



Center for Medicaid and State Operations

SMDL #04-006

September 9, 2004

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) recently approved State Plan Amendments (SPAs) for five states in order to allow them to pool their purchasing power to acquire prescription drugs for their Medicaid populations. The purpose of this letter is to clarify issues related to multi-state pooling arrangements in the event that other states decide to implement similar “purchasing pools.” In addition, this letter provides some points of consideration for states that have implemented Preferred Drug Lists (PDLs) and prior authorization requirements as part of their Medicaid supplemental rebate programs, including both state-specific supplemental rebate programs and multi-state supplemental rebate programs. In particular, to the extent that states wish to take any of these steps, we believe that it is important for CMS to provide guidance on how states can implement these programs to achieve cost savings while at the same time protecting the interests of Medicaid beneficiaries and promoting competition.

Under Sections 1927(a)(1) and 1927(a)(4) of the Social Security Act (the Act) and as previously specified in the September 18, 2002, State Medicaid Director letter, the Secretary may authorize a state to enter directly into separate or supplemental rebate agreements with manufacturers. Any drug rebate agreement between a state and a drug manufacturer may constitute a rebate agreement in compliance with the statute if CMS determines that the agreement provides for rebates that are at least as large as the rebates set forth in the Secretary’s national rebate agreement with drug manufacturers, which is published at 56 Fed. Reg. 7049 (Feb. 21, 1991). In an effort to gain additional rebates, a state can submit to CMS for its approval a SPA to allow the state to implement a prior authorization program to negotiate drug discounts for Medicaid populations or, consistent with previous guidance, to use a Medicaid prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid beneficiaries.

Under Section 1927(d)(5), States may also submit a SPA to CMS for approval in order to implement prior authorization programs to require authorization prior to dispensing covered outpatient drugs to Medicaid beneficiaries. States may establish a PDL of covered outpatient drugs that will not be subject to prior authorization and may, with CMS authorization, require manufacturers to enter into supplemental rebate agreements as a condition of including the manufacturer’s covered outpatient drugs on the state’s PDL. Many states have implemented these measures to address concerns with escalating Medicaid budgets.

Before a state decides whether to implement a PDL and pursue supplemental rebates, either on its own or as part of a multi-state pool, it must consider, and demonstrate to us that it has considered, numerous factors. These factors will ensure that any such program complies with section 1902(a)(19) of the Act, which requires that care and services under a Medicaid state plan be provided in a manner consistent with simplicity of administration and the best interests of beneficiaries. To that end, we would expect that any program will continue to ensure that appropriate medically necessary drugs will be available to Medicaid-eligible individuals. We intend to evaluate any SPA seeking to implement a prior authorization program and PDL, establish a state-specific supplemental rebate program, or join a multi-state pooling arrangement, to ensure that the state's program furthers Medicaid goals and objectives. In particular, before approving any SPA seeking to implement these initiatives, we will seek assurance from the state that its PDL is designed in a manner that balances the interests of beneficiaries in receiving medically necessary drugs with the state's interest in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner. For example, we would expect a state's PDL to be based on several factors, including the needs of the state's Medicaid beneficiaries. We further would expect a state's PDL to address the needs of beneficiaries with special and complex medical conditions. We especially urge states to consider including in their PDLs drugs that are needed by some of Medicaid's most vulnerable populations, such as individuals with HIV/AIDS, mental health conditions, cancer, and other conditions for which clinical effectiveness or individual tolerance and responsiveness to drugs frequently vary.

We also believe that the level of supplemental rebates received by states will benefit from a competitive environment. For this reason, we believe that states should not limit their choice of vendors to develop and operate a supplemental rebate program to those vendors that have current contracts with other states solely on the basis that those vendors' programs have already received CMS approval through a SPA approval. In fact, we believe that states should consider other vendors, and not necessarily seek approval to join other state purchasing pools merely because those pools already exist. There are a number of contractors in the marketplace that have the knowledge and experience to provide these services. Some of these vendors have more experience in the broader market of health insurers and payers than in Medicaid, but may provide the best value to Medicaid programs. Therefore, you should not limit your choice to vendors that have current contracts with other states, nor should you limit your attempt to join a multi-state pooling arrangement to those arrangements already approved by CMS through the SPA process. In fact, in considering any SPA request to implement a prior authorization program and PDL, establish a state-specific supplemental rebate program, or join a multi-state pooling arrangement, CMS will consider the extent to which the state considered these competitive factors and will look favorably upon a state that uses other vendors or develops multi-state pooling arrangements other than those already approved. Through these competitive efforts, states can ensure that they and the Federal Government receive high quality services at the most competitive price.

Page 3 - State Medicaid Director

The document enclosed provides additional technical guidance for states. We look forward to working with you on additional pharmacy cost savings measures in the Medicaid program. If you have questions or need additional information, you may contact Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

/s/

Dennis G. Smith
Director

Enclosures

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Kathryn Kotula
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Brent Ewig
Senior Director, Access Policy
Association of State and Territorial Health Officials

Jim Frogue
Director, Health and Human Services Task Force
American Legislative Exchange Council

Trudi Matthews
Senior Health Policy Analyst
Council of State Governments

Guidelines for Multi-State Pooling Agreements

As discussed below, states may use vendors, such as pharmacy benefit administrators (PBAs), to negotiate supplemental or multi-state pooling rebate agreements with manufacturers. Participation in any multi-state pool requires that the services of the vendor, if any, be procured by each participating state in a manner consistent with Federal and state procurement standards. While the five states participating in the new multi-state pool have contracts with the same vendor, we do not expect that all 50 states will participate in this arrangement. In fact, we believe that states should not limit their choice of vendors to develop and operate a supplemental rebate program to those vendors that have current contracts with other states solely on the basis that those vendors' programs have already received CMS approval. Moreover, we believe that states should consider other vendors, and not necessarily seek approval to join other state purchasing pools merely because those pools already exist.

We will review any SPA involving multi-state pools for compliance with section 1902(a)(19) of the Act. In accordance with these provisions, we will monitor the impact of one vendor on beneficiary access. States may form pools that use a different vendor or join together to negotiate supplemental rebates without using a vendor. Any Request for Proposal (RFP) for vendor contracts, whether issued jointly by all the states or separately by each participating state, should identify the populations for which the supplemental rebates would apply and should specify all of the states involved to clearly indicate from the outset which states are participating in the new pool.

In addition to the procurement requirements described above, each state participating in a new pool should submit a SPA package that includes the following elements:

1. **Standard multi-state pooling language incorporated into the supplemental rebate agreement portion of the state plan.** Specifically, this language should read as follows:

“CMS has authorized the state of [insert state name] to enter into the [insert the name of the multi-state pooling agreement]. This Supplemental Drug Rebate Agreement was submitted to CMS on [insert submittal date] and has been authorized by CMS.”
2. **A supplemental rebate agreement template.** Consistent with section 1902(a)(19) of the Act, we expect that the SPA would include a standard template, to ensure uniformity of the pool's supplemental rebate agreements for ease of administration. The template should be the same for each participating state and should not include an effective date that is earlier than the first day of the quarter in which the SPA was submitted. In addition, as a template, the model agreement should not contain any manufacturer-specific information.
3. **A document referenced in the supplemental rebate agreement template that indicates the state's participation in the purchasing pool.** This document

will serve as the mechanism by which other states will be added to the multi-state pooling agreement and should be filled in with any necessary state-specific information. This document will also serve as a template; therefore, it should be the same for each participating state and should not contain any manufacturer-specific information.

4. **A document that indicates if a state joining the pool intends to include its non-Medicaid program in the supplemental rebate program that has been approved by CMS, if applicable.** States that intend to include non-Medicaid programs must receive approval from CMS prior to joining the pool under the procedures outlined in the letter from Dennis Smith, Director, Center for Medicaid and State Operations, to all State Medicaid Directors (Sept. 18, 2002). In addition, each state should provide specific evidence to demonstrate that its prior authorization requirement furthers Medicaid goals and objectives and is designed to increase the efficiency and economy of the Medicaid program.

Guidance for States on Preferred Drug Lists (PDLs) and Prior Authorization

A state that seeks for the first time to use its prior authorization authority to create a PDL and to negotiate supplemental rebates (regardless of whether it seeks to join or create a multi-state pooling arrangement) must amend its state plan to refer to the supplemental rebate agreement and submit its proposed rebate agreement for CMS' authorization. Along with the implementation of a supplemental rebate program, most states have also implemented a PDL in conjunction with their prior authorization program. Because non-preferred drugs remain available to beneficiaries through prior authorization, a PDL allows states to ensure appropriate patient access to needed medications and maintain continuity of patient therapy.

1. **Patient Access to Needed Medications** - Upon implementation of a PDL, states should ensure that patients continue to have appropriate access to needed medications. A prior authorization program is intended to balance the interests of beneficiaries in receiving medically necessary drugs and the interests of states in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner. Therefore, we will seek assurance from states that all covered outpatient drugs that are not included on a PDL remain available pursuant to prior authorization, consistent with section 1927(d)(5) of the Act.
2. **Autonomy of the State PDL** - Because we are concerned about beneficiary access to medications, we would expect states to ensure that a PDL is consistent with Medicaid goals and objectives and section 1902(a)(19) of the Act.
3. **Continuity of Care** - When implementing PDLs, we urge states to be mindful of patients who are stabilized on previously prescribed, non-preferred medications. Consistent with our concerns for balancing the needs of patients with the efficiency and economy of the Medicaid program, we further urge states to consider the impact on beneficiaries of sudden changes in therapy as a result of a state's implementation of a PDL. Such a sudden change could, in some instances, result in higher costs due to a patient's failure of therapy on PDL drugs.

4. **Vendor Contracting** – In contracting with a pharmacy benefit manager or other vendor for purposes of negotiating state-specific or multi-state supplemental rebates, states should make sure that the selected contractor discloses all types of remuneration and the methodology for calculating any such remuneration, all rebate offers being made by manufacturers, and any other pertinent information including vendor administrative costs and incentives related to vendor supplemental rebate negotiation, and PDL development. We suggest that such information include descriptions of any and all payment from manufacturers or other entities involved in the manufacture, distribution, sale, or payment of pharmaceuticals.
5. **State-Specific Supplemental Rebate Agreements** – In order to realize additional cost savings, states are encouraged to continue negotiating state-specific supplemental rebate agreements, either in addition to, or in lieu of, multi-state pooling agreements.
6. **Annual Evaluations** – If states choose to participate in a multi-state pooling agreement, we recommend that those states annually evaluate and issue a public report on the aggregate cost savings associated with their participation to determine whether expenditures in other Medicaid areas, such as hospitalizations or physician services, have increased as a result of the implementation of the multi-state pooling agreement. Even if a state chooses not to participate in a pool, we encourage such an evaluation in connection with the state's PDL, prior authorization program, and state-specific supplemental rebate agreement, if applicable.
7. **Non-Medicaid Programs** - As we stated in our September 18, 2002, SMD, in submitting a SPA to link a Medicaid prior authorization program to rebates or discounts for non-Medicaid drug purchases, states should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program.