

AGENDA
COMPLIANCE AND AUDIT COMMITTEE MEETING
OF THE EL CAMINO HOSPITAL BOARD

Thursday, May 20, 2021 – 5:00 pm
 El Camino Hospital, 2500 Grant Road, Mountain View, CA 94040

PURSUANT TO STATE OF CALIFORNIA EXECUTIVE ORDER N-29-20 DATED MARCH 18, 2020, EL CAMINO HEALTH WILL NOT BE PROVIDING A PHYSICAL LOCATION FOR THIS MEETING. INSTEAD, THE PUBLIC IS INVITED TO JOIN THE OPEN SESSION MEETING VIA TELECONFERENCE AT:

1-669-900-9128, MEETING CODE: 603-158-1129#. No participant code. Just press #.

PURPOSE: To advise and assist the El Camino Hospital (ECH) Hospital Board of Directors (“Board”) in its exercise of oversight of Corporate Compliance, Privacy, Internal and External Audit, Enterprise Risk Management, and Information Technology (IT) Security. The Committee will accomplish this by monitoring the compliance policies, controls, and processes of the organization and the engagement, independence, and performance of the internal auditor and external auditor. The Committee assists the Board in oversight of any regulatory audit and in assuring the organizational integrity of ECH in a manner consistent with its mission and purpose.

AGENDA ITEM	PRESENTED BY		ESTIMATED TIMES
1. CALL TO ORDER/ROLL CALL	Sharon Anolik Shakked, Chair		5:00 – 5:01pm
2. POTENTIAL CONFLICT OF INTEREST DISCLOSURES	Sharon Anolik Shakked, Chair		5:01 – 5:02
3. PUBLIC COMMUNICATION a. Oral Comments <i>This opportunity is provided for persons in the audience to make a brief statement, not to exceed three (3) minutes on issues or concerns not covered by the agenda.</i> b. Written Correspondence	Sharon Anolik Shakked, Chair		information 5:02 – 5:05
4. CONSENT CALENDAR <i>Any Committee Member or member of the public may remove an item for discussion before a motion is made.</i> Approval a. Minutes of the Open Session of the CAC Meeting (3/18/2021) b. Proposed FY22 Committee Goals Information c. Status of FY21 Committee Goals d. Articles of Interest	Sharon Anolik Shakked, Chair	<i>public comment</i>	motion required 5:05 – 5:10
5. REVISIONS TO STARK LAW AND ANTI-KICKBACK STATUE EDUCATION	Laura Keidan Martin, Partner, Katten, LLP		discussion 5:10 – 5:40
6. REPORT ON BOARD ACTIONS	Sharon, Anolik Shakked, Chair Board Members		information 5:40 – 5:45
7. ADJOURN TO CLOSED SESSION	Sharon Anolik Shakked, Chair		motion required 5:45– 5:46
8. POTENTIAL CONFLICT OF INTEREST DISCLOSURES	Sharon Anolik Shakked, Chair		5:46 – 5:47

AGENDA ITEM	PRESENTED BY		ESTIMATED TIMES
<p>9. CONSENT CALENDAR <i>Any Committee Member may remove an item for discussion before a motion is made.</i> Approval <i>Gov't Code Section 54957.2:</i> a. Minutes of the Closed Session of the CAC Meeting (3/18/2021) Information <i>Gov't Code Section 54956.9(d)(2) – conference with legal counsel – pending or threatened litigation:</i> b. KPI Scorecard and Trends c. Activity Log March 2021 d. Activity Log April 2021 e. Internal Audit Work Plan f. Internal Audit Follow Up Table g. Committee Pacing Plan</p>	<p>Sharon Anolik Shakked, Chair</p>		<p>motion required 5:47 – 6:00</p>
<p>10. <i>Gov't Code Section 54956.9(d)(2) – conference with legal counsel – pending or threatened litigation:</i> - Review Business Continuity Program Status</p>	<p>Ken King, CAO Priya Shah, Assistant General Counsel</p>		<p>information 6:00 – 6:10</p>
<p>11. <i>Gov't Code Section 54956.9(d)(2) – conference with legal counsel – pending or threatened litigation:</i> - IT Security Discussion and Strategic Plan</p>	<p>Deb Muro, CIO; Joe Voje, CISO; Priya Shah, Assistant General Counsel</p>		<p>discussion 6:10 – 6:40</p>
<p>12. <i>Gov't Code Section 54956.9(d)(2) – conference with legal counsel – pending or threatened litigation:</i> Report Internal Audit Assessment and Proposed FY 2021 Work Plan</p>	<p>Alex Robison, Protiviti; Priya Shah, Assistant General Counsel</p>		<p>information 6:40 – 6:50</p>
<p>13. <i>Gov't Code Section 54956.9(d)(2) – conference with legal counsel – pending or threatened litigation:</i> Report Internal Audit Activity</p>	<p>Diane Wigglesworth, Sr. Dir. Corporate Compliance; Priya Shah, Assistant General Counsel</p>		<p>discussion 6:50 – 6:55</p>
<p>14. <i>Gov't Code Section 54956.9(d)(2) – conference with legal counsel – pending or threatened litigation:</i> - Compliance Work Plan Updates for FY 2021</p>	<p>Diane Wigglesworth, Sr. Dir. Corporate Compliance; Priya Shah, Assistant General Counsel</p>		<p>discussion 6:55 – 7:05</p>
<p>15. <i>Gov't Code Sections 54957 for report and discussion on personnel matters – Senior Management:</i> - Executive Session</p>	<p>Sharon Anolik Shakked, Chair</p>		<p>discussion 7:05 – 7:15</p>
<p>16. ADJOURN TO OPEN SESSION</p>	<p>Sharon Anolik Shakked, Chair</p>		<p>motion required 7:15 – 7:15</p>
<p>17. RECONVENE OPEN SESSION/ REPORT OUT To report any required disclosures regarding permissible actions taken during Closed Session.</p>	<p>Sharon Anolik Shakked, Chair</p>		<p>information 7:16 – 7:16</p>
<p>18. ADJOURNMENT</p>	<p>Sharon Anolik Shakked, Chair</p>		<p>motion required 7:16 – 7:16pm</p>

Upcoming Meetings:

August 19, 2021, September 30, 2021, November 18, 2021, January 27, 2022, March 24, 2022, May 19, 2022



**Minutes of the Open Session of the
Compliance and Audit Committee
of the El Camino Hospital Board of Directors
Thursday, March 18, 2021**

El Camino Hospital | 2500 Hospital Drive, Mountain View, CA 94040

Members Present**

Sharon Anolik Shakked, Chair
Lica Hartman
Jack Po, MD, Vice Chair
Christine Sublett
Julia Miller

Members Absent

****All via teleconference**

Agenda Item	Comments/Discussion	Approvals/ Action
1. CALL TO ORDER/ ROLL CALL	The open session meeting of the Compliance and Audit Committee of El Camino Hospital (“the Committee”) was called to order at 5:00pm by Chair Anolik Shakked. All Committee members participated via teleconference and were present at roll call. A quorum was present pursuant to State of California Executive Orders N-25-20 dated March 12, 2020 and N-29-20 dated March 18, 2020.	<i>Called to order at 5:00pm</i>
2. POTENTIAL CONFLICT OF INTEREST	Chair Anolik Shakked asked if any Committee members had a conflict of interest with any of the items on the agenda. No conflicts were reported.	
3. PUBLIC COMMUNICATION	None.	
4. CONSENT CALENDAR	<p>Chair Anolik Shakked asked if any Committee members or the public wished to discuss any item from the consent calendar. No requests were reported.</p> <p>Motion: To approve the consent calendar a) Minutes of the Open Session of the Compliance and Audit Committee Meeting (1/28/2021); and for information: b) Status of FY21 Committee Goals.</p> <p>Movant: Sublett Second: Miller Ayes: Anolik Shakked, Hartman, Miller, Po, & Sublett Noes: None Abstentions: None Absent: None Recused: None</p>	<i>Consent Calendar approved.</i>
5. REVIEW PROPOSED FY 21 FINANCIAL AUDIT PLAN	<p>Joelle Pulver and Katherine Djiauw from Moss Adams LLP joined the meeting. They reported that they will perform the financial audit for the fiscal year ending June 30, 2021. Their role is to express an opinion about whether the financial statements prepared by El Camino Health’s management are fairly presented in accordance with the GAAP (generally accepting audit principles) and government auditing standards.</p> <p>Ms. Djiauw mentioned that they will look into the internal controls of the organization as it relates to designing their audit procedure. She discussed what their responsibilities would be under the auditing standards related to the financial statements, as well as the plan, scope, and timeline in regards to the plan. At the conclusion of the audit, they will communicate their findings to the Committee and the Board with a focus on significant deficiencies or material weaknesses present within the organization.</p>	

	<p>In response to a committee member’s question, Ms. Pulver clarified that a majority of the audit will be conducted remotely given the pandemic at least until June of this year. No decisions have been made past June. She also mentioned that a majority of the decision depends on the ability to get vaccinations and, that she would likely not ask her team to be onsite if they are not comfortable doing so.</p> <p>In response to Dan Woods’, CEO, question, Ms. Pulver explained that they have not found any inherent risks of conducting a remote audit on their end, but have discussed inherent risks on their client’s end where their workforce has gone to remote working, which is not the case at El Camino Hospital. They have more concerns in these situations due to changes in internal controls which may at times create weaknesses. She also discussed the lack of face to face connection to do interviews which helps them read body language to assess how a person is feeling. She mentioned that they have addressed this to the best of their abilities by conducting video interviews as opposed to phone interviews.</p> <p>Ms. Pulver and Ms. Djiauw left the meeting.</p>	
<p>6. REVIEW PROPOSED FY 22 COMPLIANCE COMMITTEE DATES</p>	<p>Chair Anolik Shakked asked if any Committee members had any questions or concerns in regards to the dates proposed.</p> <p>In response to a committee member’s question, Ms. Wigglesworth confirmed that the proposed meeting dates for the Compliance and Audit Committee do not conflict with the El Camino Hospital Board meetings.</p> <p>Motion: To approve the dates for FY22 Compliance and Audit Committee meetings for the master calendar.</p> <p>Movant: Po Second: Hartman Ayes: Anolik Shakked, Hartman, Miller, Po, & Sublett Noes: None Abstentions: None Absent: None Recused: None</p>	<p><i>Proposed FY 22 Compliance and Audit Committee dates approved.</i></p>
<p>7. REVIEW PROPOSED FY 22 COMPLIANCE COMMITTEE GOALS</p>	<p>Ms. Wigglesworth explained that she drafted some proposed goals and also sent an email to the Committee members requesting they think about any additional goals that the committee would like to include.</p> <p>Ms. Miller shared concerns related to the security of each member’s device, especially as committee meetings are conducted online. She explained that there should be an enhanced layer of security for closed sessions. Deb Muro, CIO, agreed with Chair Anolik Shakked that this should be included on a list of security items to address, rather than a committee goal item.</p> <p>Ms. Wigglesworth suggested the Committee consider adding a goal related to receiving education regarding new guidance provided by the OIG regarding compliance programs and related fraud alerts. Chair Anolik Shakked agreed and added that education is something that should be included as a goal given that the OIG released new guidelines this year.</p> <p>In response to a committee member’s question regarding compliance committee charters and committee oversight, Ms. Wigglesworth affirmed that she could reach out to similarly structured healthcare organizations and compare other organization charters to benchmark this compliance committee focus areas.</p>	

	<p>In response to a committee members' question, Ms. Wigglesworth indicated that the current compliance committee charter allows for two or more board members and two to four advisors on the committee. Jack Po, MD added that the committee should consider expanding to look for someone that can bring in diversity. Ms. Wigglesworth confirmed that there is bandwidth to expand the Committee membership, however, the request should ultimately be taken up with the Board Chair Lanhee Chen.</p> <p>Ms. Sublett shared that it would be helpful for Information Security to identify cyber risks for the organization in the context of critical business functions. She suggested that the committee should understand how the Cybersecurity plan and initiatives are protecting critical business activities.</p> <p>Ms. Wigglesworth stated that she would take these into consideration to draft some revised FY 2022 goals for the Compliance and Audit Committee, and present these goals at the next meeting for a vote.</p>	
<p>8. REPORT ON BOARD ACTIONS</p>	<p>Jack Po, MD, reported on the board actions and discussed the materials as presented in the packet. He then directed the discussion to Ms. Miller who shared that the District Board made the decision to reappoint Don Watters to an empty seat until June 30, 2021 in addition to another three year term from July 1st, 2021 to June 30, 2024.</p> <p>Chair Anolik Shakked asked if any Committee members had any questions about the Report on Board Actions. No questions were reported.</p>	
<p>9. ADJOURN TO CLOSED SESSION</p>	<p>Motion: To adjourn to closed session at 5:45pm. Movant: Miller Second: Po Ayes: Anolik Shakked, Hartman, Miller, Po, & Sublett Noes: None Abstentions: None Absent: None Recused: None</p>	<p><i>Adjourned to closed session at 5:45pm</i></p>
<p>10. AGENDA ITEM 19: RECONVENE OPEN SESSION/ REPORT OUT</p>	<p>Open session was reconvened at 7:31. Agenda items 10-18 were discussed in closed session. During the closed session, the Committee approved the Minutes of the Closed Session of the Compliance and Audit Committee Meeting (01/28/2021).</p>	<p><i>Open session reconvened at 7:31pm</i></p>
<p>11. AGENDA ITEM 20: ADJOURNMENT</p>	<p>Motion: To adjourn at 7:32pm. Movant: Sublett Second: Miller Ayes: Anolik Shakked, Hartman, Miller, & Sublett Noes: None Abstentions: None Absent: None Recused: None</p>	<p><i>Meeting adjourned at 7:32pm</i></p>

Attest as to the approval of the foregoing minutes by the Compliance and Audit Committee of El Camino Hospital:

 Sharon Anolik Shakked
 Chair, Compliance and Audit Committee

DRAFT
FY22 COMMITTEE GOALS
 Compliance and Audit Committee

PURPOSE

The purpose of the Compliance and Audit Committee (the "Committee") is to advise and assist the El Camino Hospital (ECH) Hospital Board of Directors ("Board") in its exercise of oversight of Corporate Compliance, Privacy, Internal and External Audit, Enterprise Risk Management, and Information Technology (IT) Security. The Committee will accomplish this by monitoring the compliance policies, controls, and processes of the organization and the engagement, independence, and performance of the internal auditor and external auditor. The Committee assists the Board in oversight of any regulatory audit and in assuring the organizational integrity of ECH in a manner consistent with its mission and purpose.

STAFF: **Diane Wigglesworth**, Sr. Director, Corporate Compliance (Executive Sponsor)

The Sr. Director, Corporate Compliance shall serve as the primary staff to support the Committee and is responsible for drafting the Committee meeting agenda for the Committee Chair's consideration. Additional members of the Executive Team or outside consultants may participate in the meetings upon the recommendation of the Executive Sponsor and at the discretion of the Committee Chair.

GOALS	TIMELINE	METRICS
1. Review the Hospital and SVMD Compliance Work Plans for FY 2022.	Q1 FY22	Committee reviews and provides recommendations to the Compliance Officer.
2. Receive education on new OIG guidance regarding compliance programs and fraud alerts.	Q2 FY22	Committee receives education and recommends information that should be presented to the Board.
3. Review identified cyber risks for the organization in the context of critical business functions and how the cybersecurity plan and initiatives are protecting critical business activities.	Q3 FY22	Committee reviews and provides recommendations to the CIO.
4. Review ECH's IT Security Strategic Plan.	Q4 FY22	Committee reviews and provides recommendations to the CIO.

SUBMITTED BY:

Chair: Sharon Anolik Shakked
Executive Sponsor: Diane Wigglesworth

FY21 COMMITTEE GOALS

Compliance and Audit Committee

PURPOSE

The purpose of the Compliance and Audit Committee (the "Committee") is to advise and assist the El Camino Hospital (ECH) Hospital Board of Directors ("Board") in its exercise of oversight of Corporate Compliance, Privacy, Internal and External Audit, Enterprise Risk Management, and Information Technology (IT) Security. The Committee will accomplish this by monitoring the compliance policies, controls, and processes of the organization and the engagement, independence, and performance of the internal auditor and external auditor. The Committee assists the Board in oversight of any regulatory audit and in assuring the organizational integrity of ECH in a manner consistent with its mission and purpose.

STAFF: **Diane Wigglesworth**, Sr. Director, Corporate Compliance (Executive Sponsor)

The Sr. Director, Corporate Compliance shall serve as the primary staff to support the Committee and is responsible for drafting the Committee meeting agenda for the Committee Chair's consideration. Additional members of the Executive Team or outside consultants may participate in the meetings upon the recommendation of the Executive Sponsor and at the discretion of the Committee Chair.

GOALS	TIMELINE	METRICS
1. Review Hospital and SVMD Compliance Work Plan for FY 2021.	Q1 FY21	Committee reviews and provides recommendations to the Compliance Officer. (Reviewed and discussed at the 8/20/20 meeting)
2. Review Business Continuity and Disaster Recovery Plan with focus on effectiveness and appropriateness of COVID – 19 pandemic response and recovery.	Q3 FY21	Committee reviews and provides a report to the Board and recommendations to the COO that include assessment of COVID-19 response and recovery as well as a look back at preparedness had the anticipated "surge" occurred in FY 20 Q3 and Q4. (Reviewed and discussed at the 1/28/21 meeting)
3. Participate in education session presented by Legal Counsel regarding revisions to Stark Law and Anti-Kickback Statute	Q3 FY21 (deferred to Q4 FY21)	Committee receives education and recommends information to be presented to the Board. (Education deferred to the 5/20/21 meeting)
4. Review ECH's IT Security Strategic Plan.	Q4 FY21	Committee reviews and provides recommendations to CIO. (Review scheduled for 5/20/21 meeting)

SUBMITTED BY:

Chair: Sharon Anolik Shakked

Executive Sponsor: Diane Wigglesworth

Report on Medicare Compliance Volume 30, Number 12. March 29, 2021 After Settlement, Court OKs Some Whistleblower Allegations That DOJ Declined in Sutter Case

By Nina Youngstrom

Sixteen months after Sutter Health settled a false claims case with the Department of Justice (DOJ) over some of the allegations in a 2014 whistleblower complaint about physician arrangements, other allegations that DOJ declined to pursue are back in play. A federal court March 17 gave the whistleblower, a former compliance officer at Sutter Medical Center in Sacramento, the go-ahead to proceed with certain allegations of reverse false claims and overly generous compensation arrangements, while dismissing other allegations.^[1]

“The vast majority of the case is still alive,” said Marlan Wilbanks, the attorney for whistleblower Laurie Hanvey. He thinks it will go straight to trial. The court hasn’t concluded Sutter Health did anything wrong; it just gave the whistleblower a chance to try and prove the allegations, said attorney Jeffrey Fitzgerald, with Polsinelli in Denver, Colorado, who isn’t involved in the case. “The fact the court dismissed a fair number of claims suggests the whistleblower allegations are overbroad.”

The False Claims Act (FCA) lawsuit alleges that certain physician groups referred patients to Sutter Health in violation of the Stark Law, and in turn, Sutter Health submitted tainted claims to Medicare. None of the physician groups named in the remaining set of allegations were part of the November 2019 settlement with DOJ.^[2] Sutter Health agreed to pay \$30.5 million to resolve allegations that Sutter Medical Center paid Sacramento Cardiovascular Surgeons Medical Group (Sac Cardio) compensation for three medical director agreements and one lease for the services of physician assistants (PAs) employed by Sac Cardio that was above fair market value and didn’t satisfy a Stark Law exception, DOJ alleged. The Sac Cardio physicians referred designated health services to Sutter Medical Center Sacramento, which billed Medicare for them from Sept. 1, 2012, through Sept. 30, 2014, DOJ alleged.

In a separate settlement with DOJ, Sac Cardio agreed to pay \$506,000 to resolve allegations related to its Medicare billing for services provided at Sutter Medical Center by the leased physician assistants from May 1, 2011, through Sept. 30, 2014. According to an exhibit to the 2014 complaint, Sac Cardio leased four of its employed physician assistants (PAs) to the hospital, according to an exhibit to the complaint. The PA agreement required Sutter Health to pay Sac Cardio at the rate of \$170,000 per full-time equivalent per year and stipulated that their services couldn’t be charged to patients or payers. But the surgeons allegedly billed third-party payers for some of the PAs’ services anyway and kept the money.

Sutter Health and Sac Cardio didn’t admit liability in their settlements. Sutter Health also separately agreed to pay \$15 million in connection with a voluntary self-disclosure, mostly related to the Stark Law.

After the settlements, Hanvey on Jan. 21, 2020, filed a complaint based on the allegations that DOJ left behind. The defendants, including Sutter Health and various medical groups, filed motions to dismiss, and Judge Kandis Westmore of U.S. District Court for the Northern District of California granted in part and dismissed in part the motions to dismiss.

One of the allegations relates to Sutter Health's relationship with Sac Cardio (although Sac Cardio is not a defendant). Hanvey's new complaint alleges Sutter Health made payments to Sac Cardio outside the two years in the 2019 settlement. Sutter Health asked the court to dismiss the allegations, partly because Hanvey failed to allege any specific referrals. The judge refused, saying allegations of specific referrals aren't required at this stage.

The court also ruled that the whistleblower may proceed with her allegation of reverse false claims stemming from Sutter Health's failure to repay Medicare within 60 days of identifying overpayments in connection with Sac Cardio's referrals. "The overpayment claim is not dependent on the violation of the FCA, but on the failure to comply with Defendant Sutter Health's independent legal duty to return overpayments," the court order stated.

Some Allegations Didn't Make the Grade

The judge dismissed several of the whistleblower's allegations involving physician arrangements. One of them involves Sutter Health and a 2014 medical director agreement with Sutter Medical Group, which paid physician David K. Roberts \$270 an hour for up to 121 hours per month (\$392,040 per year). Roberts also had a busy practice, billing Medicare more than \$200,000 in 2012, and the medical directorship was intended to reward him for his high volume of referrals, the whistleblower alleged. But the court ruled the whistleblower has "not alleged fraud" because she didn't argue that Roberts was paid for 121 hours of medical director work; "Relator's allegations indicate that Dr. Roberts *could* be compensated up to this amount." Also, the whistleblower only identified a 2014 medical directorship, while referring to \$200,000 billed to Medicare in 2012. "Thus, the fact that Dr. Roberts billed over \$200,000 two years prior to the medical directorship agreement cannot lead to an inference that the agreement was problematic and meant to induce referrals," the judge said, dismissing the claims.

The judge again sided with Sutter Health about its agreements with two physician groups, East Bay Cardiac Surgery Center Medical Group and BASS Medical Group. Sutter Health had medical director and other agreements with East Bay Cardiac, which comprises two cardiovascular surgeons, from June 1, 2007, through Aug. 31, 2014. Sutter allegedly paid East Bay Cardiac \$15,000 a year for a medical directorship and administrative services, plus a flat annual fee of \$485,000 for 24/7 call coverage at Alta Bates Summit Medical Center and for an unspecified number of hours doing data collection. The flat annual amount was doubled in 2009 to \$1 million, allegedly to reward high-volume referrals, because no services were added. In 2014, Sutter Health and East Bay Cardiac entered new agreements that paid \$1.355 million, including \$862,000 for call coverage at Alta Bates Summit Medical Center. East Bay Cardiac also was paid \$850 per shift for Medical Center in Castro Valley.

But the court found the whistleblower has not pleaded a Stark violation because "it is not clear the surgeons have an ownership or investment interest in Defendant East Bay Cardiac, as required for a direct compensation arrangement." As a result, the Stark claims were dismissed.

But the whistleblower got a green light to proceed with false claims allegations involving Sutter Health and Stephen K. Liu, M.D., a physician-owned corporation made up of one physician specializing in interventional radiology. Liu was the highest-billing diagnostic radiologist in California in 2012, collecting \$4.6 million in Medicare payments, according to the court order. He referred hundreds of patients to Sutter Health every year who were covered by government payers. According to the whistleblower, Sutter Health had exclusive call coverage agreements with Liu to reward him for referrals. He was paid \$500 per shift for on-call services at the Modesto campus in September 2008, an amount that rose to \$2,000 per shift by April 2014. The agreements allowed Liu to also bill for professional services he provided while on call. The whistleblower alleged the agreements violated the Stark Law and Anti-Kickback Statute.

The judge determined that the whistleblower "has sufficiently alleged fraud as to the relationship between

Defendant Sutter Health and Defendant Liu.” The fourfold increase in on-call compensation, especially when he was allowed to bill separately for services during shifts, “creates a strong inference of improper compensation,” the court order states.

By dismissing some counts and not others with similar allegations, the judge gives some insight into what will cross the Stark threshold, Fitzgerald said. “The difference seems to be whether the relator alleged some anecdotal or atmospheric information beyond the fair-market claim,” he said. For example, the whistleblower alleged a fourfold increase in payments to Liu.

The judge’s ruling on reverse false claims gives him pause. “Part of what makes me uncomfortable about what the court did here is Sutter paid back \$30 million, and the court is saying even that is not enough to extinguish False Claims Act exposure,” Fitzgerald said. The idea that Sutter Health was hiding overpayments makes no sense, he said. “The mandatory overpayment piece says you have to give it back if you know you have an overpayment. That would assume the government didn’t know about the overpayment. Here, where the government is involved and fully aware of the allegations and potential overpayment, how can you have a new scheme to conduct new fraud by hiding an overpayment? If there is disagreement about the settlement, that can’t be a separate False Claims Act matter.”

In a statement, Sutter Health said it “reached a resolution of the matter raised by Ms. Hanvey by agreeing to make a repayment to the federal government. This settlement was not based upon any alleged payment for referrals, and there was no finding that Sutter violated the anti-kickback laws. Any assertion that the settlement was based upon a finding of payments for referrals is completely inaccurate and Sutter denies any such conduct. Sutter has in place a strong compliance program, which had identified the issues raised by Ms. Hanvey. Indeed, Ms. Hanvey was working with the hospital on the process of remediating these issues when Ms. Hanvey elected to file her lawsuit under seal. This settlement involves various matters, including a self-disclosure dating back to 2010, and two additional self-disclosures. Self-disclosures are done when providers like Sutter self-identify a potential non-compliant arrangement and voluntarily disclose those arrangements to the government. Sutter’s compliance program discovered the issues, just as it was designed to do, and Sutter brought these matters forward on our own initiative.”

Contact Wilbanks at mbw@wilbanksgouinlock.com and Fitzgerald at jfitzgerald@polsinelli.com.

¹ United States of America v. Sutter Health, Case No. 14-cv-04100-KAW (N.D. Cal., March 17, 2021).

² Department of Justice, U.S. Attorney’s Office for the Northern District of California, “California Health Group And Surgical Group Agree To Settle Claims Arising From Improper Compensation Arrangements,” news release, November 15, 2019, <https://bit.ly/39ffPog>.

Katten

PRESENTATION TO THE COMPLIANCE AND AUDIT COMMITTEE OF
THE EL CAMINO HOSPITAL BOARD OF DIRECTORS

Briefing on the New Stark Law Rules

May 20, 2021



Laura Keidan Martin, Partner, Chicago

Agenda

- Stark Law Refresher
- Significant Changes Under the New Stark Rules
 - The New Value Based Care Exceptions
 - New Commercial Reasonableness Definition
 - Other new exceptions
 - New “bright-line” standard for unlawful compensation
- How the New Rules Impact Common Physician Arrangements
- How Board can Help Promote Compliance

Stark Law Refresher

- The Stark Law “self referral” prohibition provides that a physician may not refer Medicare patients to an entity if:
 - ❖ The referral is for the furnishing of certain designated health services (“DHS”); **and**
 - ❖ There is a direct or indirect financial relationship between the referring physician (or an immediate family member) and the entity; **and**
 - ❖ No Stark Law exception applies.
- It is unlawful to bill Medicare for DHS rendered pursuant to a prohibited referral.
- A financial relationship arises when ever one party gives another ANYTHING of value, whether cash, gifts, meals or entertainment.
- The Stark Law is a “strict liability” statute – ***Intent does not matter.***
- If ECH has a financial relationship with a referring physician that does not meet an exception, ECH cannot bill Medicare for referred DHS.

Bottom line: Every financial arrangement between ECH and a physician or physician group that makes DHS referrals to ECH must satisfy a Stark exception.

Stark Law FAQs

- What are DHS?
 - DHS include all hospital services, as well as PT, OT, lab, imaging, home health and outpatient drugs (among others).
 - DHS do **not** include physician professional services (other than the professional component of imaging procedures) or the ambulatory surgical center procedures we perform at our endoscopy centers.
- What are the penalties for a Stark Law violation?
 - Entities that bill for DHS rendered pursuant to an unlawful referral are subject to recoupment and civil monetary penalty of over \$25K/claim, as well as False Claims Act (“FCA”) penalties.
- What are the most commonly applicable exceptions?
 - Fair market value (FMV), commercially reasonable leases, time shares and professional services arrangements that are set forth in writing.
 - All FMV employment relationships, regardless of whether they are in writing.
 - Non-monetary compensation up to a cap (\$429 in 2021) and medical staff benefits
 - Isolated transactions that satisfy FMV and commercial reasonableness standards
 - Electronic health record and compliance education donations

Examples of Arrangements that May Give Rise to Stark Law Violations

The following examples do not satisfy a Stark exception:

- Above fair market value (“FMV”) compensation to physicians who make referrals to ECH.
- Provision of below FMV space, equipment or services to a physician referral source.
- Payment or acceptance of compensation under a service agreement or lease with a DHS referral source that does not match the contract.
- An undocumented compensation arrangement with a non-employed physician who makes DHS referrals to ECH (even if at FMV).
- Payments to physicians and other referral sources under sham consulting, medical director or lease arrangements.
- Gifts, meals, entertainment and other “free stuff” to physician referral sources above the Stark Law annual cap (\$429 in 2021).

New Exceptions for Value-Based Arrangements (“VBAs”)

- The Final Rule, which is intended to promote cost-effective care and value-based reimbursement, establishes new exceptions for VBAs that serve one or more of the following value-based purposes:
 1. **Coordinating and managing** the **care** of a Target Population;
 2. **Improving** the **quality of care** for a Target Population;
 3. Appropriately **reducing the costs** to or growth in expenditures **of payors without reducing** the **quality of care** for a Target Population;
 4. **Transitioning from** health care delivery and payment mechanisms based on the volume of items and services **[FFS mechanisms]** provided **to** mechanisms based on the quality of care and control of costs of care for a Target Population.
- The **remuneration** must **be for or result from value based activities** for the target population by the physician recipient.
- None of the exceptions include a FMV criterion.
- All VBAs must be described in a **governing document** and have an **accountable body or person**.
- The specific elements of the exceptions vary based on the degree of financial risk and are quite technical, we will cover how these exceptions provide additional flexibility for certain types of arrangements later in this presentation.

New Definition for Commercial Reasonableness

- “Commercially Reasonable” means that an arrangement:
 - Furthers a **legitimate business purpose of the parties** to the arrangement and
 - Is “**sensible**” considering the characteristics of the parties, including their size, type, scope and specialty.
- The definition stipulates that an arrangement may be commercially reasonable **even if it does not result in profit for one or more of the parties.**
- However, while profitability is not required for commercial reasonableness, **profitability is not irrelevant** to the determination of whether an arrangement is commercially reasonable.
 - Arrangements on which ECH will lose money should have a legitimate, documented business or mission purpose (unrelated to downstream referrals).
- In addition to commercial reasonableness, most exceptions (other than new VBA exceptions) continue to incorporate a FMV criterion.

Other Significant Changes

- New exception for donations of **cybersecurity technology** to physicians **without** any physician **cost sharing** requirement.
 - The new exception applies to cybersecurity **hardware**, not just software.
- New exception for arrangements involving limited remuneration under \$5k/year (subject to annual CPI adjustments).
 - must **comport with FMV** and be **commercially reasonable**.
 - Arrangements **need not be memorialized in writing**
- New “**objective test**” to determine if compensation takes into account the volume or value of referrals or other business generated:
 - The **mathematical formula** used to calculate the amount of the compensation **includes referrals or other business generated as a variable**, and
 - The amount of the **compensation correlates with the number or value of the physician’s referrals to or the physician’s generation of other business** for the entity.

How does the Final Rule Impact Common Physician Arrangements?

- Permits medical directorships that satisfy a new VBA exception without needing to satisfy FMV criterion.
- Allows hospitals to structure commercially reasonable quality improvement programs with medical staff incentives that satisfy a VBA exception, again without worrying about FMV.
- Employed physicians also may participate in VBAs that include incentives for care coordination, quality improvement and cost reductions that are passed on to payors, even if such incentives push total cash compensation over FMV.
- More flexibility for clinically integrated networks that satisfy a VBA, including those that incentivize proper use of diagnostic tests that are DHS.
- Low-value arrangements for task force service, participation in recruitments, educational programs, etc. carry less risk.
- More flexibility for bonuses that do not vary directly based on DHS referrals or other business generated.

Guidance for Health Care Governing Boards on Compliance Oversight

- OIG and industry guidance for health care boards emphasizes the importance of leadership and culture:
 - “**Leadership should foster** an organizational **culture** that values, and even **rewards, the prevention, detection, and resolution** of quality of care and **compliance problems.**”
 - “The organization should endeavor to develop a **culture that values compliance** from the top down and fosters compliance from the bottom up. Such an organizational culture is the **foundation of an effective compliance program.**”
- The Board should receive **regular, independent reports regarding risk mitigation and compliance efforts** in a variety of areas, including audit, compliance, HR, legal, quality and information technology.
- Board members need to **understand the regulatory environment** so that they can **ask pertinent questions** and **make informed decisions** regarding the compliance program, including funding and resource allocations.

Board Oversight: Key Questions to Ask

- Does ECH have clear policies/SOPs and internal controls addressing major risk areas, including physician compensation arrangements under Stark?
- How might the new Stark Rules impact ECH policies?
- Have key leaders responsible for physician arrangements been educated on the new Stark Rules?
- Is ECH appropriately assessing, monitoring and auditing risk areas, like physician arrangements?
 - Are there regular audits to ensure that arrangements satisfy applicable commercial reasonableness and FMV criteria and that compensation paid matches contractual amounts?
- How does ECH publicize its channels for reporting suspected non-compliance?
- Are all reports of suspected non-compliance appropriately logged, reviewed, investigated and addressed?
 - Ask about the number, type, nature, and remediation of such reports.
- Do the Board and management team foster a culture that values and rewards the prevention, detection and resolution of compliance issues?
- Does the Compliance function have sufficient resources and manpower to ensure an effective compliance program?

Katten Locations

CHARLOTTE

550 South Tryon Street
Suite 2900
Charlotte, NC 28202-4213
+1.704.444.2000 tel
+1.704.444.2050 fax

CHICAGO

525 West Monroe Street
Chicago, IL 60661-3693
+1.312.902.5200 tel
+1.312.902.1061 fax

DALLAS

2121 North Pearl Street
Suite 1100
Dallas, TX 75201-2591
+1.214.765.3600 tel
+1.214.765.3602 fax

LONDON

Paternoster House
65 St Paul's Churchyard
London EC4M 8AB
United Kingdom
+44 (0) 20 7776 7620 tel
+44 (0) 20 7776 7621 fax

LOS ANGELES – CENTURY CITY

2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

LOS ANGELES – DOWNTOWN

515 South Flower Street
Suite 4150
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

NEW YORK

575 Madison Avenue
New York, NY 10022-2585
+1.212.940.8800 tel
+1.212.940.8776 fax

ORANGE COUNTY

100 Spectrum Center Drive
Suite 1050
Irvine, CA 92618-4960
+1.714.966.6819 tel
+1.714.966.6821 fax

SHANGHAI

Suite 4906 Wheelock Square
1717 Nanjing Road West
Shanghai 200040
P.R. China
+86.21.6039.3222 tel
+86.21.6039.3223 fax

WASHINGTON, DC

2900 K Street NW
North Tower - Suite 200
Washington, DC 20007-5118
+1.202.625.3500 tel
+1.202.298.7570 fax

Katten refers to Katten Muchin Rosenman LLP and the affiliated partnership as explained at katten.com/disclaimer.

Attorney advertising. Published as a source of information only. The material contained herein is not to be construed as legal advice or opinion.

**EL CAMINO HOSPITAL BOARD OF DIRECTORS
COMMITTEE MEETING MEMO**

To: Compliance and Audit Committee Meeting
From: Stephanie Iljin, Supervisor Administrative Services
Date: May 20, 2021
Subject: Report on Board Actions

Purpose: To keep the Committee informed regarding actions taken by the El Camino Hospital and El Camino Healthcare District Boards.

Summary:

1. **Situation:** It is essential to keep the Committees informed about Board activity to provide context for Committee work. The list below is not meant to be exhaustive but includes agenda items the Board voted on that are most likely to be of interest to or pertinent to the work of El Camino Hospital's Board Advisory Committees.
2. **Authority:** This is being brought to the Committees at the request of the Board and the Committees.
3. **Background:** Since the last time we provided this report to the Compliance and Audit Committee Meeting, the Hospital Board has met two times, and the District Board has met two times. In addition, since the Board has delegated specific authority to the Executive Compensation Committee, the Compliance and Audit Committee, and the Finance Committee, those approvals are also noted in this report.

Board/Committee	Meeting Date	Actions (Approvals unless otherwise noted)
ECH Board	April 7, 2021	<ul style="list-style-type: none"> - Resolution 2021-03: Board Recognition of the COVID-19 Vaccination Program Team - Quality Committee Report - FY21 Period 7 and 8 Financials - Resolution 2021-04: Temporary Suspension of El Camino Hospital Bylaws Article VIII. Section 8.3 - Revised Board Officer Nomination & Selection Procedures - Closed Session Quality Committee Report including Credentials and Privileges Report & Quality Council Minutes - Annual Summary of Physician Financial Arrangements - Medical Staff Report - Revised FY21 Advisory Committee Assignments - Letters of Reasonableness - Urology Call Panel - Acute Rehab Professional Services Agreement and Community Benefit Grant
	May 12, 2021	<ul style="list-style-type: none"> - Medical Staff Credentials and Privileges Report - Quality Council Minutes - FY21 Period 8 Financials - Medical Staff Report

Report on Board Actions
 May 20, 2021

Board/Committee	Meeting Date	Actions (Approvals unless otherwise noted)
ECH Board Education Sessions	April 14, 2021	N/A
	April 28, 2021	N/A
ECHD Board	April 7, 2021	- Proposed Resolution 2021-06: (Temporary Suspension of El Camino Hospital Bylaws Article VIII, Section 8.3
Compliance and Audit Committee	March 18, 2021	N/A
Finance Committee	March 29, 2021	<ul style="list-style-type: none"> - FY21 Period 7 and 8 Financial Report - FY22 Committee Meeting Dates - Progress Against FY21 Committee Goals - FY21 Community Benefit Grant - Closed Session Minutes of the Finance Committee (1/25/2021) - Closed Session Minutes of the Joint Finance and Investment Committees (1/25/2021) - LG Urology Call Panel Renewal - LG Acute Rehab Professional Services Agreement Renewal
	April 26, 2021	<ul style="list-style-type: none"> - Progress Against FY21 Committee Goals - Major Capital Projects in Process - FY21 Period 9 Financials

List of Attachments: None.

Suggested Committee Discussion Questions: None.