November 28, 2017

The Honorable Daniel Levinson  
Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC 20201

Dear Inspector General Levinson:

I write seeking additional information regarding the U.S. Department of Health and Human Services’ Office of Inspector General (OIG) recent rescission of an advisory opinion issued in 2006 to an unnamed “nonprofit, tax-exempt, charitable patient assistance program.”¹

The November 28th notice stated the OIG rescinded the advisory opinion because the patient assistance program (PAP) misrepresented the interactions it had with pharmaceutical manufacturer donors – from which the PAP was supposed to maintain independence. Specifically, the OIG found that the unnamed PAP “provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products,” and “allowed donors to directly or indirectly influence the identification or delineation of Requestor’s disease categories.”²

According to the OIG, the actions by the unnamed PAP “materially increased the risk that Requestor served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient.” As a result, the OIG found patients and government programs were put at risk by steering patients to more expensive, but therapeutically equivalent, branded drugs. The government programs put at risk include Medicare Part B and Part D,³ over which the U.S. Senate Committee on Finance has jurisdiction.

Co-payment assistance for drugs from PAPs have been controversial in part due to the very question of their independence from manufacturers. The seven largest copay charities reportedly received combined contributions of $1.1 billion, “fueled almost entirely by drug makers’ contributions.”⁴ One charity reportedly promoted both the tax deductibility of such donations as

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well as that the donations can be “more profitable than many of the companies’ for-profit initiatives.” Several major pharmaceutical manufacturers have reportedly received subpoenas in recent years from the U.S. Department of Justice regarding their interactions with PAPs, underscoring the widespread nature of troubling industry practices in this area.

Alleged information-sharing between PAPs and pharmaceutical manufacturers is of great concern given the potential negative impacts the breaches of independence could have on patients and federal healthcare programs. It is of even greater concern when one considers the existing questions about the independence of PAPs, and their effectiveness – or lack thereof – in lowering healthcare costs.

I am therefore requesting that you arrange a briefing for the U.S. Senate Finance Committee staff that provides more information about the OIG’s decision to rescind the PAP’s advisory opinion, as well as answers to the following questions:

1. To the extent possible given any ongoing investigations, audits or reviews by the OIG, please provide:
   a. The identity of the PAP whose advisory opinion was revoked.
   b. The identity of the donor or donors to which the PAP “provided patient-specific data.”
   c. Any additional information available about the nature of the contact between the PAP and the donors.
   d. An explanation of how the OIG came to learn about the misrepresentations this PAP made regarding its interactions with pharmaceutical manufacturers.

2. According to the rescission notice, the PAP indicated to the OIG that revoking the advisory opinion could lead the PAP to cease operations. Does OIG have any indication that such an operations halt has taken place or has begun?

3. In light of the recent rescission, does the OIG plan to audit or in any other way review PAPs and similar OIG advisory opinions?

If you or your staff have any questions regarding this request, please contact Peter Gartrell on my staff at 202-224-4515. Thank you for your attention to this important matter.

Sincerely,

Ron Wyden
Ranking Member

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