

# Compliance Considerations in Digital Pathology

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# Speaker

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*Emily has assisted pathology groups, clinical laboratories, hospitals, long-term acute care hospitals, community hospitals, physician specialty groups, telehealth providers, surgery centers, healthcare associations, pharmacies, and other healthcare providers on regulatory, licensing, compliance, reimbursement, contractual, and corporate matters. She also has significant experience with HIPAA compliance, including drafting HIPAA policies and procedures, breach response and notification, drafting responses to investigations conducted by the Office for Civil Rights, and advising clients on proactive HIPAA compliance and breach prevention.*

# Learning Objectives

- Understand regulatory framework for digital pathology
- Learn about common digital pathology arrangements
- Be aware of compliance risks associated with certain digital pathology models

- Stark Law

- Federal law that prohibits a physician from making referrals to an entity for certain healthcare services, if the physician has a financial relationship with the entity unless an exception applies
- In-Office Ancillary Services Exception
  - Stark law does not apply to services that (1) are performed by the referring physician, another physician in the same group practice, or an individual supervised by the referring physicians or another physician in the same group practice; (2) are performed in the same building as the referring physician or their group practice offers services or in another centralized location; and (3) are billed by the performing physician, the supervising physician, or their group practice
- Physician Services Exception
  - Services provided a) personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice as the referring physician; or b) under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services

- Anti-Kickback Statute
  - Federal criminal law that prohibits offering or accepting any form of remuneration or incentive for referrals of services or products covered by any federal health care program, such as Medicare or Medicaid
  - Safe Harbors may be available
- Anti-Markup
  - Applies to TC or PC that (i) was ordered by the billing physician or other supplier, and (ii) is performed by a physician who does not “share a practice” with the billing physician or other supplier. The payment to the billing physician or other supplier may not exceed the lowest of the following amounts:
    - The performing supplier's net charge to the billing physician or other supplier;
    - The billing physician or other supplier's actual charge; or
    - The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

- EKRA
  - Prohibits the payment of remuneration in return for referring a patient to a recovery home, clinical treatment facility or laboratory. EKRA is based on the Anti-Kickback Statute (AKS), which applies only to federally funded health insurance programs, such as Medicare and Medicaid. EKRA, however, broadly applies to any “health care benefit” program, including commercial insurance
- Fee Splitting Laws (state law and/or payor)
  - Practice of sharing fees with physicians in return for being sent referrals
- CLIA
- CAP
- PHE
  - Ending May 11, 2023 (unless terminated earlier)
  - Stark Waivers (didn't really apply to pathology services)

- Arrangement #1
  - Digital Pathology Company (“DPC”) offers digital pathology services to small hospital labs and physician-owned labs (“Facility Lab”)
  - Pathology groups partner with DPC to perform PC services pursuant to a professional services agreement with the Facility Lab
    - Slides are sent from the Facility Lab to a contracted slide production center that uses DPC’s digital pathology platform to be accessioned and placed on slides, which are then digitally imaged and transmitted back to the Facility Lab
    - A pathologist contracted by DPC then logs into the DPC platform, reviews the digital slide and renders a professional interpretation
      - Typically performed at a remote location that is not located within the hospital campus or office of the billing physicians’ Facility Lab

- Reimbursement for Arrangement #1
  - Facility Lab bills globally for the TC and PC
  - Variation:
    - Pathology Group bills globally for TC and PC and pays lab for performing TC and digitization of slide
  - However, physicians at referring physician group are given minority ownership in slide production center
    - Incentive to refer tests to Pathology Group who enters into arrangement because referring physician has financial relationship with slide production center

- Considerations for Arrangement #1
  - Stark
    - Financial relationships create risk
    - IOAS (digital vs. physical presence)
  - Anti-Markup
    - Location test may not be satisfied
    - No guidance from CMS permitting a digital arrangement in lieu of physical presence for purposes of satisfying the Anti-Markup Rule exceptions
  - False Claims Act

- Arrangement #2
  - Pathology Group signs W-2 with Pathologists who work for DPC
    - W-2 Pathologist is identified by DPC
    - W-2 Pathologist sits remotely at a non-Pathology Group practice location
    - W-2 Pathologists only work on DPC Cases
  - DPC sends specimens to Pathology Group that originate from referring physician identified by DPC
    - DPC essentially serving as Sales and Marketing Representative
  - Pathology Group processes and makes slides and scans them using DPC's whole slide imaging scanner
  - W-2 Pathologist views image and signs out case using DPC's information system

- Reimbursement for Arrangement #2
  - **Insurance cases**
    - Billed by Pathology Group
  - **Non-Insurance cases**
    - Client-billed by Pathology group monthly to DPC and DPC and/or professional practice affiliated with DPC bills the patient or sends a facility bill to the referring physician group
      - Accessioned by professional practice affiliated with DPC
      - Pathology Group performs TC only and bills professional practice affiliated with DPC at a facility bill rate
      - DPC or professional practice affiliated with DPC pay the W-2 Pathologist to read
      - Pathology Group does not bill for PC and instead the W-2 Pathologist bills DPC or professional practice affiliated with DPC for PC and W-2 Pathologist is paid per CPT

- Considerations for Arrangement #2
  - AKS
  - Fee splitting
    - Payment (or split of professional fee) by Pathology Group to DPC or professional practice affiliated with DPC in exchange for referrals to Pathology Group
    - DPC and its affiliated professional practice source work that the Pathology Group will perform and which is **work that could just be done by the professional practice affiliated with DPC**
      - ONLY reason they don't is because they don't have access to the applicable payor contract
  - EKRA
    - Essentially a pay to play sales and marketing arrangement
  - Payor Contract Risks
    - Payors may take issue because arrangement is a circumvention of payor agreement that creates access for providers who are not contracted with the payor
    - Payor may demand repayment or cancel payor contract altogether
  - Reminiscent of HOPD arrangements of prior years

- Arrangement #3
  - Digital pathology platform set up by pathology group
  - Does not include any financial arrangements with other groups
  - Solely used in connection with the group's work, and not based on an arrangement with a digital pathology company sourcing the work

- Reimbursement for Arrangement #3
  - Pathology Group bills for TC and PC of work performed
  - No split billing arrangements with any other group

- Considerations for Arrangement #3
  - Stark In Office Ancillary Services Exception
  - CAP/CLIA
  - PHE
    - Ending May 11, 2023

- Analyze ownership of digital pathology arrangement
- Analyze financial relationships and flow of referrals
- Review payor contracts
- Consult a healthcare attorney

# Questions?

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