Strafford

Presenting a live 90-minute webinar with interactive Q&A

Precision Medicine: Structuring Collaborations and Avoiding Fraud and Abuse Pitfalls

Navigating Healthcare Regulatory Issues Common in Precision Medicine Arrangements Among Hospitals, Health Systems, and Clinical Laboratories

THURSDAY, AUGUST 20, 2020

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Jonathan W. Heusel, MD, PhD, Professor, Pathology & Immunology, **Washington University**, St. Louis

Carolyn V. Metnick, Partner, **McDermott Will & Emery**, Chicago

Stacey L. Callaghan, Attorney, **McDermott Will & Emery**, Chicago

The audio portion of the conference may be accessed via the telephone or by using your computer's speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact **Customer Service at 1-800-926-7926 ext. 1**.

Tips for Optimal Quality

FOR LIVE EVENT ONLY

Sound Quality

If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.

If the sound quality is not satisfactory, you may listen via the phone: dial **1-877-447-0294** and enter your **Conference ID and PIN** when prompted. Otherwise, please **send us a chat** or e-mail **sound@straffordpub.com** immediately so we can address the problem.

If you dialed in and have any difficulties during the call, press *0 for assistance.

Viewing Quality

To maximize your screen, press the 'Full Screen' symbol located on the bottom right of the slides. To exit full screen, press the Esc button.

Continuing Education Credits

FOR LIVE EVENT ONLY

In order for us to process your continuing education credit, you must confirm your participation in this webinar by completing and submitting the Attendance Affirmation/Evaluation after the webinar.

A link to the Attendance Affirmation/Evaluation will be in the thank you email that you will receive immediately following the program.

For additional information about continuing education, call us at 1-800-926-7926 ext. 2.

Program Materials

FOR LIVE EVENT ONLY

If you have not printed the conference materials for this program, please complete the following steps:

- Click on the link to the PDF of the slides for today's program, which is located to the right of the slides, just above the Q&A box.
- The PDF will open a separate tab/window. Print the slides by clicking on the printer icon.

PRECISION MEDICINE: STRUCTURING COLLABORATIONS AND AVOID FRAUD AND ABUSE PITFALLS

Carolyn V. Metnick, Stacey L. Callaghan, & Jonathan W. Heusel, MD, PhD

August 20, 2020

mwe.com

McDermott Will & Emery

AGENDA

I. Introduction and Overview of Collaborative Arrangements

II. Fraud and Abuse Considerations

- Anti-Kickback Statute
- EKRA
- Medicare Beneficiary Inducement Statute
- Stark Law
- State Law Equivalents

III. Other Healthcare Regulatory Considerations

IV. Enforcement Activity

V. Practical Take-Aways

VI. Q&A

INTRODUCTION AND OVERVIEW OF COLLABORATIVE ARRANGEMENTS

- Precision medicine (personalized medicine) – *using information about a person's genes to prevent, diagnose or treat a particular disease*
  - Can help specific treatment for individual
- Collaborations vary:
  - Hospitals and health systems and labs
  - Hospitals and health systems and life science companies
  - Telemedicine companies
  - Direct to consumer

FRAUD AND ABUSE CONSIDERATIONS

Anti-Kickback Statute

- Criminal statute – criminal and civil penalties
- Broad understanding: payment for referrals
  - Precision medicine partnerships with referral component
    - Billing?
    - FMV?
    - Written agreement?
    - Safe harbor?

FRAUD AND ABUSE CONSIDERATIONS

Anti-Kickback Statute

- "Arranging for or recommending" component
- Marketing activities
  - OIG guidance
    - Compensation amount and structure
    - Identity of the party engaging in marketing and the party's relationship to the audience
    - Nature of the marketing
    - Item or service being marketed
    - Target audience
    - Additional safeguards

FRAUD AND ABUSE CONSIDERATIONS

EKRA

- Part of Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
- Prohibitions: similar to AKS
  - Include laboratory services
  - Covered by “health care benefit program”

FRAUD AND ABUSE CONSIDERATIONS

EKRA

- Precision medicine collaboration implications
  - Laboratory partner often involved
  - Billing activities?
  - Circumvention of FHB – need to consider EKRA

FRAUD AND ABUSE CONSIDERATIONS

Medicare Beneficiary Inducement Statute

- CMP Monetary Penalty Law
  - "Remuneration" includes waivers of co-payments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than FMV
  - Includes exceptions to "remuneration"
    - AKS safe harbor
    - Items or services that improve a beneficiary's ability to obtain items and services payable by Meidcare or Medicaid, and pose a low risk of harm to Meidcare and Madicaid beneficiaries

FRAUD AND ABUSE CONSIDERATIONS

Medicare Beneficiary Inducement Statute

- Precision medicine collaboration implications
  - Obtaining participants
  - Access considerations
  - Creates difficulties for well-intended collaborations

FRAUD AND ABUSE CONSIDERATIONS

Stark Law

- Stark Law – federal physician self-referral law
- Prohibits a physician from making referrals for designated health services (DHS) to an entity in which the referring physician (or a family member) has a financial interest unless an exception applies
- Financial interest – compensation, ownership or investment
- Applies to DHS entities that bill a federal healthcare program
- DHS includes clinical lab services, among other services
- Unlike AKS, no intent required

FRAUD AND ABUSE CONSIDERATIONS

Stark Law

- Any arrangement where a physician is making a referral for a lab service where payment is made by a federal payor to an entity with which physician (or a family member) has a financial relationship needs to be analyzed under Stark Law.
- Federal health care programs pay for very limited genetic tests:
  - Medically necessary and ordered by a Medicare beneficiary's treating physician
  - Next generation sequencing (NGS) when certain requirements met

FRAUD AND ABUSE CONSIDERATIONS

State Law Equivalents

- Most states have versions of AKS and Stark Law known as “Mini-AKS” or “Mini Stark Laws”. These laws can take very different forms but are generally modeled after the federal laws.
- Illinois Insurance Claims Fraud Prevention Act, 740 ILCS 92/1 et seq.
  - Unlike AKS, only prohibits payment or offering of remuneration rather than receiving or soliciting.
  - Intent requirement like AKS
  - Applies to all payors (not just federal healthcare programs)
- If fee paid to lab by provider ordering lab test is not FMV (less than FMV), there may be risk that that lab charged lower fee to induce referrals to lab.
  - Risk if third party payor is paying for any portion of test.
  - Intent would need to be present for violation.

FRAUD AND ABUSE CONSIDERATIONS

State Law Equivalents

- Health Care Worker Self-Referral Act, 225 ILCS 47/1
  - Modeled after Stark Law
  - Applies to “Health care workers” – not just physicians
  - Prohibits a health care worker from referring a patient for health services to an entity outside of health care worker’s office or group practice in which health care worker is investor, unless the health care worker directly provides health services within entity and will be personally be involved with provision of care.

OTHER HEALTHCARE REGULATORY CONSIDERATIONS

HIPAA

- Health Insurance Portability and Accountability Act of 1996, amendments related to the Health Information Technology for Economic and Clinical Health Act, and implementing regulations
  - Applies to healthcare providers engaging in certain electronic transactions
  - Privacy Rule establishes national standards relating to PHI
    - Patients have rights over health information
  - Security Rule establishes national standards to protect individuals' electronic PHI
    - Requires appropriate administrative, physical, and technical safeguards

OTHER HEALTHCARE REGULATORY CONSIDERATIONS

HIPAA

- Precision medicine collaboration implications
  - Storage of PHI
  - Use of PHI
  - Transparency
    - Required vs. appropriate authorizations
    - Up-front discussions with patients
    - Additional need for education – patients and providers

OTHER HEALTHCARE REGULATORY CONSIDERATIONS

Other Federal and State Privacy/Security Laws

- Genetic Information Nondiscrimination Act (GINA)
  - Prohibits discrimination in group health plan coverage based on genetic information
- State equivalents such as Illinois Genetic Information Privacy Act (GIPA), 410 ILCS 513/1 et seq.
  - Genetic testing information derived therefrom is confidential and privileged and may only be released to individual tested and persons specifically authorized in writing.
- Foreign laws with long-arm jurisdiction such as GDPR

OTHER HEALTHCARE REGULATORY CONSIDERATIONS

Anti-Markup Laws

- Anti-markup laws must be considered when a provider tries to markup a laboratory or test
- Federal Anti-Markup law
  - Prohibits mark-up of both technical component and professional component of a diagnostic test when physicians do not share a practice with the entity providing the test.
- State Anti-Markup laws
  - Illinois prohibits markup of anatomic pathology services (but does not apply to those ordered or provided by facilities licensed under the Illinois Hospital Licensing Act.
    - Illinois Medical Patient Rights Act (410 ILCS 50/3.3)

ENFORCEMENT ACTIVITY

- Recent enforcement activity in genetic testing field
  - September 2019, DOJ charged 35 individuals for schemes involving the ordering of cancer genetic screening tests
  - October 2019, DOJ announced settlement with UTC Laboratories, Inc. and 3 principals
- EKRA enforcement – Merced prosecution
- Anticipate additional enforcement activity relating to genomics arrangements

PRACTICAL TAKEAWAYS

- Existing arrangements and proposed arrangements should be reviewed by experienced health care regulatory counsel for legal compliance.
- Importance of fair market value opinions
- Importance of transparency and education

SPEAKERS

CAROLYN METNICK, McDERMOTT WILL & EMERY

Partner

Chicago

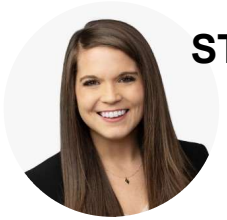
Tel +1 312 984 2170

cmetnicl@mwe.com

Carolyn V. Metnick focuses her practice on health information privacy and security. She helps covered entities and business associates develop effective policies, procedures and workforce training to comply with HIPAA and the HITECH Act. She also counsels businesses in data breach investigations and compliance with other federal and state breach notification laws, and assists businesses in responding to cyberattacks and other security breaches.

Carolyn also advises healthcare providers on transactions and business issues. She guides clients through joint ventures, mergers and acquisitions, and counsels on governance matters as well as regulatory issues. She advises on compliance with the federal fraud and abuse laws, including the Stark Law and the Anti-Kickback Statute. Carolyn's background as a former litigator helps inform her transactional work.

Carolyn serves as an adjunct instructor at the University of Illinois–Chicago, School of Public Health, Health Policy and Administration Division. She is also a Certified Information Privacy Professional/United States (CIPP/US) and a Certified Information Privacy Professional/Europe (CIPP/E).



STACEY CALLAGHAN, McDERMOTT WILL & EMERY

Associate

Chicago

Tel +1 312 984 2026

scallaghan@mwe.com

Stacey Callaghan counsels healthcare entities, healthcare technology companies, data companies, and private equity entities as they navigate transactional, regulatory, and compliance issues. She focuses on assisting clients on matters including data privacy and protection requirements under HIPAA and other privacy laws, data breach investigations and compliance, and data sharing, licensing, and de-identification arrangements. Stacey also assists clients in developing telemedicine strategies and documenting agreements given the evolving digital health regulatory landscape.

Stacey is experienced in executing healthcare transactions, and routinely guides clients through joint ventures, mergers and acquisitions and strategic collaborations. She counsels on governance matters and regulatory issues, including compliance with federal and state fraud and abuse laws.

Prior to joining McDermott, Stacey was a healthcare associate at a large US-based law firm. She is a frequent author on a variety of healthcare legal issues, primarily those issues impacting providers in the digital health space. During law school, Stacey served as the executive notes editor for the *Journal of Legislation*.

SPEAKERS

JONATHAN W. HEUSEL, MD, PHD; WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

Professor of Pathology and Immunology and Genetics

Tel +1 314 747 3887

heuselj@wustl.edu

Jonathan Heusel is an academic pathologist and physician scientist with more than 30 years' experience in molecular diagnostics, cellular and molecular immunology, and genomic medicine. Dr. Heusel is a Professor of Pathology, and of Genetics, at Washington University School of Medicine, where he serves as Director of Clinical and Translational Genomics within the Laboratory and Genomic Medicine Division of the Department of Pathology & Immunology. He also serves as Medical Director and Chief Medical Officer for the clinical next generation sequencing (NGS) laboratory, Genomics and Pathology Services (GPS@WUSTL). Dr. Heusel is certified by the American Board of Pathology in Clinical Pathology and Molecular-Genetic Pathology, with expertise in regulatory compliance for clinical molecular pathology laboratories (including NGS labs), and has been recognized for excellence as an Inspector for the College of American Pathologists. In 2016, Dr. Heusel led the consolidation of clinical cytogenetics and NGS testing services for the Pathology & Immunology Department, creating Clinical and Translational Genomics as a future-oriented environment combining clinical genomics testing operations and clinical training opportunities for pathology residents and clinical fellows in three accredited programs. In his administrative role, Dr. Heusel oversees the development and operation of clinical genomics testing in support of patient care, clinical trials and commercial contracts requiring clinical-grade testing services.

Dr. Heusel completed an undergraduate degree in Biology at the University of Nebraska, and was accepted into the Medical Scientist Training Program at Washington University in St. Louis, where graduated with his MD and a PhD in Immunology in 1995. Following a Clinical Pathology residency and a Howard Hughes Research Fellowship, he joined the Pathology Department faculty at the University of Iowa, where he pursued his research on the molecular activation of natural killer cells, developed over a dozen molecular diagnostic assays for the University of Iowa Hospitals and Clinics' Molecular Pathology laboratory, and created a broad training curriculum for residents and fellows in the areas of laboratory medicine, molecular pathology and clinical genomics.

QUESTIONS?

THANK YOU!