SAM04 Marketing of Prescription Drugs in the USA — Interactions with Healthcare Professionals

Approximate study time: 1 hour

Level: Introductory/Intermediate

Audience: Sales and marketing, regulatory affairs, and legal personnel

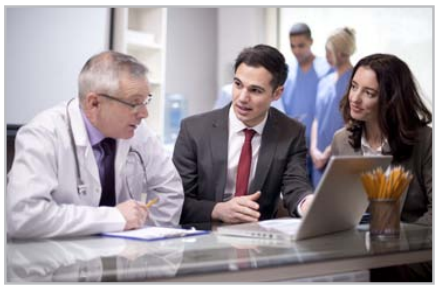
Category: Sales and marketing

Region: USA

CPD Points: 1

Module outline

- Statutes and regulations
- Regulatory and industry guidance
- Anti-Kickback Statute
- False Claims Act
- Major settlements under FCA/AKS
- Physician Payments Sunshine Act
- Drug samples
- Distribution of reprints and other publications
- Detailing by sales representatives
- Speaker programs
- Third-party scientific and educational events
- Medical advisory boards
- Responding to unsolicited requests for off-label information
- Gifts of educational or non-educational items
- Assessment



The heaviest legal penalties imposed on drug companies concern interactions with healthcare professionals in the context of prescription drug marketing, notably for violations of the Anti-Kickback Statute and the False Claims Act. Monetary penalties have amounted to billions of dollars in some cases.

Payments or other transfers of value made to certain healthcare professionals or teaching hospitals must be reported to the government. In addition, company-sponsored speaking programs and detailing by sales representatives must comply with provisions of the Federal Food, Drug, and Cosmetic Act on advertising and promotion. Industry guidance urges drug companies to follow the highest ethical standards as well as all legal requirements. In this course we identify the laws and guidance that apply, and we provide information that will help companies to market their products without incurring penalties.

In companion courses on marketing of prescription drugs in the USA, we deal with the legal and regulatory framework for advertising and promotion of drugs, with general regulatory compliance in that context, and with considerations that are particular to consumer-directed advertising and online promotion.

Who will benefit from this module?

Sales representatives and marketing personnel need to understand the legal and regulatory requirements that must be met, and the industry guidance that applies, when interacting with healthcare professionals in the context of marketing of prescription drugs in the USA. In addition, this module will be of benefit to regulatory affairs and legal personnel involved with aspects of marketing.

Learning objectives

- Identify the principal US legal statutes and regulations on interactions between drug companies and healthcare professionals (HCPs)
- Identify Important sources of guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services, the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Food and Drug Administration (FDA)
- Outline the provisions of the Anti-Kickback Statute, and access regulations on its 'safe harbors' provisions
- Outline the provisions of the False Claims Act, including the use of qui tam 'whistleblower' lawsuits, and understand the risk of heavy penalties for violations
- Comply with reporting requirements under the Physician Payments Sunshine Act
- Comply with the requirements of the Prescription Drug Marketing Act and the Affordable Care Act as regards the provision of drug samples to HCPs
- Follow guidance from the FDA on distribution of reprints and other publications to HCPs
- Comply with limitations on detailing by sales representatives
- Comply with legal requirements, and OIG, PhRMA and FDA guidance, on company speaker programs and third-party scientific and educational events
- Outline the role of medical advisory boards and comply with PhRMA guidance on bona fide consulting services
- Respond appropriately to unsolicited requests for off-label information
- Comply with PhRMA guidance on gifts of educational or non-educational items to HCPs