

Health Care Regulatory Update

2022 Compliance, Litigation and Value-Based Care Year in Review

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Presenters



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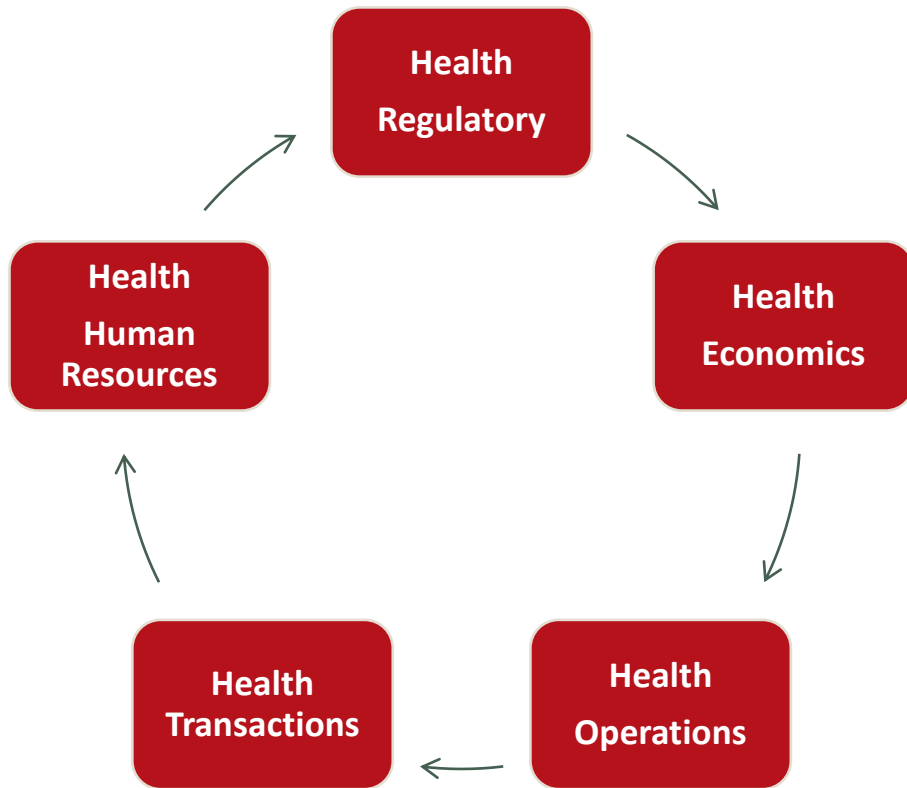
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Our Client and Industry Focused Model

Practice Groups



Service Lines

Advocacy	Antitrust	Business Organizations	Clinical Integration & Managed Care
Employment	Finance	Fraud & Abuse	Immigration
Information Technology	Labor	Litigation	Medical Staff
Mergers & Acquisitions	Operations/Clinical	Post-Acute	Privacy
Real Estate	Reimbursement	Supply Chain / Life Sciences	Tax & Tax Exemption

Agenda – Regulatory Update

- Brief 2022 Update
- Stark and Anti-Kickback
- Litigation
- Corporate Integrity Agreements
- Self-Disclosures
- Value-Based Care
- Panel Discussion and Audience Q&A



Brief 2022 Update

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A Challenging Enforcement Landscape

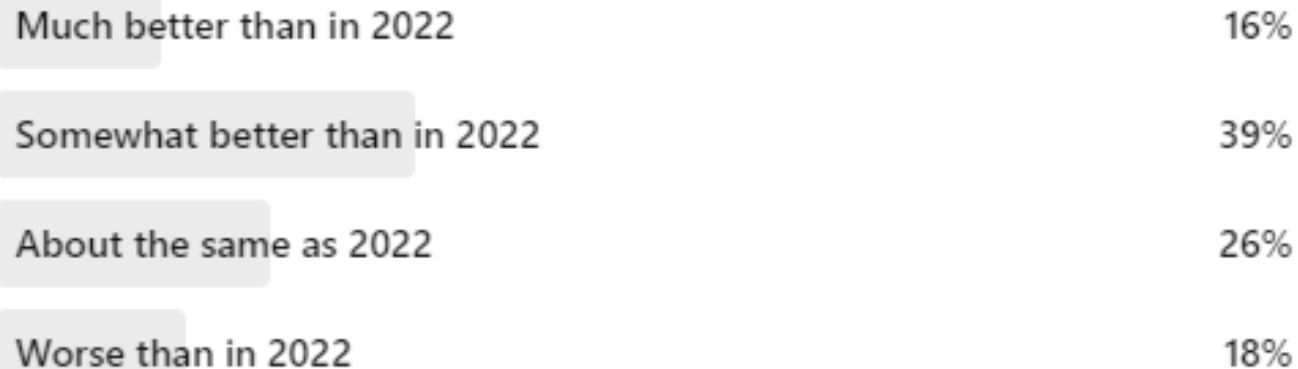
- DOJ and OIG remain the primary Federal enforcement arms, bootstrapped perceived Stark or Anti-Kickback violations into FCA cases
- Staggering number of new FCA cases the DOJ opened in the last twelve months
- DOJ becoming more proactive with sophisticated data mining and not sitting back and waiting on the next relator
- For FCA cases DOJ opens on its own, three times more likely the Government will recover and the average settlement is 20% larger
- More important than ever to be on top of known high-risk issues like physician compensation arrangements, medical necessity, upcoding, opioids, telehealth, other pandemic related false claims, etc.

Living with Financial Constraints

How do you think your health care organization will perform financially in 2023??

...see more

You can see how people vote. [Learn more](#)

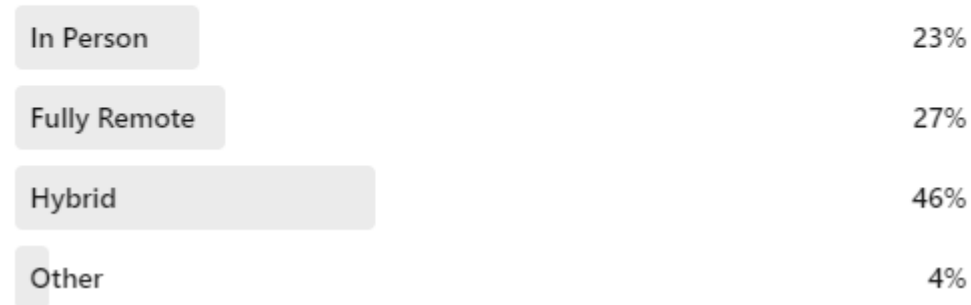


LinkedIn Poll (January 2023)

The New Legal/Compliance Normal

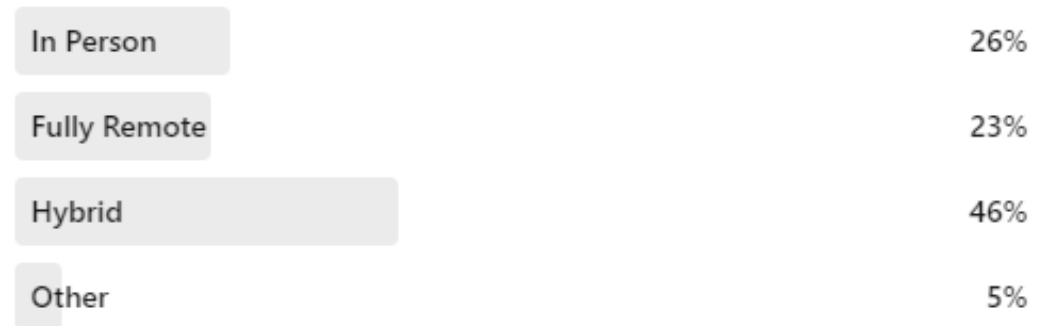
How is your health care organization's legal team staffed (e.g., in person, remote or hybrid)? See results below. Answers are anonymous.

You can see how people vote. [Learn more](#)



How is your health care organization's compliance team staffed? See results below. Answers are anonymous.

You can see how people vote. [Learn more](#)



LinkedIn Poll (January 2023)

Auditing of PHE Actions

Has your health care organization conducted a special audit of its reliance on the pandemic related waivers? All answers are anonymous.

You can see how people vote. [Learn more](#)

Yes - We have

38%

No - We haven't

63%

LinkedIn Poll (September 2022)

Ongoing Fee Schedule Transition

What Medicare Physician Fee Schedule ("MPFS") wRVU productivity are you currently using to implement your provider compensation plans?

You can see how people vote. [Learn more](#)

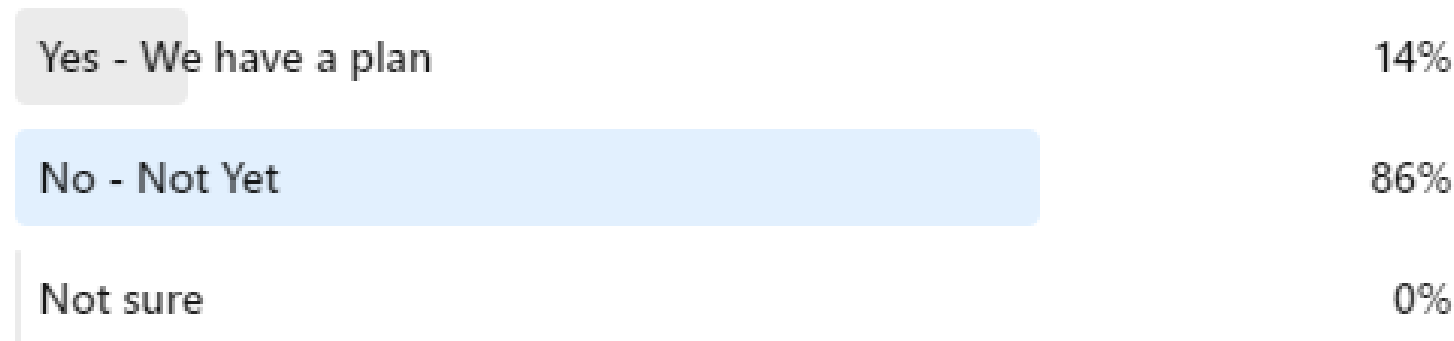
The 2020 MPFS	36%
The 2021 MPFS	12%
The 2022 MPFS	36%
Hybrid approach/redesign	15%

LinkedIn Poll (March 2022)

Planning for Split-Shared Changes

Does your health organization have a plan for the upcoming changes to APP attribution under the split-shared rules in 2024?

You can see how people vote. [Learn more](#)

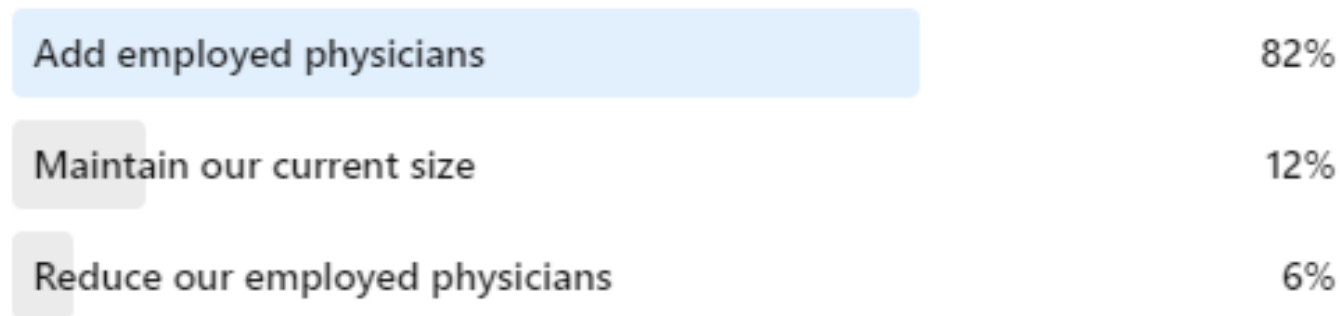


LinkedIn Poll (October 2023)

More Physician Employment is Coming

Over the next year will you your health care organization add employed physicians, maintain or reduce its size? Answers are anonymous.

You can see how people vote. [Learn more](#)



LinkedIn Poll (August 2022)

Stark and Anti-Kickback Update

Katherine Schwartz

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Recap: Changes to Stark's "Big Three"

- **The "Big 3" – Fair Market Value, Commercially Reasonable and Volume/Value**
 - 3 separate concepts, new/revised definitions and special rules
 - CMS restates/clarifies interpretations, positions and policies (42 CFR 411.351, 353, 354)
- **#1 - Fair Market Value** – Arm's length transaction, consistent with general market value
 - General application, rental of equipment, rental of office space provisions
- **#2 - Commercially Reasonable** – need legitimate business purpose
 - Sensible, considering the characteristics of the parties, including their size, type, scope and specialty
 - Does not have to "result in profit"
- **#3 - Volume/Value Standard**
 - **New Special Rules on Compensation** – Stark issue if formula includes the physician's referrals to the entity as a variable
 - Compensation must positively or negatively correlate with the number or value of the physician's referrals to the entity
 - Also applies to the "Other business generated" standard

Recap: Stark New Exceptions & Changes

- **Limited physician remuneration (411.357[z])**
 - \$5,000 in the aggregate per calendar year (now \$5,702 for CY 2023)
 - Protects short term/low dollar/unwritten arrangements
- **Reconciling compensation (411.353[h])**
 - Can reconcile and correct payment discrepancies identified up to 90 consecutive calendar days after compensation arrangement has ended
- **Writing & signature requirements (411.354[e])**
 - Allows compliance with signature and writing requirements within 90 days after start
 - Compensation must be set in advance (but need not be set out in writing before the furnishing of the items or services unless a modification)

Recap: AKS Safe Harbor Modifications

- **Personal Services and Management Contracts Safe Harbor (42 CFR 1001.952[d])**
 - "Methodology" for determining compensation set in advance
 - Eliminates requirement that part-time arrangements must specify the exact schedule, precise length and the exact charge for those intervals
- **New "Outcomes-Based Payment" Arrangements within Personal Services and Management Contracts Safe Harbor**
 - Requires achievement of one or more outcome measures based on clinical evidence or credible medical support
 - Benchmarks: quality of care, reduction in cost, or both
- **Warranty Safe Harbor (42 CFR 1001.952[g])**
 - Permits bundled items/services warranties – reimburse costs only!
 - Alters reporting requirements to accommodate outcome-based warranties

EKRA Enforcement Update

- **EKRA Recap**

- Enacted in 2018 as part of SUPPORT Act in response to the U.S. opioid epidemic
- Intended to help combat the opioid crisis and limit individuals and entities from profiting from substance abuse patients seeking treatment
- Established criminal sanctions (up to \$200,000 fine and 10 years imprisonment) for soliciting, receiving, or paying remuneration in exchange for referrals to recovery homes, clinical treatment facilities, or laboratories
- Includes government and commercial patients
- Applies to all laboratory services, not just opioid-related

- **Enforcement Action Updates**

- ***United States v. Kevin M. Dickau et al.*** Marketing Company engaged a nationwide network of recruiters, who encouraged and bribed drug-addicted individuals to enroll in rehabilitation facilities. CA physician contracted with the Marketing Company for \$5,000 to \$10,000 per patient referral
 - Attempted to disguise the payments by writing “monthly fee” on the memo line of the check
 - **Sentencing Update: Individuals involved pled guilty to crimes related to the violation of EKRA; Facility owner/physician sentenced to 15 months’ imprisonment; restitution damages of almost \$500,000).**
- ***United States v. Jonathan Markovich et al.*** 10 defendants charged for their alleged participation in conspiracies to pay and receive illegal kickbacks under EKRA (among other violations). The defendants were owners, operators, physicians, and patient recruiters for an inpatient substance abuse treatment center in Florida as well as a related outpatient program. The defendants allegedly recruited patients to the inpatient facility and outpatient program through cash payments, inter-state flights, illegal drugs, and other in-kind items.
 - **Sentencing Update: Several defendants have pled guilty and are awaiting sentencing; for those sentenced, range from 15 years’ imprisonment and restitution damages of almost \$3,000,000 (co-owner) to 13 months’ imprisonment and restitution damages of almost \$400,000 (recruiter).**

EKRA Enforcement Update Cont.

S&G Labs Hawaii v. Graves. Laboratory account manager's employment agreement: base salary + percentages of monthly net profits generated by his client accounts. Attempt to negotiate revision to compensation structure to comply with EKRA failed → breach of contract claim. Lab argued that commission-based payments would have violated EKRA.

- Court found that lab's payments to account manager didn't violate EKRA because they didn't **"induce a referral of an individual."**

U.S. v. Schena. Allegations against president of laboratory testing facility for inducing the ordering of COVID-19 bundles which required a medically unnecessary allergy test to be provided in addition to COVID-19 tests.

- **Relied on *S&G Labs Hawaii v. Graves*** to say that, because his marketers worked with physicians to obtain referrals rather than directly with individual patients, he was not liable under EKRA.
- **Court notably struck down the rationale in *Graves* as a misapplication of EKRA: no requirement of directness between the marketer and an individual.**

Best Practices

- Remain cognizant of government's commitment to enforcing EKRA
- Continue to monitor enforcement actions and ensure that marketing deals and incentive-based arrangements are EKRA-compliant
- EKRA implicates lab arrangements for **non-substance abuse related tests** – examine any type of lab arrangements for EKRA compliance, including employee and contractor compensation arrangements (particularly commission-based compensation)

Litigation Update

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Scienter

A defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it.

Scienter (cont.)

US v. Supervalu Inc., 9 F.4th 455 (7th Cir. 2021)

Applied the Supreme Court's interpretation of the Fair Credit Reporting Act's scienter provision to FCA cases, barring a finding of "reckless disregard" where the interpretation is objectively reasonable and no authoritative guidance cautioned against it.

US ex rel Proctor v. Safeway., 30 F.4th 649 (7th Cir. 2022)

Expanding on *Supervalu*, determined guidance must be authoritative, controlling on the Agency, to be the basis for a finding of "reckless disregard."

Objective Falsity

US v. AseraCare, 938 F.3d 1278
(11th Cir. 2019)

A difference of opinion about a patient's prognosis cannot show objective falsity for the purposes of the FCA.

U.S. ex rel. Druding v. Care Alternatives, 952 F.3d 89, 99-100 (3d Cir. 2020) (disagreeing with Eleventh Circuit and ruling “that a difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA liability”).

U.S. ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc., 953 F.3d 1108, 1113 (9th Cir. 2020) (finding that clinical opinions can be false).

DOJ Civil Cyber-Fraud Initiative

Deputy Attorney General Lisa O. Monaco announced today the launch of the department's Civil Cyber-Fraud Initiative, which will combine the department's expertise in civil fraud enforcement, government procurement and cybersecurity to combat new and emerging cyber threats to the security of sensitive information and critical systems.

“For too long, companies have chosen silence under the mistaken belief that it is less risky to hide a breach than to bring it forward and to report it,” said Deputy Attorney General Monaco. “Well that changes today. We are announcing today that we will use our civil enforcement tools to pursue companies, those who are government contractors who receive federal funds, when they fail to follow required cybersecurity standards — because we know that puts all of us at risk. This is a tool that we have to ensure that taxpayer dollars are used appropriately and guard the public fisc and public trust.”

DOJ, Oct. 6, 2021

**Aerojet Rocketdyne Agrees
to Pay \$9 Million to Resolve
False Claims Act
Allegations of
Cybersecurity Violations in
Federal Government
Contracts**

DOJ, July 8, 2022

**Medical Services Contractor
Pays \$930,000 to Settle False
Claims Act Allegations Relating
to Medical Services Contracts
at State Department and Air
Force Facilities in Iraq and
Afghanistan**

DOJ, March 8, 2022

Corporate Integrity Agreement Update

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CIA Changes on the Horizon

1. The role of the Compliance Officer and non-compliance job responsibilities
 - OIG will have more discretion
2. The Role of the Compliance Committee
 - OIG expects more committee involvement
3. Annual Risk Assessment Process
 - OIG expects more active involvement from operational leaders
4. IRO Review
 - Risk-based
 - Submission of a Proposal for risk areas
5. Creation of a Transition Plan
 - Due with 4th Annual Report



Self-Disclosure Update

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Self-Disclosure Best Practices

- With the increasing frequency and intensity of Federal investigations within the health care industry, proper self-reporting of known non-compliant behavior has never been more important
- Stakes too high to do otherwise, including potentially for the individuals involved who may decide against this approach
- Reasons why we are seeing more self-disclosure submissions now than at any time in the recent past
- Not a sign of a bad actor provider, but rather, a proactive risk mitigation strategy that can show an effective Compliance Program in action
- Government normally much more lenient with a self-reporting provider as opposed to the target of a Federal investigation
- Do it right through the appropriate self-reporting process to resolve the matter before it gets outside of your organization

Self-Reporting Options

- Depending on the nature of the compliance issue in question, OIG, CMS, DOJ or even a Government contractor for simple overpayments could all be self-report vehicles
- These self-reporting options are all quite different and extensive experience with each can be very helpful to guide you through the potential pitfalls
- OIG and CMS self-disclosure processes most common for perceived violations of law and they will be our focus today
- OIG Health Care Fraud Self-Disclosure Protocol
 - A “catch all” repository of many types of noncompliance under Federal health care programs, including physician arrangements with dual Stark and AKS concerns
 - Usually timely and more predictable settlement methodology

CMS Self-Referral Self-Disclosure Protocol

- Stark physician arrangement issues only
- Extensive que with many years until cases resolved
- Some good news though: recent movement with huge case backlog and average settlement still less than \$100,000 according to published CMS data

Self-Disclosure Prerequisites

- Record should speak for itself so there is nothing left for the Government to investigate
- Comprehensive internal investigation considering all relevant background facts and credible arguments before electing to self-report
- Document collection, review and interviews of key witnesses
- Corrective action that fixes the underlying compliance problem – normally situation isn't ripe for a self-disclosure unless effective remediation
- Reliability of the pertinent claims data establishing the amount of the Federal health care program overpayment
- Determination whether an independent assessment of that overpayment will be involved
- Importance of maintaining attorney-client privilege throughout the internal investigation

5 “Cs” of an Effective Self-Disclosure

- **Credibility** of the self-disclosing provider and its legal representative;
- **Comprehensiveness** of the prior internal investigation supporting the self-report;
- **Corrective action** confirming that the underlying compliance problem is a thing of the past;
- **Claims data** that is accurate and complete in identifying the overpayment; and
- **Compliance** issue is resolved before it can escalate further against the organization.

Value-Based Care Update

Jim Burke

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Value-Based Enterprises

Will your health care organization develop a value-based enterprise (VBE) in 2023?? See results below. All answers are anonymous.

You can see how people vote. [Learn more](#)



LinkedIn Poll (January 2023)

Value-Based Care

Moving From Volume to Value

Market Forces

Value-Based Enterprise

- A Tactic
- Change Physician Relationships


How to use a VBE?

Value-Based Care

Value-Based Strategies

- New Revenue Models
- Physician Engagement
- Care Management & Leveraging Data

Start with incremental change!



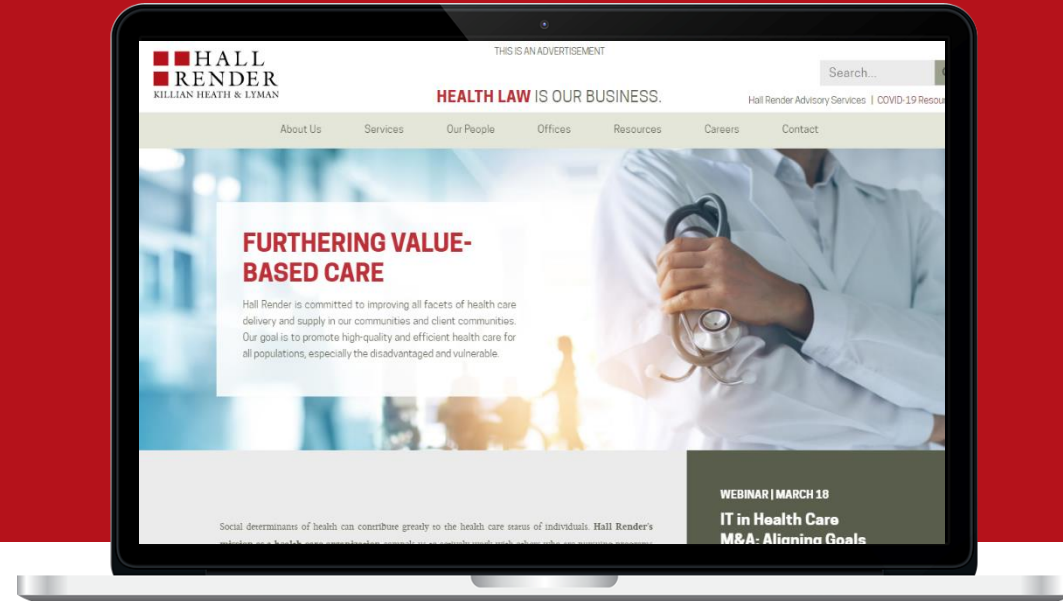
Panel Discussion and Audience Q&A

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Questions?

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