DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid , CHIP, and Survey & Certification

November 1, 2010

MEDICAID DRUG REBATE PROGRAM **Release No. 82**

Bulletin

For
Participating Drug Manufacturers

INCORRECT DRUG PRODUCT INFORMATION REPORTED TO CMS

Unit Type and Units Per Package Size

In accordance with section 1927 of the Social Security Act, labelers are required to submit and certify valid drug product data for a national drug code (NDC) before establishing and submitting quarterly pricing data. Drug product data includes both 9-digit and 11-digit NDC data fields.

Labelers are also responsible for submitting corrections to drug product data via the Drug Data Reporting for Medicaid (DDR) system. In an effort to make our reporting fields consistent and ensure uniformity in our drug product file, we request manufacturers to review their NDC's drug product data to ensure that one of the following eight unit types are used when submitting or updating product information:

For this Dosage	Apply This Unit Type	Abbreviation
Anti-Hemophilic Factor Injectables	Injectable Anti-Hemophilic Factor	AHF
All drugs dispensed in capsule form	Capsule	CAP
Drugs not identifiable by another unit; e.g., powder-filled vials, powder-filled ampules, powder-filled packets, and kits containing two or more items dispensed under one NDC and sold at a single price	Each	EA
Drugs measured by weight; e.g., creams, ointments, foams, powders, gels	Gram	GM
Drugs measured by liquid volume, e.g., oral or topical solutions, suspensions, lotions, sprays, liquid-	Milliliter	ML

filled vials, liquid–filled ampules, pre-filled syringes, all liquid ophthalmic products		
All suppositories whether dispensed individually or in dosage packets	Suppository	SUP
All drugs dispensed in tablet form	Tablet	TAB
All drugs dispensed as Transdermal Patches	Transdermal Patch	TDP

Further, we request that labelers review their drug product data to ensure that the Units per Package Size (UPPS), currently defined as the total number of units in the smallest dispensable amount for the 11-digit NDC, is submitted accurately. This is in accordance with our instruction on how to report for the UPPS field in our Drug Product Data Web File Structure and Definition on our website at http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/RecordSpecificationandDefinitions.pdf. Below is additional information on how to report the UPPS.

- When the pharmacist routinely dispenses the drug as it is packaged (an unbreakable quantity), you should show the UPPS as the actual size of the container.

  Example: The unit type is a tablet, the NDC is for a package size holding 20 tablets, and the pharmacist is expected to dispense the entire container, rather than dispensing a smaller number of tablets from it. The appropriate entry in the UPPS field is "20."

- Where the number of units in the package size is such that the pharmacist is not expected to routinely dispense the entire package to the retail customer, (a breakable quantity), the appropriate entry in the UPPS field is "1".

  Example: The unit type is a tablet, the package holds 500 tablets and the usual quantity prescribed by the doctor and dispensed by the pharmacist is fewer than 500 tablets. The UPPS entry should be "1".

In the future, we plan to post a file containing drug product data, without pricing data, at the 11-digit NDC level for labeler review on our website. We will be providing notification of such postings via our Medicaid Prescription Drug Policy & Reimbursement Updates mailing list. If you do not currently subscribe to this mailing list, please click on the following link to activate your subscription - https://subscriptions.cms.hhs.gov/service/subscribe.html?code=USCMS_589.

Drug Category and FDA Approval Date

In Manufacturer Release #80, we requested manufacturers to check the FDA website to ensure that the correct drug category is submitted to CMS. We are again requesting manufacturers to review the drug category of their reported products to ensure the accuracy of the data submitted to the CMS.

In general, those products that are approved under a New Drug Application (NDA) need to be reported to CMS as either single source (S) or innovator multiple source (I), and those products approved under an Abbreviated New Drug Application (ANDA) need to be reported to CMS as non-innovator multiple source (N).

We continue to encourage manufacturers to check the Food and Drug Administration's (FDA) NDC Directory, http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm, to determine whether

the correct application number has been reported to the FDA for the product or to identify the correct drug category for the product based on the application number assigned to the product.

The FDA has also updated their Orange Book to reflect the FDA approval date by each specific product. Therefore, manufacturers may access the FDA's Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm, and search by Application Number to determine whether a product has been approved under an NDA (marked by an "N" in front of the application number) or ANDA (marked by an "A" in front of the application number), and whether the FDA approval date reported to CMS is the same date as listed in the Orange Book.

Furthermore, we have noticed that there has been some confusion as to when a brand name product should be reported as an "I" and when it should be reported as an "S." We want to ensure that manufacturers are reporting the correct drug category for a brand name product. An "I" should be reported to CMS for a brand name drug that has a generic drug available. To know if a brand name drug has a generic drug available or not, you can access Drugs@FDA at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Addlsearch_drug_name and search by the Application Number. If a generic drug is available, you will see the link to "Therapeutic Equivalents" in the middle of the "Drugs Details" page. Click on this link to see the generic and other therapeutically equivalent drug products. If there is no generic drug available for a brand name drug, then the brand name drug should be reported as an "S" to CMS.

If you determine that an incorrect drug category has been reported to CMS for a product, please e-mail RxDrugPolicy@cms.hhs.gov to request a drug category change for the product. Please note that changing the drug category from "S" to "I" does not require CMS prior approval; therefore, please access the DDR to do so.

Also, please note that under section 510 of the Federal Food, Drug and Cosmetic Act, as amended, with some limited exceptions, firms that manufacture, prepare, propagate, compound, or process drugs in the United States or that are offered for import into the United States are required to be registered with the FDA. *See* 21 U.S.C. §§ 360(b), (c), (d), and (i). Every person who registers must, at the time of initial registration, list all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution. 21 U.S.C. § 360(j)(1). *See also* 21 C.F.R. 207.20. Registering and listing updates must include drugs not previously listed (if any), and certain changes to information for previously listed drugs. 21 U.S.C. § 360(j)(2); 21 CFR 207.21(b), 207.30. Prescription drug products that are properly listed should appear in the FDA's NDC Directory.

If you determine that your product is not currently listed or has been incorrectly listed with the FDA, please contact the FDA at eDRLS@fda.hhs.gov to update your product listing.

Penalties for Failure to Provide Timely Information and False Information

We would like to remind manufacturers that section 1927(b)(3)(C)(ii) states "any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information." Therefore, we encourage manufacturers to carefully review their drug product data submissions, determine if any necessary change is needed, and take the necessary steps to make the change.

We ask that the labelers review and update their drug product data, and submit any correction or a change request, when necessary, in accordance with the guidance provided in this release.

Questions regarding Medicaid drug provisions can be submitted through the drug policy resource mailbox at RxDrugPolicy@cms.hhs.gov.

UPCOMING FILE FORMAT CHANGE TO COLLECT MONTHLY AMP UNITS

In accordance with section 1927 of the Social Security Act, as amended by the Affordable Care Act, manufacturers are required to report the total number of units that are used to calculate the monthly average manufacturer price (AMP) for each covered outpatient drug no later than 30 days after the last day of the month. Manufacturers are to report these units by the same unit type they use to calculate the monthly AMP.

We plan to require manufacturers to report the AMP units to CMS via the Medicaid Drug Data Reporting (DDR) system for the October 2010 reporting period. The new data field will be called "AMP Units". The AMP units should include the total sum of units for all package sizes included in the calculation of the AMP, and should be reported per product code (9-digit NDC level) for the monthly reporting period covered. For system implementation purposes, the data field will be: Numeric values, 14-digit field: 11 whole numbers, the decimal place (".") and two (2) decimal places; right-justified; zero-filled.

Once approval from the Office of Management and Budget is obtained, manufacturers will be notified via the Medicaid Prescription Drug Policy & Reimbursement Updates mailing list as to when the AMP unit field is available to report in the DDR system. If you do not currently subscribe to the Medicaid Prescription Drug Policy & Reimbursement Updates mailing list, please click on the following link to activate your subscription:
https://subscriptions.cms.hhs.gov/service/subscribe.html?code=USCMS_589

Questions regarding Medicaid drug provisions can be submitted to the drug policy resource mailbox at RxDrugPolicy@cms.hhs.gov.

Suzanne Bosstick /s/ for

Barbara Edwards
Director
Disabled and Elderly Health Programs Group

Attachment:

cc:
Regional Administrators

CMS RECORD SPECIFICATION
DDR MONTHLY PRICING DATA
TEXT FILE FOR TRANSFER TO CMS

Source: Drug Manufacturers
Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "M"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size	2	11 - 12	NDC #3
Month	2	13 – 14	MM
Year	4	15 – 18	YYYY
Average Mfr Price (AMP)	12	19 – 30	99999.999999
AMP Units	14	31 – 44	99999999999.99
Filler	21	45 – 51	spaces

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