WINSTON & STRAWN LLP

NEWS

Key Takeaways From Winston's Fourth Annual Health Care & Life Sciences Summit

AUGUST 15, 2024

Members of Winston's Health Care & Life Sciences Industry Group gathered for the firm's fourth annual Health Care & Life Sciences Summit, in our Chicago office and virtually, on June 4, 2024.

The Summit's agenda was structured with general and targeted sessions to allow for a specific focus on one of three sub-sectors: health care investors, health care providers and payers, and life sciences companies. Below are key takeaways from the panels.

Regulatory Enforcement Developments for Providers and Payers

- Natalie MacLean Leino, General Counsel, Carelon Behavioral Health
- Leia Olsen, Compliance Officer – Investigations & Incidents, Ascension
- Larry Sher, Partner, Government Contracts & Grants, Winston & Strawn
- Amandeep Sidhu, Partner, Government Investigations, Enforcement & Compliance (Health Care), Winston & Strawn

TAKEAWAYS: REGULATORY ENFORCEMENT & COMPLIANCE DEVELOPMENTS

- False Claims Act (FCA) Enforcement Trends
  - $2.68 billion recovered by DOJ in 2023, the 15th straight year of where FCA recoveries exceeded $2 billion and set a record for highest number of FCA settlements and judgments in a single year (543).
  - The health care and life sciences industry continues to represent the overwhelming majority of FCA enforcement activity, with 67% of 2023 recoveries coming from companies and individuals in the industry.
  - Enforcement activity in 2023 was focused on a wide array of health care providers, goods, and services – including drug and medical device manufacturers, durable medical equipment, home health and managed care providers, hospitals, pharmacies, hospice organizations, and individual physicians.
- DOJ Mergers & Acquisitions Safe Harbor Policy

- In October 2023, DOJ announced a new policy that provider acquiring companies with an opportunity to avoid criminal exposure if misconduct at acquired companies is voluntarily disclosed within six months of a merger or acquisition (learn more here).

- Office of Inspector General (OIG) General Compliance Program Guidance
  - OIG issued its first major update on compliance guidance in 15 years, providing guidance on key federal laws, including the Anti-Kickback Statute, Stark Law, FCA, Civil Monetary Penalties, federal program exclusion, criminal healthcare fraud, and HIPAA.

TAKEAWAYS: CURRENT BEHAVIORAL HEALTH HOT TOPICS FOR PAYERS

- Behavioral health refers to whole person health. It has greatly evolved over the past 10 years and is a key enforcement area for CMS, DOJ, and State AGs.
- Some major behavioral health challenges/enforcement areas for regulators include:
  - A surge in demand in recent years, especially during and post-COVID-19;
  - Provider staffing shortages amid increasing demand;
  - Requirements to improve accessibility to behavioral health services (rural areas, children, at-risk populations) with telehealth and other new technology tools, and the post-COVID licensure based on geographic location of provider or patient for virtual/telehealth behavioral health visits/services;
  - Improvement and verification of the accuracy of network providers; and
  - Requirements to ensure behavioral health patients are treated fairly and not differently than medical patients.
- In July 2023, the Departments of Labor and Health and Human Services released a proposed rule intended to strengthen the 2008 Mental Health Parity and Addiction Equity Act (MHPAEA), which requires health plans to offer mental/behavioral health coverage in parity with the plan's coverage for other medical conditions.
  - The Act requires payors to ensure there is no discrimination/disparate treatment in coverage decisions for mental/ behavioral health services (includes prior authorizations, utilization reviews, adequacy of provider networks, etc.).
  - Instead of adding more clarity to the Act, the regulators amendments added additional requirements and raised additional compliance questions.
  - In 2024, mental health parity has risen to forefront of federal and state regulatory priorities, we expect increased enforcement as well as guidance from courts as private litigation challenging the Act and new rules wind through the courts.

The State of States: An Overview of Corporate Practice of Medicine Guidance and Enforcement

- Scott Freshour, General Counsel, Texas Medical Board
- Marcus Jimison, Deputy General Counsel, North Carolina Medical Board
- Eric Knickrehm, Partner, Mergers & Acquisitions (Health Care), Winston & Strawn

TAKEAWAYS

- Boards of Medicine counsel accept that private equity involvement in physician practice management is a fact of life.
- The key things that invite scrutiny from Boards of Medicine are issues that affect the physician-patient relationship, a physician's clinical autonomy, and patient quality of care.

- Boards of Medicine typically do not take action unless there is “Corporate Practice of Medicine + 1” where the “+1” involves risk of patient harm.
- Boards have heightened scrutiny around med spas and telehealth arrangements without proper establishment of a physician-patient relationship, including follow-up care.
- These matters are highly state- specific and physicians looking to sell their practices as well as investors looking to acquire practices should work with counsel to determine state-specific compliance matters.

Health Care M&A Deals: Are You Getting What You Think You Are?

- Dan Hoppe, Senior Vice President, Lockton
- Eric Knickrehm, Partner, Mergers & Acquisitions (Health Care), Winston & Strawn
- Conor Reidy, Partner, Antitrust, Winston & Strawn
- Kristin Wickler, Partner, Mergers & Acquisitions, Winston & Strawn

TAKEAWAYS

- Health care deal activity has increased significantly in certain sectors while decreasing in others.
  - Home health, hospice, med spas/aesthetics practices, pharmaceutical services have all been industry subsectors generating a lot of interest.
- Many private-equity-backed health care companies have been focused on add-on acquisitions or strategic carveout transactions to optimize business for eventual sale.
- Representation & Warranty Insurance coverage in health care transactions has increased in scope, with fewer categorical exclusions. More thorough due diligence equates to better coverage outcomes.
- Antitrust enforcers at the federal and state level continue to scrutinize health care transactions, with particular focus on deals involving private equity ownership and roll-up strategies.
- Notification requirements to obtain antitrust clearance of transactions—especially health care transactions—is expected to increase as the FTC intends to roll out a more burdensome HSR form and states continue to add their own notification requirements (“Baby HSR” statutes).
- A few states (California, Minnesota, Oregon) have gone beyond just notice requirements to consider legislation that would potentially prohibit health care transactions involving private equity entirely.

Navigating the Wild West of Health Care AI: How to Vet Investments, Vendors, and Tools

- Lydia Andrasz, Assistant VP, Associate GC, Transactions, Endeavor Health
- Mary Katherine Kulback, Partner, Mergers & Acquisitions, Winston & Strawn
- Dina Masiello, Senior Vice President, Assistant General Counsel, Innovation Associates
- Sean Radcliffe, Executive Vice President and General Counsel, R1 RCM

TAKEAWAYS

- Artificial intelligence technologies are becoming increasingly ubiquitous.
- Companies should consider drafting AI governance and principles documents and identifying applicable stakeholders so that all angles regarding use of AI (and legal and other implications) are considered.

- Agreements governing use of AI tools should contain very specific terms regarding data and IP ownership and usage rights.
- AI vendors should practice transparency with customers regarding the usage of customer data.
- Don't forget to consider privacy and data security implications when using AI tools.

Innovative Health Benefit Design: Addressing Social Determinants, Access, and Equity

- Amy Kearbey, Partner, Government Investigations, Enforcement & Compliance (Health Care), Winston & Strawn
- Bernard (Bernie) Knobbe, Corporate Vice President of Global Benefits, AECOM
- Susan Nash, Partner, Employee Benefits & Executive Compensation, Winston & Strawn

TAKEAWAYS

- Employers continue to be at the forefront of development of innovative employee benefit programs to recruit and retain employees while contributing to and promoting the health and wellbeing and productivity of their workforce. However, such programs must be designed to comply with an array of federal and state laws.
- Employers are quickly adapting to new health care technologies and delivery methods, including incorporation of technology in benefits programs, coverage of alternative and novel therapies to treat chronic conditions, such as GLP-1s, and broad-based adoption of telehealth benefits. Driving factors in benefit design are value-based health care, such as quality and effectiveness of health outcomes, and cost efficiency.
- The federal government has also recognized the importance of addressing social determinants of health and has created new pathways and pilot programs to promote innovative solutions through value-based care in federal health care programs.

Regulatory Enforcement Developments for Life Sciences Companies

- Tanzina Chowdhury, Legal Consultant
- David Cooner, Senior Vice President and Chief Litigation Counsel, Becton Dickinson
- Liz Leavy, Partner, Government Contracts & Grants, Winston & Strawn
- Reed Stephens, Co-Chair, Health Care & Life Sciences Industry Group, Winston & Strawn

TAKEAWAYS

- False Claims Act enforcement trends
  - Medicare reimbursement and "Medical Necessity" risk are popular theories of liability for the Department of Justice
  - "Fraud on the FDA" theories directed at medical device companies are popular whistleblower theories that have a mixed record of success with federal courts
  - Anti-Kickback trends
- Evolving class action risk for life sciences companies
  - Traditional FDA warning letter or adverse event trigger have given way somewhat to more generalized risk due to the emergence of litigation funding models that incentivize speculative lawsuits
- Maintaining effective compliance programs and global supply chain management

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Using International Investment Treaties to Mitigate Foreign Regulatory Risks in Life Sciences

- Alex Kaplan, Senior Legal Counsel, ICSID
- Imad Khan, Partner, International Arbitration, Winston & Strawn
- Conna Weiner, Mediator & Arbitrator, JAMS
- Ricardo Ugarte, Partner, International Arbitration, Winston & Strawn

TAKEAWAYS

- Life science companies that invest abroad often have rights under investment treaties negotiated by their governments that protect them from unfair and unexpected measures imposed by foreign governments that impact their investments.
- When faced with such measures, life science companies face unique challenges in deciding how best to protect their investments because of their ongoing need to maintain stable relationships with foreign regulatory agencies.
- However, when such adverse measures generate material harm, life science companies should know of their rights under these investment treaties, which include significant substantive protections and the procedural right to bring the foreign government to arbitration for full damages in a neutral international arbitration forum, such as ICSID, that avoids local court bias.

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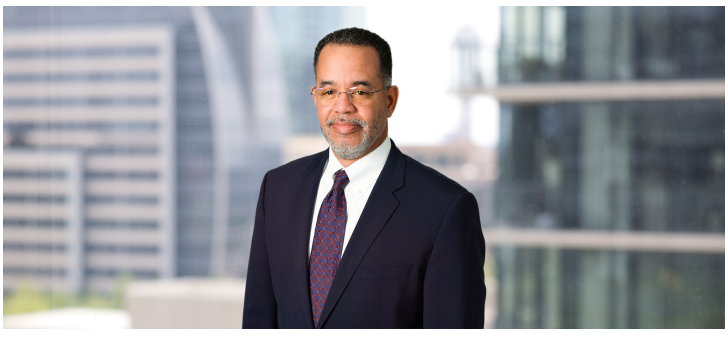

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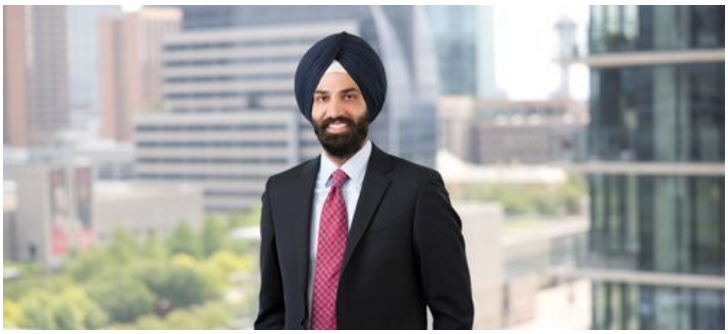

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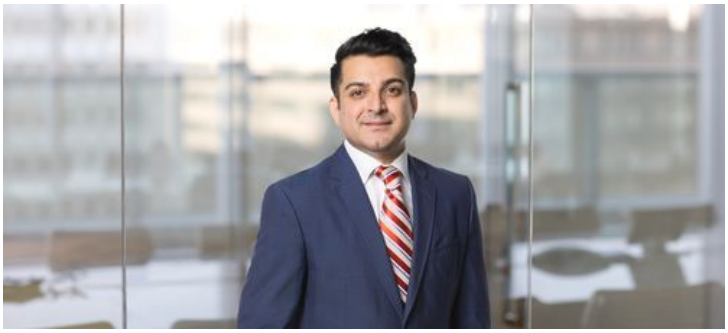

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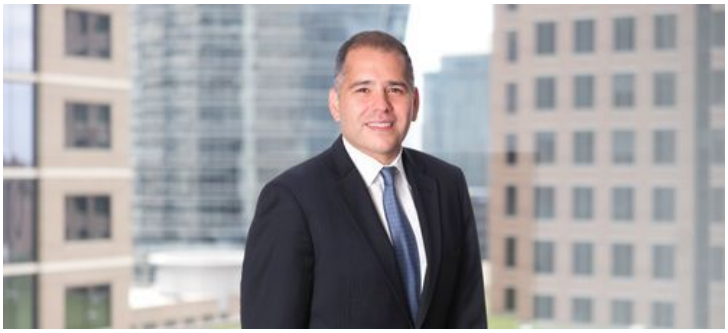

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