



For Immediate Release
November 7, 2005

OIG NEWS

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Special Advisory Bulletin Provides Guidance On Patient Assistance Programs For Medicare Part D Enrollees

Washington, DC – HHS Inspector General Daniel R. Levinson today released a Special Advisory Bulletin providing guidance on the application of OIG fraud and abuse laws to patient assistance programs (PAPs) that offer assistance in obtaining outpatient prescription drugs to financially needy Medicare beneficiaries who enroll in the Medicare Part D drug benefit.

“The OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs. Accordingly, the Bulletin makes clear that lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs,” said Inspector General Levinson.

As explained in the Bulletin, arrangements through which a pharmaceutical manufacturer would use a PAP it operates or controls to subsidize its own products that will be payable by Medicare Part D present a heightened risk of fraud and abuse. However, the Bulletin further explains that there are other options manufacturers can consider to assist financially needy Part D enrollees in obtaining outpatient prescription drugs.

For example, the Bulletin, reflecting long-standing OIG guidance, makes clear that pharmaceutical manufacturers can make cash donations to *bona fide* independent charity PAPs that are not affiliated with a manufacturer and operate without regard to donor interests, providing appropriate safeguards exist. These programs are typically operated by patient advocacy and support organizations.

The Bulletin notes that the OIG is mindful of the importance of a smooth, effective transition to alternative assistance models for beneficiaries who are currently participating in pharmaceutical manufacturer PAPs and elect to enroll in Medicare Part D. Accordingly, the Bulletin points out that, in exercising enforcement discretion with respect to the administrative sanctions under the Federal anti-kickback statute, the OIG will take into consideration whether a pharmaceutical manufacturer is taking prompt and meaningful steps to transition Medicare Part D enrollees to alternative models, such as independent charities unaffiliated with pharmaceutical manufacturers, once the benefit starts on January 1, 2006.

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“The OIG is counting on pharmaceutical manufacturers to play an important role in ensuring a smooth and effective transition,” said Inspector General Levinson.

Finally, the Bulletin makes clear that nothing in any OIG laws or regulations prevents pharmaceutical manufacturers or others from helping uninsured patients and Medicare beneficiaries who have not enrolled in Part D with their outpatient prescription drugs.

To access the Special Advisory Bulletin:

<http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBllletinFinal-Final.pdf>

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