

PANEL DISCUSSION TAKE-AWAYS

Strategies for Training and Maintaining a Compliant Nurse Educator Field Team

Emily Hodge, partner in Choate's Government Enforcement and Compliance Group, moderated the panel "Strategies for Training and Maintaining a Compliant Nurse Educator Field Team" 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 actions relating to clinical nurse educator programs over the last several years.
- We saw a few government settlements, and have seen disclosures of ongoing government investigations, as well as a number of qui tam cases in which the government has declined to intervene and even a number of instances where the government has moved to dismiss the actions, mostly successfully.
- OIG guidance suggests that there are compliant ways for manufacturers to offer product support and adherence programs and to reduce the risks associated with white coat marketing concerns.

Considerations for nurse educator programs

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

- What is the goal of the program – educational support, safety/awareness, adherence, sales? 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)? 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.
- Are the nursing services tied specifically to the product, or are the nurses providing any broader services to patients or HCPs? At what point in the process are services provided, pre-prescription or post-prescription?
 - Given the Anti-Kickback Statute considerations and OIG guidance, the services should be integrally related to the company's product, should not provide substantial independent value, and consideration should be given to the risk of influence on the prescriber's treatment determination.
- Are the nurses reporting through the commercial team or the medical team or another team? 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? What interactions are the nurses having with the commercial team and what information is being shared? 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.
 - Patient privacy and HIPAA concerns can also arise if patient information is shared.
- What monitoring is the compliance team doing – how often and in what form?
 - Regular monitoring will help identify any execution issues and will demonstrate an intent to ensure compliance.

FOR MORE INFORMATION

To learn more about strategies for training and maintaining a compliant nurse educator field team, please contact:

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