

# Patient Assistance Program Deemed Acceptable

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The Health and Human Services Office of Inspector General recently gave the green light to a redesigned patient assistance program from the drug maker Schering-Plough Corp.

Late last year, the Inspector General issued a special advisory bulletin cautioning drug makers that continuing their patient assistance programs for people enrolled in

the Medicare Part D prescription drug benefit could put them at risk for violating the federal antikickback statute. But the bulletin outlined some designs that would allow Medicare beneficiaries to continue to receive drug assistance from the companies outside of the Part D benefit.

The new advisory opinion (no. 06-03) states that the OIG will not impose administrative sanctions on Schering-Plough based on the specific design of the program's two patient assistance plans, which

offer free drugs to financially needy patients taking hepatitis or cancer drugs, and to such patients taking other outpatient prescription drugs. The advisory opinion does not apply to any other arrangements.

Under Schering-Plough's design, Medicare Part D beneficiaries are still eligible for free drugs if they meet the income eligibility requirements for the patient assistance plans and have already spent at least 3% of their household income on outpatient prescription drugs that coverage

year. The free drugs do not count toward the beneficiary's true out-of-pocket costs and will not be billed to either the Part D plan or Medicare. Schering-Plough is working with officials at the Centers for Medicare and Medicaid Services on a data-sharing agreement to notify Part D plans about beneficiary participation in the patient assistance program.

"Having reviewed the arrangement, we conclude that the arrangement contains safeguards sufficient to ensure that the [patient assistance plans] operate entirely outside the Part D benefit, and, therefore, there is minimal risk of fraud and abuse under the Part D program," Lewis Morris, chief counsel to the Inspector General, wrote in the advisory opinion. ■

The OIG advisory opinion is available online at [oig.hhs.gov/fraud/advisoryopinions.html](http://oig.hhs.gov/fraud/advisoryopinions.html).

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