



## Heidi A. Sorensen

Counsel

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### *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 ■ Administrative Law

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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 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, pharmaceutical manufacturers, medical device and durable medical equipment manufacturers, and distributors. Heidi works with senior living providers, hospitals and health systems, physical therapy and rehabilitation agencies, clinical laboratories, 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.

*Chambers USA* has recognized Heidi in their annual rankings for excellence in Healthcare.

### *Representative Experience*

- Represented a pharmaceutical manufacturer in a False Claims Act investigation involving the Anti-Kickback Statute and off-label marketing 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.
- Responded to government investigations and conducted internal investigations for skilled nursing facilities, other senior living providers, home health, and hospice companies on issues including documentation and coding, physician certifications, MDS requirements, laboratory testing (including COVID), 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 pharmaceutical manufacturers and a clinical laboratory company on compliance issues.
- 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.
- Represented pharmacy clients before the DOJ, HHS OIG, state regulators, and licensing agencies.

## ***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.

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

- *The Best Lawyers in America*®, Health Care Law
- 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