HLB
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HEALTH CARE LAWYERS

REGULATORY UPDATE

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AGENDA

- New DOJ Corporate Compliance Program Guidance
- What's new with Knox Keene?
- Medical Board Subpoena Updates
  - *Grafilo v. Cohanshohet; Grafilo v. Wolfsohn* (2019)
- Recent Developments re: Stark/AKS updates
- Co-Location Guidance (issued in draft form by CMS)

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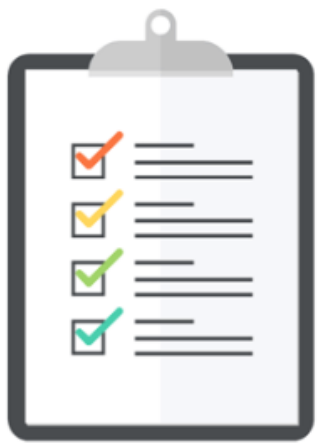
DOJ Compliance Program Guidelines

DOJ Updated Compliance Guidance

1. **Is the corporation's compliance program well designed?**
2. **Is the program being applied earnestly and in good faith?**
3. **Does the corporation's compliance program work in practice?**



U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs* (April 2019)

Well Designed?

- What do your policies and procedures look like?
- Has your organization undergone a risk assessment?
- What do internal trainings and communications look like?
- Effectiveness of reporting mechanisms?
- What about third-party relationships?

Implemented Effectively?

Does it Work?

- Continuous improvement, periodic testing, and review
- Investigation of misconduct
- Analysis and remediation of any underlying misconduct

Knox Keene Regulations

- Knox Keene Act regulates health plans in California
- New regulations are effective July 1, 2019 which will greatly broaden who must apply to the Department of Managed Health Care for a license (or an exemption from licensure)

Knox Keene Regulations – What's Changed?

- Traditional Analysis:
  - Capitation payments might require licensing ("prepaid period payments")
  - Unless a provider is capitated:
    - Only for services it is authorized to provide, and
    - By a licensed Knox Keene plan
- Brave New World
  - Shared savings, even if calculated retrospectively, can make you a Knox Keene plan if you are at "global risk" (both professional and institutional)
  - IPAs with hospital risk pools and ACOs take note!
  - Medicare ACOs and Bundled Payments are likely Knox Keene exempt

Knox Keene Regulations – Timing

- New regulations are effective July 1, 2019
- Exemption from licensure applications submitted July 1 to December 31, 2019 are deemed exempt:
  - For their remaining term, if with licensed Knox Keene plan
  - For one year if with anyone else
- Potential for "informal grandfathering" for arrangements in place prior to July 1, 2019

Medical Board Subpoenas

Medical Board Investigations

QUESTIONS AND ANSWERS ABOUT INVESTIGATIONS

Central Complaint Unit

Medical Board of California

the state agency that licenses medical doctors, investigates complaints, and disciplines those who violate the law

■ ***HOW IS THE INVESTIGATION CONDUCTED?***

Investigative steps may include, but are not limited to the following:

- Obtaining medical records or other information/evidence
- Locating and interviewing the complainant, any witnesses, and the physician
- Obtaining expert review of the case
- Drafting and serving investigational subpoenas
- Inspecting the location where the allegations occurred
- Executing search warrants
- Conducting undercover operations

In general, after information is collected and compiled and the complainant has been interviewed, the investigator, and perhaps the supervisor or a medical consultant, interviews the physician to discuss the details of the complaint and ask questions.

Quality of care issues are then reviewed by a medical expert. The standard of proof for administrative cases is "clear and convincing evidence to a reasonable certainty," a much higher standard than for civil litigation cases. This can be a very challenging when pursuing a complaint because administrative charges must be proven before an administrative law judge who uses this higher and more difficult standard.

http://www.mbc.ca.gov/Publications/Brochures/investigations_english-print.pdf

Subpoenas

- Medical Board investigators are authorized to issue subpoenas pursuant to Government Code §11181

- Don't forget privacy protections!
  - Evid. Code § 1157?
    - *Arnett v. Dal Cielo* (1996)
  - Attorney/Client Privilege
  - Patient Records
  - Constitutional right to privacy

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Grafilo v. Cohanshohet (Cal. Ct. App. 2/21/19)

- Medical Board received anonymous complaint that physician prescribing excessive narcotics.
- Potentially affected patients refused to release medical records.
- Physician refused to comply with subpoena to turn over records.
- MBC sought order compelling production of the records; trial court granted
- Court of Appeals reversed, finding that MBC failed to show good cause to compel production of medical records in light of patients' significant privacy interests.

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Grafilo v. Wolfsohn (Cal. Ct. App. 4/2/19)

- Similar facts to *Cohanshohet*
- Court of Appeals found no good cause to compel production of medical records
  - "The defects in the evidence supporting the subpoenas in Cohanshohet are present here and there are no additional facts that add substantial weight in favor of the subpoena."
  - The Medical Board "offered no evidence as to how many patients Wolfsohn treats, the percentage of his patients the five patients comprised, how often similarly-situated pain management specialists might prescribe the drugs Wolfsohn prescribed, or the likelihood Wolfsohn properly issued the prescriptions."

Recent Developments in Stark and Anti-Kickback Statutes

U.S. v. Halifax

- This case typifies new physician compensation concerns
- What did the U.S. DOJ say about physician compensation?
  - "Given that each neurosurgeon was paid total compensation that exceeded the collections received for neurosurgical physician services, Defendants could not reasonably have concluded that the compensation arrangements in those contracts were fair market value for the neurosurgical services or were commercially reasonable."
- What does this mean?
- What are the lessons?

Citizens Medical Center

- ER physicians allegedly were paid bonuses to refer to Citizen's chest center
- Cardiologists
  - Hired and given large raises compared to when in private practice
  - Citizens had "practice losses" on cardiologists
  - Cardiologists were paid below median
- GI physicians allegedly paid $1,000/day for phony "medical director" services

Stark Law Self-Disclosure Protocol

- Should be used for "Stark only" self-disclosures
- Tolls the 60-day repayment obligation, but doesn't require/permit payment with the self-disclosure!
- Requires detailed submission, including:
  - facts and circumstances of violation
  - legal analysis of why it doesn't comply
  - calculation of financial damages
- What types of compromise might be available?

Alternatives to Stark SRDP

- Report and Repay (in full) to Medicare Administrative Contractor (MAC)
- Use OIG Self-Disclosure (if colorable AKS violation)
- Others?
  - AUSA
  - DOJ
- Self-remedy?

Tips Re: SRDP

- What is the settlement timeline?
- What is the settlement process?
  - Offer amount?
  - Negotiable?
  - Timing?
  - Financial Distress?
- New Requires certification of non-compliance
- New Formula for calculating "pervasiveness" of conduct

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OIG Self-Disclosures

- For physician arrangements with colorable anti-kickback concerns, and for a multitude of other types of arrangements that present anti-kickback concerns, or other issues (false billing, patient remuneration, excluded provider, etc.)
- Process, timing and settlement amounts
- Experiences

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Co-Location Guidance

Draft CMS Guidance for Hospital Co-Location

- Issued May 3, 2019
- Comments due July 2, 2019

Distinct and Shared Space

- Defined and Distinct Spaces of Operation
  - Clinical spaces designated for patient care
- Shared Spaces
  - Public spaces and paths of travel utilized by hospital and co-located healthcare entity (e.g., public lobbies, public restrooms, main corridors (through non-clinical areas))

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Contracted Services

- Hospital is responsible for providing all of its services in compliance with CoPs
  - Under arrangement with another co-located hospital or healthcare entity?
    - Ex. Lab, dietary, pharmacy, maintenance, housekeeping, and security, utilities, alarm systems, etc.
- Staffing
  - Assigned solely for one hospital during specific shift
  - Training requirements
  - Medical Staff

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Emergency Services

- Hospitals without EDs must have appropriate policies and procedures in place for addressing emergency care needs 24/7
- Co-Location Issues
- Transfer to Co-Located facility?
- EMTALA implications?

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Any Questions

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