

What Hospital Pharmacies Need to Know about the National Drug Code and Medicaid Drug Rebate Regulations

Executive Overview

The Deficit Reduction Act (DRA) of 2005 was enacted to decrease Medicare spending and to reform the Medicaid program. One of the provisions in the DRA requires state Medicaid agencies to collect drug rebates from drug manufacturers or risk losing federal Medicaid program matching funds. The regulation implementing this provision requires hospitals to report the National Drug Code (NDC) number for drugs dispensed in hospital outpatient settings.

Reporting NDC numbers in the hospital outpatient setting is inconsistent with current processes in hospitals and requires changes in both operational and workflow activities. McKesson has discussed the implications of this requirement with the Centers for Medicare & Medicaid Services (CMS) and has made system modifications to capture the NDC number. This paper provides an overview of the regulation, its implications for hospital pharmacies, and how McKesson is addressing these regulatory changes. [Note: The letter sent by CMS to state Medicaid directors regarding these changes is posted on [the CMS Web site.](#)]

Background

The Medicare Drug Rebate program was created by the Omnibus Budget Reconciliation Act of 1990 (OBRA'90) and became effective in 1991. The law requires drug manufacturers to enter into agreements with CMS to provide rebates for their drug products that are paid for by Medicaid agencies. Outpatient Medicaid pharmacy (retail) providers have billed using the NDC, and states have submitted rebates, since the 1991 implementation.

The Deficit Reduction Act of 2005 (DRA) included new provisions that addressed the Medicaid collection and submission of data for the process of collecting drug rebates from manufacturers for physician-administered drugs.

Specifically, states are required to:

- Provide for the collection and submission of utilization data for single-source, physician-administered drugs using HCPCS J-codes or NDC numbers
- Provide for the submission of utilization data using codes specified by the Secretary of Health & Human Services (HHS) to identify drugs on the Secretary-defined list of multiple-source, physician-administered drugs

Because of the difficulties in cross-walking the HCPCS J-codes to the NDC number, many states simply require the NDC number. The DRA also provided that beginning Jan. 1, 2008, states not collecting NDC numbers on [the 20 physician-administered drugs](#) will not receive federal matching payments for the drugs unless they receive a hardship waiver.

What is an NDC number?

The NDC number identifies a drug using a 10-digit number consisting of three segments.

- The first segment is assigned by the FDA and identifies the labeler involved with the manufacturing, packaging or distribution of the product
- The second segment comprises the generic entity, strength and dosage form
- The third segment is the package code and indicates the package size

The second and third segments are assigned by the manufacturer.

The HIPAA standard calls for an 11-digit NDC. As a result, one of the three segments may include a leading zero in order to meet the HIPAA standard. The drug rebate reporting requirement calls for the 5-4-2 format; therefore, the leading zero may be added to the segment that will meet the format requirement.

For example:

XXXX-XXXX-XX = 0XXXX-XXXX-XX

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

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

State Medicaid Requirements

Since state Medicaid agencies are required to collect rebates on physician-administered drugs in order to receive federal funding, and CMS determined that the HCPCS J-Codes did not provide the specificity needed, the NDC numbers are required in order to identify the manufacturer. The NDC number submitted to Medicaid must be the actual NDC number on the package or container from which the medication was administered.

Thirty-five states requested and received a waiver from CMS that granted an extension to June 1, 2008, for the NDC reporting requirement. Only 24 of the 35 states requested and obtained a six-month waiver for hospital outpatient claims.

Implications for Hospitals

The requirement to include NDC information with drug charges means that the NDC number of the drug that was *actually* administered to the patient must be included with the charges. As a result, this rule presents some challenges in the hospital outpatient areas:

- Since hospital pharmacy dispensing is formulary-based, it is common for hospitals to purchase generic products from multiple manufacturers in order to get the best prices. Although these products are generically identical, the fact that they are supplied by more than one manufacturer means they are assigned different NDC numbers.
- NDC numbers for the same generic formulary item tend to be mixed in the hospital pharmacies (which generally have integrated inpatient and outpatient billing and dispensing systems) and in automated dispensing cabinets.
- It has not been a standard practice in pharmacies to track pharmacy-dispensed doses by the manufacturer throughout the medication-use process.
- Most hospital pharmacy information systems permit the assignment of a single NDC to the order, but this NDC may not always represent the NDC of the product that is actually pulled from the stock and dispensed to the patient. This variation is especially true in situations where mixed NDCs may exist for a given formulary item.
- In situations where the dispensing occurs from automated cabinets instead of directly from pharmacy stock locations, it is possible for mixed NDCs to exist for the same product in the same pocket of the cabinet. To accurately identify the correct NDC, the cabinet would have to provide a means for the nurse to scan or manually record the NDC upon removal, and the charge record that is sent back to pharmacy would have to include that NDC. Most dispensing devices do not currently offer this functionality.
- For multi-entity products such as IV piggybacks, IV large-volume admixtures and TPN solutions, the barcode on the label does not represent the NDCs of all entities contained in the product. Also, when hospital pharmacies compound IV admixtures or extemporaneous products, they have not typically recorded the NDC numbers of the drugs used during the compounding process.

- Not all drug manufacturers use an 11-digit NDC number. If systems record a 10-digit NDC number with the charge, the claim will fail because CMS is not configured to recognize the NDC in a 10-digit format.
- For drugs that are supplied in unit-dose containers, manufacturers often make standardized bar-code scanning difficult because they frequently assign a different NDC number to the individual unit-dose package than is assigned to the box that contains the unit-doses. The unit-dose NDC is not typically reported to CMS, so if it is scanned and included with the charge, CMS will reject it as an unrecognized code.

How McKesson Is Addressing These Regulatory Changes

Given the implications of the regulation on its customers, McKesson conducted a call with CMS in October 2007 to obtain information on the reporting requirement. During the call, McKesson explained the typical hospital pharmacy workflow process. CMS appreciated learning more about the process and the associated challenges with the new regulation and said it intended to contact providers to obtain further input regarding the implications to outpatient hospital departments. However, CMS also said that since the requirement is mandated by statute, it is required to implement it.

The operational challenges presented by these regulations are also recognized by professional organizations, such as the American Society of Healthcare Practitioners and the American Hospital Association. These organizations have also expressed their concerns to CMS. Various industry groups have been lobbying and continue to push members of Congress to either modify the current legislation or introduce new legislation to exempt hospitals from this reporting requirement.

Technology can provide an answer to these challenges, to a degree. Bar-coded medication doses as well as the implementation of bar-code scanning at the point of medication administration in outpatient departments could capture the NDC and transmit the charges after the dose is administered. However, this process would only be effective for single-entity products for which the barcode represents an NDC. For multi-entity products such as IV piggybacks, IV large-volume admixtures and TPN solutions, the barcode on the label does not represent the NDCs of all entities contained in the product. (See Appendix for specific changes to McKesson pharmacy and billing systems.)

This regulatory change presents serious challenges to the processes and workflows of hospitals as well as the designs and capabilities of the software billing systems that support those hospitals. McKesson is monitoring the industry efforts aimed at exempting hospitals from the regulation. As the implementation of the regulation takes shape, McKesson will work with customers to understand the impact of the regulation on processes and systems.

Appendix – Horizon Meds Manager

Enhancements to Horizon Meds Manager™ to Address NDC Requirements

The Deficit Reduction Act (DRA) of 2005 was enacted to decrease Medicare spending and to reform the Medicaid program. One of the provisions in the DRA requires state Medicaid agencies to collect drug rebates from drug manufacturers or risk losing federal Medicaid program matching funds. The regulation implementing this provision requires hospitals to report the National Drug Code (NDC) number for drugs dispensed in hospital outpatient settings.

Reporting NDC numbers in the hospital outpatient setting is inconsistent with current processes in hospitals and requires changes in both operational and workflow activities. McKesson has discussed the implications of this requirement with the Centers for Medicare & Medicaid Services (CMS) and has made modifications to the Horizon Meds Manager™ pharmacy information system to capture the NDC number.

Changes Already Implemented

The Horizon Meds Manager pharmacy information system has always had the ability to transmit the NDC number in the charge record. Plus, in specific Release 8.1 service packs and in Releases 8.5 and 10.0, Horizon Meds Manager provides the ability to configure inventory items to include the NDC unit of measure and the NDC quantity with the charge.

Recommendations for Improved Reporting of NDCs Now

1) Use your pharmacy software's inventory control to:

- Minimize the availability of multiple NDCs per formulary item
- Confirm that the primary NDC represents the most commonly used NDC for each formulary item
- Change the NDC before completing an order if the dispensed product has an NDC different from the primary NDC assigned in the formulary

2) Implement bedside bar-code scanning systems

Hospitals can use McKesson's Horizon Admin-Rx™ point-of-care, bar-code scanning solution to capture the correct NDC at the point of administration, except in situations where the barcode does not represent the NDC. Those situations include nonstandard medications and fluids where the inventory dispense sizes are marked as nonstandard, extemporaneous dispense sizes, compounds and intermittent, intravenous and total parenteral nutrition (TPN) solutions.

To address the new regulations, Horizon Admin-Rx will need to be implemented in all areas where outpatients are treated, such as the emergency department and outpatient surgery.

Future Enhancements

McKesson is developing a future enhancement (available soon) that enables Horizon Meds Manager to store the scanned NDC with the administration record and include it in the charge record. This enhancement assumes that Horizon Meds Manager is configured to process charges on administration.

McKesson is monitoring the status of these regulations and will evaluate how to support its Horizon Meds Manager customers in meeting these requirements.

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