

Harry Nelson

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Harry Nelson is the Founder and Managing Partner of Nelson Hardiman, LLP, the largest healthcare and life sciences specialty law firm in Los Angeles. Harry is the author of <u>The United States of Opioids: A Prescription for Liberating a Nation in Pain</u>, published by Forbes in March 2019, which received critical praise for changing the crisis-related conversation from spectacle to solutions. The book grew out of Harry's work in opioid overdose and other crisis response in behavioral health. In 2017, Harry co-authored <u>From ObamaCare to TrumpCare: Why You Should Care</u>, an exploration of U.S. health policy past, present, and future aimed at moving beyond rhetoric and hand-wringing to bipartisan dialogue.

Healthcare Leader

Like his books, Harry's work as an advisor focuses on practical solutions to problems at the intersection of healthcare transformation and regulatory and reimbursement compliance and strategy. While his experience has extended into virtually every facet of healthcare facilities and life science organizations, his work in recent years has emphasized digital and behavioral health, retail medical models, and emerging therapeutics including cannabis and biologic products.

He has earned a reputation nationally as a thought leader addressing industry challenges both tactically and strategically, helping leaders and organizations think through how to respond both proactively, in response to crisis, and in taking corrective action to remediate problems. California and federal regulators confer with him in addressing difficult problems, reflecting his reputation as an honest and thoughtful voice on healthcare problems nationally. In 2016, Harry was asked to serve on a California committee to address medical device risk issues, and, since 2017, he has taught courses for state licensing board experts.

The Future of U.S. Healthcare

In addition to his law practice, Harry frequently serves as a keynote speaker on issues related to leadership, the healthcare future, solving industry problems. He also serves as an expert witness on industry custom and practice and compliance standards related to data privacy and security, corporate practice of medicine, and other areas of healthcare and life science innovation.

Accolades

Harry serves as chair of the <u>Behavioral Health Association of Providers</u>, an education and advocacy organization that works to advance standards and develop tools to address industry challenges. His leadership has been recognized, among other distinctions, by Behavioral Health Network Resources' 2018 Addiction Advocacy Award. He is an Adjunct Clinical Assistant Professor of Anesthesiology at Keck School of Medicine of USC. Since 2010, he appears annually on lists for Best Lawyers, Southern California Super Lawyers, and receives a Martindale-Hubbell AV Preeminent rating.

The Best Lawyers in America (2024) recognized Harry for the 13th consecutive year for his specialty in Healthcare Law as well as Administrative/Regulatory Law, and he has been noted for his focus on COVID-19 since 2021. The *Daily Journal* named Harry one of the Top Healthcare Lawyers in California in 2019. Harry also garnered the Behavioral



Health Network's Addiction Advocacy Award, the Davis Direction Foundation Award, and the CLARE | MATRIX Spirit Award in 2019.

Life Outside the Firm

Harry spends his time away from work advising nonprofits on leadership and change management. He has tried to teach his four children a love for Detroit sports teams and the University of Michigan.

You can follow Harry's take on timely healthcare issues on Twitter <a>@nelsonh. His most recent work can be found at <a>www.harrynelson.com

Practice Areas

- Government Investigations
- Litigation
- Regulatory Compliance
- Transactions

Credentials

Education

University of Michigan, J.D., cum laude

University of Michigan, A.B., with high distinction

Admission

State Bar of California

State Bar of Hawaii

State Bar of Illinois



Affiliations

Adaptive Business Leaders (Healthcare)

American Bar Association

American Health Lawyers Association

American Society of Addiction Medicine

California Academy of Attorneys for Healthcare Professionals

California Academy of Attorneys for Health Care Providers

California Society of Healthcare Attorneys

Los Angeles County Bar Association

Provisors Healthcare Roundtable

Wexner Heritage Program



Experience

- Behavioral Health Patient Safety Reforms/Compliance Following patient harm incidents, oversaw national
 addiction treatment organization with compliance program design, implementation, and extensive state-level
 certification and licensure.
- Behavioral Health Compliance Oversaw development of standards and guidelines for providers and health
 plans on fraud and abuse issues, including waivers and discounts of patient financial responsibility and
 marketing activities
- Behavioral Health Strategy Developed regulatory and reimbursement model for addiction treatment provider integration of medical and mental health professional services
- Telehealth Compliance and Reimbursement Strategy Advised telehealth provider on compliance and risk management strategy in servicing Medicare beneficiaries and contracting with Medicare and in-network healthcare providers.
- Asynchronous Telehealth Strategy Advised telehealth company on regulatory strategy for roll-out of asynchronous telehealth model, including development of relationships with state regulators, self-funded employer plans, and venture investors
- FDA Lab Investigation Defended national clinical laboratory in FDA investigation and persuaded FDA to refrain from enforcement action based on corrective action plan and compliance program.
- FDA Clinical Research Compliance Advised clinical research organization (CRO) on compliance in handling research related to cannabis and CBD.
- FDA Biologic Products Compliance Prepared white paper on emerging issues in FDA regulatory pathways for stem cell therapeutics and other biologics
- Retail Medicine-Corporate Practice of Medicine Served as expert witness in successful defense of
 corporate practice of medicine investigation of national chain of retail healthcare; Oversaw compliance
 program redesign and implementation
- HIPAA Advised national physician specialty organization in developing a HIPAA-compliant patient data registry providing outcomes measurement and quality improvement.
- HIPAA Served as expert witness on cases involving allegations of data breaches; advised multiple covered entities and business associates on HIPAA privacy and data security compliance and post-brief response strategy
- **Medicare Overpayment** Represented medical group in a \$3.1 million reduction in Medicare overpayment determination via contested hearing against recovery audit contractor.
- Skilled Nursing Facilities Developed and implemented regulatory compliance programs for over 100 skilled nursing facilities (SNFs).
- Stark/Anti-Kickback Statute Oversaw implementation of corporate integrity agreement on behalf of skilled nursing facility chain following federal investigation of Stark/Anti-Kickback Statute violations.
- Fair Housing Rights Resolved disputes with five cities across California regarding complaints concerning behavioral health housing.
- Sober Living Home Successfully defended a sober living home against City of Los Angeles criminal charges based on the mischaracterization of the home as an unlicensed community care facility and misapplication of the Los Angeles City Municipal Code. Nelson Hardiman convinced the City to drop all licensing and occupancy charges, and to dismiss its case against the sober living home and the property owner, thereby enabling the home to continue to house individuals recovering from addiction.