

### Why should you be paying attention?

On November 16, 2020, the Department of Health and Human Services Office of Inspector General (OIG) issued a [Special Fraud Alert on Speaker Programs](#). This Special Fraud Alert discusses various risks associated with pharmaceutical and medical device company speaker programs including:

- Selecting high-prescribing Health Care Providers (HCPs) to speak and reward them with lucrative compensation.
- Conditioned speaker compensation on sales targets.
- Holding the speaker program at entertainment venues or during a recreational event not conducive to education.
- Holding the speaker program at high-end restaurants with expensive meals and alcohol.
- Repeat attendance by HCPs and attendance of guests that do not have a legitimate business reason to attend the speaker program.

There have been many investigations and enforcement actions implicating the Anti-Kickback Statute (AKS). These involved allegations that drug and device companies organized and paid for speaker programs with the intent to induce HCPs to prescribe or order products reimbursed by the Federal Health Care Programs.

### Example Enforcement Actions:

#### [Biogen Inc. \\$900 Million Dept. of Justice Settlement](#)

Whistleblower allegation that Biogen caused the submission of false claims to Medicare and Medicaid by paying kickbacks to physician to induce them to prescribe Biogen drugs. It was alleged that they paid HCPs in the form of speaker honoraria, speaker training fees, consulting fees and meals for speaking or attending their speaker programs in order to induce them to prescribed the Avonex, Tysabri and Tecfidera drugs in violation of the AKS.

#### [Novartis \\$591 Million Dept. of Justice Settlement](#)

Whistleblower allegation that Novartis caused the submission of false claims by paying kickbacks to HCPs to induce them to prescribe 10 different drugs. These took the form of paid physician honoraria and attendance at “tens of thousands of speaker programs and related events”. These programs were held at expensive restaurants with no discussion about the drugs and in some cases, the events never took place and the HCPs were still paid a fee. In addition, Sales Representatives selected the speakers with the intent to induce them to write more prescriptions.

### AKS [Safe Harbor](#) Requirements:

- Arrangement in writing and signed by all parties in advance.
- Compensation at fair market value and not based on the volume or value of drugs or devices ordered.
- Arrangement is commercially reasonable.
- For at least one year.

### Manufacturers Should:

- ✓ Assess the existence of a bona fide business need for the speaker program.
- ✓ Select speaker based on their medical expertise related to the drug or device.
- ✓ Set compensation at fair market value.
- ✓ Document services in a contract.
- ✓ Limit the number of speakers to the necessary amount for the educational purpose.
- ✓ Limit the number of times an HCP attends a speaker program.
- ✓ Track HCP attendance and comply with Sunshine Act/Open Payments reporting requirements.

### Manufacturers Should Not:

- ✗ Select Speakers based on the Volume or Value of drugs or devices ordered, to induce future orders, or to reward referrals.
- ✗ Have Sales Representatives involved in the selection process.
- ✗ Permit the attendance of HCP guests.

## We Are Here to Help

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info@mcra.com



www.mcra.com/contact-us



202.552.5800