

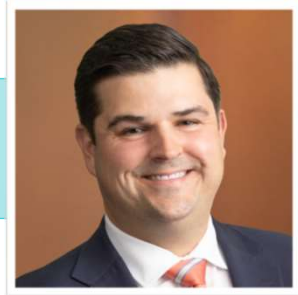
Compliance from the Cheap Seats

Anthony J. Burba
Barnes & Thornburg, Chicago, IL
Leah A. Voigt
Corewell Health, Grand Rapids, MI

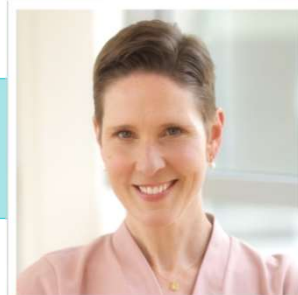


1

Presenters



Tony J. Burba
Partner
Healthcare Department
Barnes & Thornburg



Leah A. Voigt
Chief Compliance Officer
Corewell Health



2

Agenda

- Compliance Program Foundational Concepts (plus a few updates)
- Recent Enforcement Trends
- Compliance Under the Current Administration
- Navigating Federal Health Policy Changes



3

Foundational Concepts



4

Compliance and Legal Have Different Mandates



"The lawyers tell you whether you can do something, and compliance tells you whether you should...We think upper management should hear both arguments." Office of Inspector General, HHS (Pfizer)

5

Different Roles and Responsibilities

Legal

In-House Counsel	Outside Counsel
Guidance on legal/regulatory requirements as applied to business model	Provide independent, objective advice and expertise
Provide business <u>AND</u> legal advice	Offer highly specialized expertise and experience
Manage relationships with external stakeholders	Perhaps easier to deliver bad news?
Zealous advocacy for client under rules of professional conduct	Protect internal working relationships for future collaborations
	Facilitate communication with regulators and enforcement agencies
	Bandwidth to complete sensitive and/or extensive investigations

6

Different Roles and Responsibilities

Compliance

Compliance Officer

Provide independent, objective advice – what should you do?

Identify and investigate actual or potential violations of law, regulation and/or organizational policies, procedures, code(s) of conduct

Initial fact-finding to inform decision making

Continuous monitoring to mitigate risk and promote corrective action

Ensure unfiltered communication with Board and oversight committees; may also include communication with external stakeholders (e.g., regulatory agencies)

Operate and lead an effective compliance program

OIG General Compliance Program Guidance

- ① To be effective, a compliance program should have a board and senior leadership that understand its value and are committed to its success
- ② Corporate officers, managers, supervisors, health care professionals, and medical staff should be held accountable for failing to comply with, or adhere to, the applicable standards, laws, policies, and procedures



Elements of an Effective Compliance Program



DOJ Guidance for Federal Prosecutors

Fundamental questions for evaluating programs:

- 1 Is the compliance program well designed?
- 2 Is the program adequately resourced and empowered to function effectively?
- 3 Does the compliance program work in practice?

"An effective compliance program makes good business sense – it helps fulfill the fundamental mission to patients and the community and assists in identifying weaknesses in internal systems and management."



New Guidance – AI and Corporate Compliance Programs

- Released by the DOJ and updated September 2024
- Advises prosecutors to consider:
 - The technology – including AI – that a company and its employees are using to conduct business;
 - Whether the company has conducted a risk assessment regarding use of the technology;
 - Whether the company is mitigating any associated risks



11

Recent Enforcement Trends



12

Apex Medical – June 2024

- Defendants, through sales personnel and nurse practitioners, applied skin grafts without medical necessity or grafts were oversized to inflate billing
- Apex Medical received illegal kickbacks in the form of rebates for purchasing and ordering skin grafts
- Rebates were disguised by invoices that reflected the full price, not the rebated price



13

Apex Medical – Enforcement Trends

- Illegal kickback and rebates
- Focus on DME enforcement
- Criminal Charges:
 - Conspiracy
 - Health Care Fraud
 - Receipt of Kickbacks
 - Money Laundering



14

Apex Medical – Compliance Highlights

- Targeted elderly and terminally ill Medicare beneficiaries
 - Scrutiny on how providers interact with high-risk population
- False certification of Medicare compliance
- Lack of medical necessity
- Use of unqualified personnel
- Pressure on medical staff



15

SpineFrontier, Inc. – May 2025

- SpineFrontier was required to report payments or transfers of value to physicians under the Sunshine Act
- SpineFrontier CEO directed employees to report payments to surgeons as “consulting fees” even though no such consulting occurred
- CEO pled guilty; sentencing set for August 2025



16

SpineFrontier, Inc. – Enforcement Trends

- False reporting under the Physician Payments Sunshine Act
- Kickback and sham consulting schemes
 - Receipt of Kickbacks (42 U.S.C. § 1302a-7b(b))
 - Money Laundering (18 U.S.C. § 1957)
- Schemes to disguise remuneration as consulting/advisory fees



17

SpineFrontier, Inc.– Compliance Highlights

- Oversee consulting relationships
- Document time, tasks performed, and objective deliverables
- Implement rigorous Sunshine Act Reporting Protocols
 - Cross-verify consulting payments with actual work performed
- Avoid linking remuneration to product usage
 - Compensate on fair market value
 - No reference to business generated
- Audit third-party intermediaries



18

eHealth, et al. – May 2025

- Defendants include major health insurers and insurance brokers
- Insurers allegedly paid brokers to steer Medicare beneficiaries towards their MA plans
- Practices allegedly discriminated against Medicare beneficiaries with disabilities
- Originally filed as a *qui tam*



19

eHealth, et al. – Compliance Highlights

- Ensure broker compensation is aligned with beneficiary needs
- Oversee sales personnel to ensure beneficiaries aren't steered into inappropriate plans
- Understand accessibility requirements and consider how those groups face barriers to enrollment



20

Other Healthcare Enforcement Trends

Settlement
Agreements with
DOJ/OIG-HHS

Complaints
Originating with
Whistleblower

Financial/Fraud
Violations

False Claims Act
(FCA)

Healthcare
Investors

AI and Tech
Oversight



21

Other Healthcare Enforcement Highlights & Trends

- \$1.69B+ FCA Healthcare settlements/judgments (FY 2024)
 - 60% of total FCA recoveries
 - Continued priority in 2025
- 370 new *qui tam* suits filed under FCA (FY 2024)



22

Compliance Under the Current Administration



23

Executive Orders

Executive Order 14173

- Mandated DEI programs illegal
 - Does not define an “illegal” DEI program
- Directed USAG to identify enforcement targets in private sector
- Carries FCA implications for noncompliance
- Explicitly named the healthcare industry

Executive Order 14168

- Defined “sex” as “individuals’ immutable biological classification as male or female”
- Eliminated protections for gender identity



24

FCA and DEI

- Recent EOs widen path for DOJ or *qui tam* relators to assert FCA claims
- Civil Rights Fraud Initiative
- Encouraging whistleblowers to file claims under FCA against entities
- Heightened FCA Scrutiny
 - 1) **False Certification Liability**
 - Contractors must attest they do not run DEI programs that violate anti-discrimination laws
 - 2) **Regulatory Uncertainty**
 - Withdrawal on clinical trial diversity complicates compliance for healthcare institutions engaged in research and drug development
 - 3) **Government Investigations**
 - With an explicit mandate for federal agencies to target non-compliant organization, healthcare providers could face increased scrutiny from enforcement bodies



25

The Bondi Memo (2025)

- Entitled “Reinstating the Prohibition on Improper Guidance Documents”
- Prohibits use of guidance documents as an independent basis for determining a party’s rights and obligations
- Emphasized guidance documents violate the law
 - Issued without undergoing the rulemaking process established by the law
 - Acts as a substitute for rulemaking
- Ordered Associate Attorney General to deliver strategies and measures to eliminate illegal or improper use of guidance documents



26

The Bondi Memo

Falsity	DOJ attorneys must anchor falsity in text that has the force of law: statutes, regulations, or contracts
Scienter	The fact that the defendant read subregulatory guidance emphasizing the requirement may be used as evidence of knowledge but cannot, standing alone, prove falsity
Materiality	Harder for government to argue that violation of subregulatory guidance is “material”

27

The Bondi Memo – Best Practices and Takeaways

Shifts compliance target from “all agency guidance” to
“actual binding requirement”



Inventory Legal v.
Guidance Obligation



Escalate Ambiguities



Document
Deliberative Process



Prepare for Cross-
Winds



Seek Formality
Where Feasible



Engage Early When
Targeted



Align Contracts

28

Updated List of Priorities and CEP Edits to DOJ

1. Prioritization of Corporate Enforcement
2. Updates to the Corporate Enforcement Policy
3. Updates to Monitor Policy
4. Updates to Corporate Whistleblower Awards Pilot Program



29

Updated List of Priorities and CEP Edits to DOJ

Prioritization of Corporate Enforcement

Named new areas of DOJ focus in corporate enforcement

1. Matters involving national security
 - Trade
 - Foreign terrorist organizations
 - Cartels
2. Opioid crisis
3. Government fraud and waste
4. Importance of combatting actions which “circumvent the rules and regulations that protect American consumers
5. Prioritized violations of the Controlled Substance Act and the FDCA



30

Updated List of Priorities and CEP Edits to DOJ

Updates to the Corporate Enforcement Policy

- Encouraged self-disclosure of corporate misconduct
- DOJ reviewing “all existing agreements to determine if they should be terminated early”
- Required declination if company voluntarily self-discloses, fully cooperates, and appropriately remediates



31

Updated List of Priorities and CEP Edits to DOJ

Updates to Monitor Policy

- Simplified prior DOJ guidance from 10 factors to 4 factors
- Added requirements to minimize cost of monitorship
- Announced review of existing unnecessary monitorship



32

Updated List of Priorities and CEP Edits to DOJ






Updates to Corporate Whistleblower Awards Pilot Program

- Added 4 new areas a whistleblower may be eligible for an award to report misconduct
- Announced continuation of pilot program



33

Key Takeaways

-  DOJ Criminal Division will continue to prosecute corporate criminal activity
-  DOJ is placing emphasis on the “carrot” to better reward companies that engage in good corporate behavior
-  DOJ Criminal Division will decrease the imposition of monitorship
-  Policy developments signal a more favorable approach for companies
-  Companies should continue devoting resources to compliance programs and take note of DOJ focus areas



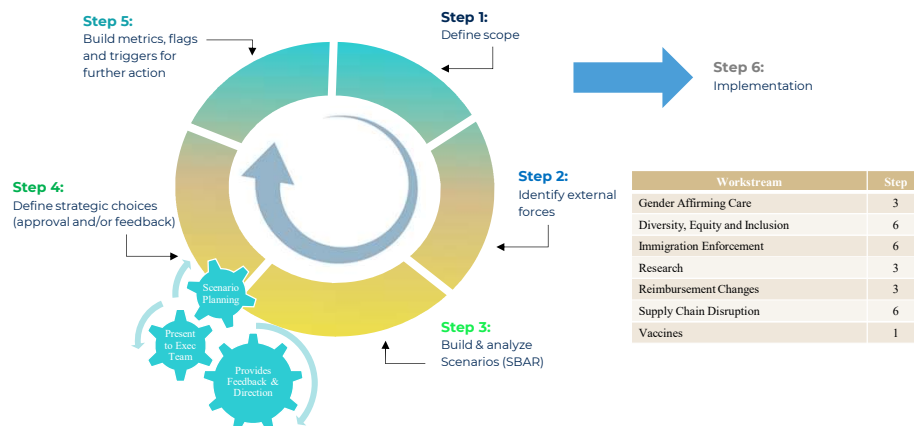
34

Navigating Federal Health Policy Changes

35

Scenario Planning

Process that helps organizations consider different potential futures. It's a way to anticipate challenges and opportunities and to mitigate future risks.



36

Workstream Summaries

	Impact	Likelihood	External Forces/ Timeline	Scenario Planning Phase
Gender Affirming Care (GAC)	Reduction of Medicaid funding, Medicare CoP tied to GAC for patients 18 and younger	High	Anticipated impact to federal Medicaid dollars and CMS rules; unknown timeline	Step 3: Planning scenarios for discontinuation of services, researching alternatives to provide care
Diversity, Equity and Inclusion	Enforcement activity, reduction or elimination of funding for DEI initiatives	High	EOs specific to DEI and subsequent policy changes, enforcement activity	Step 6: Rebranding, refocusing of existing work/initiatives
Immigration Enforcement	Immigration/ICE officers going to one of our locations for purposes of identifying/detaining a patient (or visitor)	Low	Watching for future signals indicating enforcement is shifting to include sensitive locations	Step 6: Implemented a process to support team members if the scenario occurs
Research	Funding reduction, including potential 15% cap on indirect costs and loss of current grants	Experiencing partial impact	Potential cap on indirect costs, ongoing stop work order issued for contracts	Step 3: Absorbing current financial loss into budget; scenario planning for greater impact in all areas of research

37

AMERICAN HEALTH LAW ASSOCIATION

37

Workstream Summaries

	Impact	Likelihood	External Forces/ Timeline	Scenario Planning Phase
Reimbursement Changes	Any major reduction in Medicare and/or Medicaid funding	High	Various changes resulting in decreased reimbursement	Step 3: Scenario analysis underway to determine financial impact based on specific changes, e.g., site neutrality
Supply Chain Disruption	Increase in expenses due to tariffs	Experiencing impact	Ongoing changes to tariffs	Step 6: Implemented ongoing operations to monitor & make adjustments due to increased costs from tariffs / ensure no disruption in supply availability
Vaccines	Changes to federal agency recommendations, impact to payer reimbursement	Low to Moderate	No specific risk identified yet	Step 1: Developing scope & kicking off conversations

38

AMERICAN HEALTH LAW ASSOCIATION

38

Discussion