DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

July 19, 2012

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 84**

For Participating Drug Manufacturers

UPDATING YOUR DRUG INFORMATION ELECTRONICALLY WITH THE FOOD AND DRUG ADMINISTRATION (FDA)

Under section 510 of the Federal Food, Drug and Cosmetic Act, as amended ("the Act"), and Part 207 of FDA's regulations, 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 must be registered with 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. Drug listing information must be updated in June and December each year. These 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.

Drug products are listed using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA publishes the listed NDC numbers and the associated drug product information submitted as part of the listing information in FDA's comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm.

Changes in the Federal Food, Drug, and Cosmetic Act, resulting from the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) (FDAAA), require that drug establishment registration and drug listing information be submitted electronically unless a waiver is granted by FDA. Pursuant to this provision, on **June 1, 2009**, FDA stopped accepting hardcopy/paper submission of drug establishment registration and listing information and began accepting only electronic submissions, unless a submitter obtains a waiver. Moving from a paper-based format to an electronic system is intended to improve the timeliness and accuracy of drug information submissions.

Similar to Medicare's practice in using FDA's drug product information for marketing category determinations (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/HPMS-Guidance-History.html), we will be using FDA's drug product information to verify products that are reported to the Medicaid Drug Rebate Program (MDRP). Therefore, we encourage all manufacturers that participate in MDRP to list their products electronically with FDA.

We strongly encourage all manufacturers to review their drug products and FDA's NSDE file to ensure that all of their NDCs are listed electronically with FDA. In general, CMS relies on FDA to make regulatory status determinations regarding drug products identified by NDC number, and ensuring that a drug is listed electronically will facilitate making these determinations in a timely fashion. Electronic listing also helps ensure that CMS can determine which drug products are eligible for coverage under MDRP. Therefore, we request that you ensure that your company's drug information is updated and listed electronically with FDA as we will be utilizing FDA's NSDE file to obtain or verify drug information for purposes of MDRP.

For more information regarding electronic drug registration and listing instructions, please visit FDA's website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm. To search the NSDE file by specific NDC or application number, please visit the FDA Online Label Repository at http://labels.fda.gov/.

For technical questions regarding FDA's electronic submission process, please email FDA at SPL@fda.hhs.gov. For regulatory drug registration or listing questions, please contact FDA at eDRLS@fda.hhs.gov.

Contact: RxDrugPolicy@cms.hhs.gov

REVISION OF CMS FORMS 304/304a TO INCLUDE A "FFS/MCO RECORD ID" COLUMN

Section 2501 of the Affordable Care Act amended section 1927(b) of the Social Security Act to require manufacturers that participate in MDRP to pay rebates for drugs dispensed to individuals enrolled in a Medicaid Managed Care Organization (MCO), if the MCO is responsible for coverage of such drugs. In accordance with this provision, manufacturers are responsible for paying rebates on such covered outpatient drugs effective with respect to drugs dispensed by the MCO on or after March 23, 2010 (the date of enactment). To implement this new requirement, an additional column titled "Record ID" has been added to the state invoice (i.e., CMS Form R-144) to allow states to separately identify each utilization record on an invoice as either Fee-For-Service (FFS) utilization or MCO utilization. Please note that, while the new Record ID column will enable states to separate out FFS units from MCO units on their drug rebate invoices, CMS is not mandating that states bill manufacturers with either one invoice or multiple invoices each quarter. States may choose to include both FFS and MCO units altogether on one invoice, or they may opt to submit one invoice containing all FFS units and another containing MCO

units. However, regardless of which method they choose, each state invoice should include the new "Record ID".

As you know, manufacturers use CMS Form 304 (ROSI – Reconciliation of State Invoice) for both unit adjustments and disputes in response to a state's invoice for current quarter utilization. CMS Form 304a (PQAS – Prior Quarter Adjustment Statement) is required only in those instances when a manufacturer discovers unit adjustments and/or disputes from a previous quarter's state invoice.

To keep the ROSI and the PQAS consistent with the information reported on the state invoice, CMS Forms 304 and 304a have also been revised to include a new "FFS/MCO Record ID" column. Manufacturers should use this column to separately identify each record as either FFS utilization (i.e., a Record ID of "FFSU") or MCO utilization (i.e., a Record ID of "MCOU") when the ROSI or PQAS is being submitted along with state's quarterly rebate payment. The new "FFS/MCO Record ID" column on CMS Forms 304 and 304a is the only field that was added to each form.

Additionally, in anticipation of increased state utilization due to the inclusion of MCO units, and to ensure consistency between the electronic format for CMS Forms 304 and 304a and the electronic format for CMS Form R-144 (the state invoice), we have revised several field sizes on the ROSI and the PQAS. For your convenience, we have attached the revised CMS Forms 304 and 304a, as well as the new electronic file formats (revised fields have been highlighted for easy reference).

The revisions to the state invoice and to forms CMS-304 and 304a were approved by the Office of Management and Budget (OMB) via the Paperwork Reduction Act (PRA). States had the option to use the new "Record ID" field beginning with the invoices they submitted for fourth quarter 2011 (i.e., the invoices that were sent out in February 2012); however, states are expected to use the new field beginning with the second quarter 2012 invoicing period (i.e. the invoices that states will send out in August 2012). As a result, manufacturers should have planned to update their systems to accommodate the new "FFS/MCO Record ID" field by mid-February 2012 for any fourth quarter 2011 state invoices that made a distinction between FFS and MCO units.

If you have any questions regarding the revised invoice or state utilization data format, please contact mdroperations@cms.hhs.gov.

GUIDANCE ON MANUFACTURERS PAYING REBATES FOR MEDICAID MCO ENROLLEES

This guidance responds to inquiries we have received from manufacturers regarding whether rebates are required to be paid to states in instances when MCO data does not show a paid amount for a drug it covered under its Medicaid benefit. Effective March 23, 2010, Section 2501(c) of the Affordable Care Act requires manufacturers to pay rebates for covered outpatient

drugs for Medicaid beneficiaries enrolled in MCOs when the organization is responsible for coverage of such drugs.

All claims for Medicaid covered outpatient drugs that are the responsibility of the Medicaid MCO should be part of the MCO's utilization data reported to the state. Section 2501 of the Affordable Care Act amended section 1927(b)(1)(A) of the Social Security Act to require that the manufacturers "provide a rebate …including (for) such drugs dispensed to individuals enrolled with a Medicaid MCO if the organization is **responsible for coverage** of such drugs." (Emphasis added.) While section 1927(b)(1)(A) of the Act references payments made under the state plan, the amended statutory language does not limit the provision of additional manufacturer rebates to only drugs for which the MCO incurred a cost. When a drug is dispensed to a Medicaid beneficiary under a managed care arrangement, the state has made a capitated payment to the MCO for the drug. Regardless of the payment terms negotiated as part of the contract between the MCO and its participating providers to provide Medicaid coverage, the manufacturer is responsible for payment of rebates for covered outpatient drugs dispensed to Medicaid beneficiaries enrolled in MCOs.

Please note that this policy is a further clarification of the policy specified in Manufacturer Release #54, dated May 7, 2002. Manufacturer Release #54 predates the changes made by the Affordable Care Act and is specific to fee-for-service claims paid directly by the state under the state plan. Consistent with the policy communicated in Manufacturer Release #54, manufacturers may continue to withhold payment of rebates for drugs when state Medicaid agencies do not pay a provider for a part of the fee-for-service pharmacy claims.

Contact: RxDrugPolicy@cms.hhs.gov

/s/

Barbara Edwards
Director
Disabled and Elderly Health Programs Group

Attachments