Physician-Administered Drugs - NDC

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This section is an overview of National Drug Code (NDC) billing policy for physicianadministered drugs. For claim form completion instructions, refer to the following sections in the appropriate Part 2 manual:

- Physician-Administered Drugs NDC: CMS-1500 Billing Instructions
- Physician-Administered Drugs NDC: UB-04 Billing Instructions
- CMS-1500 Completion
- UB-04 Completion: Outpatient Services
- UB-04 Completion: Inpatient Services

NDC Requirement

The Federal Deficit Reduction Act of 2005 (DRA) requires all state Medicaid agencies to collect rebates from drug manufacturers for physician-administered drugs. Only those products manufactured by companies participating in the federal Medicaid rebate program are reimbursable by Medi-Cal. Drugs are priced based on the HCPCS code. The NDC and corresponding unit of measure are used for drug rebate processing only.

Note: Federal law specifically exempts vaccines from the rebate requirement and therefore vaccines are excluded from the NDC reporting requirement. Also, payment for bulk drugs is not allowed. Bulk drugs are Active Pharmaceutical Ingredients (APIs) that are represented for use in the drug and that when used in the manufacturing, processing or packaging of a drug, become an active ingredient of the drug product. APIs are distributed in a form (for example, a kilogram of powder) that does not meet the definition of a covered outpatient drug product by the both the federal Food and Drug Administration according to the *Food, Drug, and Cosmetic Act*, Section 505, and Section 1927(k)(2) of the *Social Security Act*. (An example of such a bulk drug would be pharmaceutically active ingredients combined into a pharmaceutical product/formulation, whether the products are combined by the provider or ordered from a compounding pharmacy.)

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Providers are <u>encouraged</u> to begin billing with an NDC for physician-administered drugs beginning September 1, 2008, in conjunction with a customary HCPCS Level I, II or III code.

- Claims submitted for dates of service from September 1, 2008, through March 31, 2009, without an NDC are acceptable.
- Claims with dates of service on or after April 1, 2009, <u>must</u> include a valid NDC paired with a HCPCS code, or the claim will be denied

Billing with the Correct NDC

The NDC is a number that identifies a specific drug, and is found on the drug container (vial, bottle or tube). The NDC submitted on the claim must be the NDC number on the package or container from which the medication was administered. Providers should <u>not</u> bill for one manufacturer's product and administer another. It is considered fraudulent billing to enter an NDC on the claim for a drug other than the one administered.

Physician-Administered Drug Definition

A physician-administered drug is any covered outpatient drug provided or administered to a recipient, and billed by a provider and not self-administered by a patient or caregiver. Such providers include, but are not limited to, physician offices, clinics and hospitals. A covered outpatient drug is broadly defined as a drug that may be dispensed only upon prescription, and is approved for safety and effectiveness as a prescription drug under the Federal Food, Drug and Cosmetic Act. Physician-administered drugs include both injectable and non-injectable drugs.

The following items identify whether or not a product is a drug:

- NDC: The vial or box that held the drug has an NDC printed on it.
- <u>Lot and Expiration Date</u>: All drugs have both a lot number and an expiration date on the vial or box.
- <u>Legend</u>: This refers to statements such as, "Caution: Federal law prohibits dispensing without prescription," "Rx only" or similar wording. All prescription drugs have these types of statements.

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Radiopharmaceuticals

The radiopharmaceuticals indium and yttrium (HCPCS codes A9542 and A9543) must be billed using the same guidelines as physician-administered drugs, which are subject to the federally established 340B Drug Pricing Program.

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«Legend»

«Symbols used in the document above are explained in the following table.»

Symbol	Description
**	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
>>	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.