



Applying New Department of Justice Compliance Standards to the Managed Care Context

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Context

- Managed care industry has long had robust compliance functions, legally mandated by CMS for federal programs
- In 2017, DOJ issued new guidance regarding its evaluation of corporate compliance programs in connection with federal investigations and enforcement
- Managed care plans operating in the federal space need to be aware of new DOJ guidance and how it may impact existing practice



New DOJ Guidance

- In February 2017, DOJ issued memo titled “Evaluation of Corporate Compliance Programs”
 - Intended to be flexible, the Evaluation Guidance lists 11 topics and 120 sample questions DOJ may use when evaluating corporate compliance programs
 - Evaluation Guidance can be found at: <https://www.justice.gov/criminal-fraud/page/file/937501/download>
 - Other public statements about DOJ’s approach to compliance can be found at:
 - <https://www.corporatecrimereporter.com/news/200/hui-chen-and-andrew-weissmann-at-nyu-law-school/>
 - <https://connects.ethics.org/blogs/laura-jacobus/2016/02/01/doj-interview>
 - Evaluation Guidance based on various sources, including the U.S. Attorney’s Manual, U.S. Sentencing Guidelines, prior corporate resolution agreements, DOJ’s FCPA Guide, and OECD publications on ethics and compliance

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New DOJ Guidance

- Architect of new guidance was Hui Chen, the DOJ Compliance Counsel
 - Resigned in July 2017
 - Other key figure was Andrew Weissman, who was the Chief of the Criminal Fraud Section at DOJ when guidance was issued
 - Despite personnel changes, no indication guidance itself will not be used going forward

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Why is DOJ Guidance Important?

- Managed care is a heavily regulated industry that already has robust compliance standards
- But DOJ perspective critically important for federal programs
 - Can impact criminal/civil resolutions, the size of fines or penalties, monitoring, and the terms and conditions of a Corporate Integrity Agreement

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Why is DOJ Guidance Important?

- Focus of DOJ Evaluation Guidance is how compliance controls are actually being used and responded to by senior management and business units
 - DOJ will look beyond the elements or formal structures of compliance programs to see how they impact (or do not impact) operations of the organization both in the day-to-day and when red flags appear

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Why is DOJ Guidance Important?

- In addition to state law requirements, federal managed care programs operate under compliance mandates
 - Participants in Medicare Advantage Program or Medicare Part D have to comply with regulations regarding compliance requirements, similar to many federal and state programs. See 42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi). These regulations require, among other things: (1) certain written policies and procedures; (2) a compliance officer and compliance committee; (3) regular training and education; (4) effective lines of communication; (5) disciplinary standards; (6) monitoring and identification of risks; (7) a system for investigating and responding to compliance issues.
- However, under DOJ Evaluation Guidance, having these bare-minimum elements of a compliance program will not be enough for DOJ to view you favorably

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Why is DOJ Guidance Important?

- Hui Chen has said Compliance Officers know whether their company has a paper program or a real program in place, DOJ's primary concern:
 - "It is something that you know, frankly, early on in one's tenure on the job. The answers are not in the glossy diagrams of a company's 'core values' or their training slides; rather, they are in what happens in real life . . . You look to see not just what the policy and procedures say, but how they are actually incorporated into the operations of the company . . . I also look to see how the most front-line workers understand their jobs: Does the clerk in the accounts-payable room understand his job to be processing payments as quickly as he can, or does he understand that he is supposed to keep an eye on certain things and escalate issues he identifies? Does the new salesperson understand her job to be making the deal at all costs, or does she understand that there are boundaries? I also look at empowerment and consequences: Are the compliance and control personnel empowered to identify, escalate, and address problems? Are there consequences of non-compliance: Processes continually improved based on lessons learned; people disciplined for non-compliance; or deals rejected and approvals not granted?"
 - Hui Chen, DOJ Compliance Counsel, February 2016

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Recent Enforcement Activity Involving Managed Care

- In 2017, DOJ intervened in the *Swoben* False Claims Act litigation alleging inflation of risk adjustment scores by UnitedHealthcare (but complaint was subsequently dismissed by the court)
- In 2017, EviCore Healthcare (previously CareCore National) paid \$54 million to settle allegations that it failed to properly review prior authorizations
- In 2012, the SCAN Health Plan paid nearly \$320 million to settle allegations that it received overpayments resulting from actuarial errors that SCAN then concealed
 - SCAN also paid \$3.82 million related to allegations that it inflated patients' risk adjustment scores

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Recent Enforcement Activity Involving Managed Care

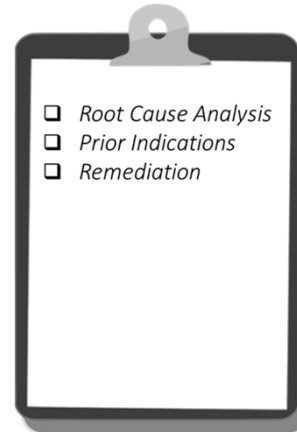
- Federal health care investigations and prosecutions are through the roof
- In FY 2016:
 - DOJ opened 975 new criminal health care fraud investigations
 - Federal prosecutors filed criminal charges in 480 cases involving 802 defendants
 - A total of 658 defendants were convicted of health care fraud-related crimes
 - DOJ opened 930 new civil health care fraud investigations and had 1,422 civil health care fraud matters pending at the end of the fiscal year
 - DOJ received \$2.5 billion in health care fraud judgments and settlements
 - Over \$5 returned for every \$1 spent on enforcement, making it a fiscal profit center

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DOJ Evaluation of Compliance Programs

- Topic 1 – Analysis and Remediation of Underlying Misconduct
- How addressed by CareFirst:
 - Root Cause Analysis is conducted on all investigations, privacy matters and compliance matters handled by the Compliance and Ethics Office and is a core responsibility of the Embedded Compliance and Ethics units.



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DOJ Evaluation of Compliance Programs

- Topic 2 – Senior and Middle Management
- How addressed by CareFirst:
 - Leadership is engaged through various avenues, including targeted communications as well as updates provided during Executive staff meetings. Support is further strengthened through CEO communications throughout the year. Compliance and Ethics provides regular reports to the Audit and Compliance Committee. Annual Compliance and Ethics Survey is conducted to measure and benchmark CareFirst's culture, tone at the top, and program effectiveness.

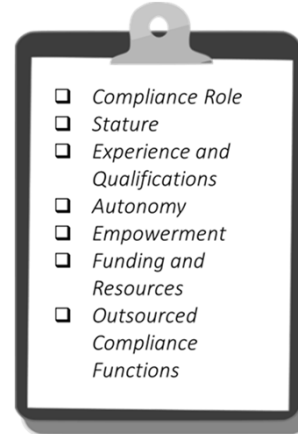


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DOJ Evaluation of Compliance Programs

- Topic 3 – Autonomy and Resources
- How addressed by CareFirst:
 - A robust corporate Compliance and Ethics Department is in place with dedicated leadership, resources and funding which reports directly to the Audit and Compliance Committee of the Board of Directors. Embedded Compliance and Ethics units have been established and funded within operational divisions to ensure Compliance and Ethics ownership at the local level.



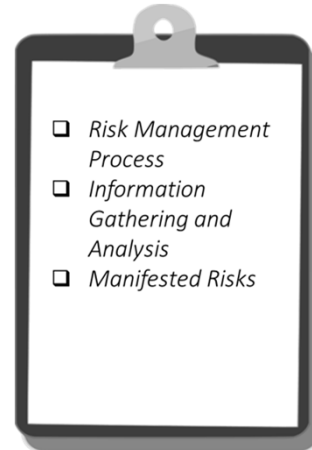
DOJ Evaluation of Compliance Programs

- Topic 4 – Policies and Procedures
 - Design and Accessibility
 - Operational Integration
- How addressed by CareFirst:
 - A Governance, Risk and Compliance program (GRC) has been developed, implemented and maintained by the Compliance and Ethics Department utilizing the Compliance 360 software which includes standards and controls to manage policy and procedure development and operational integration.



DOJ Evaluation of Compliance Programs

- Topic 5 – Risk Assessment
- How addressed by CareFirst:
 - The company undergoes a comprehensive Enterprise Risk Assessment annually. Compliance and Ethics is a key stakeholder of the Assessment process. Results are reported to the Board and incorporated into strategic planning.

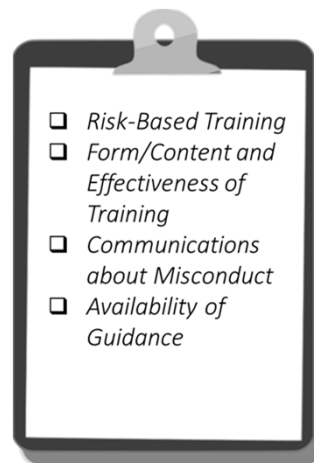


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DOJ Evaluation of Compliance Programs

- Topic 6 – Training and Communications
- How addressed by CareFirst:
 - Company-wide mandatory training is required upon hire and annually thereafter on various risk based topics. Role-specific training and communications are developed and targeted as necessary.

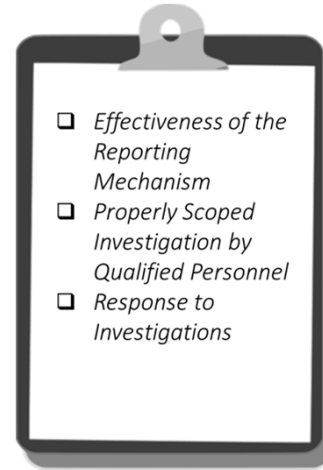


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DOJ Evaluation of Compliance Programs

- Topic 7 – Confidential Reporting and Investigation
- How addressed by CareFirst:
 - Various reporting mechanisms are available to associates including access to the Compliance and Ethics Department via a helpline and email, as well as an anonymous hotline and online report form. Investigations are handled by a dedicated Compliance and Ethics Investigator in partnership with HR. Investigations are managed through GRC software to ensure consistency, scope and response.

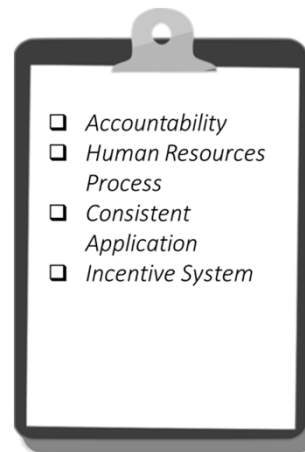


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DOJ Evaluation of Compliance Programs

- Topic 8 – Incentives and Disciplinary Measures
- How addressed by CareFirst:
 - Compliance and Ethics is part of the Annual Performance Assessment and Review process for all associates. Compliance and Ethics works closely with Human Resources on all investigations to ensure accountability. Human Resources works with management on applying consistent disciplinary action when appropriate. CareFirst recognition program expressly recognizes “Excellence in Ethics.”

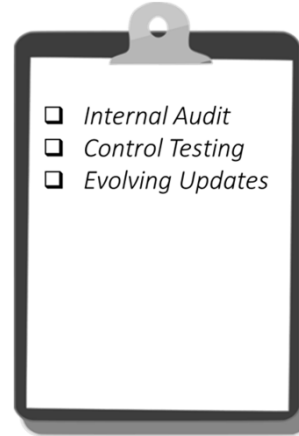


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DOJ Evaluation of Compliance Programs

- Topic 9 – Continuous Improvement
- How addressed by CareFirst:
 - CareFirst undergoes thorough review and testing annually by a third party audit firm, as well as regular oversight by the MAR office. Internal Audit Department develops an annual audit plan based on the Annual Risk Assessment that includes audit and testing of company controls . Audit Reports are given to Executive Leadership and the Audit and Compliance Committee. All policies are managed through C360 as well as reviewed and updated on a regular basis.

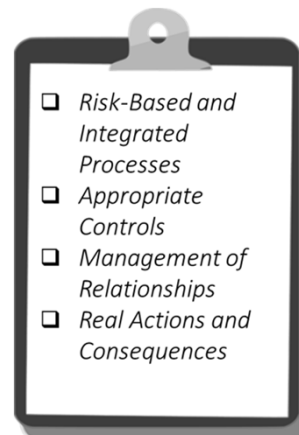


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DOJ Evaluation of Compliance Programs

- Topic 10 – Third Party Management
- How addressed by CareFirst:
 - The Procurement Department has established policies and processes and works closely with Legal to manage relationships and implement controls throughout the procurement process. Each business unit is responsible for vendor management and oversight within their operational area.

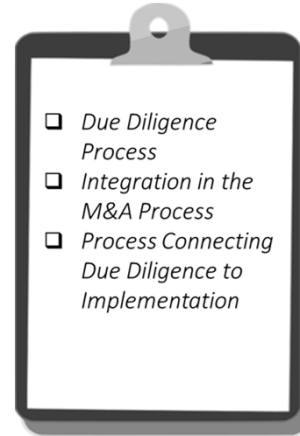


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DOJ Evaluation of Compliance Programs

- Topic 11 – Mergers and Acquisitions
- How addressed by CareFirst:
 - Generally, CareFirst does not use an acquisition strategy to achieve its goals; however, for those organizations that we directly invest in, we follow a comprehensive and detailed due diligence process.



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DOJ Guidance in Managed Care Context

- DOJ Evaluation Guidance Impact on *Investigations*
 - 42 C.F.R. § 422.503(b)(4)(vi)(G) and related guidance requires “a system for promptly responding to compliance issues as they are raised”
 - But DOJ wants to know if your investigation and analysis identifies the “root cause” of the misconduct, who made that analysis, and what specific remediation is being undertaken to prevent it in the future

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DOJ Guidance in Managed Care Context

- DOJ Evaluation Guidance Impact on ***Oversight***
 - 42 C.F.R. § 422.503(b)(4)(vi)(B) requires “the designation of a compliance officer and a compliance committee who report directly and are accountable to the organization's chief executive or other senior management”
 - But DOJ wants to know whether your senior leaders have encouraged this type of misconduct through words or actions, whether your senior leaders have demonstrated their commitment to compliance and remediation of misconduct, and whether your compliance functions have sufficient sway within the company to effect change

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DOJ Guidance in Managed Care Context

- DOJ Evaluation Guidance Impact on ***Discipline***
 - 42 C.F.R. § 422.503(b)(4)(vi)(E) requires “[w]ell-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program”
 - But DOJ wants to know what disciplinary actions the company has taken in response to misconduct, whether disciplinary rules were applied consistently, and what incentives exist for ethical behavior

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Conclusion

- DOJ Evaluation Guidance does not reinvent the wheel on compliance, but it is a critically important source to consider as you develop, monitor, and assess your own organization's compliance function

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Questions?

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