National Drug Code (NDC) Requirements for Physician-Administered Medications

The Deficit Reduction Act of 2005 (DRA) requires that all state Medicaid programs require the submission of National Drug Codes (NDC’s) on claims submitted with HCPCS codes for physician-administered drugs in an outpatient setting. In 2008, the Alabama Medicaid Agency began requiring the NDC number for the top 20+ physician-administered multiple source drugs. **Effective October 1, 2010,** the NDC number will be mandatory on physician-administered drugs in the following ranges: *J0000-J9999, *S0000-S9999 and *Q0000-Q9999. Providers are required to submit their claims with the exact NDC that appears on the product administered on HCPCS-1500 or UB-04 claims. The NDC is found on the medication's packaging and must be submitted in the 5digit-4digit-2digit format. As this process is to facilitate Medicaid drug rebates from manufacturers, providers are required to utilize drugs manufactured by companies who hold a federal rebate agreement. These NDCs will be the only ones Medicaid will cover for payment.

Please see the following section for answers to the most common questions. If you have further questions or concerns about this information, please contact Provider Assistance Center at 1-800-688-7989.

**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?**

The Deficit Reduction Act of 2005 (DRA) includes provisions about the state collection of data for the purpose of collecting Medicaid drug rebates from drug manufacturers for physician-administered drugs. Since there are often several NDCs linked to a single HCPCS code, the Centers for Medicare & Medicaid Services (CMS) deems that the use of NDC numbers is critical to correctly identify the drug and manufacturer in order to invoice and collect the rebates.

2. **Which providers are affected by this requirement?**

All fee-for-service providers who bill physician-administered HCPCS drug codes are affected. Physician-administered drugs include any covered outpatient drug billed either electronically or on paper CMS-1500 or UB-04 claim forms.

3. **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 covered by Medicaid. Manufacturers that do not sign an agreement with CMS are not eligible for federal Medicaid coverage of
their products. Outpatient Medicaid pharmacy providers bill with NDCs and Alabama Medicaid has received rebates for these claims since 1991. The DRA has now expanded the rebate requirement to physician-administered drugs.

4. **What is an NDC?**

The National Drug Code (NDC) is a universal number that identifies a drug. The NDC number consists of 11 digits in a 5-4-2 format. The first five 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 zeroes can be assumed and need to be used when billing.

For example:

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

The NDC is found on the drug container (i.e., vial, bottle, tube). The *NDC submitted must be the actual NDC number on the package or container from which the medication was administered.* Do not bill for one manufacturers product and dispense another. It is considered a fraudulent billing practice to bill using an NDC other than the one administered. Please note: NDCs listed above have hyphens between the segments for easier visualization. When submitting NDCs on claims, submit the 11-digit NDC number with no hyphens or spaces between segments.

5. **Does the drug administered and billed to Medicaid with an NDC have to be a “rebatable” drug?**

Yes. For products to be eligible for coverage by Medicaid, manufacturers must first sign a rebate agreement with CMS.

6. **How do I know if a drug is rebatable?**

You may refer to the CMS website [http://www.cms.gov/MedicaidDrugRebateProgram/10_DrugComContactInfo.asp](http://www.cms.gov/MedicaidDrugRebateProgram/10_DrugComContactInfo.asp) to determine if an NDC is manufactured by a company that participates in the Federal Drug Rebate Program.

7. **Will my claim be denied or rejected if the drug is non-rebatable?**

Yes

8. **Will my claim be denied or rejected if I don’t include the NDC?**

Yes, claims without the proper NDC qualifier and NDC that are not currently included in the Medicaid Physician-Administered multi-source Top 20+ HCPCS drug listing will deny beginning October 1, 2010. Claims with a date of service prior to this will pay, but an informational denial code will be posted on your Remittance Advice. Claims containing HCPCS from the Top 20+ HCPCS drug list will continue to deny if the NDC is not included.
9. If 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 must be the actual NDC number on the package or container from which the medication was administered.

10. Do drugs that are billed through a hospital outpatient department require an NDC?

Yes. Effective September 2008, Alabama Medicaid began requiring outpatient hospital departments to submit NDC numbers to accompany claims for the top 20 multi-source drugs that are billed separately on institutional claim forms that are identified on the claim with a Level II HCPCS code. Effective October 1, 2010, this will expand to all physician-administered drugs.

11. My clinic/hospital participates in the 340B program. Do I need to submit NDC codes for drug claims?

No. CMS has stated that this provision of the DRA does not apply to 340B drugs billed to Medicaid programs at the acquisition cost of the drug.

12. Do all J-code claims (or other drug codes) require an NDC?

No. For example, HCPCS codes considered a device do not have an NDC number. Examples are *J7321, *J7323, *J7324 and *J7325. To identify if a product is a drug, look for these three items: NDC- the package or container that held the drug would have an NDC on it; Lot and Expiration Date- All drugs have both a lot number and expiration date on the vial or container; Legend- This refers to statements such as, “Caution; Federal law prohibits dispensing without prescription, “Rx only” or similar words. All prescription drugs have these types of statements.

13. Do radiopharmaceuticals or contrast media require an NDC?

No. Not at this time.

14. Do vaccines/immunizations require an NDC?

No. Vaccines are not included in the rebate requirements.

15. Are Medicare claims included in the NDC requirement?

Yes. Because the state may pay Medicare coinsurance and deductibles, claims for recipients that are dually eligible for Medicare require NDCs with the HCPCS codes.

16. Should I bill the HCPCS code and NDC of a drug if I did not provide the drug, but just administered it?

No. For example, if the patient has a prescription filled and brings the drug into the office to have the physician administer it, the drug may not be billed by the physician. The physician should only bill for the administration of the drug. The retail pharmacy would have already billed for the drug.
17. **How do I bill for a drug when only a partial vial was administered?**

If the drug is packaged in a multi-dose vial (can be used for more than one patient), then only the units administered should be billed to Medicaid.

If the drug is packaged in a single-dose vial that cannot be used for multiple injections, payment is allowed for the amount of the drug or biological discarded along with the amount administered, up to the maximum number of allowed units. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient.

18. **How do I bill multiple NDCs to a single HCPCS code?**

If two or more NDCs are to be submitted for a procedure code, the procedure code must be repeated on separate lines for each unique NDC. On the first line, the procedure code, NDC and procedure quantity are reported with a **KP modifier** (first drug of a multi drug). On the second line, the procedure code, NDC and procedure quantity are reported with a **KQ modifier** (second/subsequent drug of a multi drug).

When reporting more than two NDCs per procedure code, the KQ modifier is also used on the subsequent lines.

19. **Will Alabama Medicaid post a procedure code/NDC code crosswalk?**

No. Alabama Medicaid will not be doing this because rebates are dependent upon correct NDCs being used. The actual NDC on the container that is administered is the one to be billed.

20. **I have heard that only single-source drugs and 20 multiple source drugs will require NDCs. Can I just submit NDCs for just those drugs?**

No. At this time, states are mandated to submit rebates on 20 drugs, but they are encouraged to expand their rebate program beyond that and Alabama Medicaid intends to do so. All physician-administered medications will require submission of NDCs. Please Note: Some products not traditionally considered drugs are included in those mandated for rebate (for example, *J7050 Infusion, normal saline, 250 cc), so don't overlook these products when submitting NDCs.

21. **How should I bill for a compound drug that was purchased from a compounding pharmacy?**

When HCPCS codes for purchased compounded drugs are billed, only one NDC can be used per procedure code. Providers must include the HCPCS procedure code, billing units and corresponding covered NDC number on the claim form. For example, for *J1094 Injection, dexamethasone acetate, 1 mg the NDC billed should be the one that represents the drug as described in the HCPCS code definition, in this case, dexamethasone acetate. Refer to Provider Alert dated September 27, 2010 for more information on the requirements when compounded drugs are billed by non-pharmacy providers.
Resources

For details on the Deficit Reduction Act (DRA):
http://www.cms.gov/Reimbursement/10_MedicaidPrescriptionDrugsundertheDRA.asp

CMS ASP pricing and HCPCS/NDC crosswalk:
http://www.cms.gov/McrPartBDrugAvgSalesPrice/01a19_2010.asp#TopOfPage

Medicaid Drug rebate program: http://www.cms.gov/MedicaidDrugRebateProgram/

Alabama Provider Insider Newsletters, July 2008, April 2009, April 2010:
http://medicaid.alabama.gov/CONTENT/2.0_Newsroom/2.3_Publications.aspx

Provider Alerts dated January 12, 2010, August 3, 2010 and September 27, 2010:


Drug Manufacturers with federal rebate agreement:
http://www.cms.gov/MedicaidDrugRebateProgram/10_DrugComContactInfo.asp


Other resource for HCPCS codes and billing: https://www.dmepdac.com/crosswalk/index.html;

Medicaid Drug Rebate State Releases (updates on new and terminated manufacturer rebate agreements and other valuable information pertaining to the drug rebate program):
http://www.cms.gov/MedicaidDrugRebateProgram/02_StateReleases.asp

Automated Voice Response System (AVRS), to check the status of an NDC: 1-800-727-7848

Provider Assistance Center: 1-800-688-7989

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