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Drug Companies Urged to Continue Drug Giveaways

By John Reichard, CQ HealthBeat Editor

A coalition of nine organizations that serve poor people without health coverage is urging big drug companies not to drop their programs to give free or discounted drugs to people who can't afford them.

The organizations fear companies will end their drug giveaways because of the new Medicare drug benefit and the drug industry's reading of guidance issued in December by the HHS Office of the Inspector General.

GlaxoSmithKline, AstraZeneca, Takeda Pharmaceutical, Eli Lilly, and TAP Pharmaceutical plan to end assistance programs to low-income seniors, the Wall Street Journal reported Jan. 13.

In a letter to 13 drugmakers, the coalition of about 300 non-profit hospitals, health systems and community health centers argues that completely eliminating programs could have drastic implications for low-income seniors. Many low-income patients have long relied on industry patient assistance programs and could have difficulty paying for their medications even with the prescription drug benefits now offered under the new Part D of Medicare, according to the group.

It notes, for example that “a Part D enrollee with an income as low as \$14,355 could be required to pay an average premium of \$35 per month in addition to a \$250 annual deductible and 25 percent of their drug costs upon entering the program.”

The group said its members were concerned about the impact of Medicare Part D on Medicare beneficiaries between 150 percent and 200 percent of the federal poverty level.

“Under Part D, these beneficiaries will be responsible for the full cost-sharing responsibilities, and we fear many may simply be unable to afford Part D coverage.”

The coalition mailed the letter to Amgen; Astra-Zeneca; Bayer, Biogen, Bristol-Myers Squibb, Gilead Sciences, Glaxo SmithKline, Merck, Novartis, Pfizer, Hoffmann LaRoche, TAP Pharmaceutical, and Wyeth Pharmaceuticals.

Drug Companies Anticipated Part D

A letter last year from GlaxoSmithKline to members of the company's assistance program, Bridges to Access, stated that Part D enrollees would no longer be able to get prescription drugs through the program after the start of the drug benefit, which began on Jan. 1. The letter adds that Medicare-eligible members of Bridges to Access who have not enrolled in Part D may remain in the assistance program until the Part D enrollment period closes May 15.

The changes are based on guidance issued by the HHS Inspector General, GlaxoSmithKline

said.

The Pharmaceutical Research and Manufacturers of America said on Jan. 10 that the Inspector General's guidance document may make it more difficult for the assistance programs to continue as currently structured.

HHS Inspector General Daniel R. Levinson said in announcing the guidance Nov. 7 that the document makes clear that drugmakers and others can lawfully provide assistance to low-income beneficiaries under the Medicare drug law.

Levinson said for example that drug companies could contribute to independent charities that run assistance programs. He added that the guidance makes clear that nothing in federal law or regulations keeps drug companies from helping uninsured patients or Medicare beneficiaries who do not enroll in Part D.

But a drug company maintaining its own pharmacy assistance program for Part D enrollees appears to raise concern that the manufacturer is violating federal laws barring kickbacks. The concern is that assistance could be perceived as an attempt to steer the patient to the manufacturer's drug in using the drug benefit instead of a cheaper generic.

The OIG's guidance document, published Nov. 22 in the Federal Register, states that company assistance programs "that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute."

Companies are suggesting that the door may still be open to maintaining some form of assistance. PhRMA said it is seeking clarification from the OIG or the Centers for Medicare and Medicaid Services "to allow assistance programs the option of providing free medicines to low-income beneficiaries enrolled in the new Medicare drug benefit" if they can be structured to protect Medicare.

And the GlaxoSmithKline letter states that it will investigate other options that would allow it to offer assistance consistent with the OIG guidelines.

But PhRMA Senior Communications VP Ken Johnson said companies would like to continue providing free or low-cost drugs to seniors when they reach that portion of the Medicare drug benefit in which the beneficiary must pay 100 percent of prescription costs, known as the "doughnut hole." But that does not appear to be in the cards. "We are not very optimistic that the OIG is going to make a mid-course correction," he said.

Johnson said that it's inaccurate to say companies are ending assistance to low-income seniors or other Americans. "Many of our companies will continue to provide assistance to seniors who choose not to take advantage of Medicare's prescription drug benefit," he said. In addition, they will continue to offer assistance to low-income Americans outside Medicare who are uninsured.

Johnson said the reason companies don't give to independent charities that could assist Part D enrollees is that the companies he represents are already giving hundreds of millions of dollars to charities.

"As an industry we cannot understand why we cannot donate medications in lieu of dollars,"

he said.

- [Sample letter to drugmakers \(pdf\)](#)

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