

Morgan Lewis

A FAST BREAK YEAR IN REVIEW

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Top 10 Health Law Items for 2019



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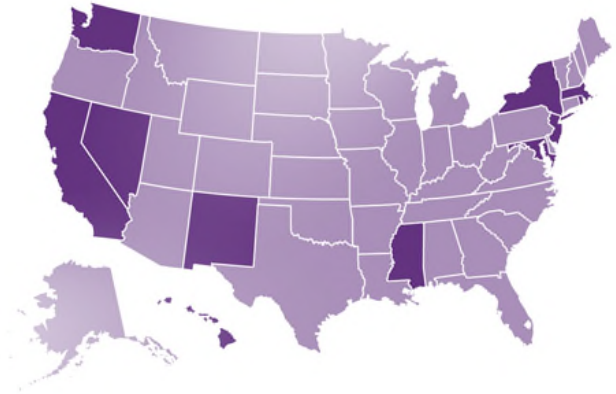
10. *Escobar*
9. GDPR and US State Analogs
8. *Cochise*
7. DOJ Compliance Guidance
6. The Rise of Preventive and Low Acuity Care
5. *AseraCare*
4. Digital Health at the FDA and Beyond
3. Price Transparency
2. Stark and AKS Reform Rules
1. *Allina*

10. *Escobar*

- Evolution of DOJ's litigation position on *Escobar* materiality standard:
 - a government failure to act is irrelevant unless there was notice of prior violations. Inaction is not otherwise probative of materiality;
 - an FCA plaintiff (DOJ or relator) does not have to identify prior government action or inaction at the motion to dismiss stage, there is a presumption of materiality in the complaint allegations; and
 - the materiality presumption may be rebutted at the summary judgment stage, presumably after discovery
- Even in recent CMS letter on *Allina*, *Escobar* standard for materiality was given consideration

9. GDPR and US State Analogs

- General Data Protection Regulation (GDPR) is a set of rules enacted in the European Union in 2018
 - Significant consent and use requirements related to many types of personal data, including health data
- California Consumer Privacy Act (CCPA) inspired by GDPR
 - creates an array of new consumer privacy rights
 - allows California consumers to make requests of businesses to disclose what personal information the business has shared and also to delete or no longer share that information
- At least 10 other states have introduced similar privacy legislation

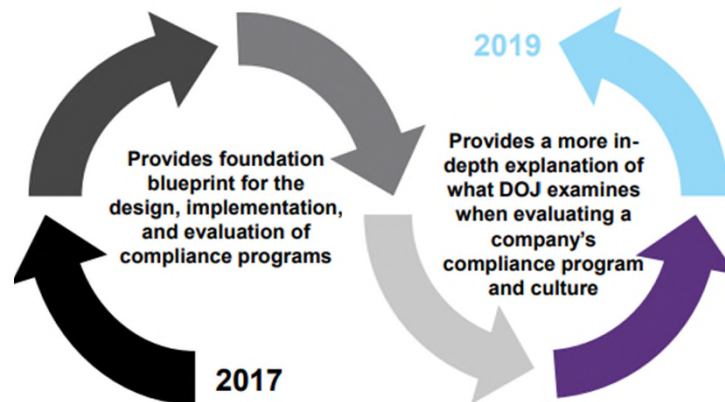


8. *Cochise*

- In May 2019, the Supreme Court ruled in *Cochise Consultancy v. United States ex rel. Hunt* that relators enjoy the same three-year tolling period in declined qui tam cases that the government does in intervened cases
- Cochise effectively extends the SOL period for declined qui tams
- Under the FCA, relators may have the option of pursuing a qui tam in the event that DOJ declines to intervene
 - Now subject to DOJ approval
 - DOJ declines approximately 75-80% of filed qui tams, meaning there are hundreds of cases filed each year where relators must proceed alone
- However, Supreme Court declined to allow relators to serve as responsible government officials

7. DOJ Compliance Guidance

- The “Evaluation of Corporate Compliance Programs,” published on April 30, 2019, updates guidance previously released on February 8, 2017
 - provides companies with increased clarity on the government’s evaluation of corporate compliance programs.
- The DOJ Fraud Section places **effectiveness** at the epicenter of its factors to be utilized when evaluating a company’s compliance program in the context of a criminal investigation



6. The Rise of Preventive and Low Acuity Care

- In 2018/2019, CMS has taken significant steps to get patients care on either a preventive basis or before the issue becomes severe
 - Enhancements to virtual check-ins and other telehealth primary care services
 - Increased use and flexibility of chronic care management, transitional care management, and remote patient monitoring
- Other rule-making seeks to enhance patient incentives to take ownership of their health, particularly in preventive care situations
- Thematic change at CMS representing a necessary aspect of the switch from volume to value

5. *AseraCare*

- Hospice case in Eleventh Circuit
 - On appeal, the Eleventh Circuit held that mere differences of reasonable opinion regarding a patient's prognosis is not sufficient evidence to show FCA liability.
 - In an exhaustive review of the Medicare program and the False Claims Act, the Court held that in hospice cases the government must show facts surrounding the physician's eligibility certification that are inconsistent with the proper exercise of physician judgment.
 - The Court acknowledged that the Medicare hospice benefit was structured to consider good-faith subjective clinical opinions and two physicians may reasonably hold different opinions on prognosis and eligibility. At trial, this exact point was part of the testimony of the Medicare agency witnesses.
- Ramifications for FCA cases and Medicare appeals related to medical necessity

4. Digital Health at the FDA and Beyond

- Telehealth and Digital Health are rapidly growing
 - Bringing significant disruption to the health care industry
- FDA has incorporated a new methodology for review of various digital health products, particularly those that use machine learning and AI to expand their capabilities
- Telehealth bills, including the SUPPORT Act of 2018 and the proposed CONNECT Act, will enhance Medicare coverage for digital health products and telehealth services in near future
 - Medicare Advantage plans already set to begin widespread use of telehealth in 2020

3. Price Transparency

- Price transparency rules impacting hospitals, health plans and third-party payers released by the administration promise to substantially change how health plans, consumers, and providers will interact over the coming years
 - Released in November
 - Hospitals must make “standard charge” information available online, to post this data for a limited set of “shoppable services” in a “consumer-friendly” manner and form, and to disclose contract rates with health plans.
 - Group health plans and health insurance issuers make information on claims payment policies, rating practices, and cost sharing available to the public and also disclose negotiated rates with providers and out-of-network estimates for consumers.

2. Stark and AKS Reform Rules

- “Regulatory Sprint to Coordinated Care”
 - 2 proposed rules issued in October – one from OIG on AKS and CMP changes, the other from CMS on Stark Law changes
- Four goals
 - Improving a patient’s ability to understand his/her treatment plans and be empowered to make decisions
 - Increasing providers’ alignment on end-to-end treatment
 - Providing incentives for providers to coordinate and collaborate care with their patients
 - Encouraging information sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data
- Both rules seek to incentivize providers to take financial risks with respect to patient care for purposes of “value-based arrangements”

1. *Allina*

- June 2019 opinion from Supreme Court in *Azar v. Allina*
 - Requires CMS to follow notice-and-comment rule-making when adopting a “statement of policy” that establishes or changes a “substantive legal standard.”
 - Significant impact on policy making process for CMS
- In October, HHS General Counsel released letter outlining the Department’s interpretation of *Allina*
 - “The Supreme Court made clear that Congress has imposed more stringent procedural requirements for certain Medicare rules than the framework that otherwise would apply under the Administrative Procedure Act (APA).”
 - To the extent a guidance document created a new “statutory or regulatory norm,” it would be necessary to undergo notice and comment rulemaking in order to provide a basis for enforcement.

Thanks!



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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, telehealth companies, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

Thanks!

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Dani has significant healthcare regulatory, fraud and abuse and healthcare transactions due diligence experience. Dani has assisted a broad range of healthcare clients, including retail pharmacies, vision care providers, physician practices, hospices, home health agencies, and private equity investors. While at George Washington School of Law, Dani was a paralegal in the Civil Fraud Section at the Department of Justice, where she worked extensively on healthcare fraud investigation and litigation matters.

Join us next month!

Please join us for next month's webinar:

"Fast Break: Allina"

Featuring Greg Etzel

➤ Tuesday, January 28 3:00 PM (EST)