Leveraging the Legal-Compliance Relationship

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Objectives for today

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- ✓ Explore ways that your compliance officer and legal counsel can work together to maximize value, eliminate redundancies, and provide clear, effective guidance to the organization
- ✓ Understand how to distinguish between matters that can be successfully handled internally and factors suggesting that use of outside counsel or consultant is necessary
 - ✓ Preserving attorney-client privilege
 - ✓ Strategies for cost effectively analyzing and defending external audits, inspections, compliance reviews, compliance training, etc.
 - ✓ Weighing the "legally sufficient" vs. "best practice" approaches
- ✓ Managing the "tsunami of data" and understand which data sets put your organization "on notice"

First Things First: The "Independence" Issue

- Arguably, a Compliance Officer's most important relationship is with the General Counsel and, by extension, outside counsel
 - The need for independence should not restrict or limit how closely a Compliance Officer works with the G.C. or outside counsel
 - o Independence is a primarily personal attribute
 - ★ Corporate reporting lines can reinforce independence
 - **▼** Do not rely on reporting relationships alone to establish your independence
 - The Compliance Officer and Counsel roles are actually "interdependent"
 - Consult with regulation to decide whether a particular reporting relationship is required (e.g. publicly held corporations) and structure the roles accordingly
 - * Remember not to limit the inter-dependence of the 2 roles

Independence, continued



- This does not mean that all the work must be performed by, or under the direction of, outside counsel
- Compliance officers can and should evaluate the need for corrective action at all stages of matter development
- Managing the costs of a compliance matter (including audits, investigation, interviews, etc.) is a shared responsibility
 - **★** Engage in an on-going discussion regarding budgets, next steps and contingency plans

The Privilege Issue

- With certain compliance matters, the need for attorney-client privilege is real
 - Despite the presence or absence of an attorney-client relationship, remember that facts are not subject to privilege
 - **▼** But how facts are used may be privileged
 - o Should compliance officers have their "own" counsel
 - **★** Does such a need reveal larger, more fundamental, problems within the organization?
 - o Pros and cons of conducting internal vs. external reviews
 - o Does the scope of privilege extend to reviews by in-house counsel?
 - **▼** NY AG current position is that mandatory investigative reports are not privileged

Essential Purposes – Contrast or Harmony?



- "Protect & Defend" vs. "Find & Fix"
 - Does the role of counsel to protect and defend conflict with the role of the compliance officer to find and fix?
 - These are not mutually exclusive and are generally harmonious
 - **x** Consider: The "head in the sand" is no defense
 - x Consider: The "known or should have known" standard
 - ▼ Consider: Corrective action can be undertaken in a manner that does not reveal privileged information
 - ▼ Consider: Corrective action is not about pointing fingers or assessing blame
 - ▼ Consider: GM ignition switch issue − liability concerns appear to have influenced the decision not to redesign or recall earlier
 - GM was broadly criticized for its handling of the matter but preserved the privilege of internal investigation work papers prepared by outside counsel, even though counsel's report was made publicly available

Early Risk Assessment – Key to Managing Costs

- Not all risks are created equal, and no transaction or investigation is ever risk-free
 - o Ask counsel for an honest assessment of risk
 - Understand that determining which risks are acceptable to the organization is a board-level responsibility
 - O When is "legally sufficient" enough?
 - ★ Is the "best practice" approach too much, too expensive or potential fodder for additional legal exposure (ex: not following an overly complicated policy)
- Are there internal disagreements regarding risk that outside counsel can help resolve?

Managing costs, continued

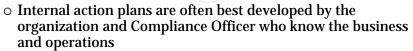
- Remember: there are costs to both internal and external work
- Understand the time involved for the outcome needed (e.g. policy, opinion or guidance document should requirement a smaller investment)
- Specific strategies for leveraging the relationships may include:
 - Drafting vs. editing consider having documents drafted internally and sent to counsel for final review (i.e. current statutory/regulatory requirements and/or tone)
 - ▼ Consider the audience when setting tone and complexity
 - ▼ Policies and internal guidance memos do not require statutory citations

Cost-Effective Strategies



- ▼ The factual development of a matter is <u>always</u> a critical stage but which facts are actually critical?
 - o Engage counsel to help identify which facts, if established, avoid the need for reporting or disclosure
- ★ Who interviews whom?
 - o Use counsel to narrow issues or conduct key interviews related to critical facts identified
 - o Keep outside counsel posted on the facts as they develop.
 - This does not mean relying on outside counsel to develop the facts.
- o Facts: organizing data vs. positioning data
 - ▼ If data is being modeled or produced in anticipation of litigation, assure that it is performed at the request of, and under the direction of, counsel

Developing Action Plans



- ★ Having said that, outside counsel may notice gaps in the plan or spot areas that are likely to be criticized by government agencies
- **★** Evaluate where your action plan falls on the "best practice vs. legally sufficient" spectrum
- o Ask:
 - Can my organization successfully implement this action plan?
 o If so, at what cost?
 - o In what timeframe?
 - **★** Will the action plan actually solve the problem (or just identify who is to blame if the problem recurs)?

Using the QA/PI Process



- Quality Assurance /Process Improvement
 - o A protected environment but privilege is not absolute.
 - o Examine state regulations and case law decisions
 - o Federal regulations protect hospital QA Committee work products
 - Most states broadly protect hospital QA work products
 - In NY, even with comprehensive "whistleblower" laws, hospitals have been able to successfully protect confidential QA documents, including selfdisclosed adverse events (i.e. NYPORTS)
 - o Nursing home QA records have somewhat less protection
 - Federal Nursing Home Reform Act provides a privilege for information "developed by" Quality Assurance committees.
 - But called an "exceedingly narrow" exception by the Missouri Supreme Court.
 - NY Court of Appeals held that the privilege extends to work actually performed by QA Committee members or by others at the Committee's express direction but not to other records considered by the Committee. Matter of Subpoena to Jane Doe.

Managing the "Tsunami of Data"



Examine your data feeds

- O Ask how are data sets stored and used?
- Raw, unanalyzed data at what point is it a liability?
 - ▼ Does raw data put the organization "on notice"
 - × False Claims Act intent − "known or should have known" standard
- Data that is produced and distributed by the government puts a provider on notice and <u>must</u> be reviewed
 - o PEPPER reports
 - o Comparative Billing Reports
 - o CERT, ADR and RAC audit results
 - o 5-Star ratings

Questions?



- Feel free to contact the speakers:
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