United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

April 28, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
314G Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

As you know, implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) is in full swing. I commend you and your staff at the Centers for Medicare and Medicaid Services (CMS) for your efforts to implement major provisions of the landmark bill in a timely manner. This legislation, the result of many years of debate in Congress, is far-reaching and complex. Despite tight timelines and a tremendous workload, CMS has met nearly all deadlines over the past 16 months. And, according to your projections, we can expect the new benefits under Medicare Advantage and the Part D drug benefit to be available on January 1, 2006, as the statute requires.

Given the scope and importance of the new law, proper implementation requires careful consideration and balancing of a wide range of stakeholder views, including those of beneficiaries, providers, health plans and insurers, taxpayers and Congress. As CMS proceeds toward approving new plans to participate in the program and making the new benefits operational in January 2006, I offer the following concerns and suggestions.

As you know, I have deep reservations regarding CMS' administration of the Medicare Drug Discount Card, which became effective in May 2004. Medicare beneficiaries in Montana had a choice from among more than 40 drug cards, with different enrollment fees, administered by different plan sponsors, providing varying discounts for different drugs, and arrangements with different pharmacies. Many Montana seniors told me that they had difficulty discerning among these choices. And as a result, the vast majority of Montana seniors – including thousands who stand to benefit from the $600 low-income transitional assistance – decided to forgo enrollment in the drug card altogether. I strongly urge CMS to heed the lessons of the drug card program by exercising vigorous review of plan applications for Medicare Advantage and the

Medicare Part D drug benefit and approving only those plans that meet the highest standards.

This course of action is especially important for beneficiaries who will transition from Medicaid drug coverage into the Medicare drug benefit program. The prescription drug plans that you approve will take over the responsibility of covering medications for beneficiaries who are eligible for both Medicaid and Medicare – so-called dually eligible beneficiaries. These individuals typically have higher than average drug utilization and poorer health status, and they will be among the first to enroll and receive coverage through the new plans. Nearly 40 percent of these beneficiaries have a cognitive or mental impairment, and one in three has a limitation in performing basic activities of daily living.

The CMS final regulation and corresponding guidance lacks sufficient protections or plan requirements to assure continuity of care for dually eligible beneficiaries. The ability to maintain current drug therapy is vitally important, particularly for beneficiaries with mental illnesses who are stabilized on medications. Imposing rigorous formularies and coverage rules, such as fail first and prior authorization requirements, could impede access to medications that are already working for patients. Treatment failure due to plan policies that exclude or hinder coverage for drugs that beneficiaries are currently taking could lead to hospitalization, institutionalization, or other avoidable and costly health events. Your recommendation that beneficiaries in Medicaid fill 60- or 90-day prescriptions in December 2005, prior to transition of their drug coverage to Medicare, is not a workable solution. Many beneficiaries live in states, such as Montana, where Medicaid limits prescriptions to 30 days.

I am pleased that CMS will require plans to cover all or nearly all drugs in certain pharmacologic classes, although you did not take the additional step to guarantee that required drug products be available at preferred status. I also appreciate your decision to automatically enroll dually eligible beneficiaries into drug plans. However, that measure was only a half step toward assuring that these beneficiaries will receive continuity of care. Moreover, it is possible, if not likely, that many beneficiaries could fall through the cracks and ultimately not be assigned to a plan. To address this scenario, CMS should establish a special, national help-line or some other specific means for these beneficiaries to seek assistance if they experience problems with assignment to a prescription drug plan. Calling 1-800-Medicare may not be sufficient.

To ensure that plans fully address the needs of this vulnerable population, CMS should take the additional step of approving only those plans using Medicaid "best practices" to cover dually eligible beneficiaries. Another approach would be to "grandfather" in certain chronic care drugs on which beneficiaries are stabilized unless there is a medical necessity for them to switch. I urge CMS to do as much as possible to ensure continuity of coverage for medically necessary medications and protect the health of these beneficiaries. Failure to do so will have serious adverse consequences for beneficiaries, the new drug program and taxpayers.

Second, CMS should apply the non-discrimination rule to protect beneficiaries from inappropriate use of *any* cost management tool that prescription drug plans propose to employ, including formularies, cost-sharing tiers, benefit design, prior authorization, and step therapy programs. Plans that attempt—by any means—to exclude or impede access to medications for beneficiaries with serious chronic conditions or special needs should be rejected. Applying such a stringent review will be a challenge for CMS. But I believe that the enforcement of the non-discrimination rule is one of the most important regulatory tools CMS has to require that private plans meet the needs of the Medicare population, as intended by the MMA. It is equally important that CMS devote appropriate resources and staff to properly review plan submissions in light of this standard. Otherwise, Medicare beneficiaries may have multiple plan options but fewer legitimate choices that provide appropriate access to the drugs they need.

Third, the appeals and exceptions process may also fall short because of key problems. For example, it is unclear how beneficiaries will be informed of their appeal and exceptions rights. Although notice may be posted or provided by network pharmacies, there is no requirement that all pharmacies provide individuals with direct notice of their appeal rights. Even though most beneficiaries will learn that their prescriptions are not covered at the pharmacy, the final regulation requires beneficiaries to get an official denial from their plan before they can appeal or seek an exception to the formulary.

It is also unclear what information a physician must provide in order to prove that an exception to the formulary is medically necessary. Although the final rule provides some criteria plans might apply, it gives plans broad discretion to establish the standards by which an exception would be granted, which means these standards could vary significantly from plan to plan.

Another short-coming of the appeals and exception process is the issue of access to medications while an appeal is pending. The final rule does not require plans to provide continued coverage of a needed medication while an appeal is pending. This protection is currently available to dually eligible beneficiaries and should be extended under the new Medicare drug benefit program. It is critical that beneficiaries have appropriate recourse when plans deny coverage of a prescription. I am concerned that the final regulation fails to strike the right balance and urge you to consider changes that will strengthen them.

Although a strong exceptions and appeals process is important, it is not a reasonable safety valve for poor formulary design or other aspects of plan coverage that limits access or discourages enrollment of high cost Medicare beneficiaries. Reliance on an exceptions process to the formulary through an appeal is both burdensome to beneficiaries and costly to all stakeholders. Compared to current Medicaid due process rights and the more robust appeal standards in the current Medicare program, the final rule delegates too much authority for establishing these standards to the drug plans. This

issue further underscores the need for and importance of rigorous review of plan applications for Medicare Advantage and the Medicare Part D drug benefit.

Fourth, I remain troubled by CMS' treatment of Native Americans under the Part D benefit. Specifically, CMS has determined that the Indian Health Service (IHS) will not be allowed to assist with Part D premiums or cost-sharing, which could prove a significant barrier to Part D access for many Native Americans. On the issue of pharmacy access, CMS has stated that it will require prescription drug plans to contract with Indian Health Service and Tribal pharmacies, including Urban Indian Program pharmacies – but only if these pharmacies comply with standards established by the plans. Guidelines for these standards are not spelled out in sufficient detail, which could result in significant variation in access for Native Americans across plans, or even *no* access to an IHS or Tribal pharmacy in some cases.

Pharmacy access for non-Native American beneficiaries also could be problematic. The MMA required plans to meet the TRICARE standard for pharmacy access. This standard stipulates that plans must have an in-network retail pharmacy within a maximum distance of specific percentages of rural, urban and suburban beneficiaries. Without an in-network pharmacy, Medicare beneficiaries will be forced to pay higher cost-sharing for their drugs or may not be able to fill a prescription. Unfortunately, CMS has decided to allow plans to meet a pharmacy access standard that is less stringent than TRICARE by designating pharmacies within a plan's network as "preferred" and "non-preferred."

Under TRICARE, cost-sharing is uniform for all in-network pharmacies. By allowing pharmacies within a network to be designated as preferred and non-preferred (and, accordingly, allowing differential cost-sharing), CMS circumvents the goal of the TRICARE standard and the intent of Congress. Moreover, CMS staff have acknowledged that beneficiaries in certain parts of the country, most likely rural or frontier areas, could be left without access to a preferred, in-network pharmacy. The MMA conference report language clearly states that "the minimum in-network pharmacy for each plan offered by a PDP or MA plan in a geographic area must provide access to pharmacies that is not less restrictive than the TRICARE access standards." It is imperative that CMS prohibit plans that circumvent this clear policy goal from participating in the program.

Finally, CMS' process of evaluating preferred provider organizations (PPOs) could leave too many rural areas without any participating physicians or specialists. In order to attract regional PPOs into the program, the MMA provided specific financial incentives, such as risk corridors and the opportunity for regional bids to affect regional benchmarks. It also established a fund to help PPOs contract with rural hospitals. But the final regulation went beyond these statutory incentives to encourage PPO participation. For example, the final rule granted broad exceptions to network adequacy standards, which gives regional PPOs less responsibility to contract with providers than plans operating on a local basis. Neither the final rule nor subsequent guidance specified the

criteria CMS would use to grant or reject network exceptions. I am concerned that the exceptions process will be too lenient, providing incentives for regional plans to ignore rural and frontier areas, and creating an un-level playing field for local plans. I urge CMS to approve network exceptions only in the rarest circumstances – for instance, where a single provider in an area jeopardizes the ability of a plan to construct an entire network.

The MMA created an historic opportunity to improve Medicare for the people it serves. I appreciate the magnitude of the job CMS has undertaken, and I remain deeply committed to the improvements offered through this legislation, so long as CMS implements it as Congress intended and in a way that is fair to all stakeholders – including beneficiaries and taxpayers. I look forward to your response to my concerns. And I look forward to the implementation of the new and long-awaited drug benefit for America's seniors.

Sincerely,

Max Baucus

Max Baucus