

May 4, 2006

MEDICAID DRUG REBATE PROGRAM

RELEASE #141



For State Medicaid Directors



COMPENDIA CLARIFICATION

The Deficit Reduction Act of 2005, Pub. L. 109-171, amended the drug rebate provisions to include a reference to certain successor publications. Specifically, the amendment, effective February 8, 2006, clarified that the reference to the United States Pharmacopoeia-Drug Information in section 1927(g)(1)(B)(II) includes its successor publications.

We are also reiterating the definition of medically accepted indication. Section 1927(k)(5) defines “medically accepted indication” to mean any use for a covered outpatient drug which is approved by the Food and Drug Administration, or a use which is supported by one or more citations included or approved for inclusion in the compendia specified in subsection (g)(1)(B)(II) – the American Hospital Formulary Service Drug Information, United States Pharmacopoeia-Drug Information (or its successor publications), and the DRUGDEX Information System. The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II). Prior approval policies may be put in place, but prior authorization cannot be used to deny the off-label indications supported by citations included or approved for inclusion in the above-referenced compendia.

/s/

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Director
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cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

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