



## OIG Issues Fraud Alert Related to HCP Speaking Engagements

The Office of Inspector General (“OIG”) for the Department of Health and Human Services (“HHS”) issued a Special Fraud Alert on November 16, 2020 (“Alert”) highlighting the risks associated with certain healthcare professional (“HCP”) speaker or educational programs sponsored by pharmaceutical or medical device companies. Certain programs can create risk under the Anti-Kickback Statute (“AKS”), and both the company and HCP could be subject to civil, criminal or administrative (e.g., exclusion from Federal healthcare programs) enforcement actions.

The Alert noted that speaker programs do not inherently violate AKS, but provided a list of characteristics it would consider *suspect* including, but not limited to:

- Little or no substantive information is presented at the program.
- Alcohol (especially if free) is available or a meal exceeding modest value is provided to attendees.
- The program location is not conducive to exchange of educational information (e.g., sporting venue).
- The company sponsors numerous programs on the same topic without recent substantive change in relevant information.
- The program centers on a product with no new medical / scientific information or new FDA approved / cleared indications.
- HCPs attend the same or substantially the same topics more than once (or attend after speaking).
- Attendees include individuals who do not have a legitimate business reason to attend the program (e.g., family or friends of an HCP).
- Marketing or business units influence selection of speakers based on past / expected revenue that the speaker may generate.
- The company pays HCPs above fair market value (“FMV”) or in a manner that takes into account the volume or value of present / expected business generated by the HCPs.

MRC Global is a leading provider of regulatory, quality and valuation consulting services to the life sciences industry. Our team of experts understands that HCP engagement is a key component to success for many medical device, pharmaceutical and other life sciences companies, yet it may create significant risks as noted in the Alert. MRC Global can work in partnership with counsel or senior leadership to determine fair market value HCP payments and document the appropriateness of speaker programs to protect against regulatory scrutiny. This process includes the examples noted in the Alert, as well as others not listed, such as ensuring that an appropriate needs assessment is in place and travel / expense reimbursement policies are appropriate.

In addition to speaker programs, MRC Global can help minimize risk under all types of HCP relationships, including but not limited to, consulting services, advisory board participation, royalty arrangements, acquisition due diligence / valuation and co-marketing initiatives. Our industry-leading HCP classification service ensures that individuals can be matched with tiered rate structures (e.g., local, regional or national KOL rates) in a consistent, compliant and efficient manner.

Please contact us with questions or for additional information:

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