



ALERTS

Drug And Medical Device Companies Subject Of Special Fraud Alert On Speaker Programs

December 4, 2020

Highlights

The Office of the Inspector General recently released a Special Fraud Alert related to healthcare professionals and paid speaker programs

The alert made clear that the agency is skeptical about the educational value of such programs

The OIG warned both manufacturers and healthcare providers that they could face criminal and civil liability if they engage in such training programs

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) has issued a fraud alert related to paid speeches or presentations made by physicians or healthcare professionals on behalf of pharmaceutical or medical device companies.

The [Special Fraud Alert: Speaker Programs](#), issued in mid-November, expresses skepticism about such programs' educational value and concern that they may violate the Anti-Kickback Statute (AKS). The OIG defined a "speaker program" "as company-sponsored events at which a physician or other health care professional (collectively "HCP") makes a

RELATED PEOPLE



Anthony J. Burba

Partner
Chicago

P 312-338-5908
F 312-759-5646
Tony.Burba@btlaw.com

RELATED PRACTICE AREAS

Litigation
Trial and Global Disputes

RELATED INDUSTRIES

Healthcare

speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company.”

According to the OIG, under the open payments law, drug and device companies have disclosed almost \$2 billion in payments to physicians for such speaker programs in the last three years. In noting its skepticism, the OIG suggested that “HCPs can access the same or similar information provided in a speaker program using various online resources, the product’s package insert, third-party educational conferences, medical journals, and more. Ultimately, the OIG warned that “both the company and the HCPs may be subject to criminal, civil, and administrative enforcement actions” and that its alert was intended to discourage such arrangements.

The OIG identified nine prudential factors it would consider in evaluating whether a speaking arrangement would be suspect under the anti-kickback laws, including:

1. The amount of substantive information actually transmitted at the event
2. Whether alcohol or exorbitant meals are served
3. The location of the program
4. Whether the company puts on repeated events on the same topic or product
5. If the programs are attended by the same healthcare professionals on a recurring basis
6. The relevance and recency of the topic or device
7. Whether non-healthcare professionals attend
8. Any influence by the company’s marketing department on the content or attendees
9. The fair market value, or lack thereof, of any payments to the healthcare professionals

It is notable that the OIG chose to release the alert in the midst of a pandemic, where such events are likely not occurring, and only weeks before releasing a [final rule significantly expanding the scope of allowable collaborative healthcare arrangements](#) under the AKS.

The OIG’s dim view of speaker programs also arguably undervalues the role they play in providing education to physicians from emerging markets and underserved areas, where resources for attending third-party conferences, or access to the internet or top medical journals, may be limited.

To obtain more information regarding this alert, contact the Barnes & Thornburg attorney with whom you work or Tony Burba at 312-338-5908 or tony.burba@btlaw.com.

© 2020 Barnes & Thornburg LLP. All Rights Reserved. This page, and all information on it, is proprietary and the property of Barnes & Thornburg LLP. It may not be reproduced, in any form, without the express written consent of Barnes & Thornburg LLP.

This Barnes & Thornburg LLP publication should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own lawyer on any specific legal questions you may have concerning your situation.