



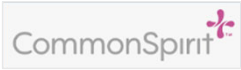
AHLA In-House Counsel Virtual Training

Compliance vs Legal

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ROLES & RESPONSIBILITIES

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 LEGAL	 COMPLIANCE
Primary role: • Interpret laws and regulations • Advise on legal risk • Defend the organization when things go wrong Typical activities: • Contract drafting and negotiation • Regulatory interpretation • Providing legal opinions • Managing litigation and enforcement actions • Privilege protection Posture: • Reactive and proactive • Risk-based and strategic • Often confidential and privileged	Primary role: • Ensure the organization actually follows applicable laws, regulations, and internal policies • Advise on execution/implementation risk Typical activities: • Developing policies and procedures • Training employees • Auditing and monitoring • Running reporting systems (hotlines, investigations) • Corrective action and remediation • Reporting to leadership and the board Posture: • Preventive • Operational • Transparent and documented • Often not privileged

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 ARRANGEMENTS • FMV • Review and Approval • Post-operationalized issues	 INVESTIGATIONS • Information Gathering • Interviews • Analysis • Corrective Actions	AREAS THAT MAY OVERLAP • What are our shared objectives? • What strategies can be employed to ensure the compliance and legal teams avoid duplication? AMERICAN HEALTH LAW ASSOCIATION
 CONFLICTS OF INTEREST • Employees • Physicians • Board Members	 COMPLIANCE POLICIES & PROCEDURES • Code of Conduct • Compliance • Privacy & Security	
 DUE DILIGENCE • Arrangements • Billing Practices • Conflicts of Interest	 SELF-DISCLOSURES • Health Care Fraud (SDP) • Self-Referral (SRDP) • HHS Grant or Contractor • State Medicaid • DOJ Voluntary (VSD)	

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STRATEGY: DEFINE ROLES & RESPONSIBILITIES

Responsible	Carries out the task
Accountable	Delegates work and is the last one to review before deemed complete
Consulted	Provides input based on impact or domain of expertise. (Not directly involved in carrying out the task)
Informed	Needs to be kept in the loop, rather than roped into details

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KNOWLEDGE CHECK

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PRIVILEGE

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QUICK REVIEW

Privilege Protects:

- Requests for legal advice
- Legal analysis and opinions
- Litigation strategy
- Regulatory defense discussions

Privilege Does Not Protect:

- Underlying facts
- Business decisions
- Compliance failures
- Routine operational communications

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SCENARIOS

Scenario 1: Everything Goes Through Legal

What happens:

- Compliance routes routine monitoring, audits, and issue tracking through legal “to preserve privilege”
- Legal becomes a bottleneck
- Issues are discussed but not documented operationally

Why is this could be a problem:

- Regulators view this a privilege misuse
- Compliance program appears weak or nonexistent
- Remediation is delayed or unclear

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SCENARIOS

Scenario 2: Privilege In Place of Fixing the Problem

What happens:

- Internal investigation identifies a compliance gap
- Legal memo documents risk
- Business continues conduct without changes
- Later enforcement occurs

Why this could be a problem:

- Regulator view: knowledge + inaction = aggravating factor
- Privileged documents may become discoverable under crime-fraud exception, waiver theories, cooperation obligations
- Privilege does not protect bad facts

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SCENARIOS

Scenario 3: Compliance Can't Speak Freely

What happens:

- Compliance staff are told: “don’t write that down”, “send it to legal only”, “avoid creating discoverable documents”

Why this could be a problem:

- Compliance program fails basic regulatory expectations
- Lack of documentation = lack of compliance
- Regulators expect evidence of controls, not silence

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SCENARIOS

Scenario 4: Privilege Creates a False Sense of Safety

Reality:

- Privilege can be waived
- Regulators may demand factual disclosures
- Settlement negotiations often require transparency

Enforcement Themes Worth Noting

- *In False Claims Act cases, internal awareness of compliance failures - even if discussed with counsel - can support “knowledge” or “recklessness”.*
- *In HIPAA and CMS enforcement, lack of documented compliance efforts often worsens the outcome.*
- *In Corporate Integrity Agreements, regulators explicitly require non-legal compliance documentation and reporting.*

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ASK YOURSELF

1. WHAT IS YOUR ORGANIZATION'S ATTORNEY-CLIENT PRIVILEGE APPETITE?
2. DO YOU THINK IT'S OVERDONE? DOES IT LOOK TOO DEFENSIVE?
3. IF EVERYTHING IS ATTORNEY-CLIENT PRIVILEGED DOES IT WEAKEN THE PRIVILEGE?
4. DO YOU END UP WAIVING THE PRIVILEGE ANYWAY?
5. HOW DO YOUR COMPLIANCE OFFICERS KEEP THE NECESSARY EXECUTIVES INFORMED?

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DIFFERING RISK TOLERANCES

Who gets to decide?

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TYPES OF DECISIONS

Legal Interpretation

Compliance Design & Operational

Enterprise Risk Appetite

When Legal and Compliance aren't aligned:

- Ask, is this a question of legal interpretation or regulatory expectation? Or both?
- Clarify positions, risks they each see, assumptions being made
- If necessary, escalate to a risk tolerance decision making body

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CONSIDERATION: ESCALATION MODEL



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HYPOTHETICAL EXAMPLE

Legal says marketing practice is arguably permissible. Compliance says regulators have cited similar practices. Business wants to proceed.

Now What?

- Legal advises
- Compliance outlines necessary baseline controls
- Business decides whether to accept residual risk



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Case Study

Tenet Healthcare Non-Prosecution Agreement 2016

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BREAKDOWN

Legal Defense	Why Still Deemed Non-Compliant
Tenet's in-house and outside counsel were involved in reviewing agreements with referral sources — and at times were told certain documentation reflected legitimate business arrangements. Those analyses may have, at points, suggested there were plausible legal interpretations of the contracts.	The DOJ alleged that, in some cases, executives concealed the true nature of the referral arrangements from lawyers because they understood those arrangements wouldn't be approved if fully disclosed. The presence of legal review or plausible defenses does not immunize conduct from being judged noncompliant if material facts are hidden or if the conduct falls below compliance expectations.
Tenet had an existing Corporate Integrity Agreement (CIA) in place from an earlier settlement, requiring robust policies, disclosures, and internal controls to ensure compliance with healthcare law.	The alleged arrangements continued despite the CIA. Legal defensibility (e.g., CIA requirement to have robust policies) isn't the same as actual compliance effectiveness; a function can be technically defensible in structure but noncompliant in execution.

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Case Study

Community Health Network 2023 (and into 2025)

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BREAKDOWN

Legal Defense	Why Still Deemed Non-Compliant
Hospital obtained outside valuation opinions to justify compensation levels. If those valuations conclude the compensation is defensible, the hospital argues that it acted reasonably under the law.	Compensation was allegedly well above FMV- sometimes double private practice levels, and it was alleged CHN provided inaccurate data to the valuation firm. Therefore did not have effective processes to validate accurate data before relying on it nor did it have effective processes to assess commercial reasonableness, undermining their defense. Bonuses were allegedly tied to referral volume, violating Stark's prohibition on compensation influenced by referral generation. Therefore compensation allegedly took into account volume or value of referrals even if the provider believed it had defensible methodologies.
Physician compensation and related regulatory rules are "complex and highly regulated", implying that other reasonable actors might interpret them differently, not that CHN intentionally sought to violate the law.	Enforcement agencies (e.g., DOJ, HHS-OIG) apply their own interpretations of statutory requirements that may diverge from internal views. A health system may think an arrangement is defensible, but if regulators disagree on the application of exceptions or fair market value, that can trigger FCA liability.
Did not involve the quality or appropriateness of patient care.	Claims submitted to Medicare were therefore allegedly "false" under the False Claims Act.

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ALIGNMENT

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Pit Stop to Ensure Alignment

Before responding to a question that may not have an obvious answer or relies on a risk tolerance, make sure you are aligned on your positions



Have the Teams Meet Regularly

Facilitate open lines of communication between the teams

Standing check-ins/touch bases



Address Contradictory Guidance

Take the time to examine when contradictory guidance has occurred, establish a unified position going forward

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THANK YOU



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