U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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Grassley affirms Medicare's authority to ensure access to needed medicines for beneficiaries

WASHINGTON — Sen. Chuck Grassley, chairman of the Senate Committee on Finance, today released his exchange with the Medicare administrator about the agency's role in ensuring that seniors and Americans with disabilities have good access to the drugs they may need under the Medicare prescription drug benefit.

In response to Grassley's letter, the Medicare administrator agreed that the Medicare Modernization Act of 2003 gave the Centers for Medicare and Medicaid Services the authority to review plans' proposed formulary designs and to disapprove designs that may discriminate against certain groups of beneficiaries.

The text of Grassley's letter follows here. The text of the reply from Administrator Mark McClellan is attached in a pdf file.

September 24, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
314G Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Dr. McClellan

Thank you for your participation in last week's Senate Finance Committee hearing, "Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rule."

As I am are sure you know, many advocacy groups have raised questions about the authority that the Centers for Medicare and Medicaid Services (CMS) has to review drug formularies under the new Medicare prescription drug benefit and about the process used by the United States Pharmacopeia (USP) for establishing the model set of drug categories and classes. It is my understanding that

several of my colleagues in the House of Representatives also have written directly to the USP on these issues.

After listening to and reading about these concerns, I am deeply troubled by the apparent misinterpretation of the authority of CMS to review plan drug formularies. Specifically, there appears to be an erroneous belief that the USP draft model guidelines constitute an acceptable formulary and that CMS does not have the authority to disapprove a formulary that complies with the USP guidelines for drug categories and classes, but that is deficient in other respects. Since these interpretations are wholly incorrect, I am writing to ensure that CMS understands Congressional intent on these matters.

The Medicare Modernization Act (MMA) establishes a voluntary safe harbor for the drug categories and classes used by Part D plans. If a Part D plan's formulary uses the USP drug categories and classes, however, this does not mean that it is exempt from further scrutiny by CMS. Thus, using the USP drug categories and classes will not guarantee that CMS will approve its formulary.

If a plan chooses to use USP's model guidelines for the drug categories and classes, then only the drug classification system is exempt from further scrutiny. I want to be clear that Congress constructed this safe harbor narrowly such that it applies only to the Part D plan's choice of categories and classes themselves. Under the MMA, CMS is required to subject the actual drugs

chosen to be on the formulary, as well as any tiered co-pay structure that a plan decides to use, to a much more extensive review, even if the classification schema conforms to the USP model.

Section 1860D-4(b)(3)(C)(i) of the MMA requires that "the formulary must include drugs within each therapeutic category and class of covered Part D drugs," which CMS in its recent proposed rule has taken to mean at least two drugs in each category. In keeping with Congressional intent, CMS should consider this requirement a floor, not a ceiling and not an absolute standard. For many treatments - HIV/AIDS medications, for example - I understand from current practice in the pharmacy benefit management industry, that more than two drugs are necessary. Thus, no matter how broadly or narrowly USP defines the categories and classes, plans would have to provide a wide range of drugs in order to have an acceptable formulary. I expect CMS to consider this kind of information in reviewing, approving, or disapproving Part D plan bids.

Congress clearly intended that CMS have the necessary authority to ensure that all Part D plans offer a medically necessary range of drugs, while at the same time giving plans some flexibility in their formulary design. This flexibility is vitally important to empower plans in their negotiations with drug manufacturers so that they can achieve significant discounts on prices and save money for both beneficiaries and taxpayers.

" Section 1860D 11(e)(2)(D) of the MMA gives the Secretary authority to approve or disapprove plan designs. The Secretary may only approve the plan design if he or she "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." If CMS were to find that a plan substantially discriminates, for example, against beneficiaries

with mental illness by including an inadequate range of anti-depression drugs, the MMA requires the agency to require the plan to modify its formulary design or face disapproval.

While some have argued that language in Section 1860D-11(i) which stipulates that CMS is prohibited from requiring that plans offer "a particular formulary" proscribes the agency's formulary review authority, this is not the case. Requiring plans to address formulary inadequacies is not the same as "require[ing] a particular formulary." CMS should not interpret this language as hindering its authority to conduct vigorous reviews of plans' proposed formulary designs.

" In addition, section 1860D-4(b)(3)(B) of the MMA sets requirements on the plans' pharmacy and therapeutics committees. Specifically, it notes that: "In developing and reviewing the formulary, the committee shall (i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and (ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy." If CMS determines that a plan had ignored the weight of scientific evidence that a drug is medically necessary or particularly advantageous for some beneficiaries, the agency, to enforce the MMA, would be expected to require the plan to add the drug to its proposed formulary or face disapproval.

" Finally, section 1860D-11(d)(2) gives the Secretary the authority to "negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan." This provides the agency with considerable authority and flexibility to address any formulary adequacy issues not covered by the sections cited above.

I would also note that plans' formularies are not the final word on what drugs are covered in Medicare. By law, plans that use a formulary must have an exceptions process as well as an appeals process to make sure that beneficiaries have access to medically necessary drugs, even if the plan has a restriction on its formulary. CMS again has ample authority under the MMA to review those processes to ensure that beneficiaries have access to the drugs they may need and that these processes are not overly burdensome or confusing.

I hope that this review and legislative analysis of the MMA allays any concerns that beneficiaries and their advocates may have about these issues. I know that we share the goal of providing beneficiaries access to a wide range of prescription drugs. I look forward to working with you to implement this important law and provide much needed prescription drug benefits to our seniors and disabled Medicare beneficiaries.

Sincerely,

Charles E. Grassley
Chairman