

Emergency Rules

Title 13—DEPARTMENT OF SOCIAL SERVICES Division 70—MO HealthNet Division Chapter 20—Pharmacy Program

EMERGENCY RULE

13 CSR 70-20.340 National Drug Code Requirement

PURPOSE: This rule implements the requirement for the National Drug Code (NDC) for all medications administered in the clinic or outpatient hospital setting. The Deficit Reduction Act of 2005 (DRA) requires states to collect rebates for certain physician-administered drugs.

EMERGENCY STATEMENT: On April 13, 2015 the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) issued a final report entitled Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs. The OIG alleges that Missouri claimed federal reimbursement that was unallowable because it did not comply with the federal Medicaid requirements for billing manufacturers for rebates for physician administered drugs. For a covered outpatient drug to be eligible for federal reimbursement under the Medicaid program, a drug manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the states (Social Security Act Section 1927). To collect these rebates, states must submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for all single source physician-administered drugs and for the top twenty (20) multiple-source physician-administered drugs. OIG recommended that the state update its Medicaid Management Information System (MMIS) to reject all physician-administered drugs that do not include NDCs in order to improve that state's ability to ensure that all such drugs eligible for drug rebates are invoiced. The Department of Social Services (DSS), MO HealthNet Division (MHD) does not believe the disallowance of federal funds is warranted. In order to limit future financial damage to the state Medicaid program, the MHD is filing this emergency rule to require that all Medicaid claims for all medications administered in the clinic or outpatient hospital setting (physician administered drugs) meet the requirement of containing NDC. The division finds this emergency rule necessary to promote the compelling governmental interest of complying with federal law and providing continued federal reimbursement for Medicaid physician-administered drugs. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended by the Missouri and United States Constitutions. The MO HealthNet Division believes the emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed June 19, 2015, becomes effective July 1, 2015, and expires December 28, 2015.

(1) Effective for dates of service on or after July 1, 2015, MO HealthNet Division (MHD) will require the National Drug Code (NDC) for all medications administered in the clinic or outpatient hospital setting, to comply with federal law. MHD must collect the eleven- (11-) digit NDC on all outpatient drug claims submitted to MHD from all providers for rebate purposes in order to receive federal financial participation. Providers will be required to submit their claims with the exact NDC that appears on the product dispensed or administered to receive payment from MHD. The NDC is found on the medication's packaging and must be submitted in the five (5) digit – four (4) digit – two (2) digit format. If the NDC does not appear in the five (5) – four (4) – two (2) digit format on the packaging, zero(s) (0) may be entered in front of the section that does not have the required number of digits.

(2) All drug products produced by manufacturers that have entered into a rebate agreement with the Federal Government are reimbursable under the MHD Pharmacy Program, with the exception of Drug Efficacy Study Implementation (DESI) drugs and drugs specified in Section 13, "Benefits and Limitations," in the Pharmacy Manual. The MHD Pharmacy Manual can be found on the MHD website at: http://manuals.momed.com/collections/collection_pha/print.pdf. A list of manufacturers that have entered into a rebate agreement with the Federal Government (along with the Labeler Code which is the first five (5) digits of the NDC number by which products may also be identified), can be found on the Centers for Medicare and Medicaid Services (CMS) website, in Drug Manufacturer Contact Information at: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>. Products for which the Labeler Code is not included on the list are not reimbursable under the MHD Pharmacy Program.

(3) Drug charges submitted by providers on an electronic Professional or Institutional ASC X12 837 Health Care claim transaction or manually entered on a medical or outpatient claim into MHD's billing website eMOMED (www.emomed.com), are to be billed with a valid J-Code and a valid NDC for each medication, including injections, provided to the participant. Medical or outpatient claim lines submitted with a J-Code without the corresponding NDC will be denied. For medical or outpatient claims correctly submitted with the appropriate J-Code and the corresponding NDC, the system will automatically generate a separate drug claim for the NDC to process as a pharmacy claim and will appear as a separate claim on your Remittance Advice. The corresponding line with J-Code and NDC will be dropped from the medical or outpatient claim. If an NDC is not provided, the J-Code will remain on the claim to report the denied line. If the drug being provided does not have a J-Code associated with it, the appropriate Healthcare Common Procedure Coding System (HCPCS) procedure code should be submitted with an NDC. For drugs without a valid HCPCS procedure code, revenue code 0250 "General Classification: Pharmacy" must be used with the appropriate NDC. Only drugs and items used during outpatient care in the hospital are covered. Take-home medications and supplies are not covered by MHD under the Hospital Program.

(4) A critical component to submitting claims with an NDC is to ensure that the appropriate HCPCS procedure code is billed with each NDC. To ensure accurate billing of drug charges, MHD will use the Noridian Crosswalk (www.dmeptac.com) to determine whether the appropriate HCPCS procedure code is billed for the submitted NDC. Claims will be denied if the NDC submitted is not valid for the HCPCS procedure code submitted.

(5) Section 1927(j)(2) of the Social Security Act calls for hospital dispensing covered outpatient drugs to bill the plan (MHD) "no more than the hospital's purchasing cost according to State Plan" as a condition of being exempt from the NDC reporting requirement. Claims from 340B health care facilities for outpatient hospital covered drugs must be submitted with an NDC and/or a valid J-Code (not a dump code) for MHD to be able to identify the drug dispensed and to verify that the amount submitted is the facility's actual acquisition cost for each item and quantity billed.

(6) All drug claims shall be routed through an automated computer system to apply edits specifically designed to ensure effective drug utilization. The Preferred Drug List (PDL) and clinical edits are designed to enhance patient care and optimize the use of program funds through therapeutically prudent use of pharmaceuticals. The edits are based on evidence-based clinical criteria and nationally recognized peer-reviewed information. This clinical information is

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paired with fiscal evaluation and then developed into a therapeutic class PDL recommendation. The PDL process incorporates clinical edits, including step therapies, into the MHD pharmacy program. Claims for drugs will automatically and transparently be approved for those patients who meet any of the system approval criteria. For those patients who do not meet the system approval criteria, the drugs will require a call to the MHD Drug Prior Authorization hotline at (800) 392-8030 to initiate a review and potentially authorize payment of claims. Providers may also use the CyberAccess tool to prospectively determine if a drug is a preferred agent or requires edit override, electronically initiate an edit override review, and to review a participant's MHD paid claim history.

(7) The quantity to be billed for injectables and other types of medications dispensed to MHD participants must be calculated as follows:

(A) Containers of medication in solution (for example, ampoules, bags, bottles, vials, syringes) must be billed by exact cubic centimeters or milliliters (cc or ml) dispensed, even if the quantity includes a decimal (e.g., if three (3) 0.5 ml vials are dispensed, the correct quantity to bill is 1.5 mls);

(B) Single dose syringes and single dose vials must be billed per cubic centimeters or milliliters (cc or ml), rather than per syringe or per vial;

(C) Ointments must be billed per number of grams even if the quantity includes a decimal;

(D) Eye drops must be billed per number of cubic centimeters or milliliters (cc or ml) in each bottle even if the quantity includes a decimal;

(E) Powder filled vials and syringes that require reconstitution must be billed by the number of vials;

(F) Combination products, which consist of devices and drugs, designed to be used together, are to be billed as a kit. Quantity will be the number of kits used;

(G) The product Herceptin, by Genentech, must be billed by milligram rather than by vial due to the stability of the drug; and

(H) Non-Vaccines for Children (VFC) Immunizations and vaccines must be billed by the cubic centimeters or milliliters (cc or ml) dispensed, rather than per dose.

(8) Contrast materials and radiopharmaceuticals used in radiologic procedures may be billed separately using the appropriate HCPCS code and/or the NDC representing the materials or agent used in the procedure. If available, MHD would prefer the NDC for reporting purposes. If the material or agent used does not have an NDC, the appropriate HCPCS code alone is acceptable. All HCPCS codes for contrast materials and radiopharmaceuticals are manually priced and must be billed with the manufacturer's invoice of cost attached to the claim.

AUTHORITY: sections 208.153 and 208.201, RSMo Supp. 2013. Emergency rule filed June 19, 2015, effective July 1, 2015, expires Dec. 28, 2015. An emergency rule covering this same material will be published in the August 3, 2015, issue of the Missouri Register.