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Complete Healthcare Compliance Manual
Conflicts of Interest: Relationships with Industry-Medical Device Manufacturers and Pharmaceutical Companies

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What Are the Conflicts of Interest Involving Relationships with Medical Device Manufacturers and Pharmaceutical Companies?

Relationships between healthcare providers and medical device manufacturers and pharmaceutical companies can result in conflicts of interest if the relationship personally benefits the provider and unduly influences the provider's clinical judgment or actions. These conflicts of interest ultimately could lead to patient harm as well as potential compliance issues that could result in civil, criminal, or administrative enforcement actions and financial penalties. The same can be true for relationships between healthcare organizations that are recipients of funding or other compensation from medical device manufacturers and pharmaceutical companies. The financial relationship could cloud the decision-making of healthcare organization leadership because of the incentive.

In fact, the Department of Health & Human Services Office of Inspector General (OIG) issued a special fraud alert November 16, 2020, highlighting the fraud and abuse risks associated with pharmaceutical and medical device companies offering remuneration to healthcare providers for participating in company-sponsored speaker programs about drugs or devices targeted at other healthcare providers.[2] The alert notes that over the past three years, drug and device companies have reported paying nearly $2 billion to healthcare providers for speaking engagements, and the OIG and Department of Justice (DOJ) have investigated and resolved a number of fraud cases involving allegations that remuneration violated the Anti-Kickback Statute.[3] As a result, the government has pursued civil and criminal cases against individuals and companies involved in speaker programs.

Among the cases, the OIG found that drug and device companies:

- Selected high-prescribing healthcare providers to be speakers and paid them well, with some receiving hundreds of thousands of dollars.
- Required speakers to write a minimum number of prescriptions in order to be paid the speaking fee.
- Held programs at entertainment venues (e.g., wineries, adult entertainment facilities, sports stadiums) or during recreational events, such as fishing trips and golf outings, that were not conducive to education.
- Held programs at high-end restaurants that included expensive meals and alcohol. The OIG noted that in one case, the average food and alcohol cost was more than $500 per attendee.
- Invited an audience of healthcare providers who previously had attended the same program or invited the providers' friends, family members, or significant others who did not have a legitimate business reason to participate in the program.

For years, story after story has circulated in the news about inappropriate financial relationships between

healthcare providers and industry that led to negative consequences or even patient death. One such example was the story of Jesse Gelsinger, an 18-year-old who had a rare metabolic disorder that caused a high level of ammonia in his blood.[4] His condition was not life-threatening, but he opted to participate in a gene therapy clinical trial at the University of Pennsylvania in 1999. In the study, an adenovirus was injected into Jesse's bloodstream, he developed a severe immune reaction to it, and he died four days later. An investigation revealed ethical, technical, and regulatory issues with the clinical trial and that the principal investigator—who also was the head of the institute where the procedure was performed—had a substantial financial stake in the company providing funds to finance the research—a potential conflict of interest.

Despite industry guidance that emerged in the early 2000s and the passage of Internal Revenue Service (IRS) laws and the Sarbanes-Oxley Act of 2002, which focused on inappropriate financial relationships and conflicts of interest among nonprofits and for-profits, years of allegations of improper relationships between healthcare providers and device and pharmaceutical manufacturers led to a series of probes into conflicts of interest by Senator Chuck Grassley.[5][6] Grassley compared documentation from manufacturers with data from universities and identified several cases where individuals substantially understated money they had received from pharmaceutical companies, for example. Among the findings:

- An Emory University physician earned more than $2.8 million from drugmakers between 2000 and 2007, yet failed to report more than $1.2 million to the university and violated federal research rules.[7] The physician signed a letter promising Emory University that he would earn less than $10,000 a year from the pharmaceutical company to comply with federal rules, but on the same day, he was found at the Four Seasons Resort in Jackson Hole, Wyoming, earning $3,000 of what would become $170,000 in income from the company.
- A University of Cincinnati physician disclosed to the university that she made $100,000 from eight drug companies, when she was really paid $238,000 from just one company for the defined period.[8]
- Two Harvard University physicians who practiced at Massachusetts General Hospital reported making several hundred thousand dollars each from drugmakers from 2000 to 2007, when each actually made more than $1.6 million.[9]