WILSON SONSINI

Healthcare and FDA Regulatory

HIGHLIGHTS

- **A Team Anchored by Former Senior Government Officials**
  Wilson Sonsini's healthcare and Food and Drug Administration (FDA) regulatory attorneys have served in senior roles at the Department of Health and Human Services and the FDA, shaping the rules now governing health data and digital health.
- **Counsel for Innovators in Healthcare and Life Sciences**
  We represent the founders, executives, inventors, and investors building the future of healthcare and life sciences—from digital health and health tech start-ups to medical device and pharmaceutical companies—as well as the venture firms that back them and the health systems and health plans that implement these technologies.
- **Regulatory Strategy for New and Developing Technologies**
  We advise clients on how to effectively navigate the complex, rapidly evolving regulatory environment to enable them to launch innovative products and business models, including when technology is advancing faster than regulations.

OVERVIEW

When the most innovative companies seek guidance on navigating the complex healthcare regulatory and legal landscape, they turn to Wilson Sonsini. Our leading healthcare regulatory team understands the health innovation market and the complex regulatory landscape, and works seamlessly with our corporate and transactions teams to provide practical advice and judgment to help companies succeed in their business strategies.

Wilson Sonsini advises the companies and investors at the forefront of healthcare and healthcare technology, from care delivery and digital health companies to life science businesses, and from early-stage innovators to established industry stakeholders, as they maneuver through a rapidly changing regulatory landscape. Building on the firm's decades of experience in technology and life sciences, our attorneys bring deep healthcare and FDA regulatory knowledge to the novel questions that arise as technology reshapes how care is delivered, how health data moves, and how products reach the market.

Our work spans the full life cycle of a healthcare or healthcare technology business, from the initial design of compliant care delivery structures to the execution of financings, acquisitions, and exits. We help healthcare and healthcare technology companies better understand the complex regulations required for them to achieve successful scale and exit, including health data strategy and Health Insurance Portability and Accountability Act (HIPAA) compliance, FDA regulatory pathways for digital health and software-based products, healthcare fraud and abuse, corporate practice of medicine (CPOM), state licensure requirements, the use of AI in healthcare delivery, and the regulatory dimensions of healthcare transactions and financings. Our team also advises on consumer and wellness products, including FDA, Federal Trade Commission, and related regulatory requirements, and works closely with our Antitrust and Competition team. Several members of the team bring government regulatory experience, offering firsthand insight into how regulators approach emerging technologies.

We advise clients in the following areas:

- **AI in healthcare and digital health:** We help clients navigate the regulatory questions raised by AI and software in care delivery, including data access and use, FDA oversight, clinical decision support, AI practicing medicine under state CPOM rules, transparency and disclosure obligations under state AI laws, liability for AI-assisted decision-making, and AI governance. Learn more on our AI in Healthcare, Digital Health, and FDA pages.
- **Health data privacy, security, access, interoperability, and information blocking:** As the demand for health data grows, we are uniquely positioned to counsel clients on health data access and privacy and security protections, including HIPAA, 42 C.F.R. Part 2, state health privacy laws such as the Washington My Health My Data Act, information blocking rules, interoperability regulations, Trusted Exchange Framework and Common Agreement (TEFCA), and the data-sharing arrangements at the core of digital health and health tech businesses. We advise on navigating regulations, supporting compliance, handling security incidents, managing enforcement, and engaging with federal agencies.
- **FDA regulatory:** We advise on FDA regulatory pathways, product lifecycle management, go-to-market strategies, manufacturer/sponsor regulatory obligations during preclinical and clinical stages, due diligence and regulatory support in corporate, licensing, and other transactional matters, transfer or ownership change of FDA regulatory assets and filings, preparations for commercial launch, advertising and promotional review, and post-market FDA regulatory compliance matters for a broad range of life sciences and technology clients. These include companies focused on pharmaceuticals, biologics, medical devices, digital health tools, software as a medical device, AI-enabled products, wellness products, diagnostics, research-use-only products, and other novel technologies and products in life sciences and health care. Learn more on our FDA and Life Sciences pages.
- **Healthcare fraud and abuse:** Wilson Sonsini counsels clients on the federal Anti-Kickback Statute, the Stark Law, the Eliminating Kickbacks in Recovery Act (EKRA), the False Claims Act, the Civil Monetary Penalties Law and beneficiary inducement prohibitions, the Sunshine Act, and analogous state laws, including state anti-kickback, self-referral, and fee-splitting laws. We advise on the requirements for billing federal, state, and commercial payors for healthcare services, and we help clients build billing and reimbursement practices and compliance programs that reduce fraud and abuse exposure. We also assist clients structure compliant compensation and equity arrangements with referral sources and physicians, and we handle internal and board investigations and respond to government inquiries.
- **CPOM and healthcare delivery:** The firm advises on CPOM restrictions, fee-splitting rules, and the structuring questions that arise when technology-enabled companies participate in the delivery of care. We help companies design and implement management services organizations-professional corporation (MSO-PC) structures on a nationwide scale, including drafting and negotiating management services agreements, continuity planning agreements, and the full set of underlying agreements to comply with CPOM laws. As clients scale and enter new states, we support the ongoing operation of these structures, and we represent companies in investigations and defense of claims that they have failed to comply with CPOM laws.
- **Value-based care:** We counsel clients on the arrangements and regulatory considerations involved in value-based and risk-based care models, including the value-based enterprise safe harbors and exceptions under the Anti-Kickback Statute and Stark Law, fee-splitting constraints, and the formation and operation of value-based care enablement companies.
- **Healthcare transactions and regulatory diligence:** We provide healthcare regulatory counsel for transactions ranging from earliest-stage financings to IPOs and mergers and acquisitions, representing both companies and investors. The firm leads healthcare regulatory diligence, identifying and resolving healthcare regulatory risks, including any filings required for change of ownership or control, and we advise on structuring the transaction, healthcare representations and warranties, and the healthcare regulatory disclosures in registration statements, including the risk factors and regulatory sections of the S-1. We also guide clients through state healthcare transaction notification laws, analyzing whether a filing is required, preparing and submitting the notification, and managing any resulting government review. Additionally, we help companies prepare for an acquisition or due diligence process and develop strategies to remediate regulatory issues.
- **State licensure and regulatory compliance:** We advise healthcare and health technology companies operating across multiple jurisdictions on the full range of state licensure, registration, and regulatory requirements that apply to their businesses and care delivery models. Our work covers the threshold question of whether a given license, registration, or authorization is required, how to obtain and maintain it, how substantive state requirements apply to a company's specific operations, and what filings or approvals are triggered by a change of ownership or control.
- **Federal agency engagement:** Drawing on the team's government background, we help clients navigate and engage with federal agency processes affecting emerging healthcare technologies to impact policy and regulation.