PRACTICES

Corporate

INDUSTRIES

Healthcare
Cannabis and Psychedelics

EDUCATION

University of Utah S.J. Quinney College of Law, J.D., 2010
Honors
Pro Bono Award

Brigham Young University, B.S., 1995

BAR ADMISSIONS

Utah

Watch Kristy's Introduction Video

Kristy M. Kimball

Partner

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Kristy leverages corporate experience and deep knowledge of the healthcare and life sciences industries to help clients create practical and transformative compliance solutions that work across an organization.

Kristy worked for 13 years in sales and management roles for Pfizer Consumer Healthcare, which is among the largest healthcare companies in the world. She decided to attend law school to enhance her ability to assist healthcare and life science companies to navigate the ever-evolving and increasingly complex federal and state regulations. She partners with her clients to focus on strategic business and growth opportunities to maximize their long-term success.

Kristy has served as outside counsel to several major Utah healthcare companies, including the largest hospital holding company in the United States. She counsels clients in the healthcare and life sciences industry on a spectrum of operational and regulatory issues, including fraud and abuse, HIPAA, and state licensure and credentialing. She has also represented medical device and pharmaceutical companies, as well as clinical laboratories, providing guidance on compliance, FDA audits, threatened FDA adverse action, and the federal Sunshine Act.

Kristy is the founder and past chair of the Health Law Section of the Utah State Bar Association.

EXPERIENCE

Healthcare Law Compliance and Regulations:

- Fraud and Abuse: Stark, Anti-Kickback Statute, False Claims Act
- Centers for Medicare & Medicaid Services
- Credentialing, licensing, peer review
- Privacy requirements: HIPAA
- Billing and Reimbursement issues
- Compliance programs

Life Sciences Law:

Kristy advises medical device and pharmaceutical companies, as well as clinical laboratories in legal and regulatory matters, including:

- FDA
    - 510(k) clearances and other regulatory authorization for

medical devices (e.g. Emergency Use Authorizations for COVID-19 tests) FDA inspections
    - FDA 483 observations and negotiating resolutions
    - FDA recalls
    - Adverse event (AE) and medical device report (MDR) reporting
    - FDA warning letter response
    - Advertising and promotion compliance
    - Current good manufacturing practices (cGMPs) and quality systems
- Laboratories
    - Clinical Laboratory Improvement Amendments (CLIA) compliance
    - Regulatory surveys and investigations
    - Responding to allegations of non-compliance (CMS Form 2567)
    - Compliance with federal Fraud and Abuse Laws (False Claims Act, Anti-Kickback Statute, and Stark)

CLIENT RESULTS

Healthcare Law and Regulatory Compliance

Ensuring compliance with HIPAA, PPACA, Medicare/Medicaid, Stark, Anti-Kickback Statute, and other fraud and abuse laws and regulations.

Assisting health institutions and physicians on issues related to medical staffing, credentialing, licensing, peer review, fair hearings, bylaws, and policies and procedures.

Assisting health care entities with Recovery Audit Contractor (“RAC”) audits, Medicare and Medicaid appeals, billing and reimbursement issues, compliance investigations, allegations of “overpayments,” and self-disclosures.

Providing DOPL defense and assist with reporting errors to the National Practitioner Data Bank for medical professionals, including physicians, physician assistants, nurse practitioners, nurses, dentists, and chiropractors.

Assisting health care professionals in formation of physician group practices, joint ventures, sales, mergers and acquisitions, buy-sell agreements, employment agreements, recruitment agreements, real estate transactions, lease agreements, and contracting.

Assisting Life Science companies to comply with FDA, FTC, HHS, and CMS laws and regulations.

Life Sciences

Assisting Life Science companies to comply with FDA, FTC, HHS, and

CMS laws and regulations.

Advising and representing high-profile clinical laboratory on 483 Observation responses, resulting in full resolution of CMS concerns.

Representing clients in the FDA product approval process, including 510(k)s and PMAs.

Assisting companies to manage FDA inspections, 483 observation responses, providing responses to FDA warning letters, working with FDA officials to resolve concerns, managing product recalls, and developing strategies to correct compliance issues, including current good manufacturing practices (cGMPs) and quality systems.

Advising clients on reimbursement issues related to medical devices and laboratory testing.

PUBLICATIONS

"Navigating Utah's Expanded Peer Review Privilege: A Roadmap for Healthcare Providers," *Health Law Update*, July 15, 2025

"DOJ Announces Significant Changes to Corporate Criminal Enforcement Policies," *Holland & Hart News Update*, November 9, 2021

SPEAKING ENGAGEMENTS

"Navigating the Practical Implications of Medical Practice and Healthcare in a Post-*Dobbs* World," Moderator, *University of Utah S.J. Quinney College of Law and Virtual Event*, March 28, 2025

"Legal Updates for Healthcare Providers ," *Rural 9: Health Law Update*, October 12, 2023

"2023 Healthcare Compliance Webinar Series: Hospital Medical Staff Credentialing and Corrective Actions," *Holland & Hart Health Law Webinar*, August 17, 2023

"Regulatory Environment Regarding Medical Professionals," *Utah State Bar, Health Law Section*, February 28, 2023

"Navigating New State Abortion Bans in the Intermountain West," *Holland & Hart Webinar*, Co-presenter, July 28, 2022

"Representing Hospitals During a Pandemic: The Wild, Wild West of Health Law in 2020," *The 8th Annual Law and Biomedicine Colloquium, S.J. Quinney College of Law*, January 18, 2022

"FDA Regulatory Compliance Issues for Medical Device Companies," *Holland & Hart Health Law Compliance Webinar Series*, April 1, 2021

"Unique Compliance Concerns Applicable to Utah," *Holland & Hart Health Law Compliance Webinar Series*, February 23, 2021

"HIPAA," *Holland & Hart Health Law Compliance Webinar Series*,

February 11, 2021

"Preparing for an FDA Facility Inspection and Responding to a 483 Letter," *Celesq*, Webinar, September 1, 2020

RECOGNITION

- *Utah Business Magazine*, Utah Legal Elite, Healthcare, 2020-2021

PROFESSIONAL AND CIVIC AFFILIATIONS

- Health Law Section of the Utah State Bar, Chair, 2024-present; Vice Chair, 2023-2024; Founder and Past Chair, 2012-2014
- Utah Health Policy Project, Board Member, 2011-present
- Utah Governor’s Task Force on Health Privacy, Member
- American Health Lawyers Association, Member
- American Bar Association, Health Law Section, Member
- Erin Kimball Memorial Foundation, Board of Directors, Member
- Big Brothers Big Sisters of Utah, Board of Directors, Former Member