

Life Sciences Corporate Transactions Due Diligence Checklist

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FDA Regulation

- Review target company's **clinical trial and research** set-up, approvals, milestones, subject selection and related contracts.
- Analyze target company's **product approval/clearance** strategy and/or status, including pipeline products.
- Evaluate target's **advertising and promotional** policies, including off-label communications.
- Check integrity of target's **quality systems** and review inspections history.
- Assess any outstanding **inspection observations**, including target's follow-up.
- Assess relevant **recall history**, including target's follow-up and close-out.

HHS Office of Inspector General and Department of Justice Oversight

- Evaluate target's **U.S. and international anti-corruption compliance programs**, comparing against OIG and DOJ guidance and Federal Sentencing Guidelines.
- Understand target's customer and health care **provider interactions** and compliance with **industry codes of ethics**.
- Assess target's **physician ownership** and **other financial relationships** with physicians in light of OIG guidance on physician- owned companies.
- Review and analyze target's discount and rebate practices and **value-based arrangements** (e.g. risk-based outcomes guarantees, warranties and pricing).
- Evaluate target's use of **co-pay assistance, co-pay relief programs or reimbursement support programs**.
- Review impact of potential OIG regulatory changes on **drug pricing and rebates**, if applicable.

Centers for Medicare and Medicaid Services

- Understand **Open Payments/Sunshine Act** compliance and key disputes.
- Analyze existing **coverage, coding and reimbursement** of product or procedure using product (or coverage, coding and reimbursement strategy).
- Evaluate impact of CMS payment rules and **advanced payment models** on product, procedures using product.
- Understand **drug rebate/best price reporting** compliance, if applicable.

Data Privacy and Cybersecurity

- Review target's compliance policies and practices with respect to HIPAA, state privacy laws, the EU's GDPR requirements and other **patient privacy and consumer privacy** obligations.
- Understand the scope and policies related to target's collection, use, access, storage, transmittal and destruction of sensitive data.
- Appraise target's privacy compliance program and infrastructure.
- Assess target's data security policies, procedures, and incident response plans.
- Evaluate history of any data breaches or security incidents, including relevant follow-up.
- Understand target's practices with respect to **cybersecurity of medical technology** (if applicable).
- Assess data security policies and procedures, disaster recovery and incident response plans, cybersecurity audits and penetration tests, as applicable.

SEE REVERSE FOR ADDITIONAL INFORMATION

Government Enforcement

- Analyze scope, impact and potential costs of any past, present or anticipated government enforcement actions, investigations or audits.
- Understand target's obligations under corporate integrity agreements or other settlement agreements with the government, if applicable.

State Regulation

- Evaluate target's compliance with state supply chain licensure requirements.
- Analyze target's compliance with state marketing restrictions and transparency requirements.

Other Risk Areas

- Consider public perception specific to company or industry that could impact deal valuation or closing obligations. Product liability concerns? Product pricing issues?

Always consider how the responses to each question or area of inquiry could impact:

- **Deal valuation** (*i.e.* is the risk area so significant that the deal should be viewed as worth less than previously thought?)
- **Deal terms** (*i.e.* is the risk area so significant that the transactional documents should incorporate additional representations, warranties, indemnity provisions and escrow agreements or other comfort?) or
- **Deal closing** (*i.e.* does the risk require mitigation before the deal can close?).

Contact Information

If you have any questions about this alert or would like assistance in conducting health care regulatory due diligence in connection with your transactions, please contact:

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