Iowa Department of Human Services

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INFORMATIONAL LETTER NO.1663

DATE: April 27, 2016

TO: Iowa Medicaid Physicians, Hospitals, Advanced Registered Nurse Practitioners, Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), Podiatrists, Community Mental Health Centers, Clinics, Family Planning Clinics, Screening Centers, Maternal Health Clinics, Ambulatory Surgical Centers, Mental Hospital, Institutional-General, Certified Nurse Midwives, Certified Registered Nurse Anesthetists Providers and Managed Care Organizations (MCOs)

FROM: Iowa Department of Human Services, Iowa Medicaid Enterprise (IME)

RE: Physician-Administered Drugs and National Drug Code (NDC) Billing Requirements

EFFECTIVE: Immediately

This Informational Letter updates and summarizes prior Informational Letters including numbers 593, 647, 693, 803, and 1484 regarding NDC billing requirements for all physician-administered drugs, which includes any covered outpatient drug provided or administered to a member, which is billed by a provider other than a pharmacy. Such providers would include, but not be limited to, physician offices, clinics, or other outpatient settings.

To comply with the Centers for Medicare and Medicaid Services (CMS) requirements pursuant to the Federal Deficit Reduction Act (DRA) of 2005, the IME requires providers to submit the NDC for each Healthcare Common Procedure Coding System (HCPCS) code drug. States must collect certain data for the purpose of submitting and collecting Medicaid drug rebates from drug manufacturers for certain physician-administered drugs in order for Federal Financial Participation (FFP) to be available for payment of these drugs. Reimbursement is based on the HCPCS code while the NDC is used for drug rebate processing.

The NDC reporting requirement **applies to**:

- Drug products administered in an office/clinic or other outpatient setting billed with the following types of HCPCS Level II procedure codes, which must also include the corresponding NDC number.
  - “A” codes (for radiopharmaceuticals only), “C” codes, “J” codes, and “Q” codes.
  - HCPCS Level II codes specified as “not otherwise classified” (NOC) and “not otherwise specified” (NOS) (e.g., J3490, J999 and C9399).
- Paper claim forms CMS-1500 and UB-04 as well as Electronic Data Interchange (EDI) transactions 837P and 837I.
- Medicare crossover claims.
- Hospitals billing drugs with HCPCS Level II codes which are billed separately, and the cost is not reflected in a corresponding Ambulatory Patient Classification (APC) payment.

Claims billed with revenue codes 251-259 and 634-636 will also require a corresponding CPT/HCPCS Level II procedure code and NDC reporting.

The NDC reporting requirement **does not apply to:**

- Physician-administered drugs rendered in an outpatient hospital setting and as billed with the appropriate HCPCS Level II code, where the physician-administered drug being rendered, is reflected/included in the APC being billed for the total services being rendered. Per CMS guidance, such drugs included in the APC "bundled payment" methodology are exempt.
- Devices - items considered by the Food and Drug Administration (FDA) to be "devices" and not "drugs".

In addition to the HCPCS Level II code and units of service, the following is required when billed to Iowa Medicaid:

1. **NDC – The NDC number serves as a universal product identifier for drug products and if not provided the claim will be denied.**

    a. NDC Format: The NDC number consists of 11 digits in a 5-4-2 format. Be sure to include any leading zeros to maintain the 5-4-2 configuration.
    b. Adding the NDC Number to a claim:
        i. CMS-1500: In box 24A enter qualifier "N4" followed by the NDC number in the gray area above the date of service. No spaces or symbols should be used in reporting this information. Note that only the CMS 1500 (08/05) version of the form is allowed after May 1, 2007.
        ii. UB-92 and UB-04: enter the NDC number under "form locator 43-description."
        iii. 837P and 837I (Electronic Transaction): enter the NDC number in loop 2410 which directly follows the HCPCS code.
    c. Correct NDC Submitted: The NDC submitted to Medicaid must be the actual NDC number on the package or vial from which the medication was administered. Do not bill for one manufacturer's product and dispense another. It is considered a fraudulent billing practice to bill using an NDC other than the one administered.
    d. NDC Documentation: Providers must ensure that the NDC number of the administered drug is noted in the patient's file. The NDC must match the drug administered and not the number from another manufacturer's product, even if the chemical name is the same.
    e. HCPCS/NDC Valid Combination: The NDC submitted must be a valid corresponding NDC to the procedure code submitted.
    f. 340B Claims: NDCs must be submitted. While 340B purchased claims are not eligible for drug rebates, NDCs are required to receive federal funding for the payment of the claim and must follow the billing requirements in Informational Letter No.1638-MC.[1]
    g. Medicare Crossover Claims:
        i. Cross-over claims are claims sent to Iowa Medicaid after they are paid (primary) by a Medicare intermediary, but some Medicaid payment eligibility still remains. Typically, this means Medicaid covers a Medicare coinsurance and/or deductible for a member who is "dual-eligible" (i.e., has Medicare

[1] https://dhs.iowa.gov/sites/default/files/1638-MC_Update-340B_DrugPricing%20Program.pdf

primary and Medicaid secondary) and who qualifies for such additional payments. NDCs must be submitted on crossover claims.

ii. The NDC must be included with the J-Code or other applicable HCPCS Level II code on the claim filed with MEDICARE, in order for the crossover claim to be payable by MEDICAID.

iii. Claims forwarded to the IME electronically by Medicare: To report the NDC on these claims, simply include it on the original claim to Medicare on the 837P Electronic Transaction. On this transaction (which is required by Medicare), the NDC number is reported in loop 2410, which directly follows the HCPCS code. This is exactly the same as claims submitted directly to Medicaid on the electronic format.

iv. Cross-over claims submitted to the IME on paper: For claims that do not cross through the "coordination of benefits" (COB) process (currently this includes all Medicare HMO claims), providers must include a copy of the CMS-1500 claim form to report the NDC along with the usual Medicare Explanation of Benefits (EOB). All the usual Medicaid CMS 1500 claim instructions apply (the NDC is in box 24A: enter qualifier "N4" followed by the NDC number in the gray area above the date of service). Complete instructions are available online on the DHS Claim Forms and Instructions[2] web page.

h. Radiopharmaceuticals: Are subject to the NDC reporting and rebate requirements.

i. NDC Requirement Exemptions: Devices

i. There are a number of items considered by the FDA to be "devices" and not "drugs". These "device" items do not have an NDC number. Rather, the FDA's "Center for Devices and Radiological Health" assign these items a unique device identification number. However, these items are still billed with J codes. As such, "device" items billed with J codes are not subject to the NDC requirement applicable to J code "drugs.

ii. The following single source "device" codes are exempt from the "NDC" and, hence, rebate requirement:

Viscosupplement Products

• J7321 – Hyaluronan or derivative, for intra-articular injection, per dose (Hyalgan or Supartz)
• J7322 – Hyaluronan or derivative, for intra-articular injection, per dose (Synvisc)
• J7323 – Hyaluronan or derivative, for intra-articular injection, per dose (Euflexxa)
• J7324 – Hyaluronan or derivative, for intra-articular injection, per dose (Orthovisc)
• J7330 – Carticel (chondrocyte implant)

Skin Substitutes

• Q4106 – Dermagraft
• Q4101 – Apligraf
• Q4102, Q4103 – Oasis
• Q4104, Q4105 – Integra
• Q4107 – GRAFTJACKET
• Q4109 – TissueMend
• Q4110 – PriMatrix

[2] https://dhs.iowa.gov/ime/Providers/claims-and-billing/ClaimsPage

• Q4111 – GammaGraft

Allografts (Injectable)

• Q4112 – Cymetra
• Q4113 – GRAFTJACKET
• Q4114 – Integra

j. Audits: If a provider is dispensing or administering one drug and billing for an NDC different from the drug being dispensed or administered, it is considered fraud, which can result in claims being recouped, sanctions, and termination of provider agreements. This includes the billing of an invalid HCPCS/NDC combination. The Program Integrity Unit will be monitoring for this in their reviews.

2. Rebate Status

a. Rebate Requirements: Only rebate eligible single source and top 20 multi-source drugs will be reimbursed. **NOTE:** To facilitate reimbursement of the most cost-effective drugs by maximizing the Medicaid drug rebates, providers will soon be required to utilize only drugs manufactured by companies who hold a federal rebate agreement. These rebate eligible NDCs will be the only ones eligible for coverage and payment by Medicaid.
b. Rebate Agreements: The Medicaid Drug Rebate Program requires a drug manufacturer to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) for states to receive Federal funding for outpatient drugs dispensed to Medicaid patients.
c. Rebatable NDC List Website: Iowa Medicaid posts the following lists quarterly and the posting date of the list will be the effective date of any coverage change: 1) rebatable drugs; and 2) all multi-source drugs not in the top 20. See the Rebatable Drug List for J-Code Billing[3] on the DHS website. If a drug is not included in either of these lists, then it is not payable.
d. Rebate Requirement Exemptions: Federal law specifically exempts **vaccines** from the rebate eligibility requirement; however NDCs must still be reported.
e. Verification: Providers should review the "J" codes and NDCs on this listing to determine those that are rebatable and payable by the IME.

If you have any questions, please contact the IME Provider Services Unit at 1-800-338-7909, or by email at imeproviderservices@dhs.state.ia.us.

[3] http://dhs.iowa.gov/ime/providers/claims-and-billing/RDL