The Healthcare Law Section Presents

18th Annual Healthcare Law Compliance Symposium: Part II

Thursday, October 14, 2021
3:30 - 5:45 P.M.
Via Zoom
2.0 hours Gen. CLE Credit

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18th Annual Healthcare Law Compliance Symposium, Part II

Program Title
Healthcare Law

Section/Committee

Thursday, October 14, 2021 3:30 PM
Zoom Webinar

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Program Date and Time
Event Location

Participant Name
State Bar Number
Profession, if not a lawyer

Please rate by circling the appropriate number ( 5 = highest rating; 1 = lowest rating )

Speakers
Ilan Shapiro Strygler
Rick Rifenbark
Heather Deixler

Usefulness of Information

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Overall program rating

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Contribution of written materials to the learning experience
(Consider whether the material contained significant, current intellectual or practical content)

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Did the program meet your expectations?

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If no, Please explain

Did the promotional materials accurately describe the program?

☐ Yes ☐ No

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How did your hear about the program?

☐ E-Mail ☐ Brochure ☐ LACBA Website ☐ LACBA Publications ☐ Other

If other, Please explain

Please rank the factors that influenced your attendance at this program.

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Other

Please sign this form and return to: Los Angeles County Bar Association, Events Department, P.O. Box 55020, Los Angeles, CA 90055-2020
Number of years in practice __________________ Number of lawyers in firm __________________

List of your area(s) of practice/interest

Who recommends/authorizes CLE attendance in your firm?

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What program length do you prefer?

☐ 1 Hour ☐ 2 Hours ☐ 3 Hours ☐ All-day

What time of day do you prefer to attend program?

☐ Weekday before 10 a.m. ☐ Weekday lunch ☐ Weekday evening

☐ Weekend ☐ Other __________________

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18th Annual Healthcare Law Compliance Symposium, Part II
October 14, 2021 from 3:30 - 5:45 p.m.

Session 1: Keynote Address
Advancing Health Care Equity in Covid Times

• Ilan Shapiro Strygler, M.D., Medical Director of Health Education & Wellness, AltaMed Health Services

Session 2: Understanding the New Stark Law and Anti-Kickback Statute Regulations

• Rick Rifenbark, Polsinelli
• Heather B. Deixler, Latham & Watkins
Ilan Shapiro Strygler, M.D.
Medical Director of Health Education & Wellness, AltaMed Health Services
ishapirostrygler@altamed.org

About
My passion has always been to convert health information into action improving the wellbeing of our communities. Born and raised in Mexico City, I had the honor of being the liaison between Mexico and the World Health Organization after finishing Med School. This was the moment that proved to me that healthcare systems need to be connected with the most important aspect: the community.

As a Pediatric Resident at Mount Sinai Children's Hospital in Chicago; were the reality of Social determinants of health was a reflection of the changes needed, I was determined to make a difference in the community, so I began doing this thru Policy and Advocacy. As part of these activities, in the Mexican Consulate, I created a Health Bulletin and a board of physicians to give advice in hardship moments for families. On the international arena, I had the honor to be elected for the first Advisory Board in conjunction with the Mexican Foreign Affairs and Health Ministries, for the program Ventanillas de Salud; a Federal program that devotes its efforts to improve the wellbeing of Mexicans abroad.

Currently actively involved creating Binational Public Health Programs to reach Hispanic communities on both sides of the border; I was invited to become a part of The White House Hispanic Policy Group and participated in advocacy groups like Sargent Shrivers Center as well as becoming a spokesperson for the American Academy of Pediatrics and winner of the highest Mexican federal award for community that help Mexican abroad: The Othli.

Since 2009, I have been regularly appearing on several national and international outlets (such as CNN, NBC, Telemundo, Univision, EstrellaTV and radio) to share information about emerging healthcare topics; translating “Medicalish” to an understandable language for all ages and stages in a human life.

I’m a believer that the intersection between health and technology can be efficient, affordable and can bring better health outcomes for our community; I have had the pleasure of being a part of HoyHealth, Solera Network, MeHealth, and other technology based initiatives.

In 2018 I was elected to be a Board Member of LA Care and have been participating in the National Hispanic Medical Association Boards; building pipelines, services and representation of our community.

Following my pediatric and public health passion, I practiced as a pediatrician in Florida, which led me to AltaMed, one of the largest FQHC in the US as the Medical Director of Medical Education and Wellness with a great dynamic team serving over 300k patients.

I am an energetic physician that creates solutions for our Community.
ADVANCING HEALTH CARE EQUITY IN COVID TIMES

Ilan Shapiro Strygler, M.D.
Medical Director of Health Education & Wellness, AltaMed Health Services
ishapirostrygler@altamed.org

COVID-19 has brought attention to how disparities and social determinants of health have punctured our community. This conversation will address why we need to move forward with a new approach to health and wellness that goes beyond the four walls of the clinic.

In the past 18 months the interaction of chronic diseases, lack of opportunities and mortality in communities of color was not a surprise. The compounding effect of multiple layers of problems reflect the lack of health system and policy strong enough to mitigate the loss of death and suffering.

The connection between a virus and policy before 2019 was just an academic exercise. Today, the importance of creating a bridge for policy and compliance is key to moving forward to mitigate our current pandemic and, most importantly, to prepare for the next one.

The main objectives for this conversation will be:

1) How did we get to this point?
2) Why were communities of color affected?
3) How testing works
4) How vaccines work
   a. Levels of research
   b. Emergency vs. full approval
   c. Kids and the vaccine
5) What about medications and other treatments?
6) The role of public health policies for testing and vaccination
7) How will this end?
Session 2:  
Understanding the New Stark Law and Anti-Kickback Statute Regulations

• Rick Rifenbark, Polsinelli
• Heather B. Deixler, Latham & Watkins

Heather Deixler, counsel in the San Francisco and Silicon Valley offices of Latham & Watkins LLP, advises companies operating in the healthcare industry on healthcare regulatory and data privacy and security matters. Ms. Deixler is a Certified Information Privacy Professional (CIPP/US and CIPP/E), and currently serves as a Vice Chair of the ABA Health Law Section Interest Group Executive Leadership Team, and Chair of the American Health Lawyers Association (AHLA) Health Information & Technology (HIT) Practice Group’s Tech Licensing and Intellectual Property Affinity Group. Ms. Deixler previously served as an Adjunct Professor in the Health Law LLM program at the University of Washington School of Law. Prior to attending law school Ms. Deixler worked as a research technician in a neurophysiology laboratory in Dijon, France, and as a clinical research assistant at the Beth Israel Deaconess Medical Center in Boston. Ms. Deixler holds a BA from the University of Pennsylvania, an MPhil from the University of Cambridge and a JD from the University of Washington School of Law.

Rick Rifenbark is a shareholder in the Los Angeles office of Polsinelli. Rick’s practice is a blend of health care regulatory compliance and transactions. He regularly advises clients on health care fraud and abuse laws and other regulatory issues, including the federal anti-kickback statute, stark physician self-referral law, false claims act, state licensing issues, corporate practice of medicine doctrines, and state fraud and abuse laws. Rick also negotiates and drafts transactional agreements, including merger and acquisition, affiliation, professional services, and management agreements. Rick currently serves as the Co-Chair of the Health Law Committee of the California Lawyers Association.
RECENT CHANGES TO STARK AND THE AKS
Recent Changes to Stark and the AKS

▪ **Physician Self-Referral Laws**
  ▪ Federal Stark Law
  ▪ California Self-Referral Law

▪ **Anti-Kickback Laws**
  ▪ Federal AKS
  ▪ California AKS
Stark and AKS Refresher

**Stark**
- Prohibits referrals of designated health services (DHS) by physicians if a financial relationship exists
- Financial relationship = ownership/investment or compensation relationship
- Strict liability law – must meet an exception

**Anti-Kickback Statute**
- Prohibits offering, soliciting, receiving, accepting anything of value in exchange for referrals
- Compliance with safe harbors protects a financial arrangement
- Intent-based law – compliance with safe harbor not mandatory, but law violated if even “one purpose” of arrangement is to induce referrals
Stark and AKS – Recent Settlements

- In the last few months:
  - Bayada Home Health - $17M FCA/AKS Settlement (Sept. 2021)
  - Panda Conservation Group (Laboratory) – Guilty Plea $73M kickback conspiracy (Sept. 2021)
  - Alliance Family of Companies (EEG Testing) - $15.3M AKS Settlement (July 2021)
  - Akron General Health System - $21M Settlement (Stark) (July 2021)
Timeline – “Patients Over Paperwork” Initiative

- CMS published a Request for Information (RFI) on June 25, 2018, seeking input from stakeholders about how to address regulatory barriers to a value-based healthcare payment and delivery system under Stark

- CMS published a Notice of Proposed Rulemaking on October 17, 2019, that proposed sweeping reforms of the regulations that interpret Stark (84 FR 55766)

- CMS and OIG publish final rules on December 2, 2020, to be effective on January 19, 2021 (with certain exceptions)
HHS “Regulatory Sprint” — Value-Based Stark Exceptions / AKS Safe Harbors

General Purposes:

1. Remove barriers to innovation
2. Flexibility for coordinated / cost-effective care
3. Incentives to transition from volume-based to outcomes-based care

Common Framework / Definitions:

▪ Stark / AKS exceptions / safe harbors use common framework / definitions
▪ AKS safe harbors generally narrower than Stark exceptions

Common ground:

▪ Application to all payors (Government Healthcare Programs and Commercial)
▪ Three Tracks: (1) No Risk (2) Meaningful Risk (3) Full Risk
▪ “Greater flexibility” the more risk assumed
## Overview of Stark / AKS Value-Based Rules

3 New Stark Exceptions / AKS Safe Harbors for “Value-Based Arrangements”

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<th>Stark Law – Exceptions</th>
<th>AKS – Safe Harbors</th>
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<td><strong>Value-Based Arrangements</strong> (no risk) [§ 411.357(aa)(3)]</td>
<td><strong>Care Coordination Arrangements</strong> (no risk) [§ 1001.952(ee)]</td>
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<td><strong>Meaningful Downside Financial Risk to Physician</strong> (≥10% downside risk) [§ 411.357(aa)(2)]</td>
<td><strong>Substantial Downside Risk</strong> (risk threshold varies by payment method - generally must be ≥20-30% risk to VBE) [§ 1001.952(ff)]</td>
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<td><strong>Full Financial Risk</strong> (100% downside risk) [§ 411.357(aa)(1)]</td>
<td><strong>Full Financial Risk</strong> (100% downside risk) [§ 1001.952(gg)]</td>
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Value-Based Arrangements – Common Nomenclature

- **Value-Based Activity**: provision of item or service; taking of action; refraining from action (excludes making of referral)
- **Value-Based Arrangement**: arrangement for at least one value-based activity for the target population between or among the Value-Based Enterprise (VBE) and VBE participants
- **Value-Based Enterprise**:
  - Two or more VBE participants
  - Accountable body / person responsible for financial and operational oversight
  - “Governing document”
- **Value-Based Purpose**:
  - Coordinating and managing care
  - Improving quality of care
  - Reducing costs / growth in expenditures without reducing quality
  - Transitioning from system of volume to value
- **Value-Based Enterprise Participants**: individual / entity engaging in at least one value-based activity in VBE
  - AKS Safe Harbors excludes pharma manufacturers; DMEPOS manufacturers, distributors, suppliers; labs; others
- **Target Patient Population**: identified patient population using “legitimate and verifiable” criteria set out in advance in writing
Value-Based Activities – Examples

- OIG Examples:
  - VBE participant provides health technology under a value-based arrangement for recipient to use to track patient data in order to spot trends in health care needs and to improve patient care planning
  - VBE Participant provides care coordinator who works with recipient to help transition certain patients between care settings
  - Fitness tracker for patients - may constitute a value-based activity, if doing so is reasonably designed to achieve a value-based purpose

- CMS Examples:
  - Routine post-discharge meetings between hospital and physician primarily responsible for patient’s care post-lower extremity joint replacement procedures
(1) Value-Based Arrangements - Value-Based/Care Coordination Arrangements (No risk)

General Requirements

1. Key terms in writing, signed by parties (remuneration set in advance)
2. No inducement to reduce / limit medically necessary services
3. Patient choice / physician’s ability to act in best interest of patients
4. No condition re referrals of non-target population or non VBA business

Key Distinction: AKS Safe Harbor applies only to non-monetary remuneration

Other distinctions:

AKS Safe Harbor

- VBE Participant must pay at least 15% of costs
- Terms must specify at least one specific, evidence-based outcome measure
- Marketing or patient recruitment activities prohibited
- “limited technology participants”
AKS Care Coordination — *Focus on Digital Health*

- Intended to protect wide range of **digital health technologies** for coordination and management of patient care
- OIG examples:
  - **diabetes management services** that leverage devices and cloud storage services to monitor blood sugar levels and transmit data
  - **associated internet or other connectivity services**, necessary and used to enable operation of item or service to coordinate / manage care
  - **software solutions** enabling hospitals to access data from cardiac devices used by EMS providers in the field to coordinate and manage care of patients undergoing a cardiac emergency (e.g., connectivity services, such as mobile hotspots and plans, necessary to enable the EMS providers to transmit data from the field to the hospital)
(2) **Value-Based Arrangements** – *Substantial (Meaningful) Downside Risk*

### KEY DISTINCTIONS

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| Physician must repay VBE no less than 10% value of remuneration received for failure to achieve VB purpose | • **Substantial Downside Financial Risk:** 3 options:  
  - financial risk of at least 30% of any loss on all covered items and services;  
  - financial risk of at least 20% of any loss on a defined clinical episode of care; or  
  - VBE’s receipt of prospective per-patient payment for predefined set of items/services furnished to target patient population  
  
  • **Meaningful share:** 2 options:  
    - VBE assumes two-sided risk for at least 5% of losses and savings, as applicable, realized by VBE pursuant assumption of substantial downside financial risk; or  
    - VBE participant receives from VBE a prospective per-patient payment for predefined set of items/services furnished to the target patient population and does not otherwise claim payment for such items and services  
  
  - Remuneration must be directly connected to at least one of VBE’s value-based purposes, or used predominantly to engage in value-based activities connected to items/services for which the VBE has assumed substantial downside financial risk  
  - Losses must be calculated using *bona fide* benchmarks |
(3) Value-Based Arrangements – Full Financial Risk

Protects in-kind or monetary remuneration (excluding ownership/investment interests or distributions related thereto) between VBE and a VBE participant if VBE has **assumed full financial risk from a payor**

**AKS:**

- **Full Financial Risk:** VBE is financially responsible on *prospective basis* for cost of all items and services covered by payor for each patient in target patient population for specified term

- **Requires a Connection to Value-Based Purposes:** Remuneration exchanged between VBE and VBE Participant under must be connected to one or more value-based purposes but need not be connected to the purpose of coordinating / managing care for the target patient population

- **Quality and Utilization Review:** VBE must establish quality assurance programs to protect against underutilization and assess the quality of care for target patient population

**Stark:**

- **Full Financial Risk:** VBE is financially responsible on a *prospective basis* for the cost of **all** patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time

- **Remuneration Unrelated to Target Population Not Protected:** does protect remuneration unrelated to the target patient population, such as general marketing or sales arrangements, though CMS does note that the remuneration itself could be used for the benefit of patients that are not part of target patient population
Value-Based Enterprise

- Outcomes-based payment arrangements
- Bundles
- Value-based contracting
- Capitation
Value-Based Arrangements — Key Takeaways

- Stark / AKS requirements based on level of risk
- Focused on payor arrangements
- Key questions to address when establishing potential VBE:
  - What is problem you are trying to solve?
  - What benchmark can you establish?
  - What quality metrics can you develop to achieve three part aim?
But Wait, There’s More! Other Stark Changes of Interest

▪ “Commercially reasonable”
  ▪ Must further a legitimate business purpose and be sensible when considering the characteristics of the parties, including size, scope, and specialty
  ▪ Does the arrangement make sense as a means to accomplish the parties’ goals?
  ▪ Losing money does not automatically mean the arrangement is not commercially reasonable

▪ Key points and considerations:
  ▪ The revised definition may provide parties with greater flexibility in determining what is considered commercially reasonable
  ▪ Arrangements that lose money—but serve other important needs—may still be commercially reasonable
Other Stark Changes of Interest

▪ “Volume or value” and “other business generated”
  ▪ New guidance regarding when compensation will take into account the “volume or value” of referrals or “other business generated”
  ▪ Clarification between productivity payments and hospital facility fees
  ▪ Implications for indirect compensation arrangements

▪ Key points and considerations:
  ▪ New guidance provides more clarity
  ▪ CMS clarifications provide greater flexibility for certain arrangements
Other Stark Changes of Interest

- Limited remuneration to a physician
  - New exception! 42 CFR 411.357(z)
  - Up to $5,000 per physician per calendar year (adjusted for inflation) for the provision of items or services
  - No written agreement required
  - Must be FMV and commercially reasonable
  - Limitations on percentage-based and per-unit methodologies if they reflect business generated by lessor (or provider of in-kind amount) for lessee (or payor of monetary compensation)

- Key points and considerations:
  - This may solve smaller Stark problems you encounter
Other Stark Changes of Interest

- Donation of cybersecurity technology and related services
  - New exception! 42 CFR 11.357(bb) (and 1001.952(jj) under the AKS)
    - Must be in writing
    - Cannot take into account referrals or other business
    - Physician or physician’s practice cannot make the receipt or amount of the donation a condition of doing business

- Key points and considerations:
  - Provides an opportunity for hospitals and other providers to donate helpful technology to community physicians
Other Stark Changes of Interest

- EHR donation exception
  - Removal of sunset provision – now a permanent exception
  - 15% physician contribution lives on
  - Permits donations of upgrades/replacement technology
  - Similar changes under the AKS

- Key points and considerations:
  - This has been a valuable exception allowing technology donations to community physicians
  - Removal of sunset provision means that hospitals can continue to implement EHR donation programs
Other Stark Changes of Interest

- Isolated financial transactions
  - New definition – 42 CFR 411.351
  - CMS clarified the use of this exception – does not protect a single payment for multiple or repeated services

- Key points and considerations:
  - Due to perceived abuse of this exception, parties should be more cautious in how they use this exception to solve potential disputes
  - Unclear what constitutes a “bona fide dispute”
Other Stark Changes of Interest

▪ Special rules for reconciling compensation
  ▪ 42 C.F.R. 411.353(h)
  ▪ Allows parties to true up mistakes in compensation during the term of the agreement and for 90 days following the termination or expiration of the agreement.

▪ Key points and considerations:
  ▪ Useful rule for correcting mistakes in compensation
Other Stark Changes of Interest

- Group practice profit shares and productivity bonuses
  - No split pooling of DHS overall profits based on service line
  - Groups may split DHS profits based on physician’s participation in a value-based enterprise
  - Effective January 1, 2022

- Key points and considerations:
  - These rules are technical, but the takeaway is that it may be necessary to review existing contracts to confirm physician group compensation complies with the new rules
Other Stark Changes of Interest – Quick Hits

- Electronic signatures
- 90-day grace period for writing requirement
- Non-exclusive rental arrangements
- Removal of AKS compliance requirements
- Payments by a physician exception
- Physician recruitment exception
- Remuneration for non-physician practitioner patient care services
- Period of disallowance
AKS Changes of Interest

- Personal services and management contracts
  - Removal of requirements specific to part-time contracts
  - Aggregate compensation not required to be set in advance
  - Changes regarding outcome-related compensation

- Key points and considerations:
  - Arrangements are now more likely to qualify for safe harbor protection
  - Closer alignment with Stark rules
AKS Changes of Interest

- Local transportation safe harbor
  - Expanded mileage limits for rural areas
  - Eliminates mileage limitations for transporting patients back to residences
  - Application to rideshare arrangements

- Key points and considerations:
  - Greater flexibility for a safe harbor that facilitates patient access to care
AKS Changes of Interest – Quick Hits

- Warranties
- Electronic Health Records Items and Services
Key Takeaways – What To Do Now?

▪ Regulatory changes are always a good time for a compliance review

▪ Pay attention to effective dates of changes

▪ Pay attention to new rules v. clarifications of existing law

▪ Evaluate current arrangements in light of the Stark and AKS revisions
  ▪ Are certain arrangements now lower risk going forward?
  ▪ Are there arrangements that will need to be restructured or reevaluated (e.g., POD compensation)?

▪ Consider whether your arrangement constitutes a Value-Based Enterprise
What to Do if there is a Potential Stark/AKS Issue?

- Is the arrangement covered by any of the temporary COVID flexibilities?
- Is there a way to remedy the potential non-compliance?
- Can you unwind the potentially non-compliant arrangement?
- Self-disclosure?
Summary

- New flexibility and new options under Stark and AKS – but compliance still matters
- Value-based arrangement flexibility is tied to the tier of downside risk (i.e., more risk means more flexibility)
- Stark and AKS rules for value-based arrangements are similar, but beware of the differences
- Now is a good time to focus on Stark and AKS compliance
Contact Information

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