

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, CHIP and Survey & Certification**

**Disabled and Elderly Health Programs Group**

October 7, 2011

TO: Drug Rebate Technical Contacts  
FROM: Medicaid Drug Rebate Program  
SUBJECT: Deleted Products--Immediate Action Required

The Centers for Medicare and Medicaid Services (CMS) has determined that the following device products do not meet the definition of a covered outpatient drug as set forth in Section 1927(k)(2) of the Social Security Act (the Act). The Food and Drug Administration (FDA) has informed us that these products received FDA clearance under the 510(k) premarket notification submission process used for certain devices under the federal Food, Drug and Cosmetic Act. As a result, they are not “covered outpatient drugs” as defined in section 1927(k)(2) of the Act are therefore no longer eligible for inclusion in the Medicaid Drug Rebate Program or eligible for FFP as covered outpatient drugs. The device products that are no longer rebate eligible are as follows:

<b>NDC</b>	<b>Product Name</b>
00095-0070-14	Tropazone lotion
00095-0071-12	Tropazone CR (Tropazone cream)

**Consequently, these NDCs should be deleted from your state Medicaid Drug Rebate system as of the date of this notice.** The labeler of these products is responsible for paying rebates on these NDCs if they were dispensed prior to the date of this notice. In addition, the third quarter 2011 tape to states will be the last quarterly tape that will include these NDCs, in order to facilitate rebate billing for any utilization that occurred in good faith prior to the date of this notice. States are reminded that these drugs are no longer eligible for FFP as covered outpatient drugs or qualify for coverage under the Medicaid Drug Rebate Program. However, we note that although these products are not eligible for Medicaid coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services or EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or as other covered items and services to the extent that such coverage is consistent with the approved state plan.