

## PANEL DISCUSSION TAKE-AWAYS

### Key Considerations for Working with Nurse Educator Field Teams

Emily Hodge, partner in Choate's Government Enforcement and Compliance Group, moderated the panel "Key Considerations for Working with Nurse Educator Field Teams" at CBI's Compliance Congress for Specialty Products Conference. Below are key take-aways from the discussion and considerations for nurse educator programs.

#### Key take-aways

- There has been an uptick in enforcement actions relating to clinical nurse educator programs in the last couple years
- We have seen recent government settlements, and several disclosures of ongoing government investigations, as well as a number of qui tam cases in which the government has declined to intervene and the relators are proceeding with the cases
- OIG guidance suggests that there are compliant ways for manufacturers to offer adherence programs and to reduce the risks associated with white coat marketing concerns, although allegations in a number of the qui tam cases suggest that the mere provision of these services may be an unlawful kickback
- It will be important to monitor the ongoing government investigations and the qui tam cases to determine what the government's position will be on these programs generally

#### Considerations for nurse educator programs

In the meantime, for companies operating these programs, there are a number of considerations for mitigating risk potentially posed by these programs, some of which include:

- Are the nurses reporting through the commercial team or are they given training that resembles the training provided to sales reps? Are the materials the nurses are using focused on disease state education or are they promotional? Do the nurses receive incentive compensation that is based on metrics like those of a sales team? Are the nurses transparent with patients and HCPs about their affiliation with the company and their role?
  - Depending on how closely the nurse role resembles a sales role, their role may be viewed as commercial rather than clinical, and concerns about white coat marketing may arise
- Are the nursing services tied specifically to the product, or are the nurses providing any broader services to patients or HCPs?
  - Given the Anti-Kickback Statute considerations and OIG guidance, the services should be integrally related to the company's product and provided after a clinical decision has been made by the patient's HCP to prescribe the product
- What is the relationship between the nurses and the sales team and what information is being shared?
  - Close interactions with the sales team can suggest the nurses are in a promotional role, and patient privacy and HIPAA concerns can also arise if patient information is shared
- Can the company generally justify the need for the program and clearly identify its intent in a way that is consistent with OIG guidance and the Anti-Kickback Statute? How complex is the product to administer (how much nursing support is reasonably needed as compared to how much is being provided)? How would the nurses and others at the company describe the goal of the program – to support adherence, or to sell the product? Are nurses encouraged or advised to recommend the product or to influence an HCP's choice of product?
  - Intent, optics, and execution of the program are all relevant factors in assessing compliance risks.

#### FOR MORE INFORMATION

To learn more about compliance considerations for nurse educator programs, please contact:

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