akerman

Blog Post

Healthcare Providers: Please Be Wary of Accepting Those Gifts!

December 14, 2020
By Kirk S. Davis

There has been a longstanding and regrettable practice in the healthcare industry of pharmaceutical and medical device companies giving physicians gifts as illegal inducements. Concerned about this continued trend, the U.S. Department of Justice (DOJ) and the Department of Health and Human Services' Office of Inspector General (OIG) issued important warnings regarding providing inducements to healthcare providers (HCPs) – just in time for the holiday season! On October 29, 2020, the DOJ announced its first-ever enforcement action for a violation of the Open Payments Program reporting requirements. On November 16, 2020, the OIG issued a Special Fraud Alert regarding the potential Anti-Kickback Statute implications inherent in speaker programs. Pharmaceutical manufacturers, medical device companies, and HCPs should read the guidance carefully and be extremely cautious before accepting or offering any remuneration this holiday season and beyond.

Violations of the Open Payments Program

"The Open Payments [P]rogram is a statutorily-mandated program that promotes transparency by providing information to the public about the financial relationships between the pharmaceutical and medical device industry, and certain types of [HCPs]." 84 FR 62568, 62914 (November 15, 2019).

Related People

Kirk S. Davis

Related Work

Healthcare
Healthcare Fraud and Abuse
Hospitals and Health Systems

Related Offices

Miami
Tampa

Health Law Rx

Akerman Perspectives on the Latest Developments in Healthcare Law

Visit this Akerman blog

Manufacturers of drugs and devices are required to report honoraria, gifts, travel expenses, meals, grants, and other compensation provided to HCPs. Open Payments reporting must be completed annually by the 90th day of the next calendar year. Any manufacturer who knowingly fails to *timely* report designated payments to the Centers for Medicare & Medicaid Services (CMS) is subject to a civil monetary penalty (CMP) for *each* unreported payment, which in 2020 ranges from $11,766.00 to $117,664.00. 42 CFR § 403.912(b)(1); 45 CFR § 102.3. The maximum annual penalty for a manufacturer who knowingly fails to report such payments in 2020 is $1,176,638.00. 42 CFR § 403.912(b)(2); 45 CFR § 102.3.

Lack of compliance with Open Payments Program requirements creates the appearance of fraud. This was made clear by the DOJ's announcement that Medtronic will pay $1.11 million to settle claims that it failed to report payments it made for over 100 events at a restaurant owned by a South Dakota neurosurgeon. The events were social gatherings attended by the physician's friends and business partners where Medtronic paid for their meals and drinks.

The DOJ also required Medtronic to pay $8.1 million to resolve allegations that it violated the False Claims Act by paying kickbacks to the physician to induce him to use intrathecal infusion pumps that Medtronic manufactures.

Special Fraud Alert: Speaker Programs

As with the OIG enforcement action discussed above, remuneration provided to HCPs may create the appearance of illegal inducements. In its Fraud Alert, the OIG expressed concern that companies are spending significant money on speaker programs and are paying remuneration to HCPs in connection with those programs. Speaker programs may violate the Anti-Kickback Statute when one purpose of the remuneration to the HCP is to induce or reward referrals. "***If the requisite intent is present, both the company and the HCPs may be subject to criminal, civil, and administrative enforcement actions***." See Special Fraud Alert. Manufacturers who organize or pay remuneration associated with the speaker program may face liability. In addition, HCPs who are paid to speak at the program and HCP attendees who receive remuneration from the company (e.g., free food) may also face liability.

The Special Fraud Alert highlights the following factors that may make an arrangement suspect under the Anti-Kickback Statute:

- Little or no substantive information conveyed
- Alcohol is available and free
- Meals exceed modest value
- Venues not conducive to education (e.g., sports venue)
- Same or substantially the same topics presented repeatedly
- No new or recent FDA-approved indication for an existing product
- HCPs attend programs on the same or substantially the same topics more than once
- Attendees have no legitimate reason to attend the program (e.g., friends and family of HCP speaker/attendee)
- Company's marketing business units influence the selection of speakers
- HCP speakers/attendees are selected based on past or expected ordering of the product (e.g., expected revenue to be generated by HCP speaker/attendee ordering drug)
- HCP speakers are paid more than fair market value for speaking services
- Compensation for HCP speakers takes into account the volume or value of past business or potential business.

More On The Horizon

These actions are only the beginning in what is likely to be a wave of more enforcement actions. The federal government has indicated that it will not tolerate unlawful inducements to HCPs. The OIG Special Fraud Alert warns that "[p]arties involved in speaker programs may be subject to increased scrutiny." Further, the HHS General Counsel and CMS Chief Legal Officer issued the following statement: "Manufacturers that misreport their financial relationships with healthcare providers erode the integrity of the Open Payments Program and will be held accountable. CMS looks forward to continued partnership with the [DOJ] to resolve allegations of manufacturers skirting their Open Payments obligations."

To avoid potential investigations and enforcement actions, HCPs and manufacturers should heed the federal government's guidance.

- Manufacturers: Think carefully before resuming speaker programs after the COVID-19 pandemic. Consider alternative, less-risky means to convey information to HCPs. It is also imperative to be diligent in reporting any remuneration that is required to be reported under the Open Payments Program.
- HCPs: Be cautious when participating in speaker programs. There should be zero doubt as to the legitimacy of any speaker program. Consider alternative ways to gather the necessary information.

---

without seeking the advice of legal counsel. Prior results do not guarantee a similar outcome.