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 State Operations

SMDL #02-014

September 18, 2002

Dear State Medicaid Director:

This letter is to clarify issues related to supplemental drug rebate agreements and prior authorization of Medicaid covered outpatient drugs. A number of States have sought CMS approval of supplemental drug rebate agreements between a State and drug manufacturers with respect to Medicaid covered outpatient prescription drugs. Some of these States subject covered outpatient drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients.

Medicaid Supplemental Drug Rebate Agreements

States may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). The drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secretary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a State and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if CMS determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that States that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.

We remind States that supplemental drug rebates must be "considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance" as required by section 1927(b)(1)(B) of the Act.

Prior Authorization Requirements Related to Supplemental Rebate Agreements

States may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients. Section 1927(d)(1)(A) of the Act permits States to subject any covered outpatient drug to a requirement of prior authorization as long as the State complies with the requirements set forth in section 1927(d)(5). A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to reduce the costs to the Medicaid program for prescription drugs.

A prior authorization program does not need to comply with the requirements for restrictive formularies. The formulary provisions of section 1927(d)(4) were added to the drug rebate provisions in 1993 to give States additional authority to implement restrictive formularies. Congress passed paragraph (d)(4) expressly stating that "[a] prior authorization program established by a State under [section 1927(d)(5)] is not a formulary subject to the requirements of this paragraph."* Furthermore, since concerns related to drug use, monitoring, waste, fraud or abuse are separately and independently addressed by the procedures authorized by sections 1927(d)(6) and 1927(g), a prior authorization program need not be limited to those concerns. The Act affords States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.

The operation of a prior authorization program used to negotiate drug discounts for the Medicaid population is a significant component of a State plan. We would therefore expect that a State that does not currently have an approved prior authorization State plan amendment, and that seeks to undertake such a program, would submit to CMS for review a State plan amendment incorporating the program's prior authorization requirements, while simultaneously seeking CMS's authorization for its proposed separate or supplemental rebate agreement. A State that has an approved State plan amendment governing prior authorization requirements, but which seeks for the first time to use its prior authorization authority to negotiate drug discounts for the Medicaid program, must amend its State plan to refer to the separate or supplemental rebate agreement and submit its proposed rebate agreement for CMS authorization.

* Of course, the formulary provisions of section 1927(d)(4) continue to apply if a State chooses to make judgments about the therapeutic advantages of a drug excluded from a formulary, and the State plan must permit coverage of any such drug pursuant to a prior authorization program that complies with section 1927(d)(5).

Non-Medicaid Supplemental Rebates and Medicaid Prior Authorization

A number of States secure prescription drug benefits, rebates, or discounts for non-Medicaid populations by linking such benefits to a Medicaid prior authorization program. The Act does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases. However, the establishment of a prior authorization program for Medicaid covered drugs to secure drug benefits, rebates, or discounts for non-Medicaid populations is a significant component of a State plan and we would therefore expect that a State would submit such a program for CMS review under the State plan process. Similarly, the use of any pre-existing prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid populations would constitute a "[m]aterial change[] in State law, . . . policy, or in the State's operation of the Medicaid program" and we would therefore expect that a State would submit a plan amendment to CMS for review. (See section 430.12(c)(1)(ii) of the regulations.) In submitting such a State plan amendment, the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program. A State could make such a demonstration by submitting appropriate evidence that its prior authorization requirement is designed to increase the efficiency and economy of the Medicaid program. A State could demonstrate that its prior authorization requirement furthers Medicaid goals and objectives by submitting appropriate evidence that the requirement sufficiently benefits the Medicaid population as a whole by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible.

If you have any questions regarding CMS policy relating to supplemental drug rebate agreements or prior authorization programs, please direct them to Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

/s/

Dennis G. Smith
Director

cc:

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