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Frequently Asked Questions

Compliance Preparations Relevant to Launching a Commercial Life Sciences Company

The success of a commercial launch hinges on a wide variety of factors, including appreciating the new regulatory risks that arise when evolving from a research and development organization to a commercial life sciences company. Below are some frequently asked compliance questions that should be considered before a company's commercial launch.

How do I start building a corporate compliance program?

It is critical to establish the infrastructure of an effective corporate compliance program, including the resources necessary to build and implement the program across the organization. This infrastructure includes:

- Formally establishing and recognizing the corporate compliance program through a Board of Directors resolution. This step demonstrates the Board's commitment to compliance and its fiduciary obligations of providing oversight of the corporate compliance program.
- Drafting or revising a corporate code of conduct and ethics appropriate for a commercial life sciences companies. While companies may have a code of conduct that addresses securities requirements, such codes often lack key health regulatory provisions necessary for a commercial life sciences organization.
- Developing charters for the compliance program and compliance committee. These charters document the composition, roles, responsibilities and resources of the compliance program.
- Determining a job description and reporting structure for the chief compliance officer.
- Implementing key compliance resources, including (i) adopting compliance policies/procedures to establish compliance parameters; (ii) providing compliance training to educate employees, contractors and vendors on compliance expectations; (iii) implementing a compliance reporting mechanism to identify compliance concerns; (iv) conducting compliance auditing and monitoring activities to proactively identify compliance issues; (v) conduct compliance investigations to determine the root cause of compliance issues; and (vi) taking disciplinary and corrective action to address and deter compliance violations.

Who To Contact

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Why is a corporate compliance program important?

An effective compliance program can guide an organization in ethical and legal conduct, and demonstrate its desire to be a good corporate entity and business partner. It also can reduce the risk of a legal, regulatory or ethical violation, and help the organization to proactively identify and address potentially problematic activity before it becomes a serious issue for the organization.

If an issue does arise, an effective compliance program can reduce criminal liability and other harm to the company.

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What training should be provided to the Board of Directors and Company's Leadership to prepare it to become a commercial organization?

Your company's Board of Directors should receive training relating to its fiduciary obligations to oversee the corporate compliance program. The Department of Health and Human Services Office of Inspector General (OIG) has issued a number of guidance documents related to Board oversight, available here. The Board and company's leadership also should be well aware of the key health regulatory laws, regulations and industry guidance applicable to commercial life sciences companies, including, by way of example, anti-kickback laws, false claims laws, anti-bribery and corruption laws, laws related to promotional activities, transparency requirements, and state and local marketing laws.

Do you have a list of compliance policies and procedures that a commercial life sciences company should develop?

The compliance policies/procedures that a life sciences company should develop and implement will depend on a number of factors, including the specific business activities that the company conducts that warrant establishing compliance parameters in order to minimize risk to the organization. Companies should be diligent in identifying areas of compliance risk, and developing, maintaining and updating policies and procedures relevant to this risk. Key policies/procedures to consider include:

- Gifts, meals and entertainment
- Interactions with health care professionals
- Interactions between commercial and medical employees
- Fair market value
- Promotional speaker programs and engaging HCP speakers
- Promotional communications (including social media) and promotional review committee
- Booths, exhibits and displays
- Charitable donations, grants, fellowships, sponsorships and corporate memberships
- Advisory boards and consultants
- Field call plans
- Field compensation plans
- Company-conducted product training (including product education and demonstration)
- Product samples, coupons and vouchers
- Transparency, licensure and marketing compliance
- Medical information requests and communications
- Adverse event reporting and risk evaluation and mitigation strategies (REMS) management

Are we now subject to "sunshine" laws?

A commercial organization will need to evaluate and comply with applicable marketing and transparency laws at the federal, state and local levels. The company should implement a comprehensive aggregate spend policy/procedure to ensure that it remains compliant with regulations governing tracking, aggregating, reporting, certifications, audits and dispute resolution, among other items. It also will be important to evaluate the company's methodology for tracking and reporting applicable transfers of value, including implementation of an aggregate spend tracking system. Template agreements governing transfers of value may need modifications relevant to transparency requirements.

What other internal controls should be considered as part of an effective compliance program?

There are a myriad of items that a comprehensive compliance program will need to consider as a company evolves into a commercial life sciences organization. These include, by way of example, debarment and exclusion status checks, patient assistance programs, interactions with professional and patient organizations, customer/trade contracting, government program pricing strategies, and document retention and management practices. The key is to realize that a compliance program is never "done", but requires continuous review and updates to ensure that it remains fresh, relevant and effective.