



→ Sara Helene Shanti

Partner

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Sara Helene Shanti is a partner in the Corporate Practice Group in the firm's Chicago office. She is the host of the Health-e Law podcast, produced by Sheppard Mullin's Digital Health Team.

Areas of Practice

Sara's practice sits at the forefront of health-technology by providing practical counsel on healthcare innovation and complex data privacy matters. Using her medical research background and HHS experience, Sara advises providers, payors, start-ups, technology companies, and their investors and stakeholders on digital and novel healthcare regulatory compliance matters, including artificial intelligence and machine learning (AI/ML), augmented and virtual reality (AR/VR), data assets and privacy, gamification, implantable and wearable devices, and telehealth.

Sara has deep experience advising clients on data use and protection under Part 2, HIPAA, GINA, and state privacy laws, such as BIPA and CCPA, and multinational border transmissions. She also assists clients in implementing compliance programs, launching health innovations and investments, and responding to governmental investigations. Her experience extends to consumer and patient rights, including under the American Disabilities Act and Section 1557, medical staff relationships, and navigating the evolving regulatory landscapes for next-generation technology.

At the cutting edge of advising on "data as an asset" programming, red team technology reviews, and information blocking and interoperability under the 21st Century Cures Act, Sara's practice includes mergers and acquisitions involving crucial, high-stakes, and sensitive data in areas of digital health platforms, medical and wellness devices, and web-based applications and treatment.

Sara also has deep experience with telehealth prescribing laws, including the Ryan Haight Act, and with entities offering services in sensitive healthcare areas, such as behavioral health, fertility, genetics, and substance abuse.

Sara serves as an advocate for minor and patient rights, working as a court-appointed guardian. Before receiving her law degree, Sara applied her biology degree towards medical research projects, concentrating on epigenetics and immunologic responses in cancer patients. Prior to private practice, Sara worked for the U.S. Department of Health and Human Services Office for Civil Rights.

Honors

Rising Stars in Law, *Crain's Chicago Business*, 2021

Experience

- Represented national health systems and Fortune 50 companies in the creation and implementation of a global data privacy and security compliance plans, data breach investigations, and Attorneys General inquiries.
- Represented hospitals and national practices in DOJ and HHS criminal and civil investigations, claim disputes, and subsequent corrective action plans.
- Represented a global medical device company in restructuring compliance program to minimize EU, federal, and state data privacy risks to \$90M+ annual service contracts.
- Represented a Fortune 100 company in acquiring FDA mobile applications.
- Represented a Fortune 100 company and state-of-the-art academic facility in a clinical research unit partnership and related compliance matters.
- Represented investors on regulatory matters in a \$100M+ acquisition of a lab testing company and a \$1B+ acquisition of a foreign healthcare company.
- Represented a pediatric hospital with respect to innovative delivery systems and community outreach efforts.
- Represented global transportation companies related to healthcare transport and reimbursement matters.
- Represented global mobile application and national telemedicine companies in healthcare regulatory matters and start-up initiatives.

Articles

- Wellness Apps: Look Who's Tracking
American Health Law Association Business Law and Governance Practice Group, 11.13.2023
- Sheppard Mullin's Top 10 Takeaways from HLTH 2023
10.18.2023
- AI in Healthcare: Key Considerations Checklist
LexisNexis Practical Guidance, 08.25.2023
- Cautions and Legal Considerations of Using Generative AI in Healthcare
Lexis Nexis Practical Guidance, 2023
- Breaking Down The Long-Awaited HHS Info Blocking Rule
Law360, 08.15.2023
- Addressing Legal Issues Raised By AI Use In Health Care
Law360, 07.13.2023
- Health Care Info Blocking Rule Changes To Watch For
Law360, 06.29.2023
- AI in Healthcare: Cautions and Considerations of a Healthcare Revolution
Practical Guidance, 06.19.2023

- AI/ML: Considerations of Healthcare's New Frontier
MedCity News, 05.26.2023
- DEA Proposes Rule for Post-PHE Telemedicine
Chicago Medicine Magazine, 04.2023
- Eye on Privacy 2021 Year in Review
01.11.2022
- "Protecting Continuity, Workforce, and Physical Assets During the Pandemic," *ACC Docket*, May 2020
- "Current business trends to keep an eye on in the age of COVID-19," *Chicago Daily Law Bulletin*, April 22, 2021
- "Protecting Continuity, Workforce, and Physical Assets During the Pandemic," *ACC Docket*, May 2, 2020
- "Alphabet's COVID-19 project underscores privacy concerns with big tech," *Modern Healthcare*, March 21, 2020
- "What Investors Should Understand About Data Privacy & Security Risks & Opportunities – 5 Key Takeaways," *The Healthcare Investor*, March 2018
- Co-author, "Impact of the European Union's Recently Enacted General Data Protection Regulation ("GDPR") on U.S. Academic Medical Centers," *American Health Lawyers Association E-Alert*, May 2016
- Co-author, "Impact of the European Union's Approved General Data Protection Regulation on Scientific Research and Secondary Uses of Personal Data," *Bloomberg BNA Medical Research Law & Policy Report*, February 2016

Healthcare Law Blog Posts

- "FemTech Meets DiagnosTech: A Discussion with Deirdre O'Neill," April 29, 2024
- "Gamification – Playing for Health: A Discussion with Craig Lund," April 23, 2024
- "HHS Announces 42 Part 2 Final Rule to Align with HIPAA," March 14, 2024
- "Digital Health to the Rescue – Improving Access to Specialized Care: A Discussion with Viveka Rydell-Anderson," January 16, 2024
- "AI as an Aid – Emerging Uses in Healthcare: A Discussion with Jim Gatto," January 8, 2024
- "In Tech We Trust? The Case for Transparency: A Discussion with Dr. Laura Tully," December 21, 2023
- "Health-e Law Launches: New Podcast Covers Health-Tech and Law," December 8, 2023
- "AI's Executive Order and Its Key Healthcare Implications," November 10, 2023
- "Caught in the Web: Hospital Associations Sue OCR on Third-Party Web Tracking Guidance," November 7, 2023
- "Sheppard Mullin's Top 10 Takeaways from HLTH 2023," October 18, 2023
- "Tele-Prescribing Flexibilities Extended Again in Second Temporary Rule," October 17, 2023
- "At HLTH 2023: The Digital Health Symphony, A Care Coordination Orchestra with No Maestro," October 10, 2023
- "At HLTH 2023: General Catalyst's HATCo Introduces a Radically Ambitious and Transformative Model for Healthcare," October 9, 2023

- "Texas is Making Moves on a Comprehensive Consumer Privacy Law," May 25, 2023
- "DEA and SAMHSA Extend Tele-Prescribing Flexibilities," May 12, 2023
- "Laboratory and Pathology Information Blocking Concerns," May 12, 2023
- "OCR Announces Proposed Rulemaking to Strengthen Reproductive Health Privacy," April 18, 2023
- "HHS OCR Delivered Annual Reports to Congress," April 17, 2023
- "DEA Proposes Rule for Post-PHE Telemedicine," March 7, 2023
- "ICYMI: HIPAA and Social Media IRL," February 8, 2023
- "Web Tracking Creates a Web of Data Privacy Risks," February 8, 2023
- "The Transformation in Behavioral Digital Health Services," January 31, 2023
- "Recent Developments in Telehealth Enforcement," December 12, 2022
- "Proposal to Overhaul Privacy Law Governing Substance Use Disorder Treatment Records," December 2, 2022
- "The FemTech Revolution," October 11, 2022
- "Proposed Rule Leverages Section 1557 for Healthcare Equity," August 22, 2022
- "Supreme Court Discrimination Case Narrows Scope of Restitution for Individuals," May 25, 2022
- "Top 5 Legal Issues in Digital Health to Watch for in 2022," February 1, 2022

Privacy Law Blog Posts

- "FDA Joins Other Regulators in Focus on AI and Machine Learning," November 22, 2021

Media Mentions

VIVE 2024 - What Threat or Opportunity Should Health IT Leaders be Keeping Their Eye On?
Healthcare IT Today, 05.09.2024

Lean Digital: General and Long-Term Considerations for Obesity
Healthcare IT TODAY, 05.03.2024

Lean Digital: How Apps and Services Can Help Control Weight
Healthcare IT TODAY, 04.29.2024

Mind Your Business: Wash. Privacy Law Ignites National Prep
Law360, 04.02.2024

Survey Finds Just 4 in 10 Healthcare Orgs. Review AI Guidance
Law360, 02.28.2024

Did a Computer Write This?: Ethical and Legal Questions About the Use of Large Learning Models in Scientific Research
NeurologyToday, 02.01.2024

What's Special About AI Risks and Remedies in Health Care?

Healthcare IT Today, 12.29.2023

Establishing trust and transparency in AI

HIMSS TV, 12.15.2023

Zealous for Wellness: The Ongoing Quest for Standard Measures

Healthcare IT Today, 11.16.2023

Most Hospital Websites use Third-Party Trackers. Here's what that Means for Data Privacy

LinkedIn News, 11.16.2023

Zealous for Wellness: How to Replace Hype with Data

Healthcare IT Today, 11.15.2023

The Lonely Epidemic: Social Isolation and Technology

Healthcare IT Today, 08.29.2023

With PHE Over, Teleprescribing Regulatory Landscape Shifts

Managed Healthcare Executive, 05.2023

Proposed HIPAA rule would protect PHI related to reproductive health care

Part B News, 05.08.2023

As PHE Nears End, Know When Audio-Only Care Becomes ePHI – and Stay Compliant

Part B News, 04.24.2023

6 Steps For Shoring Up Your Revenue Cycle's Telehealth Billing

HealthLeaders, 10.18.2022

Implement 6 tips to manage telehealth compliance risks

Part B News, 10.10.2022

Conduct Regular Checkups of Your Provider's Public Claims Data

Part B News, 10.03.2022

Use the OIG's Data Brief on Telehealth to Boost Your Compliance Efforts

Part B News, 09.26.2022

Don't let OIG fraud alert disrupt your practice's telehealth program

Part B News, 08.29.2022

Telemedicine or telescam? Heed the warnings in the latest special fraud alert

Part B News, 08.15.2022

AHLA's Speaking of Health Law: The Digital Health Revolution: Realities and Legalities

AHLA, 07.19.2022

Speaking Engagements

- "Wellness Apps and Tracking Technologies, a Virtual Networking Event by the BLG PG," American Health Law Association, November 14, 2023

- "Legal Changes in the Digital Health Space," MichBio, Life Sciences Showcase, September 18, 2023
- "Exploring the Impact of the Pandemic on Information Security and Privacy in the United States," June 28, 2023
- "Changing Landscape of Whistleblowing: Exploring New Standards and Accountability," June 28, 2023
- Moderator, "Cybersecurity and Patient Safety: Hot Topics," December 2022
- "The Impact of Artificial Intelligence on Data Privacy, Security, and Liability," November 2020
- "Data Security Issues Related to Wearables and Trackers," September 2020
- "Diversity & Implicit Bias: Challenges and Strategies for Inclusion," June 2020
- "COVID - 19 Critical Legal Implications," March 2020
- "Emerging Financing Alternatives for Life Sciences Companies: Opportunities and Pitfalls You Need to Know," October 2019
- "Investments in Provider Support Technology: Mobile Apps, Revenue Cycle Businesses, and Similar Investments," 16th Annual Healthcare and Life Sciences Private Equity and Finance Conference, February 2019
- "Digital Health and Cybersecurity," 10th Annual Pharmaceutical and Medical Device Conference, November 2018
- "HIPAA and Mobile Health Applications," HIPAA Webinar Series, September 2018
- "Wearable Devices and Data Security," Healthcare Litigation and Compliance Webinar Series, August 2018
- "HIPAA Audits and HIPAA Enforcement – Lessons Learned," HIPAA Webinar Series, July 2018
- "Telemedicine in Nephrology," 16th Annual Business and Legal Issues in Dialysis and Nephrology Symposium, May 2018
- "What Investors Should Understand about Data Privacy and Security Risks and Opportunities," 15th Annual Healthcare and Life Sciences Private Equity and Finance Conference, February 2018
- Group Health Plan HIPAA Compliance Trainings, November-December 2016
- "HIPAA Compliance Demystified," MATTER – Chicago Healthcare Startup Incubator Workshop, May 2015
- Expert panelist for International Device and Pharmaceutical Privacy Consortia, 2011-2015
- Expert panelist for Illinois Association of Health Care Attorneys, 2012-2014
- HIPAA Omnibus Rule Webcast: New Regulation Considerations, HealthITSecurity, June 2014

Events

22nd Advanced Summit on Life Sciences Patents

Balancing Innovation and Data Privacy: Navigating Global Regulatory Frontiers in Digital Health and Therapeutics

Fairfield Inn & Suites Manhattan Times Square South, New York, NY, 05.29.2024

Is Your Website A Data Breach Liability? Legal and Regulatory Considerations Around Website Technology & Third-Party Tracking in Healthcare

Webinar, 02.09.2023

WHLC Dobbs Series Part 2
Privacy in the Wake, and a Legislative Awakening.
Webinar, 07.26.2022

Does HIPAA Apply to You? A Guide for Retailers in 2022
Webinar, 05.19.2022

Memberships

American Health Lawyers Association, 2011-Present
B-Sharp (Network for Women In-House Attorneys), 2019-Present
Chicago Volunteer Legal Services (Active Court-Appointed GAL), 2011-Present
Illinois Association of Healthcare Attorneys, 2011-Present
International Association of Privacy Professionals 2013-Present

Podcasts & Webinars

Health-e Law Episode 9: Remote Patient Monitoring Innovating Health Tech with Dr. Vipul Kella of Physio AI
05.02.2024

Health-e Law Episode 7: Health Vibes at ViVE with Sara Shanti and Carolyn Metnick
03.21.2024

Health-E Law Episode 6: FemTech Meets DiagnosTech with Dierdre O'Neill of Hertility Health
03.07.2024

Health-e Law Episode 5: Gamification: Playing for Health with Craig Lund
02.14.2024

Health-e Law Episode 4: What to Watch for in '24: Costs, Consolidation and Tech with Eric Klein of Sheppard Mullin
01.17.2024

Health-e Law Episode 3: Digital Health to the Rescue: Improving Access to Specialized Care with Viveka Rydell-Anderson of Pacific Vision Foundation
12.07.2023

Health-e Law Episode 2: AI as an Aid: Emerging Uses in Healthcare with Jim Gatto of Sheppard Mullin
12.07.2023

Health-e Law Episode 1: In Tech We Trust? The Case for Transparency with Dr. Laura Tully of ChatOwl
12.07.2023

Health-e Law Episode 0: Trailer
11.30.2023

Your Website A Data Breach Liability? Legal and Regulatory Considerations Around Website Technology & Third-Party Tracking in Healthcare

02.09.2023

WHLC Dobbs Series, Part 2: Privacy in the Wake, and a Legislative Awakening

07.26.2022

Health Equity and ACA Section 1557: The Future of Nondiscrimination in Healthcare

02.10.2022

Practices

Corporate

Digital Health

Healthcare

Privacy and Cybersecurity

Women in Healthcare Leadership Collaborative

Industries

Artificial Intelligence

Healthcare

Education

J.D., Loyola University Chicago School of Law, 2009

B.S., Biology, University of Michigan, 2002

Admissions

Illinois