

## Kara Sweet

### Associate

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Kara Sweet is an associate with Foley & Lardner LLP and member of the firm's Government Enforcement, Defense, and Investigation Practice and Telemedicine & Digital Health Industry Team.

Kara works with hospitals and health systems, physician practice groups, pharmacies, durable medical equipment companies, laboratories, and emerging technology companies across the country. Her work focuses on federal and state health care regulatory compliance, conducting internal investigations, and defending government investigations and enforcement actions, especially related to actions arising out of the False Claims Act (FCA), Anti-Kickback Statute (AKS), and Stark Law.

Before joining Foley, Kara held a clerkship for the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG) where she worked extensively on exclusion appeals, self-disclosures, corporate integrity agreements, and reportable events. She also held an internship at the U.S. Attorney's Office Western District of Missouri.

## Representative Experience

### Health Care Compliance and Regulatory

Kara has advised large hospital and health systems, physician practice groups, and pharmacies on wide ranges of federal and state health care regulatory compliance.

- Keeping various clients informed of COVID-19 related requirements and waivers, including CMS' Hospital without Walls and Hospital at Home programs, Provider Relief Funds (PRF), and federal and state vaccination mandates.
- Advising health care entities on state regulatory issues including state licensing and change of ownership.
- Counseling physician and other clinician practices on the corporate practice restrictions on their professions.

- Assisting health care clients with a broad range of transaction matters, including mergers and acquisitions, affiliations, and formation of friendly professional corporations.

### **Health Care Litigations and Internal Investigations**

Kara has represented companies, including medical devices companies, laboratories, and other health care industry participants, in investigations and litigation initiated by the federal government and whistleblowers. Kara has experience not only in the FCA and state FCA, but also in the Anti-Kickback Statute (AKS) and Stark Law. She analyzes, investigates, and litigates these statutes.

- Represented a laboratory company in False Claims Act and Anti-Kickback Statute matter alleging improper kickbacks in exchange for referrals.
- Assisted a large health care entity responding to a civil investigative demand (“CID”) related to alleged COVID-19 fraud.
- Provided health care counsel to a medical equipment company responding to DOJ allegation of False Claims Acts violation related to Medicaid reimbursement fraud.
- Represented a provider group in a False Claim Act, Stark Law, and Anti-Kickback matter alleging improper contracting to induce referrals.

### **Telemedicine, Telehealth, Virtual Care, Digital Health**

*“Foley is the premier firm for telehealth counsel.”*

*“A market leader in telemedicine issues.” “This is the Dream Team.”*

*– Chambers USA: America’s Leading Business Lawyers (2020 – 2021)*

Kara helps entrepreneurs and emerging companies navigate state and federal laws governing telemedicine and digital health, including federal and state COVID-19 public health emergency waivers, telemedicine modalities and technology, mail order pharmacy arrangements, telehealth-based substance use disorder treatment regulations, school-based virtual care programs, scope of practice and supervision requirements, and Medicaid enrollment.

- **Telehealth-Based Substance Use Disorder Treatment.** Helped an emerging digital health company involved in the treatment of opioid use. The advice included determining substance use disorder licensing requirements, controlled substance prescribing limitations, and nurse practitioner scope of practice, supervision requirements, and prescribing authority across multiple states. The work helped the company strategically determine potential market entry points for successful launch.
- **Remote Patient Monitoring and Clinical Staff.** Worked with several digital health companies offering remote patient monitoring services develop their corporate structure in various states. The work included advising on billing considerations along with nurse practitioner, nurse, certified nurse assistant, licensed vocational nurse, and medical assistant scope of practice and supervision requirements. The work allowed the company to comply with regulatory requirements while providing a scalable, affordable staffing model for RPM.

- **School-Based Telehealth and Medicaid Enrollment.** Advised a school-based telemedicine program offering telehealth services across multiple states, without any brick and mortar locations, on the requirements for enrolling in Medicaid programs. The work allowed the company to create a corporate structure that fit within its strategic growth plan and adhered to state laws and payer requirements.
- **COVID-19 Licensure and Modality Waivers.** Advised various telehealth companies on navigating federal and state changes in provider licensure and telehealth modalities during the COVID-19 public health emergency. The work allowed the companies to immediately take action and expand their platforms to provide services across multiple states.
- **Direct to Consumer Televeterinary Service.** Advised a pet pharmacy on options for direct to consumer virtual veterinary prescription offerings. The work involved advising on states' corporate practice of veterinary medicine prohibitions, establishing veterinarian-client-patient relationship, and fraud and abuse concerns. The pharmacy was able to evaluate its corporate structure in compliance with various federal and state requirements.

## Affiliations

- Member, American Health Lawyers Association (AHLA)

## Presentations and Publications

- Co-author, "Court Calls Underlying Legal Standards "No Model of Clarity" but Allows False Claims Act Case To Proceed Anyway," *Health Care Law Today* (January 11, 2023)
- Co-author, "FCA Managed Care Case Update: A Court's View of ICD Guidelines in Risk Adjustment Cases," *Health Care Law Today* (December 27, 2022)
- Co-author, "New Jersey Allows Asynchronous Telemedicine," *Health Care Law Today* (January 6, 2022)
- Co-author, "Red Light – Green Light: CMS Vaccination Mandate is On Again in 26 States?" *Health Care Law Today* (December 15, 2021)
- Co-author, "CMS Requires Self-Disclosure Protocol: Top Takeaways," *Health Care Law Today* (November 9, 2021)
- Co-author, "New Jersey's Telemedicine Business Registry: What You Need to Know," *Health Care Law Today* (September 1, 2021)
- Co-author, "Chapter 9: The Alphabet Soup of Medicare and Medicaid Contractors," American Bar Association's *Physician Law: Evolving Trends & Hot Topics 2021* (July 26, 2021)
- Co-author, "CMS to Permanently Cover Audio-Only Telemedicine for Mental Health," *Health Care Law Today* (July 21, 2021)
- Co-author, "From Petri Dish to Main Dish: The Legal Pathway for Cell-Based Meat," *The Kentucky Journal of Equine, Agriculture, & Natural Resources Law* (June 2021)
- Contributing author, "The risks of 'swapping' for durable medical equipment," *McKnight's Long-Term Care News* (April 14, 2021)
- Co-author, "COVID-19 Food & Beverage Regulatory Updates," *Coronavirus Resource Center: Back to Business* (September 8, 2020)

- Co-author, “COVID-19: Free Lodging, Free Testing, Free of OIG Enforcement?” *Coronavirus Resource Center: Back to Business* (August 10, 2020)
- Co-author, “COVID-19 Food & Beverage Regulatory Updates,” *Coronavirus Resource Center: Back to Business* (July 27, 2020)
- Co-author, “FDA Increases Scrutiny of COVID-19 Serology Tests: What Commercial Manufacturers Need to Know,” *Coronavirus Resource Center: Back to Business* (May 6, 2020)
- Co-author, “Meat and Poultry Industry Gets New COVID-19 Guidance from CDC and DOL,” *Coronavirus Resource Center: Back to Business* (April 28, 2020)
- Co-author, “Implications for the Cannabis Industry Due to the Coronavirus,” *Coronavirus Resource Center: Back to Business* (April 17, 2020)
- Co-author, “COVID-19: Idaho Governor Suspends More Regulations Relating to Telehealth and Medical Licensing,” *Coronavirus Resource Center: Back to Business* (April 13, 2020)
- Co-author, “FDA Publishes Enforcement Policies to Address Coronavirus Personal Protective Equipment Shortages,” *Coronavirus Resource Center: Back to Business* (April 6, 2020)
- Co-author, “Managing the Commercial Impact of the Coronavirus: Food & Beverage,” *Coronavirus Resource Center: Back to Business* (March 6, 2020)
- Co-author, “Telehealth: Massachusetts’ Proposed Act to Improve Health Care by Investing in Value,” *Health Care Law Today* (January 29, 2020)
- Contributor, “Key Takeaways from USDA’s Interim Hemp Production Rule,” *Foley Insights* (November 1, 2019)

## Sectors

- [Cannabis](#)
- [Food & Beverage](#)
- [Health Care & Life Sciences](#)
- [Pharmaceuticals](#)
- [Racial Justice & Equity](#)
- [Telemedicine & Digital Health](#)

## Practice Areas

- [False Claims Act](#)
- [Government Enforcement Defense & Investigations](#)
- [Government Solutions](#)
- [Health Care Regulatory](#)
- [Litigation](#)

## Education

- Georgetown University Law Center (J.D., with honors, 2019)
  - Executive Editor for the Food and Drug Law Institute’s *Food and Drug Law Journal*
- Saint Louis University (B.S., summa cum laude)

## **Admissions**

- Maryland
- Colorado
- District of Columbia
- United States District Court of Colorado