MEMORANDUM

TO: Potential Part D Sponsors, State Medicaid Directors, and State Pharmaceutical Assistance Programs (SPAPs)

FROM: Leslie Norwalk, Deputy Administrator
Centers for Medicare & Medicaid Services (CMS)

SUBJECT: SPAP Assistance for Low Income Subsidy Eligible Individuals under the Medicare Prescription Drug Benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) presents new opportunities for states to save money on the costs of their Medicaid programs, state pharmaceutical assistance programs and on the costs of their retirees' health benefits, while maintaining or improving drug coverage. To take advantage of these savings, the law does require some changes in the way that states provide their coverage to low-income beneficiaries. CMS has taken many steps to assist states in capturing the intended savings. This memorandum describes some of these opportunities, and also outlines other approaches that are contrary to Medicare policy goals and questionable under the law.

The MMA allows SPAPs to "wrap around" the Medicare benefit to fill gaps in coverage and for State programs that meet the definition of "SPAP," the program's wrap-around payments will count as if they were paid by the beneficiary for purposes of filling the coverage gap and meeting the catastrophic limit. As a result, SPAPs will be able to provide the same or better coverage for beneficiaries who receive coverage through state programs now, at a lower cost per beneficiary for the states because of the availability of the Medicare drug benefit. Coordinating with Medicare frees up significant amount of state funds, allowing for the expansion of the population served by state SPAP programs. In fact, we estimate that the savings that will accrue to States as a result of Medicare Part D displacing SPAP expenditures for low-income beneficiaries will be approximately $600 million per year, or about $3 billion over the five-year period from CY 2006-2010.

A State program may still be considered an SPAP if some or all of its program funding is from private sources (for example, from charities or independent foundations), and payments made by SPAPs will count towards an enrollee's true out-of-pocket costs (TrOOP). This will allow the enrollee to reach the catastrophic coverage faster, at which point the Medicare program pays for at least 80% of the costs.

The MMA provided $125 million in grants to 21 SPAPs to educate their enrollees about the new benefit. States with qualifying SPAPs can use these funds to establish telephone support and counseling for those eligible for the new drug benefit to help them select and enroll in a drug plan.

States are permitted and encouraged to help their beneficiaries choose a Medicare drug plan. Indeed, CMS strongly encourages states to support beneficiary choice of any of the qualified Medicare drug plans that they prefer and that is best for them. However, CMS is concerned about Plans or State programs that are designed to go beyond support and eliminate choice for the low-income subsidy population by steering them into one preferred PDP, particularly if the preferred PDP then transfers cost savings back to the states at the expense of Medicare beneficiaries and Federal taxpayers**.** These programs do not meet the definition of SPAPs. They also may increase costs for all Medicare beneficiaries and the Medicare program. Additionally, we believe that the establishment of such State programs may violate Federal fraud and abuse laws.

Specifically, it has been brought to our attention that some states are being encouraged to direct lower-income beneficiaries into State-preferred prescription drug plans (PDPs) under the new Medicare prescription drug benefit. In return for directing their beneficiaries to these particular preferred PDPs, the States – either independently or through the preferred PDP, would receive rebates and other financial concessions from drug manufacturers. Generally stated, the proposals would: (1) be directed toward beneficiaries who are eligible for the low income subsidy under the Medicare drug benefit; (2) be structured so that the State program would act as the authorized representative of its enrollees and, as such, enroll beneficiaries into the preferred PDP(s); (3) be designed so that the State program or State retains rebates from drug manufacturers at the expense of Medicare beneficiaries and the Medicare program. We understand that some States have even begun the process of drafting and enacting legislation that would allow them to act as the authorized representative of their State program enrollees and auto-enroll them into a specific PDP.

We are particularly concerned about PDPs transferring to State programs or states cost savings (rebates) generated from drug sales to low-income subsidy beneficiaries rather than the PDP using those rebates to lower the actual drug prices and catastrophic costs for Medicare beneficiaries and to reduce the cost of the prescription drug benefit. Such a transfer of cost savings (rebates) to a state by a PDP could mean that the PDP bid would not "reasonably and equitably" reflect the cost of the benefits provided. As stated in the final rule, CMS will negotiate bids submitted by applicants to ensure that the bids are reasonable. CMS has the authority to ask bidders to provide information about rebates and discounts they are receiving from manufacturers and others, in order to ensure that they are negotiating as vigorously as possible, so that we can evaluate comparisons in drug prices between PDPs. 70 Fed. Reg. 4299-4300. Additionally, Medicare will pay the bulk of a low-income beneficiary's prescription drug costs through the low-income subsidy and the Federal government pays 80 to 85 percent of any prescription drug costs a PDP incurs once a beneficiary has reached a catastrophic limit (equal to $3,600 in out of pocket spending in 2006). Thus, any rebates that are not used to lower negotiated prices are likely to increase drug payments by beneficiaries and the cost-sharing Medicare will pay on behalf of low-income subsidy individuals. Also, higher negotiated prices would cause a beneficiary to hit his or her catastrophic limit more quickly, thus leading to higher reinsurance payments from the Federal government. In short, this transfer of rebates to states will likely result in higher costs for all Medicare beneficiaries and the Medicare Program.

We believe these types of proposals could create significant fraud and abuse concerns for PDPs, States and manufacturers, including potential Federal antikickback concerns under section 1128B(b) of the Social Security Act [42 U.S.C. § 1320a-7b(b)]. Unlike cases where a State is actually assisting the beneficiary with his or her purchase of prescription drugs or where manufacturer rebates are being used directly to finance a cash assistance program for low-income individuals, under the proposals we have reviewed, the Federal government – through the low income subsidy – and not the State would be providing the majority of the financing for the prescription drugs. In other words, the State receives a financial benefit even though it incurs little to no financial burden, while the Federal government and Medicare beneficiaries do not receive the benefit, although Federal taxpayers are bearing most to all of the costs.

For the reasons noted above, we intend to issue a Medicaid Drug Rebate Program Release to clarify that SPAPs that engage in the types of arrangements described above will not meet the criteria of an SPAP under Medicaid. The result of this clarification will be that the rebates they receive will be treated as creating a new "best price" under section 1927 of the Social Security Act. In addition, because state programs that "discriminate based upon the part D plan in which the [SPAP] individual is enrolled," do not meet the definition of an SPAP under the statute, see § 1860D-23(b)(2), any SPAP that automatically enrolls its beneficiaries in a preferred PDP cannot be considered an SPAP under section 1860D-23(b) of the Social Security Act. Therefore, once such enrollment begins occurring, the SPAP will no longer be eligible for the transitional grant funds under section 1860D-23(d) of the statute. Moreover, these State programs do not qualify as an SPAP and these funds will not count as beneficiary true out of pocket spending, thus extending the time it takes the beneficiary to reach catastrophic coverage.

Finally, we would like to reiterate that the legal basis for approving a state plan amendment that seeks to leverage Medicaid prior authorization programs in order to secure for the State manufacturer rebates for the low-income subsidy population covered by the Medicare prescription drug benefit is questionable, at best. In a State Medicaid Director letter issued September 18, 2002, we explained that CMS must review and approve any programs where a State wishes to place Medicaid-covered drugs on a prior authorization list as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements that benefit *non-Medicaid* populations. Because low-income subsidy individuals will receive the bulk of their cost-sharing and premium assistance for prescription drugs from the Medicare program and not Medicaid, we consider this population to be akin to the non-Medicaid population discussed in the State Medicaid Director letter. We are especially concerned about programs directed toward dually eligible individuals. As these individuals are already receiving Medicaid benefits, we do not believe that State assistance for prescription drug costs would result in Medicaid savings or reducing the number of individuals becoming eligible for the Medicaid program. We do not believe that these proposals would further the goals and objectives of the Medicaid program; therefore, we do not plan to approve any such prior authorization programs.

We will continue to work closely with States on approaches to implement the Medicare drug benefit that reduce costs for all parties, not that shift costs inappropriately to Medicare beneficiaries and the Medicare Program. We are working closely with States to assure that the

phase-down contribution calculation is accurate and fully reflects all appropriate State data, and that all other data related to state costs and benefits are considered appropriately, to assure that the Medicare drug benefit reduces costs for states. We are also contributing to the administrative costs of enrolling low-income subsidy eligible individuals into the Part D program. States will receive matching Federal funds when they decide to provide Medicaid beneficiaries with an advance supply of drugs during the transition to the Part D program and will continue to match State Medicaid costs for drugs excluded under Part D. Further, we are assisting States to ensure that State retiree benefit systems receive full financial support from Medicare for qualifying contributions. Finally, through other forthcoming guidance and individualized assistance to states, we are helping states with SPAPs to transition their programs to provide less expensive but equally comprehensive benefits through "wraparound" support for Medicare drug plans. This strong partnership between CMS and States will protect beneficiaries while resulting in overall savings to States.