DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

SEP 24 2004

The Honorable Charles Grassley
United States Senate
Washington, DC 20510

Dear Senator Grassley:

I want to thank you for your letter addressing the role of CMS in reviewing plan formularies in the new Medicare drug benefit. Your letter makes many important points about the Agency's legal authority under the Medicare Modernization Act (MMA) to review plans' proposed bids, and we fully concur with your analysis.

CMS intends to have a vigorous and comprehensive review of drug plans offered in the new Medicare Part D to ensure that all beneficiaries have access to needed medications. Formulary design will be an important element for meeting this goal. Formulary design will also significantly affect plans' negotiations with manufacturers, as rebate deals often turn on formulary placement. As you note, it will be important for Medicare Part D benefits to do both, giving plans room to negotiate and lower costs while protecting beneficiaries. CMS takes this task seriously and is committed to making sure that Part D plans achieve both low costs and effective access to medicines.

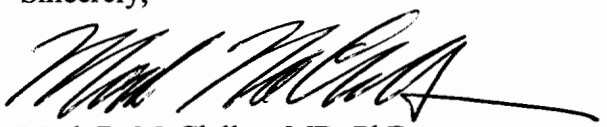
You are correct to note that the process currently underway at United States Pharmacopeia (USP) to develop model guidelines for drug categories and classes is only one aspect of CMS's formulary review. USP has a valuable technical role to play to devise a set of model categories and classes. Under the law, plans may choose to use USP's categories and classes, or they may devise their own systems. Either way, CMS will review the drugs chosen to populate the formulary, the co-pays, the utilization review approaches, and the exceptions and appeals processes the plans propose to use. All these pieces together are critical for making sure that beneficiaries have a drug benefit that encourages cost-effective use of prescription drugs while preserving access to all of the medications they need. As you note, the statute gives us clear authority for all of these important oversight steps.

We also fully agree that the MMA requirement that Medicare drug plans include at least two drugs in each category and class should be viewed as a floor rather than an absolute standard. Our proposed rule reflects this. In the preamble, we noted that "it is our expectation that plans' formularies will provide Part D enrollees a *comprehensive benefit* – one that covers an amount and variety of drugs sufficient to treat all disease states." In some categories and classes two may suffice. In others, like the HIV / AIDS medications you cited, more than two will certainly be necessary, and CMS would not approve any plan that placed onerous restrictions on these drugs. We also note in the preamble that we expect plans to provide a variety of strengths and dosages of covered drugs as well as a "wide range of generic drugs," as generics can greatly reduce costs for both beneficiaries and the taxpayers.

CMS intends to further articulate our formulary review procedures in the final rule (expected out early next year) and in sub-regulatory guidance so that all potential bidders can know what is expected of them and how the review process will be conducted. Those standards will require drug plan formularies to provide a reasonable choice of drugs that reflects current medical practice. We will also review individual formularies to make sure that each plan's drug benefit is adequate, particularly for the vulnerable populations that Medicare serves, and to prevent any discriminatory practices. We intend to seek comments from all interested parties on our overall formulary review framework before it is finalized early next year. We look forward to continuing to work closely with you and other members of Congress, as well as patient groups and health professionals, to make sure that our formulary review framework and the drug benefit provide access to high-quality medicines at the lowest possible cost.

Thank you again, and I look forward to continuing to work with you in the months ahead as we implement the many improvements in Medicare benefits that the MMA provides.

Sincerely,



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