COVINGTON

Medical Device & Digital Health Symposium

OCTOBER 26, 2023 | MANDARIN ORIENTAL | BOSTON, MA

Plenary Session Materials and CLE Information

Plenary Session Supporting Materials

Plenary Session One: Is Break Time Over? Emerging FDA and DOJ Enforcement Trends in the Medical Device and Digital Health Industries

- Deputy Attorney General Lisa Monaco's Memo (Sept. 15, 2022)
- Updated Criminal Division Corporate Enforcement and Voluntary Self-Disclosure Policy (Jan. 17, 2023)
- DOJ's Announcement of FCA Priorities (Feb. 2023)
- DOJ's FY2022 FCA Statistics
- OIG Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies
- DOJ Press Release: Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations
- Settlement Agreement
- OIG Report: Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks
- OIG Toolkit for Analyzing Telehealth Claims and Assess Program Integrity Risks

Plenary Session Two: MedTech M&A: The Current Environment and Deal Management

- DOJ Provides Further Voluntary Disclosure Incentives, This Time Linked to M&A Transactions, and Signals Other Areas of Focus | Covington & Burling LLP
- Federal Trade Commission and Department of Justice Propose Sweeping Changes to the Hart-Scott-Rodino Form
- The FTC Seeks to Ban Non-Competes & Brings Related Enforcement Actions | Covington & Burling LLP

Plenary Session Three: Artificial Intelligence in Healthcare and Life Sciences - Regulatory and Commercial Trends, Risk and Opportunities

- Framework for the Future of AI: Senator Cassidy Issues White Paper, Seeks Public Feedback
- FDA Guidance: "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions"
- Change is Coming for Software and AI Medical Devices in the UK
- California AG Probes for Potential Bias in Healthcare Algorithms, Federal Attention Continues
- 5 Key Takeaways from FDA's Final Guidance on Regulation of Clinical Decision Support Software: FDA Outlines Significant Changes for CDS | Covington & Burling LLP
- 5 Digital Health Issues to Watch at FDA in 2022

CLE Credit

Each plenary session is approved for 1.0 Professional Practice (Transitional & Non-Transitional) credits in New York and 0.75 General credits in California. Uniform Certificates of Attendance can also be provided for those barred in other jurisdictions.