



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

FEB - 9 2006

The Honorable Billy Tauzin
President and CEO
The Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW
Washington, DC 20005

Dear Mr. Tauzin:

Pharmaceutical companies' patient assistance programs (PAPs) have proven to be a vital source of medication for many Americans. However, there has been concern about federal laws and regulations affecting pharmaceutical companies' ability to continue these programs with the advent of the Medicare prescription drug benefit. I wanted to take this opportunity to clarify any confusion that may exist.

As you know, the decision to operate a PAP is up to each pharmaceutical company, not the United States Government. The terms and conditions are determined by the company, without government involvement. Recent guidance from the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) make clear that lawful opportunities exist to provide drug assistance to Medicare beneficiaries. This guidance is attached for your review.

Specifically, PAPs can continue to assist Part D enrollees through a properly structured program that operates entirely outside the Part D benefit. Under this approach, the beneficiary does not use his or her Part D benefit to obtain the drug and the cost of the drug is not applied toward the enrollee's true out-of-pocket costs.

Other opportunities exist as well. Many pharmaceutical companies have donated to bona fide independent charities that operate PAPs that serve financially needy Medicare and other patients. Nothing in the law prevents pharmaceutical companies from continuing to support these vital programs.

The recent OIG guidance clearly supports the continuation of assistance by pharmaceutical company PAPs for needy Medicare beneficiaries and provides guidance on properly structuring such arrangements, including programs operating outside Part D.

Again, HHS recognizes the value of pharmaceutical PAPs to their clients, including Medicare beneficiaries. It is my hope that HHS and PhRMA can work together to create opportunities for the Medicare drug benefit and PAPs to work in tandem.

Sincerely,

A handwritten signature in black ink that reads "Michael O. Leavitt".

Michael O. Leavitt

Enclosures