

## Heidi A. Sorensen

### Counsel

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*Heidi builds on her previous experience at the Office of Counsel to the Inspector General of the Department of Health and Human Services to assist clients with health care regulatory, compliance, and fraud and abuse matters.*

Heidi A. Sorensen is counsel in the Health Care Group and focuses her practice on health care fraud and abuse and compliance matters, including the Anti-Kickback Statute. Heidi advises retail and specialty pharmacies, pharmacy benefit managers, and pharmaceutical manufacturers. Heidi also advises medical device and durable medical equipment manufacturers and distributors. Heidi also works with skilled nursing facilities, hospitals and health systems, physical therapy and rehabilitation agencies, and other health care providers. She assists clients in False Claims Act (FCA) investigations, negotiating FCA settlements and corporate integrity agreements, and matters that fall under the Civil Monetary Penalties Law and Office of Inspector General (OIG) exclusion authorities. Heidi advises clients on Medicaid issues, providing regulatory advice, helping clients defend Medicaid audits and investigations, conducting internal investigations, and representing clients in administrative hearings and appeals.

Heidi helps clients develop compliance programs and implement corporate integrity agreements. Heidi has developed compliance programs for multinational life sciences companies, including pharmaceutical, medical device, and DME manufacturers.

Heidi previously served as chief of the Administrative and Civil Remedies Branch in the Office of Counsel to the Inspector General (OCIG) at the Department Health and Human Services. Heidi served as the OCIG's coordinator for both the Provider Self-Disclosure Protocol and the Physicians at Teaching Hospitals national project. Heidi also served the OCIG as senior counsel and deputy branch chief.

#### **Representative Experience**

- Represented a pharmaceutical manufacturer in a False Claims Act investigation involving the Anti-Kickback Statute and off-label marking issues.
- Represented multiple health and hospital systems in False Claims Act investigations and negotiation of settlements and corporate integrity agreements involving Anti-Kickback Statute, Stark Law, quality of care, and medical necessity issues.
- Represented a medical device manufacturer in negotiating and implementing a corporate integrity agreement as part of a settlement involving Anti-Kickback Statute issues.
- Conducted internal investigations for skilled nursing facilities on issues including documentation and coding, physician certifications, MDS requirements, and employment of excluded persons.
- Conducted an internal investigation for a pharmacy benefit manager, resulting in self-disclosure and resolution of an Anti-Kickback Statute issue.
- Defended national chain and independent retail, mail-order, and specialty pharmacies in state Medicaid program audits.
- Served as an expert witness for a pharmaceutical manufacturer on compliance programs and promotional practices.

- Represented a physician practice in an appeal and negotiations that resulted in reinstatement into Medicare after the practice's Medicare revocation for employing an excluded person. Also represented the practice in self-disclosing and settling the employment of the excluded person.
- Advised a client on the potential exclusion implications of a proposed plea agreement in a DOJ criminal investigation of health care antitrust issues.
- Assisted veterinary pharmacies in drafting and negotiating various agreements, including supply, pharmacy fulfillment, marketing, and licensing agreements.
- Assisted pharmacy and veterinary pharmacy clients in responding to state board of pharmacy inquiries on licensing, privacy, and consumer protection issues and making various disclosures to state boards.

## ***Publications & Presentations***

### ***Presentations***

- "Developments in Federal Prosecutions, and Significant Changes to the OIG Self-Disclosure Protocol," Health Law Roundtable, Taos, NM, January 23-26, 2020.
- "Birds-Eye View on the Current Regulatory Status of Drug Manufacturer Rebates," CBI's 5th Annual PBM Contracting Conference, Chicago, IL, August 21-22, 2019.
- "Anatomy of a Self-Disclosure," Association of Corporate Counsel Webcast, May 21, 2019.
- "Implementation and Effectiveness of Compliance Programs and Anatomy of a Corporate Integrity Agreement," HCCA San Juan Regional Conference, San Juan, Puerto Rico, May 16-17, 2019.
- "Commercialization Risk and Compliance," *ThinkSet Podcast*, April 26, 2019.
- "Stark Conundrums in Physician/Hospital Relationships," 36th Annual National CLE Conference, Snowmass Village, CO, January 2-6, 2019.
- "Top 10 Things You Need to Know About Disclosing to the Federal Government," Washington Executive Certification Course, Health Ethics Trust, Alexandria, VA, May 14-16, 2018.
- "Stark Law and Anti-Kickback Statute Update," Florida Hospital Association Health Law Summit, Orlando, FL, February 8, 2017.
- "Final CMS 60-Day Rule: Reporting and Refunding Overpayments for Providers and Suppliers," Strafford, webinar, April 7, 2016.
- "Informal Dispute Resolution Process for Nursing Facilities," The New England Alliance Fall Regional Conference, September 2014.
- "Understanding the False Claims Act (FCA) and Ongoing Government Enforcement and Compliance Efforts," 13th Annual Rx Drug Pricing Boot Camp, American Conference Institute, April 2014.
- "How to Avoid Unintended Consequences of CMS Enhancement of Medicare Enrollment Requirements," HCCA 16th Annual Compliance Institute, Las Vegas, NV, April 29 - May 2, 2012.

### ***Professional & Community Engagement***

- Women's Bar Association of the District of Columbia, Health Law Committee, co-chair (2002–2006); treasurer (2001–2002); Women's Bar Association Foundation, treasurer (2003–2005)
- American Health Lawyers Association
- Health Care Compliance Association

- American Society for Pharmacy Law
- Councilmember, Ward 5, Town of University Park, MD (2012–2015)
- George Washington University, Graduate Certification Program in Healthcare Corporate Compliance, guest lecturer

### *Education*

- Georgetown University (J.D., 1993)
- Colgate University (A.B., 1986)

### *Languages*

- Italian

### *Admitted to Practice*

- District of Columbia
- Maryland

### *Related Services*

Health Care | Life Sciences | Health Care Regulatory Counseling and Fraud & Abuse | Health Care Litigation | Corporate Compliance Programs | White Collar, Government & Internal Investigations | False Claims Act