

Center for Medicaid and State Operations

July 11, 2006

SMDL 06-016

Dear State Medicaid Director:

The Deficit Reduction Act of 2005 (DRA) includes new provisions regarding State collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. Section 6002 of the DRA adds section 1927(a)(7) to the Social Security Act (the Act) to require States to collect rebates on physician-administered drugs.

This letter provides a brief summary of the new provisions regarding State collection and submission of utilization data for certain physician-administered drugs. In order for Federal financial participation (FFP) to be available for these drugs, the new provisions require that States:

- Provide for the collection and submission of utilization data for single source, physician administered drugs using codes such as the Healthcare Common Procedure Coding System (HCPCS) J-Codes and/or National Drug Code (NDC) numbers, in order to secure rebates for such drugs administered on or after January 1, 2006;
- Provide for the submission of utilization data using codes specified by the Secretary to identify drugs on the Secretary defined list of multiple source, physician-administered drugs in order to secure rebates for such drugs administered on or after January 1, 2008.

States must also provide, not later than January 1, 2007, that utilization data for single source and Secretary-specified multiple source physician-administered drugs, be submitted using National Drug Code numbers (unless the Secretary specifies an alternative coding system).

Section 1927(a)(7)(B)(i) requires the Secretary to publish, not later than January 1, 2007, a list of the 20 physician-administered multiple source drugs that the Secretary determines have the highest dollar volume of physician-administered drugs dispensed under Medicaid. The list of top 20 drugs may be modified by the Secretary from year to year to reflect changes in volume.

As noted, an alternate coding system may be designated for these drugs. However, because we believe that the use of NDC numbers is critical to correctly identify the manufacturer in order to collect rebates, we do not anticipate specifying such an alternative coding system.

Physician-administered drugs are usually billed by providers to Medicaid using HCPCS J-codes. Many States are taking steps to collect rebates by using crosswalks developed to link HCPCS J-codes to NDC numbers because the NDC number is necessary for States to bill manufacturers for rebates. (Internet address for crosswalk may be found on the CMS Web site at http://new.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp). However, States have encountered difficulty in linking procedure codes for multiple source physician-administered drugs to a

single NDC number for the purpose of billing for rebates, as there may be several NDC numbers linked to a single HCPCS J-code. The requirements set forth by section 6002 of the DRA will facilitate States' billing of manufacturers for rebates for multiple source physician-administered drugs.

Section 1927(a)(7)(D) allows the Secretary to delay application of the collections and submission requirements discussed above to prevent hardship to States that need additional time to implement the reporting systems required by section 6002. We do not expect States to need additional time to implement the provision for single source drugs as many States are already collecting rebates for single source, physician-administered drugs. Nonetheless, any such requests should be sent to me as soon as possible.

We intend to publish a rule that is consistent with this letter and would provide additional guidance regarding the DRA amendments to section 1927.

If you have any questions regarding these provisions, you may contact Ms. Gale Arden, Director, Disabled & Elderly Health Programs Group, at (410) 786-6810, or Deirdre Duzor, Director, Division of Pharmacy, at (410) 786-4626.

Sincerely,

/s/

Dennis G. Smith
Director

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cc:

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