

April 17, 2006

Mr. Daniel R. Levinson, Inspector General  
Department of Health and Human Services Room 5541 Cohen Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Inspector General Levinson,

We are writing to express our support for the continued availability of pharmaceutical manufacturer patient assistance programs (PAPs). As you know, manufacturer PAPs provide free or subsidized medications to thousands of individuals, including Medicare beneficiaries, who might not otherwise be able to afford their prescription drugs. Many seniors and individuals with disabilities who participate in manufacturer PAPs have chronic conditions. These beneficiaries must take very expensive prescription drugs - which often do not have generic drug equivalents - to manage those conditions and to maintain their quality of life. Without assistance from a PAP, some Medicare beneficiaries may not otherwise be able to afford their prescription drugs, even if they are enrolled in the new Medicare prescription drug benefit.

We appreciate that your office issued the Special Advisory Bulletin on Patient Assistance Programs last November. The goal of this Bulletin was to clarify the applicability of the federal anti-kickback statute to all PAPs, including those offered by pharmaceutical manufacturers. Unfortunately, it is our understanding that the Bulletin may have had the opposite effect. As a result, several pharmaceutical manufacturers have indicated that they will discontinue their prescription assistance to Medicare beneficiaries as of May 15.

Your office has achieved significant accomplishments in reducing waste, fraud and abuse in the Medicare Part A and Part B programs. We applaud the OIG's efforts in assisting, developing and implementing a comprehensive strategy to identify and prevent fraud, waste and abuse under Medicare Part D. Working with the Centers for Medicare and Medicaid Services (CMS), the Federal Bureau of Investigation (FBI) and prosecuting attorneys at the Department of Justice (DOJ), the OIG has recognized the importance of protecting Medicare beneficiaries and taxpayers' dollars. That said, we are troubled that the OIG's Guidance may limit-albeit unintentionally-beneficiary access to necessary medications. We are particularly concerned about the ongoing availability of manufacturer PAPs for three groups of Medicare beneficiaries: 1) low-income beneficiaries of limited means who do not qualify for the low-income subsidy; 2) low-income beneficiaries between 135 percent and 150 percent of poverty who qualify for the low-income subsidy, but pay 15 percent coinsurance for their prescriptions; and 3) higher-income beneficiaries with catastrophic prescription drug needs who currently derive a significant benefit from participation in pharmaceutical manufacturer PAPs.

It is our understanding that some companies have requested advisory opinions from the OIG regarding the legality of the specific design of their PAPs. We understand that this process is iterative and that the OIG often must ask the requester for additional information. We hope, though, that the OIG will continue to work as expeditiously as possible in responding to these requests, which may help mitigate this situation. Again, we urge you to work to further clarify the legal guidance on the manufacturer PAPs as expeditiously as possible. We believe a resolution can be achieved that allows pharmaceutical manufacturers to continue providing much needed assistance to certain groups of Medicare beneficiaries in a manner that does not violate the integrity of the Medicare program.

We thank you for your prompt attention to and consideration of this request. Because of the seriousness of this matter, we are instructing our staff to contact your office Monday to discuss this issue further.

Sincerely,

Charles E. Grassley  
Chairman

Max Baucus  
Ranking Minority Member

Orrin G. Hatch  
Chairman  
Health Care Subcommittee

John D. Rockefeller IV  
Ranking Minority Member  
Health Care Subcommittee

cc: Michael Leavitt, Secretary, Health & Human Services