



Center for Medicaid , CHIP, and Survey & Certification

August 4, 2010

TO: Drug Rebate Technical Contacts

FROM: Medicaid Drug Rebate Program

SUBJECT: Deleted Products--Immediate Action Required

The FDA has determined that the following active Exocrine Pancreatic Insufficiency NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval. 69 Fed. Reg. 23410 and 72 Fed. Reg. 60860 (April 28, 2004 and October 26, 2007). According to the FDA, these products do not have approved applications; therefore, CMS has determined that the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program. **Consequently, the following Exocrine Pancreatic Insufficiency NDCs should be deleted from your state Medicaid Drug Rebate system as of the date of this notice.** The labelers of these products are responsible for paying rebates on any of the NDCs if they were dispensed prior to the date of this notice. In addition, states should be aware that the third quarter 2010 tape to states will be the last quarterly tape that will include the NDCs in order to facilitate rebate billing for any utilization that occurred in good faith prior to the date of this notice. However, states are reminded that no Federal Financial Participation (FFP) will be available for these drugs after the date of this notice for purposes of the Medicaid Drug Rebate Program. As a reminder, while these products are not eligible for Medicaid coverage under the Medicaid Drug Rebate Program, they might be eligible for coverage under other Medicaid benefit categories such as home health services or EPSDT services, depending on whether such coverage is consistent with the State plan.

NDC	Product Name
00045-0341	PANCREASE/MT (r) PANCRELIPASE CAPSULES
00045-0342	PANCREASE/MT (R) PANCRELIPASE CAPSULES
00045-0343	PANCREASE/MT (R) PANCRELIPASE CAPSULES
00045-0346	PANCREASE MT 20