Laboratory Compliance

AKS & EKRA

Jonathan Carr, JD

Compliance Officer

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INTRODUCTIONS

Emily Johnson, JD
Attorney at McDonald Hopkins LLC

Elizabeth Sullivan, JD
Attorney at McDonald Hopkins LLC

Emily A. Johnson

Member

Emily focuses her practice on matters primarily for clients in the healthcare industry. She provides regulatory and compliance assistance on both a federal and state level. She has assisted 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 has provided support to entities during licensure and accreditation surveys and assisted in navigating state professional licensure laws, CLIA standards and state and federal laboratory laws and regulations, government and private payor reimbursement, state and federal fraud and abuse rules, state telehealth laws, and state and federal pharmacy regulation. She also has advised clients on direct to consumer testing issues and applicable state requirements.

She also has experience with provider-based compliance issues and the 340B Federal Drug Pricing Program, including implementation, program compliance, audit preparation, and preparing for audits conducted by the Office of Pharmacy Affairs.

In addition, she 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.
Prior to joining McDonald Hopkins, Emily served as healthcare attorney/senior consultant at a national legal-based healthcare management consulting firm and outside counsel to the National Association of Boards of Pharmacy.
Emily earned a J.D. from The John Marshall Law School in 2010. She received a B.A., Dean's List, from Illinois Wesleyan University in 2005.

Elizabeth Sullivan

Member; Chair, Healthcare Practice Group

Liz is Chair of McDonald Hopkins' national Healthcare Practice Group and a member of the firm's Board of Directors. She began her legal career in the Healthcare Practice group at McDonald Hopkins and later served as an attorney in the legal department at The Cleveland Clinic Foundation before returning to McDonald Hopkins as a member.

While at the Cleveland Clinic, Liz provided regulatory advice and transactional guidance to various service lines, including the clinical laboratory, professional pathology, imaging, transplant, and remote and distance health teams. Over the course of her career, Liz has assisted various types of healthcare providers, including clinical laboratories, hospitals, physician specialty groups, telehealth providers, transplant centers, and surgery centers. Liz has experience providing regulatory, licensing, compliance, reimbursement, contractual, and corporate guidance to clients. She has advised clients on state professional licensure laws, CLIA standards, state laboratory laws, government and private payor reimbursement policies and billing rules, federal and state fraud and abuse rules and regulations, state telehealth laws, and HIPAA rules and regulations. She has provided assistance to entities during licensure and accreditation surveys, government investigations, and through payor audits and disputes.

In addition to providing regulatory guidance to clients, Liz is also knowledgeable in evaluating how a business opportunity or arrangement implicates a provider’s unique regulatory framework. Liz has counseled clients not only on the regulatory aspects of an arrangement as described above, but she is also experienced in reviewing and negotiating relevant contractual and legal documentation in connection with contemplated business arrangements.

Liz earned a J.D. and Certificate of Advanced Studies in Health Law from the University of Pittsburgh School of Law, an M.A. in Bioethics and a B.A., cum laude, in Political Science from Case Western Reserve University.

ARUP Laboratories

Eliminating Kickbacks in Recovery Act (EKRA)

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Background

- The World Outside
  - Commercial Incentives are Everywhere
    - Cash back credit cards; frequent flyer miles; free gift with a purchase; one free with the purchase of three etc.
  - Why Are Health Care Entities Treated Differently?
    - Inappropriate arrangements in health care have the potential to result in overutilization, increased program costs, improperly influenced medical decision making, patient steering and unfair competition
    - Judgments about medical care should not be influenced by financial incentives

Background

- Anti-Kickback Statute (AKS)
  - Prohibits knowing and willful
    - Intent is required
  - Payment or receipt of remuneration
    - Remuneration = anything of value (cash, free rent, meals, etc.)
    - Judgments about medical care should not be influenced by financial incentives
  - Intended to induce patient referrals
- Penalties
  - Fines, jail, exclusion from Federal health care programs

EKRA

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- Eliminating Kickbacks in Recovery Act of 2018 (EKRA)
  - Effective October 24, 2018
  - Passed as a part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)
  - Intended to address America's opioid epidemic
  - Applies to recovery homes, clinical treatment facilities, and laboratories
  - Prohibits solicitation, receipt, payment, or offer of remuneration to induce patient referrals
  - Extends to services covered by both government **and** private payors
  - Essentially expands prohibited conduct that would be an AKS violation if a government payor were involved to services paid for by ANY payor

EKRA - Prohibited Conduct

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- Knowingly and willfully:
  - Soliciting or receiving any remuneration directly or indirectly for referring a patient or patronage to a recovery home, clinical treatment facility or lab; or
  - Paying or offering any remuneration directly or indirectly.
- To induce a referral of an individual to a recovery home, clinical treatment facility, or lab; or
- In exchange for an individual using the services of that recovery home, clinical treatment facility, or lab

Definition of a Laboratory

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- Applies to all laboratories
- “[A] facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.” 42 U.S.C. 263a
- Applies to both clinical AND anatomic pathology labs
- Not limited to substance abuse/toxicology testing

EKRA Exceptions

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- Discount obtained by provider of services or other entity if reduction is properly disclosed and reflected in costs claimed by provider
- ***Payment by employer to W-2 or 1099 for employment, if the payment is not determined by or does not vary by:***
  - ***# of individuals referred to a particular recovery home, clinical treatment facility or lab;***
  - ***# of tests of procedures performed; or***
  - ***Amount billed to or received from payor***

EKRA Exceptions (cont'd)

- Discount in price of drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program
- Payment made by a principal to an agent for services rendered under a personal services and management contract that meets AKS requirements (Adopts AKS Personal Services and Management Contracts Safe Harbor)

EKRA Exceptions (cont'd)

- Waiver or discount of any coinsurance or copayment by a payor if:
  - Waiver or discount is not routinely provided; and
  - Waiver or discount is provided in good faith
- Remuneration described in 1128B(b)(3)(l) of the Social Security Act (Adopts AKS FQHC Safe Harbor)

EKRA Exceptions (cont'd)

- Remuneration made pursuant to an alternative payment model or payment arrangement used by a State, health insurance issuer, or group health plan if HHS has determined such arrangement is necessary for care coordinate or value-based care
- Any other payment, remuneration, discount or reduction determined by the AG in consultation with HHS

Penalties

- Under EKRA:
  - Fined not more than $200k/offense; and/or
  - Imprisoned not more than 10 years
- Other possible implications:
  - Loss of payor contracts
  - Potential exclusion

Preemption

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- EKRA does not apply to conduct:
  - prohibited under AKS
  - prohibited by state laws on the same subject matter
- Unclear how to reconcile conduct that meets an AKS safe-harbor, but does not meet an EKRA exception
- No legislative history because added to SUPPORT Act so late

EKRA Updates

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- Updates
  - No clarifying regulations as of today
  - Current industry trends
  - *S&G Labs Hawaii, LLC v Graves*
    - Federal court case
    - Interesting case/data point
    - Continue to hope that this will spur the government to provide clarification

EKRA Updates (cont'd)

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- *U.S. v. Mark Schena (N.D. Cal.)*
  - This is a criminal case, unlike S&G Labs, which was a civil contract dispute
  - This is a Department of Justice (DOJ) enforcement action
  - Owner of Arrayit, a lab company offering allergy testing
    - Charged with health care fraud, wire fraud, and EKRA
    - Indictment includes EKRA violations based on payment for referral in April 2020
    - In Early February, Schena's team filed a motion to dismiss EKRA based on *S&G Labs* case (Hawaii case)
    - The DOJ disagreed and pushed back arguing that the reasoning of the *S&G Labs* case was incorrect
    - Schena attempted to argue that EKRA did not apply because the marketers worked with physicians and not patients directly.
    - Court did not agree with this proposition, instead finding that the act of marketing is an inducement to refer an individual and can violate EKRA when such marketers are paid on a per specimen, per person, or percentage of reimbursement
  - Currently pending appeal by Schena

Future

- Professional associations and stakeholders are advocating for clarification
- Unclear whether the government will address
- Affected providers should continue to monitor

Questions?

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