

VIRTUAL CONFERENCE

Healthcare Enforcement Compliance Conference

November 16–18, 2020

Gain insight into properly monitoring, detecting, investigating, and managing violations. Hear directly from government officials and learn from the unique perspectives of those who deal with regulations daily.

Register by October 30 to save

Learn more and register
hcca-info.org/2020HECC



About the virtual conference

Hear firsthand from government officials about regulatory changes, expectations, and key priorities at the Healthcare Enforcement Compliance Conference. Gain the knowledge and skills needed to properly address potential violations and improve your organization's compliance program.

Attendees will enjoy compliance sessions and industry updates in an interactive, online experience while earning live Compliance Certification Board (CCB)[®] continuing education units (CEUs).

New lower pricing is now available! Additional registration discounts apply for SCCE & HCCA members. Group discounts are also available.

Attendees can purchase the conference session recording package for only \$100. Take advantage of this affordable opportunity to hear the sessions you may have missed and earn non-live CCB CEUs.

Who should attend?

- Compliance officers
- Chief quality officers
- Presidents/CEOs
- Senior internal auditors
- Directors of compliance
- Regulatory/risk officers
- Government employees
- General counsel
- Compliance attorneys

Learning objectives

Attendees will gain valuable insight into current enforcement issues. They also will gain a greater understanding about how to detect problems and properly investigate violations within their organizations. Session topics this year will include:

- False Claims Act
- Cybersecurity & Healthcare Privacy
- Fraud Enforcement
- Corporate Integrity Agreements & IRO
- Enforcement in Clinical Research
- Privacy Regulations
- Managed Care
- Telehealth
- CMS Oversight
- Anti-Kickback Statute and Stark Law
- Compliance Investigations
- Opioid Crisis

Schedule at a glance

All times listed are in Central Standard Time (CST)

Monday, November 16

8:50–9:00 AM CST	Opening Remarks		
9:00–10:15 AM CST	General Session: Government Enforcement Panel – Kirk Ogrosky, Partner, Arnold & Porter LLP (Moderator); Greg Demske, Chief Counsel to the Inspector General, HHS Office of Inspector General; Allan Medina, Chief of the Department of Justice, U.S. Department of Justice, Health Care Fraud Unit, Criminal Division; Jamie Ann Yavelberg, Director, U.S. DOJ		
10:15–10:30 AM CST	Break		
10:30–11:30 AM CST CONCURRENT BREAKOUT SESSIONS	101 HHS' Regulatory Sprint to Coordinate Care – Ben Wallfisch, Senior Counsel, Office of Counsel to the Inspector General, HHS	102 False Claims Act Liability in Post-Acute Care – Claudia E. Reingruber, Shareholder, Saltmarsh, Cleaveland & Gund; Tamar Abell, CEO, TBA Compliance; William T. Mathias, Co-Chair Health Law Group and Fraud and Abuse Team, Baker Donelson	103 Preventing Enforcement Actions in Clinical Research: Operational Strategies for Avoiding Financial Frauds – Kate Cohen, Executive Director of Compliance/Chief Compliance Officer, SIU Medicine; Sarah Couture, Managing Director, Ankura
11:30–11:45 AM CST	Break		
11:45 AM–12:45 PM CST CONCURRENT BREAKOUT SESSIONS	201 Managed Care Enforcement and Compliance – Ben Singer, Partner, O'Melveny & Myers LLP; Barbara Fonte, Vice President of Managed Care and Population Health, Jackson Health System; Sarah Kessler, Senior Counsel, HHS-OIG; Pamela C. Brecht, Partner, Pietragallo Gordon Alfano Bosick & Raspanti, LLP	202 How OIG Uses Data in its Affirmative Cases & How Data Can be Incorporated into Compliance – Geoffrey Hymans, Senior Counsel, Office of Inspector General, US Health and Human Services; Barry Grosse, Chief Compliance Officer, University of Miami Health System	203 The Myth(s) of Median to 75th: New Perspectives on Assessing, Managing and Monitoring Physician Compensation Arrangement Risk – James G. Sheehan, Chief, Charities Bureau, NY Attorney General; Heather L. Fields, Shareholder, Chair - Hospital/Health Systems Practice, Reinhart Boerner Van Deuren s.c.; Adam Klein, Principal, ECG Management Consultants
12:45–1:30 PM CST	Mid-Conference Break		
1:30–1:35 PM CST	Opening Remarks		
1:35–2:35 PM CST	General Session: Whistleblowers: Who Are They, Why Do They Bring Cases, and What Makes a Good Whistleblower Case – Jeb White, President & CEO, Taxpayers Against Fraud Education (Moderator); Susan Gouinlock, Senior Partner, Wilbanks & Gouinlock LLP; Andy Stone, Partner, Stone Law Firm LLC; Sarah "Poppy" Alexander, Associate, Constantine Cannon LLP		
2:35–2:50 PM CST	Break		
2:50–3:50 PM CST CONCURRENT BREAKOUT SESSIONS	301 Federal Administrative Sanctions – Jennifer Leonardis, Senior Counsel, HHS, Office of Inspector General; Julie E. Kass, Shareholder, Baker Donelson	302 Compliance Session TBA	303 Lessons Learned from Stark Investigations – David Glaser, Shareholder, Fredrikson & Byron PA; Matthew Krueger, United States Attorney, Eastern District of Wisconsin
3:50–4:05 PM CST	Break		
4:05–5:05 PM CST CONCURRENT BREAKOUT SESSIONS	401 Enforcement and Compliance for Pharmacies – Jennifer Krusa, Chief Compliance Officer, PharmScript; Daniel Meier, Healthcare Regulatory and Transactional Attorney, Benesch Friedlander Coplan & Aronoff; Josh Lichtblau, Director, Medicaid Fraud Division, NJ Comptroller's Office	402 Why Whistleblowers Matter to Healthcare Compliance – Edward Baker, Counsel, Constantine Cannon LLP; Sandra Miller, Attorney, Wombile Bond Dickinson (US) LLP	403 Trends and Best Practices in Healthcare Privacy and Security Investigations – Timothy Noonan, Deputy Director, Health Information Privacy Division, U.S. Department of Health and Human Services Office for Civil Rights; Jonathan Skrmetti, Chief Deputy Attorney General, Office of Tennessee Attorney General; Brian Stimson, Principal Deputy General Counsel, U.S. Department of Health and Human Services
5:05–5:20 PM CST	Break		
5:20–6:20 PM CST CONCURRENT BREAKOUT SESSIONS	501 Self-Disclosure Protocol – Dennis Pangindian, Associate Counsel, HHS, Office of Inspector General; Tony Maida, Partner, McDermott Will & Emery	502 The Secret Sauce for Complying with Privacy Regulations – Karen Snyder, Director, Healthcare & Life Sciences Channels & Solutions, Iron Mountain; Darrell Contreras, Chief Compliance Officer, Millennium Health	503 Encryption: Policy to Practice, Lower Risk, Increase Compliance! – Uday Ali Pabrai, CEO, ecfirst

Schedule at a glance

All times listed are in Central Standard Time (CST)

Tuesday, November 17

8:55–9:00 AM CST	Opening Remarks		
9:00–10:00 AM CST	General Session: CMS Update – Kim Brandt, Principal Deputy Administrator, CMS		
10:00–10:15 AM CST	Break		
10:15–11:15 AM CST CONCURRENT BREAKOUT SESSIONS	601 Negotiating CIAs: What's New, What's Different, What Do You Need to Know? – Mary Findley, Senior Director, Alvarez & Marsal Healthcare Industry Group; Felicia Heimer, Senior Counsel, HHS - OIG	602 Civil and Criminal Telehealth Enforcement Matters; DME, Pharmaceutical and Other Covered Items and Services – Jason Mehta, Partner, Bradley Arant Boulton Cummings; Colin Huntley, Deputy Director, U.S. DOJ	603 Understanding and Preserving Privilege During Compliance Investigations – Anna Grizzle, Partner, Bass, Berry & Sims PLC; Aleah Schutze, Of Counsel, Steptoe & Johnson PLLC; LeToia Crozier, Chief Compliance Officer, naviHealth
11:15–11:30 AM CST	Break		
11:30 AM–12:30 PM CST CONCURRENT BREAKOUT SESSIONS	701 Laboratory Enforcement and Compliance – Andrea Treese Berlin, Senior Counsel, HHS, Office of Inspector General; Brandy Frey, Chief Compliance and Privacy Officer, Health Network Laboratories; Ryan Stumphauzer, Partner, Stumphauzer Foslid Sloman Ross & Kolay	702 340 B Compliance – Cindy K. Bartlett, VP Chief Compliance Officer, St. Charles Health System; Barbara Williams, Partner, Powers Pyles Sutter & Verville	703 Three Competing Perspectives on Federal Healthcare Enforcement Trends: Federal Prosecutor, In-House Counsel, Outside Counsel – Scott McBride, Partner, Lowenstein Sandler, LLP; Bernard Cooney, Assistant United States Attorney, Office of the United States Attorney, District of New Jersey; Joseph Mack, Senior Compliance Counsel, Bayer U.S.
12:30–1:15 PM CST	Mid-Conference Break		
1:15–1:20 PM CST	Opening Remarks		
1:20–2:20 PM CST	General Session: DOJ's Consumer Protection Branch: Safeguarding Americans from Dangerous Drugs and Devices – Gustav Eyler, Director, Consumer Protection Branch, U.S. Department of Justice		
2:20–2:35 PM CST	Break		
2:35–3:35 PM CST CONCURRENT BREAKOUT SESSIONS	801 Get 'Em Where it Hurts: Using Compensation to Influence Compliance – Steve Schoenly, Asst Vice President, University of Miami Health System; Alyssa Lawrence, Senior Director, UHealth Compliance, University of Miami Health System	802 Enforcement and Compliance Risks Associated with the Opioid Crisis: Who's to Blame Will Cast a Wide Net – Natalie A. Waites, Assistant Director - Fraud Section, Civil Division, US Department of Justice; Robert G. Trusiak, Compliance Officer, Catholic Charities Diocese of Rochester	803 Ask the Stark Professionals – Charles Oppenheim, Partner, Hooper Lundy Bookman, PC; Lester Perling, Partner, Nelson Mullins Broad and Cassel; Robert Wade, Partner, Barnes & Thornburg LLP
3:35–3:50 PM CST	Break		
3:50–4:50 PM CST CONCURRENT BREAKOUT SESSIONS	901 CMS Oversight and Enforcement of Safety and Quality Standards – Peter Urbanowicz, Managing Director, Alvarez & Marsal; David Wright, Director, Quality and Safety Oversight Group, CMS	902 Big Data: How Can It Be Shared and What Are the Considerations Regarding Enforcement? – Marti Arvin, Executive Advisor, CynergisTek, Inc; - Blaine Kerr, Sr. Director of Security and Privacy Compliance, Ensemble Health Partners	903 Hot OIG Target Area: Device Reporting & Related Outlier – Michael Calahan, PA, MBA, Vice President of Hospital & Physician Compliance, HealthCare Consulting Solutions (HCS)
5:00–6:00 PM CST	Virtual Social Event		

Schedule at a glance

All times listed are in Central Standard Time (CST)

Wednesday, November 18

9:00–10:30 AM CST CONCURRENT BREAKOUT SESSIONS	W1 Compliance, Internal Investigations and Self Disclosure: Building the Team, Process, and Resolution – Gabriel Imperato, Managing Partner, Nelson Mullins Broad and Cassel; Nancy Hayt, VP, Corporate Responsibility, AdventHealth	W2 Medical Necessity and Civil and Criminal Liability – Judy Ringholz, VP of Compliance and Ethics & Chief Compliance Officer, Jackson Health System; Jeff Dickstein, Partner, Phillips & Cohen LLP; Brian Bewley, Partner-Life Sciences and Healthcare, Goodwin Procter LLP; Alison Rousseau, Senior Trial Counsel for Health Care Fraud, U.S. DOJ	W3 Electronic Health Records Fraud Enforcement: What, Why, and Thoughts for Compliance Professionals – Ryan O’Quinn, Partner, Chair, Miami Litigation Practice, DLA Piper LLP; Joshua A. Boxer, General Counsel, Chief Compliance Officer, Integra Connect; Karen Stewart, Surveillance Program Manager, Drummond Group (ONC-ACB)
10:30–10:45 AM CST	Break		
10:45 AM–12:15 PM CST CONCURRENT BREAKOUT SESSIONS	W4 Negotiating and Mediating False Claims Act Cases – Sean B. O’Connell, Counsel, Hunton Andrews Kurth LLP; Janice Symchych, Mediator/Arbitrator JAMS-Minneapolis; Marc S. Raspanti, Partner, Pietragallo Gordon Alfano Bosick & Raspanti, LLP; David Cohen, Senior Trial Counsel, U.S. DOJ	W5 Compliance Officers, General Counsel and Enforcement – Mara Senn, Director and Senior Counsel of Global Compliance Investigations, Zimmer Biomet; Jeff Hessekiel, Executive Vice President and General Counsel, Exelixis Pharma; Kirk Ogrosky, Partner, Arnold & Porter LLP	W6 Data Analytics and AI to Detect and Defend Fraud – Samantha B. Badlam, Counsel, Ropes & Gray LLP; Emily Treanor, Enterprise Relationship Executive, Lextegrity
12:15–1:00 PM CST	Mid-Conference Break		
1:00–2:30 PM CST CONCURRENT BREAKOUT SESSIONS	W7 Anatomy of a False Claims Act Case – Gabriel Imperato, Managing Partner, Nelson Mullins Broad and Cassel (Moderator); Sean O’Connell, Counsel, Hunton Andrews Kurth; Michael Morse, Partner, Pietragallo Gordon Alfano Bosick; Lisa Re, Assistant Inspector General for Legal Affairs, HHS, Office of Inspector General; Arthur Di Dio, Senior Trial Counsel, U.S. DOJ	W8 Medicaid Fraud Enforcement Update – Jack Wenik, Partner, Epstein Becker & Green PC; Josh Lichtblau, Director, Medicaid Fraud Division, NJ Comptroller’s Office	W9 Litigating a False Claims Act Case – Scott Grubman, Attorney, Chilivis, Grubman, Dalbey & Warner, LLP; Linda McMahon, Senior Trial Counsel, U.S. DOJ
2:30–2:45 PM CST	Break		
2:45–4:15 PM CST CONCURRENT BREAKOUT SESSIONS	W10 CIAs and IROs: What Are They and Why Do They Matter? – Bert F. Lacativo, Sr Managing Director, GlassRatner Advisory & Capital Group LLC; Steve Ortquist, Founder & Principal, Arete Compliance Solutions, LLC; Laura Ellis, Senior Counsel, HHS, Office of Inspector General	W11 Is your Conflicts of Interest Program Effective? – Julie Hamilton, Managing Director, Deloitte & Touche LLP; Debra Berns, Senior Vice President and Chief Risk Officer, Memorial Sloan Kettering Cancer Center; Colleen Curran, JD, Managing Director, Alvarez & Marsal Healthcare Industry Group	W12 Understanding the Components of a Comprehensive Compliance Risk Assessment Process – Anne Daly, Chief Compliance & Integrity Officer, Children’s Hospital of Chicago Medical Center; Tom Herrmann, Managing Senior Consultant, Strategic Management Services
4:15–4:30 PM CST	Break		
4:30–6:00 PM CST CONCURRENT BREAKOUT SESSIONS	W13 DOJ Updated Guidance: June 2020 – Judy Ringholz, VP of Compliance and Ethics & Chief Compliance Officer, Jackson Health System; Sally Molly (invited), Chief, Strat, Policy/Training Unit, U.S. DOJ Criminal Division, Fraud	W14 Handling a Criminal Healthcare Fraud Case – Ralph Caccia, Partner, Wiley Rein LLP	W15 Root Cause Analysis Workshop – Dwight Claustre, Retired Compliance Professional; Rosalind Cordini, Senior Vice President/Director of Compliance Services, Coker Group

Agenda

All times listed are in Central Standard Time (CST)

MONDAY, NOVEMBER 16

8:50 – 9:00 AM CST

Opening Remarks

9:00 – 10:15 AM CST

General Session: Government Enforcement Panel

KIRK OGROSKY, Partner,
Arnold & Porter LLP (Moderator)

GREG DEMSKE, Chief Counsel to
the Inspector General, HHS Office
of Inspector General

ALLAN MEDINA, Chief of the Department
of Justice, U.S. Department of Justice,
Health Care Fraud Unit, Criminal Division

JAMIE ANN YAVELBERG,
Director, U.S. DOJ

10:15 – 10:30 AM CST

Break

10:30 – 11:30 AM CST

CONCURRENT BREAKOUT SESSIONS

101 HHS' Regulatory Sprint to Coordinate Care

LEVEL: INTERMEDIATE

BEN WALLFISCH, Senior Counsel, Office
of Counsel to the Inspector General, HHS

To the extent HHS publishes any
Regulatory Sprint final rules before the
conference, OIG and CMS representatives
will discuss the Regulatory Sprint to
Coordinated Care and the provisions of
any final rule, including:

- The legal and policy drivers of the
Regulatory Sprint to Coordinated Care
- Overview of the provisions of any final
rules

102 False Claims Act Liability in Post-Acute Care

LEVEL: BASIC

CLAUDIA E. REINGRUBER, Shareholder,
Saltmarsh, Cleaveland & Gund

TAMAR ABELL, CEO, TBA Compliance

WILLIAM T. MATHIAS, Co-Chair
Health Law Group and Fraud and
Abuse Team, Baker Donelson

- A review of recent False Claims Act
cases, both civil and criminal, and
current enforcement focus areas in
Medicare for SNF, home health and
hospice providers
- Challenges facing post-acute providers,
including those associated with new
payments systems and regulatory
requirements, and new claim audit
initiatives
- Current enforcement trends, including
potential liability for providers and
management, sources of data to manage
risk, expectations from CMS that
providers have effective compliance
programs, and enhanced focus on
"worthless care" concerns

103 Preventing Enforcement Actions in Clinical Research: Operational Strategies for Avoiding Financial Frauds

LEVEL: ADVANCED

KATE COHEN, Executive Director
of Compliance/Chief Compliance
Officer, SIU Medicine

SARAH COUTURE, Managing
Director, Ankura

- Billing errors in Clinical Research can
and have resulted in large settlements
arising from False Claims Act violations
- Accurate billing for research activities
is dependent on an multi-step
process involving numerous players,
departments, and functions. Breakdowns
at any point in the process can result in
large fines, settlements, and CIAs
- This presentation will show how
successful clinical research billing (CRB)
revolves around ensuring your clinical
research operations team is effectively
communicating and that the rules are
properly interpreted and applied

11:30 – 11:45 AM CST

Break

11:45 AM – 12:45 PM CST

CONCURRENT BREAKOUT SESSIONS

201 Managed Care Enforcement and Compliance

LEVEL: BASIC

BEN SINGER, Partner,
O'Melveny & Myers LLP

BARBARA FONTE, Vice President
of Managed Care and Population
Health, Jackson Health System

SARAH KESSLER, Senior Counsel, HHS-OIG

PAMELA C. BRECHT, Partner, Pietragallo
Gordon Alfano Bosick & Raspanti, LLP

202 How OIG Uses Data in its Affirmative Cases & How Data Can be Incorporated into Compliance

LEVEL: INTERMEDIATE

GEOFFREY HYMANS, Senior Counsel,
Office of Inspector General,
US Health and Human Services

BARRY GROSSE, Chief Compliance Officer,
University of Miami Health System

- Learn how the OIG uses data to develop
affirmative Civil Monetary Penalties Law
and Exclusion cases
- Learn how data can be used in
unorthodox ways, such as to prove
knowledge, or in quality-of-care cases
- Learn how both large and small entities
can incorporate data analysis into their
compliance programs

Agenda

All times listed are in Central Standard Time (CST)

203 The Myth(s) of Median to 75th: New Perspectives on Assessing, Managing and Monitoring Physician Compensation Arrangement Risk

LEVEL: INTERMEDIATE

JAMES G. SHEEHAN, Chief, Charities Bureau, NY Attorney General

HEATHER L. FIELDS, Shareholder, Chair - Hospital/Health Systems Practice, Reinhart Boerner Van Deuren s.c.

ADAM KLEIN, Principal, ECG Management Consultants

- Impact of USA ex rel. Bookwalter v. UPMC 938 F.3d 397 (3d Cir. December 20, 2019) the new Stark burden of proof is on the hospital
- Lessons from litigated cases about improving your organization's physician compensation arrangement risk assessment process and strategies and resources for identifying and managing outlier arrangements at an enterprise level
- Innovative, lower cost, and more effective risk management alternatives for determining and monitoring FMV and commercial reasonableness, including tips for mitigating risks inherent in relying on survey data and "independent" FMV reviews

12:45 – 1:30 PM CST

Mid-Conference Break

1:30 – 1:35 PM CST

Opening Remarks

1:35 – 2:35 PM CST

General Session: Whistleblowers: Who Are They, Why Do They Bring Cases, and What Makes a Good Whistleblower Case

JEB WHITE, President & CEO, Taxpayers Against Fraud Education (Moderator)

SUSAN GOUINLOCK, Senior Partner, Wilbanks & Gouinlock LLP

ANDY STONE, Partner, Stone Law Firm LLC

SARAH "POPPY" ALEXANDER, Associate, Constantine Cannon LLP

2:35 – 2:50 PM CST

Break

2:50 – 3:50 PM CST

CONCURRENT BREAKOUT SESSIONS

301 Federal Administrative Sanctions

LEVEL: BASIC

JENNIFER LEONARDIS, Senior Counsel, HHS, Office of Inspector General

JULIE E. KASS, Shareholder, Baker Donelson

302 Compliance Session TBA

LEVEL: TBA

303 Lessons Learned from Stark Investigations

LEVEL: ADVANCED

DAVID GLASER, Shareholder, Fredrikson & Byron PA

MATTHEW KRUEGER, United States Attorney, Eastern District of Wisconsin

- A U.S. attorney and defense lawyer discuss how cooperation between the government and defendants can lower the cost of an investigation
- Analysis of Stark's complexities, including how regulatory definitions can undermine arguments for both parties
- Exploration of the limitations in salary survey data and why it can be difficult to evaluate fair market value compensation

3:50 – 4:05 PM CST

Break

4:05 – 5:05 PM CST

CONCURRENT BREAKOUT SESSIONS

401 Enforcement and Compliance for Pharmacies

LEVEL: BASIC

JENNIFER KRUSA, Chief Compliance Officer, PharmScript

DANIEL MEIER, Healthcare Regulatory and Transactional Attorney, Benesch Friedlander Coplan & Aronoff

JOSH LICHTBLAU, Director, Medicaid Fraud Division, NJ Comptroller's Office

- Medicaid Enforcement Behind the Scenes: Identifying a healthcare provider/supplier with a focus on comparing claims, data mining and oddities
- Pharmacy's Response: How to prepare for a state Medicaid review/audit, seek guidance and address the issues
- Resolution: Counsel's role in considering options such as paybacks to MACs, use of the self-disclosure protocol or proceeding to litigation after appeals are exhausted, including discussion about cases and documentation

402 Why Whistleblowers Matter to Healthcare Compliance

LEVEL: INTERMEDIATE

EDWARD BAKER, Counsel, Constantine Cannon LLP

SANDRA MILLER, Attorney, Wombile Bond Dickinson (US) LLP

- In light of recent research suggesting that companies with robust internal reporting systems are more profitable, and have lower litigation costs, than those that do not, what is the best way to handle whistleblower complaints to minimize risk?
- What is the process by which whistleblower complaints are filed, investigated, and litigated by the government?
- Strategies and best practice techniques to evaluate, litigate, and settle FCA qui tam complaints

403 Trends and Best Practices in Healthcare Privacy and Security Investigations

LEVEL: INTERMEDIATE

TIMOTHY NOONAN, Deputy Director, Health Information Privacy Division, U.S. Department of Health and Human Services Office for Civil Rights

JONATHAN SKRMETTI, Chief Deputy Attorney General, Office of Tennessee Attorney General

BRIAN STIMSON, Principal Deputy General Counsel, U.S. Department of Health and Human Services

- Trends in management and reporting of health information privacy and security incidents
- Emerging federal and state enforcement priorities regarding health information privacy and security
- Best practices for regulated entities involved in health information privacy or security investigations

5:05 – 5:20 PM CST

Break

5:20 – 6:20 PM CST

CONCURRENT BREAKOUT SESSIONS

501 Self-Disclosure Protocol

LEVEL: BASIC

DENNIS PANGINDIAN, Associate Counsel, HHS, Office of Inspector General

TONY MAIDA, Partner, McDermott Will & Emery

- Understanding the landscape:
 - 60 Day Overpayment Rule
 - The Civil Money Penalties Law (CMPL)
- Deciding whether to disclose and where to disclose
- Resolutions under OIG's Self-Disclosure Protocol

502 The Secret Sauce for Complying with Privacy Regulations

LEVEL: INTERMEDIATE

KAREN SNYDER, Director, Healthcare & Life Sciences Channels & Solutions, Iron Mountain

DARRELL CONTRERAS, Chief Compliance Officer, Millennium Health

- Privacy is more of a priority than ever. Organizations must be able to react and respond quickly to increasing consumer privacy concerns, data breaches, and heavy-hitting regulations such as the CCPA and GDPR
- The key to a successful privacy program is instituting an information lifecycle management (ILM) program that provides strong governance rooted in policy. This protects your organization from compliance risks and is vital to protecting patient privacy
- Join us to discuss the impact of today's privacy regulations and learn how ILM enables you to secure a unified view of patient data and related obligations, dispose of PHI in accordance with retention requirements, and reduce exposure to data breaches

503 Encryption: Policy to Practice, Lower Risk, Increase Compliance!

LEVEL: INTERMEDIATE

UDAY ALI PABRAI, CEO, ecfirst

- Examine encryption mandates defined in HIPAA Security, HITECH Act, PCI DSS, state regulations and more
- Review specific areas that encryption can have a significant impact in lowering enterprise risk, while improving compliance posture
- Step through core elements of an encryption policy to address both at-rest and in-motion requirements and understand how to simplify the use of encryption in your organization and do so consistently

Agenda

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**TUESDAY,
NOVEMBER 17**

8:55 – 9:00 AM CST

Opening Remarks

9:00 – 10:00 AM CST

General Session: CMS Update

KIM BRANDT, Principal Deputy
Administrator, CMS

10:00 – 10:15 AM CST

Break

10:15 – 11:15 AM CST

CONCURRENT BREAKOUT SESSIONS

601 Negotiating CIAs: What's New, What's Different, What Do You Need to Know?

LEVEL: INTERMEDIATE

MARY FINDLEY, Senior Director, Alvarez
& Marsal Healthcare Industry Group

FELICIA HEIMER, Senior Counsel, HHS - OIG

- New provisions and requirements in the CIA
- Provisions OIG is willing to negotiate
- Top 10 FAQs

602 Civil and Criminal Telehealth Enforcement Matters; DME, Pharmaceutical and Other Covered Items and Services

LEVEL: INTERMEDIATE

JASON MEHTA, Partner, Bradley
Arant Boult Cummings

COLIN HUNTLEY,
Deputy Director, U.S. DOJ

- Understand the risks and opportunities associated with telemedicine
- Understand the government's increasing focus of telemedicine-related cases and what is to come
- Understand the contours of telemedicine's rules and how Medicare's reimbursement paradigms have changed with COVID

603 Understanding and Preserving Privilege During Compliance Investigations

LEVEL: INTERMEDIATE

ANNA GRIZZLE, Partner,
Bass, Berry & Sims PLC

ALEAH SCHUTZE, Of Counsel,
Step toe & Johnson PLLC

LETOIA CROZIER, Chief Compliance
Officer, naviHealth

- Compliance professionals periodically discover regulatory violations while undertaking their compliance duties. It is extremely important that compliance professionals work closely with their organization's legal department when such matters arise
- This presentation will discuss the various types of privilege and will help compliance professionals identify when and how they should involve their organization's legal department in an investigation in order to establish and maintain privilege
- We will provide specific examples and practical advice regarding how to communicate information within an organization, while still maintaining privilege

11:15 – 11:30 AM CST

Break

11:30 AM – 12:30 PM CST

CONCURRENT BREAKOUT SESSIONS

701 Laboratory Enforcement and Compliance

LEVEL: BASIC

ANDREA TREESE BERLIN, Senior Counsel,
HHS, Office of Inspector General

BRANDY FREY, Chief Compliance and
Privacy Officer, Health Network Laboratories

RYAN STUMPHAUZER, Partner,
Stumphauzer Foslid Sloman Ross & Kolay

- Recent case studies, with a discussion of what those cases tell us about risks related to medical necessity and arrangements
- Practical solutions and best practices for mitigating risk
- Updates on the Eliminating Kickbacks in Recovery Act

702 340 B Compliance

LEVEL: INTERMEDIATE

CINDY K. BARTLETT, VP Chief Compliance
Officer, St. Charles Health System

BARBARA WILLIAMS, Partner,
Powers Pyles Sutter & Verville

- Understand significant 340B program requirements and need for a robust 340B compliance program
- Obtain practical advice on implementing a 340B compliance program and key issues to target
- Hear 340B experts' views on hot topics in the 340B program

703 Three Competing Perspectives on Federal Healthcare Enforcement Trends: Federal Prosecutor, In-House Counsel, Outside Counsel

LEVEL: ADVANCED

SCOTT MCBRIDE, Partner,
Lowenstein Sandler, LLP

BERNARD COONEY, Assistant United
States Attorney, Office of the United
States Attorney, District of New Jersey

JOSEPH MACK, Senior Compliance
Counsel, Bayer U.S

- The panel will discuss current enforcement trends in the federal health care arena. Topics will include recent enforcement cases involving the False Claims Act, speaker programs, and the Anti-Kickback Statute
- The panel will discuss how the recent election may influence Department of Justice priorities and trends in healthcare enforcement
- The panel will discuss how in-house attorneys and compliance professionals can help their business leaders understand areas of enforcement and give practical tips on how best to partner with internal stakeholders in this regard

12:30 – 1:15 PM CST

Mid-Conference Break

1:15 – 1:20 PM CST

Opening Remarks

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All times listed are in Central Standard Time (CST)

1:20 – 2:20 PM CST

General Session: DOJ's Consumer Protection Branch: Safeguarding Americans from Dangerous Drugs and Devices

GUSTAV EYLER, Director,
Consumer Protection Branch,
U.S. Department of Justice

2:20 – 2:35 PM CST

Break

2:35 – 3:35 PM CST

CONCURRENT BREAKOUT SESSIONS

801 Get 'Em Where it Hurts: Using Compensation to Influence Compliance

LEVEL: BASIC

STEVE SCHOENLY, Asst Vice President,
University of Miami Health System

ALYSSA LAWRENCE, Senior Director,
UHealth Compliance, University
of Miami Health System

- Carrot or the stick: determining reward or consequence shapes human behavior
- Governance impacts ability: how compliance can work with management to achieve goals
- Money talks: if you can equate compliance with compensation, you're in the gold

802 Enforcement and Compliance Risks Associated with the Opioid Crisis: Who's to Blame Will Cast a Wide Net

LEVEL: INTERMEDIATE

NATALIE A. WAITES, Assistant
Director – Fraud Section, Civil Division,
US Department of Justice

ROBERT G. TRUSIAK, Compliance Officer,
Catholic Charities Diocese of Rochester

- How do compliance professionals manage, and not overmanage, mismanage or not manage the crisis
- Government and responses to the opioid crisis
- Next steps for tomorrow morning

803 Ask the Stark Professionals

LEVEL: ADVANCED

CHARLES OPPENHEIM, Partner,
Hooper Lundy Bookman, PC

LESTER PERLING, Partner, Nelson
Mullins Broad and Cassel

ROBERT WADE, Partner,
Barnes & Thornburg LLP

- Brief overview of the Stark Law
- Respond to pre-submitted & live questions regarding case examples of the application of the Stark Law
- Opportunity for an open discussion for compliance officers, lawyers, and executives who have questions related to the Stark Law

3:35 – 3:50 PM CST

Break

3:50 – 4:50 PM CST

CONCURRENT BREAKOUT SESSIONS

901 CMS Oversight and Enforcement of Safety and Quality Standards

LEVEL: INTERMEDIATE

PETER URBANOWICZ, Managing
Director, Alvarez & Marsal

DAVID WRIGHT, Director, Quality and
Safety Oversight Group, CMS

- Learn how CMS is enhancing its oversight activities, including oversight of State Survey Agencies and accrediting organizations, in order to fulfill its critical obligation to develop and enforce essential standards for safety and quality
- Measures providers can implement to recognize and address quality and safety deficiencies to avoid increased survey activity and enforcement actions
- If a CMS survey is inevitable, learn how to prepare for and what to expect during the visit and how to best respond to CMS requests and findings

902 Big Data: How Can It Be Shared and What Are the Considerations Regarding Enforcement?

LEVEL: INTERMEDIATE

MARTI ARVIN, Executive
Advisor, CynergisTek, Inc

BLAINE KERR, Sr. Director of
Security and Privacy Compliance,
Ensemble Health Partners

- Brief primer on the way in which individually identifiable information can be shared with regulatory parameters, both federal and state
- Discussion of considerations when evaluating the sharing of big data sets with third parties for healthcare operations and/or research
- Overview of the enforcement trends: Where it has been, where it is going, consumer privacy concerns, class actions and more

903 Hot OIG Target Area: Device Reporting & Related Outlier

LEVEL: TBA

MICHAEL CALAHAN, PA, MBA,
Vice President of Hospital &
Physician Compliance, HealthCare
Consulting Solutions (HCS)

- Review the newest OIG-favored target area for hospital audits and learn the 2020 rules & regulations as well as Medicare Program changes for medical device credit reporting
- Hospital Inpatient, Hospital Outpatient and ASC: Do you know how to identify which devices get reported when a credit is received? Do you know how to correctly report the credits in each of these settings
- Clouding the picture for accurate reporting: Newly invigorated OIG audits with a specific target of APC outlier payments related to medical device credits-do you know if you are receiving additional outlier payments

4:50 – 5:00 PM CST

Break

5:00 – 6:00 PM CST

Virtual Social Event

WEDNESDAY, NOVEMBER 18

9:00 – 10:30 AM CST

CONCURRENT BREAKOUT SESSIONS

W1 Compliance, Internal Investigations and Self Disclosure: Building the Team, Process, and Resolution

LEVEL: ADVANCED

GABRIEL IMPERATO, Managing Partner, Nelson Mullins Broad and Cassel

NANCY HAYT, VP, Corporate Responsibility, AdventHealth

- Identifying potential non-compliance through an effective compliance program
- Organizational governance and internal investigations; authority and practical considerations
- Methodology for internal investigations; establishment, personnel and resources, probable cause and preponderance of evidence, privilege, and findings of fact
- Practical tips; investigation workplan, conducting interviews, collecting documents and e-data, establishing facts and final report
- Resolution; remedial action and self-disclosure and managing the risk
- Compliance professionals and best practices

W2 Medical Necessity and Civil and Criminal Liability

LEVEL: INTERMEDIATE

JUDY RINGHOLZ, VP of Compliance and Ethics & Chief Compliance Officer, Jackson Health System

JEFF DICKSTEIN, Partner, Phillips & Cohen LLP

BRIAN BEWLEY, Partner-Life Sciences and Healthcare, Goodwin Procter LLP

ALISON ROUSSEAU, Senior Trial Counsel for Health Care Fraud, U.S. DOJ

- Medical necessity cases are very much alive in the FCA world, though the environment is ever-changing. This panel, consisting of an attorney in DOJ's Civil Division, a health system chief compliance officer, defense counsel and relator's counsel will examine the evolving landscape
- We will consider the primary legal issues involved in medical necessity cases, recent relevant court rulings, as well as the regulations typically in play in common questions of medical necessity
- We will discuss when fraudulent conduct becomes criminal conduct in cases alleging medically unnecessary testing and/or procedures
- Do robust compliance measures prevent medical necessity cases, do aggressive defense tactics head them off, we will examine the effect of compliance and defense strategy on DOJ investigations of allegations of lack of medical necessity

W3 Electronic Health Records Fraud Enforcement: What, Why, and Thoughts for Compliance Professionals

LEVEL: INTERMEDIATE

RYAN O'QUINN, Partner, Chair, Miami Litigation Practice, DLA Piper LLP

JOSHUA A. BOXER, General Counsel, Chief Compliance Officer, Integra Connect

KAREN STEWART, Surveillance Program Manager, Drummond Group (ONC-ACB)

- Overview of government enforcement actions related to EHR providers. A new era in enforcement: software meets false claims
- Accreditation and ongoing compliance obligations related to EHR providers and those providers who use them for incentive reporting
- Proactive measure for compliance professionals to prevent and mitigate exposure

10:30 – 10:45 AM CST

Break

Agenda

All times listed are in Central Standard Time (CST)

10:45 AM – 12:15 PM CST

CONCURRENT BREAKOUT SESSIONS

W4 Negotiating and Mediating False Claims Act Cases

LEVEL: ADVANCED

SEAN B. O'CONNELL, Counsel, Hunton Andrews Kurth LLP

JANICE SYMCHYCH, Mediator/Arbitrator JAMS-Minneapolis

MARC S. RASPANTI, Partner, Pietragallo Gordon Alfano Bosick & Raspanti, LLP

DAVID COHEN, Senior Trial Counsel, U.S. DOJ

- The increased difficulties in negotiating and settling False Claims Act cases
- Understanding the roles of the different stakeholders in False Claims Act cases and what they're entitled to
- Understanding the risks of going to trial and why it may be the best option

W5 Compliance Officers, General Counsel and Enforcement

LEVEL: TBA

MARA SENN, Director and Senior Counsel of Global Compliance Investigations, Zimmer Biomet

JEFF HESSEKIEL, Executive Vice President and General Counsel, Exelixis Pharma

KIRK OGROSKY, Partner, Arnold & Porter LLP

W6 Data Analytics and AI to Detect and Defend Fraud

LEVEL: INTERMEDIATE

SAMANTHA B. BADLAM, Counsel, Ropes & Gray LLP

EMILY TREANOR, Enterprise Relationship Executive, Lextegrity

- Kickbacks and fraud can hide in dark corners of your organization. Data analytics and AI can provide powerful tools to prevent and detect such behaviors. Join an interactive panel using sample data and visualizations
- Learn from a former in-house compliance counsel and current outside counsel with enforcement expertise about how data analytics and AI can transform the risk management efforts of healthcare organizations of any size
- Learn how shifting expectations of government agencies mean that not using data analytics and AI to prevent and detect kickback and fraud risks is no longer a viable option for healthcare organizations

12:15 – 1:00 PM CST

Mid-Conference Break

1:00 – 2:30 PM CST

CONCURRENT BREAKOUT SESSIONS

W7 Anatomy of a False Claims Act Case

LEVEL: INTERMEDIATE

GABRIEL IMPERATO, Managing Partner, Nelson Mullins Broad and Cassel (Moderator)

SEAN O'CONNELL, Counsel, Hunton Andrews Kurth

MICHAEL MORSE, Partner, Pietragallo Gordon Alfano Bosick

LISA RE, Assistant Inspector General for Legal Affairs, HHS, Office of Inspector General

ARTHUR DI DIO, Senior Trial Counsel, U.S. DOJ

- The Investigation Phase: subpoenas/ CIDs, data analysis, witness interviews and more
- The Negotiation Phase: initiation, ADR, scope of release, monetary and other issues
- The Resolution Phase: settlement agreements, individual liability, CIAs/ OIG and relator issues

W8 Medicaid Fraud Enforcement Update

LEVEL: BASIC

JACK WENIK, Partner, Epstein Becker & Green PC

JOSH LICHTBLAU, Director, Medicaid Fraud Division, NJ Comptroller's Office

- Recent developments in Medicaid fraud/ abuse enforcement at the state level, including regarding managed care organizations
- Focus on home health, adult day care and other providers receiving extra scrutiny
- Government and defense perspectives in responding to Medicaid fraud and abuse investigations

Agenda

All times listed are in Central Standard Time (CST)

W9 Litigating a False Claims Act Case

LEVEL: ADVANCED

SCOTT GRUBMAN, Attorney, Chilivis, Grubman, Dalbey & Warner, LLP

LINDA MCMAHON, Senior Trial Counsel, U.S. DOJ

- Define and discuss key provisions of the False Claims Act that regularly get litigated
- Identify emerging issues that often arise during FCA litigation
- Learn strategies for maximizing discovery in FCA cases

2:30 – 2:45 PM CST

Break

2:45 – 4:15 PM CST

CONCURRENT BREAKOUT SESSIONS

W10 CIAs and IROs: What Are They and Why Do They Matter?

LEVEL: INTERMEDIATE

BERT F. LACATIVO, Sr Managing Director, GlassRatner Advisory & Capital Group LLC

STEVE ORTQUIST, Founder & Principal, Arete Compliance Solutions, LLC

LAURA ELLIS, Senior Counsel, HHS, Office of Inspector General

- An introduction to Corporate Integrity Agreements (CIAs) and the requirement for the settling organization to engage an Independent Review Organization (IRO)
- Receive an overview of who can become an IRO along with a discussion of the IRO function
- Learn how an IRO interfaces with the organization, its expectations and reporting responsibilities

W11 Is your Conflicts of Interest Program Effective?

LEVEL: INTERMEDIATE

JULIE HAMILTON, Managing Director, Deloitte & Touche LLP

DEBRA BERNIS, Senior Vice President and Chief Risk Officer, Memorial Sloan Kettering Cancer Center

COLLEEN CURRAN, JD, Managing Director, Alvarez & Marsal Healthcare Industry Group

- Highlights of regulatory and enforcement activity related to conflicts of interest (COI)
- Components of an effective COI program
- Lessons learned and tactical steps for assessment and enhancement of COI programs

W12 Understanding the Components of a Comprehensive Compliance Risk Assessment Process

LEVEL: INTERMEDIATE

ANNE DALY, Chief Compliance & Integrity Officer, Children's Hospital of Chicago Medical Center

TOM HERRMANN, Managing Senior Consultant, Strategic Management Services

- Review the importance of risk assessment in health care compliance, including an overview of historical and recently published health care regulator guidance and enforcement (DOJ, OIG, OCR etc.)
- Outline and discuss the core components for a credible compliance risk assessment process
- Elaborate on processes, tips, and best practices for implementing and supporting compliance risk identification and mitigation

4:15 – 4:30 PM CST

Break

4:30 – 6:00 PM CST

CONCURRENT BREAKOUT SESSIONS

W13 DOJ Updated Guidance: June 2020

LEVEL: INTERMEDIATE

JUDY RINGHOLZ, VP of Compliance and Ethics & Chief Compliance Officer, Jackson Health System

SALLY MOLLY (INVITED), Chief, Strat, Policy/Training Unit, U.S. DOJ Criminal Division, Fraud

W14 Handling a Criminal Healthcare Fraud Case

LEVEL: ADVANCED

RALPH CACCIA, Partner, Wiley Rein LLP

W15 Root Cause Analysis Workshop

LEVEL: INTERMEDIATE

DWIGHT CLAUSTRE, Retired Compliance Professional

ROSALIND CORDINI, Senior Vice President/Director of Compliance Services, Coker Group

- Participants will review and understand the Department of Justice's 2017 guidance pertaining to the performance of root cause analyses
- Participants will understand the root cause analysis structure and purpose
- Participants will perform a root cause analysis pertaining to a [mock] serious compliance issue to learn skills for the performance of a root cause analysis in their institutions/organizations

Healthcare Enforcement Compliance Conference

November 16–18, 2020 • VIRTUAL CONFERENCE

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Wednesday | 9.0 CCB CEUs

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