



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



JAN 04 2018

By Email and U.S. Mail

James C. Stansel
Executive Vice President and General Counsel
Pharmaceutical Research and Manufacturers of America
950 F Street, NW, Suite 300
Washington DC 20004

RE: Drug Companies that Provide Free Drugs to Federal Health Care Program
Beneficiaries Impacted by Caring Voice Coalition, Inc.'s Decision Not to Provide
Patient Assistance in 2018

Dear Mr. Stansel:

We are contacting you about an emergent issue we believe may interest PhRMA and its members whose drugs are used by patients who have been receiving financial assistance from Caring Voice Coalition, Inc. (CVC). CVC today announced that it would not provide patient financial assistance in 2018.¹ We understand that some patients affected by this decision may face significant financial barriers to obtaining critical drugs.

Given these circumstances, we have considered our enforcement approach to entities that manufacture, sell, or distribute outpatient prescription drugs (collectively, Drug Companies) that provide free drugs to Federal health care program beneficiaries impacted by CVC's decision. The Office of Inspector General (OIG) will not pursue administrative sanctions against any Drug Company for providing free drugs during 2018 to Federal health care program beneficiaries who were receiving cost sharing support for those drugs from CVC as of November 28, 2017, as long as the Drug Company complies with the safeguards described in this letter.

As you may know, OIG issued a Final Notice of Rescission of OIG Advisory Opinion No. 06-04² to CVC³ on November 28, 2017, because CVC failed to fully, completely, and accurately

¹ See <http://www.caringvoice.org/decision-2018-financial-assistance/>.

² Final Notice of Rescission of OIG Advisory Opinion No. 06-04 (Nov. 28, 2017), available at: <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf>.

³ OIG generally does not identify an advisory opinion requestor; however, we are departing from this general policy in this instance because OIG has received inquiries from patients who received assistance from CVC and because CVC has, itself, publicized the fact that it is the entity whose opinion we rescinded.

disclose all relevant and material facts to OIG. CVC's failure to comply with the certifications it made to OIG materially increased the risk that it served as a conduit for improper financial assistance from a Drug Company donor to a patient. Of course, the absence of a favorable advisory opinion does not prevent CVC from engaging in any activity. Nevertheless, CVC has decided not to provide assistance in 2018. Based on contacts from patients and other interested persons, OIG understands that the absence of CVC support may affect patients' access to critical drugs.

One potential avenue for patients to receive such drugs is for a Drug Company to provide such drugs without charge to the patient or any Federal health care program. In fact, OIG has previously issued advisory opinions approving of specific arrangements under which Drug Companies provide free drugs.⁴ Nevertheless, OIG has also noted that free drug programs that are not properly structured can implicate, and potentially violate, the Federal anti-kickback statute.⁵ For example, free drug programs that provide assistance only during a portion of the Medicare Part D coverage year, such as only during the Medicare Part D coverage gap (i.e., "wrapping around" the Part D benefit) pose a heightened risk of fraud and abuse because the Medicare Part D plans remain responsible for coverage before and after the coverage gap.

After consideration of all the relevant circumstances, OIG has determined that Drug Companies will not be subject to OIG administrative sanctions if they provide free drugs in 2018 to Federal health care program beneficiaries who were receiving cost-sharing support from CVC as of November 28, 2017, under the following conditions:

- The free drugs are provided in a uniform and consistent manner to Federal health care program beneficiaries who: (i) were receiving cost sharing assistance from CVC for the same drug(s) as of November 28, 2017; and (ii) have been impacted by CVC's decision not to provide assistance in 2018.
- The free drugs are awarded without regard to the beneficiary's choice of provider, practitioner, supplier, or health plan.⁶
- The free drugs are not billed to any Federal health care program, counted toward the beneficiary's Medicare Part D true out-of-pocket costs (TrOOP), resold, or otherwise billed to a third-party payor.
- The provision of the free drugs is not contingent on any future purchases or orders of the drugs or any other item or service.

⁴ See, e.g., OIG Advisory Opinion No. 06-03 (Apr. 18, 2006).

⁵ See, e.g., 70 Fed. Reg. 70,623 (Nov. 22, 2005).

⁶ Some free drug programs may direct beneficiaries to a particular pharmacy (e.g., a specific mail order pharmacy) to fill their free drug prescriptions. Because prescriptions for free drugs are not payable by Medicare or State health care programs, a free drug program that requires beneficiaries to use a particular pharmacy to fill their free drug prescriptions would not implicate the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act.

- The Drug Company maintains accurate, contemporaneous, and complete records of the free drugs it furnishes to Federal health care program beneficiaries.

This letter does not provide general guidance to Drug Companies on how to structure a program that provides free drugs to Federal health care program beneficiaries. The enforcement approach we outline here applies only to free drugs provided in 2018 to Federal health care program beneficiaries who were receiving cost sharing support from CVC for those drugs as of November 28, 2017.

We hope that this guidance assists PhRMA and its interested members in considering what actions they may wish to take to address the significant financial barriers patients who formerly received CVC assistance may face in obtaining the drugs they need.

Sincerely,



Gregory E. Demske
Chief Counsel to the Inspector General