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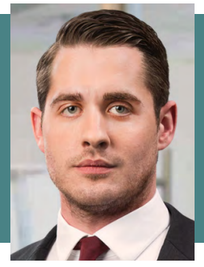

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Strategic Compliance: The Benefit of a Results-Oriented Approach to Corporate Compliance Programmes

By Nicole Rodriguez Van Dyk & Jimmy Threatt

As corporations face an increasingly complex regulatory landscape, robust corporate compliance programmes have never been more essential. This is especially true for healthcare companies, which operate at the intersection of administrative, civil, and criminal oversight. This article focuses on the strategic importance of maintaining effective, results-oriented compliance programmes. Even when compliance programmes fail as preventative measures, they are critical tools in the corporate toolkit to limit the scope of misconduct, mitigate damages, and position companies to reach favourable resolutions with government agencies. Gone are the days of reliance on formalistic programmes designed to 'paper the file'; companies must focus on the effectiveness of their programmes in practice to take full advantage of United States Department of Justice (DOJ) guidance regarding compliance programmes in criminal charging decisions and to avail themselves of civil and administrative mitigation policies that depend on early detection and self-reporting of misconduct.

In June 2020, the DOJ's Criminal Fraud Division updated its guidance for the evaluation of corporate compliance programs, which sets out the factors federal prosecutors consider when deciding whether to bring criminal charges or to instead negotiate alternative resolutions.[1] The DOJ's updated guidance adds detailed evaluation criteria that make clear an increased focus on prioritising function over formalism.

DOJ's guidance is organised around three "fundamental questions": (i) "Is the corporation's compliance programme well designed?"; (ii) "Is the programme being applied earnestly and in good faith?"; and (iii) "Does the corporation's compliance programme work in practice?"[2] Demonstrating increased focus on function, the most recent update urges prosecutors to consider whether "the programme [is] adequately resourced and empowered to function effectively" in engaging in that inquiry.[3]

The updated evaluation criteria related to each area also eschew a one-size-fits-all programme driven by design formalism. Instead, the update recognises that an effective programme must be tailored to the specific needs of the company, accounting for such factors as its industry, size, location(s) of operations, and areas where it may be especially vulnerable to misconduct, either by its own employees or third parties.[4] Its new "design" criteria focus on

1. See "Evaluation of Corporate Compliance Programs," U.S. Department of Justice Criminal Division (June 2020) at 1 <https://www.justice.gov/criminal-fraud/page/file/937501/download>
2. Id. at 1-2.
3. Id. at 1-2.
4. Id. at 1, 3.

metrics-based assessments and adjustments to a programme's processes based upon how well it has performed in identifying misconduct.[5] Its resource allocation criteria are structured around the principle that "[e]ven a well-designed compliance programme may be unsuccessful in practice if implementation is lax, under-resourced, or otherwise ineffective."[6] And its guidance in practice focuses on the effectiveness of audit protocols, properly scoped investigations by independent personnel, and swift disciplinary action to detect and remediate misconduct.[7]

Ultimately, companies would do well to heed the DOJ's updated guidance to its prosecutors: "if a compliance programme did effectively identify misconduct, including allowing for timely remediation and self-reporting, a prosecutor should view the occurrence as a strong indicator that the compliance programme was working effectively."[8] In other words, focus on monitoring the results and adjusting processes to drive robust reporting, effective investigations, and swift remediation, rather than implementing a one-size-fits-all programme driven by formulaic protocols.

The importance of implementing effective compliance programmes is not merely theoretical. In a criminal investigation, meeting the DOJ's revised criteria may mean the difference between an indictment and a pass. But a focus on the results of compliance programmes is also necessary to allow healthcare companies to avail themselves of regulatory self-disclosure protocols to mitigate, or avoid altogether, civil and administrative penalties that can be levied in the absence of (or in addition to) criminal penalties.

5. See id. at 2-9.
6. See id. at 9-14.
7. See id. at 14-18.
8. Id. at 14.

For example, in May 2019, the Civil Division of the DOJ issued formal guidance regarding the evaluation of cooperation credit in civil False Claims Act investigations, explaining that credit can be earned when "entities or individuals voluntarily self-disclose misconduct that could serve as the basis for False Claims Act (FCA) liability and/or administrative remedies, take other steps to cooperate with FCA investigations and settlements, or take adequate and effective remedial measures."[9]

Likewise, the HHS-OIG administers the Self-Disclosure Protocol (SDP), which is the primary avenue for healthcare providers that are subject to OIG's CMP authorities to self-disclose potential violations of any federal criminal, civil, or administrative law.[10] Because securing the full benefits of SDP depends on a voluntary self-disclosure prior to the initiation of an OIG investigation, a compliance programme that is actually effective at detecting and addressing misconduct is critical to quickly identify and investigate potential wrongdoing and evaluate whether to make a self-disclosure.[11] In making a disclosure, companies are expected to provide a detailed analysis of the conduct, describe the corrective action taken, and give an estimate of the financial impact to each affected federal healthcare programme.[12] OIG's holistic approach to assessing penalties in a given case accords great weight, in particular, to the thoroughness of a company's internal investigation and resulting disclosure.[13]

9. Justice Manual 4-4.112 <https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112>
10. "OIG's Provider Self-Disclosure Protocol," HHS-OIG (April 2013) at 3 <https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>
11. Id. at 5-6.
12. Id. at 6.
13. Id. at 13.

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The benefits of self-disclosure to the Civil Division of DOJ or to OIG can be immense. For example, OIG applies a presumption against seeking expensive and burdensome corporate integrity agreements for self-disclosing parties.[14] Self-disclosing parties are also typically subject to substantially reduced damages multipliers, which can decrease a company’s exposure by tens of millions of dollars.[15] DOJ’s FCA cooperation policy similarly provides for reduced penalties and damages.[16]

In short, the old adage that “the best defence is a good offence” should remain the guiding mantra for healthcare companies facing an increasingly complex regulatory landscape and expanding incentives for effectively identifying and self-disclosing misconduct. Companies should take the government’s focus on function seriously and create compliance programmes with robust investigatory mechanisms that can achieve early detection of potential wrongdoing and implement swift and comprehensive remedial action. Those that don’t proceed at their own peril.

14. Id. at 2.
15. Id.
16. Justice Manual 4-4.112 <https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112>

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