to be available for these drugs. 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.

2. What is the Drug Rebate Program?

The Medicaid Drug Rebate Program was created by the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and became effective 1/1/1991. The law requires that drug manufacturers enter into an agreement with CMS to provide rebates for their drug products that are paid for by Medicaid. Outpatient Medicaid pharmacy providers have billed with NDCs and submitted for rebates since 1991. The DRA has now expanded the rebate requirement to physician-administered drugs.

3. What is an NDC?

The 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 manufacturer of the drug and are assigned by the Food and Drug Administration. The remaining digits are assigned by the manufacturer and identify the specific product and package size. 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

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

XXXXX-XXXX-X = XXXXX-XXXX-0X

The NDC is found on the drug container, i.e. vial, bottle, tube. The NDC submitted to Medicaid must be the actual NDC number on the package or container from which the medication was administered. Do not bill for one manufacturer's product and dispense another. The benefits of accurate billing include reduced audit, telephone calls and manufacturers dispute of their rebate invoices. It is considered a fraudulent billing practice to bill using an NDC other than the one administered.

4. Does the drug administered by the physician and billed to Medicaid with an NDC have to be a "rebateable" drug?

At the present time the Department will reimburse for medications administered and billed by the physician regardless of the rebate status of the product used. However, in the future Medicaid may reimburse only for rebateable drugs. Check the website listed in Question 5 to become familiar with manufacturers who have signed a rebate agreement with CMS and their products.

5. How do I know if a drug is rebateable?

You may refer to the Centers for Medicare and Medicaid website at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/I0DrugComContactInfo.asp> to determine if an NDC is manufactured by a company that participates in the Federal Drug Rebate Program. The list of manufacturers that supply rebateable drugs can change quarterly.

6. Will my claim be denied or rejected if the drug is non-rebateable?

Not at this time.

7. Do I need to include units for both the HCPCS code and the NDC?

Yes. Provider reimbursement is based on the HCPCS description and units of service. The State's mandated rebate submission is based on the NDC and those units.

8. Are the HCPCS code units different from the NDC units?

Yes.

Use the HCPCS code and service units as you have in the past; this is the basis for your reimbursement.

NDC units are based upon the numeric quantity administered to the patient and the unit of measurement. The unit of measurement (UOM) codes are:

F2 = International Unit

GR=Gram

ML = Milliliter

UN = Unit (Each)

The actual metric decimal quantity administered and the unit of measurement are required for billing. If reporting a fraction, use a decimal point. For example: Three 0.5ml vials are dispensed, the correct quantity to bill is 1.5 ml.

9. If the physician administered a vial of medication to a patient, do I bill the NDC units in grams, milliliters, or units?

It depends on how the manufacturer and CMS have determined the rebate unit amount. The rule of thumb is:

- If a drug comes in a vial in powder form and has to be reconstituted before administration, then bill each vial (unit/each) used. (UN)
- If a drug comes in a vial in a liquid form, bill in milliliters. (ML)
- Grams are usually used when an ointment, cream, inhaler, or a bulk powder in a jar are dispensed. This unit of measure will primarily be used in the retail pharmacy setting and not for physician-administered drug billing. (GR)
- International Units will mainly be used when billing for Factor VIII-Antihemophilic Factors. (F2)

For example:

1. A patient received 4 mg Zofran IV in the physician's office. The NDC you used was 00173-0442-02, which is Zofran 2 mg/ml in solution form. There are 2 milliliters per vial. You would bill J2405 (ondansetron hydrochloride, per 1 mg) with 4 HCPCS units, and since this drug comes in a liquid form, you would bill the NDC units as 2 milliliters. (ML2)

2. A patient received 1gram of Rocephin IM in the physician's office. The NDC of the product used was 00004-1963-02, which is Rocephin 500 mg vial in a powder form that you needed to reconstitute before the injection. You would bill J0696 (ceftriaxone sodium, per 250 mg) with 4 HCPCS units, and since this drug comes in powder form, you would bill the NDC units as 2 Units (also called 2 Each). (UN2)

Please note: NDCs listed above have hyphens between the segments for easier visualization. When submitting NDCs on claims, submit as an eleven digit number with no hyphens or spaces between segments.

10. How will NDC information be billed on electronic and paper claims forms?

See billing instructions for the paper claim forms on the Nebraska Medicaid website at:

<http://www.hhss.ne.gov/reg/appx/atc471.htm>

This will bring you to Title 471 Appendix material. Then you may choose the instructions you need.

You may bill claims electronically through your clearinghouse using your Companion Guide as a reference.

11. If the NDC is not rebateable or I am not sure which NDC was used, can I pick another NDC under the J-Code and bill with it?

No. The NDC submitted to Medicaid must be the actual NDC number on the package or container from which the medication was administered. It is considered a fraudulent billing practice to bill using an NDC other than the one administered.

12. Do radiopharmaceuticals or contrast media require an NDC?

Not at this time. CMS has been asked for clarification as to whether or not these agents will be included in the rebate program and until that information is provided, these agents will not require NDCs.

13. Do vaccines/immunizations require an NDC?

No. Vaccines are not included in the rebate requirements.

14. Are Medicare primary claims excluded from the NDC requirement?

No. Medicare primary claims will require NDCs with the HCPCS codes.

15. Do dentists need to bill with both HCPCS codes and NDC numbers?

No. Use of NDCs with HCPCS codes is not applicable to dentists.

16. Do anesthesia drugs require NDCs?

Not when the drugs used for local anesthesia, or conscious sedation are bundled together under other codes. If these drugs are billed separately, the NDC is required.

18. Do I bill the HCPCS code and NDC of a drug if I just administer the drug?

No. For example, if the patient brings an allergy extract from his allergist to have the family physician administer it, the drug may not be billed by the family physician. The family physician should only bill for the administration of the drug. The allergist would have already billed for the drug.

19. How do I bill for a drug when only a partial vial was administered?

The HCPCS procedure code used for reimbursement with corresponding units should be billed in order for you to be properly reimbursed for the drug.

When calculating the NDC units, the HCPCS procedure code units should be converted to the NDC units, using the proper decimal units.

For example:

If the previously mentioned patient (see Question 10) received only 2 mg of Zofran and you used the same NDC which is Zofran 2 mg/ml in a 2 ml vial, the billing would look like this:

HCPCS J2405 (ondansetron hydrochloride, per 1 mg) 2 units

NDC 00173044202 ML1

20. What happens if I enter incorrect NDC units?

Claims continue to process using the procedure code units and no adverse effects should be noticed by the provider. Rebates will be billed to manufacturers by cross walking the procedure code units. However, in the future, this may not be the case and it is important for providers to become familiar with the correct UOM and how to determine the NDC units.

22. My clinic is associated with a 340B participating hospital. Do I need to submit NDC codes for drug claims?

Yes. 340B providers are not addressed by the DRA, nor has CMS made a ruling regarding the exclusion of 340B providers from this program. Until a ruling is issued on a federal level, 340B providers are not excluded from this program.

23. I have heard that only 20 products will require rebates. Can I just submit NDCs for those 20 products?

No. While it is true that at this time, states will be mandated to submit for rebates on 20 drugs, they are encouraged to expand their rebate program beyond that and Nebraska Medicaid intends to do so.

The "mandatory 20" will change yearly, to simplify billing for providers and processing for the Department, claims for all physician administered medications will require submission of NDCs.

Please note: some products not traditionally considered "drugs" are included in those mandated for rebate; (e.g. J7050 Infusion, normal saline, 250 cc) so don't overlook these products when submitting NDCs.