

# Rule speeds approvals for ‘breakthrough’ devices, other commercially covered services

Senior Counsel [Alan J. Sedley](#) was recently interviewed by Part B News to discuss a new final rule that allows items and services to gain approval for Medicare reimbursement more quickly than in the past, particularly medical devices that clear a specific FDA hurdle.

## From the Article:

*Alan J. Sedley, senior counsel with the Nelson Hardiman firm in Los Angeles, notes that “breakthrough” technology was originally “the primary focal point” of the rule, as suggested by then-President Trump’s Oct. 3, 2019, Executive Order, which called for regulations to be written so that “innovative products are brought to market faster, and so that such products, including breakthrough medical devices and advances in telehealth services and similar technologies.”*

[Part B News AJS Interview](#)

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## 8 Nelson Hardiman Attorneys Named to the 2021 Southern

# California Super Lawyers List

Nelson Hardiman is proud to announce that Attorneys [Rob Fuller](#), [Mark Hardiman](#), [Sara Hersh](#), [John A. Mills](#), [Harry Nelson](#), [Jonathan Radke](#), [Zachary Rothenberg](#), and [Alan J. Sedley](#) were named to the 2021 Southern California Super Lawyers list. Each candidate is evaluated on 12 indicators of peer recognition and professional achievement. Only 5% of attorneys in Southern California receive this distinction.

2021 marks the *11th consecutive year* that Co-Founder and Managing Partner [Harry Nelson](#) has been named as one of Southern California's Super Lawyers.

Congratulations to all for the selection to this prestigious list!

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## Should You Apply for Government Assistance?

Co-Founder and Managing Partner [Harry Nelson](#) was interviewed by [U.S. News & World Report](#) regarding public assistance programs for help relating to healthcare.

### From the article:

*Medicaid. For those with low incomes and limited assets, Medicaid provides free health insurance. Many states have expanded Medicaid coverage in recent years, so more people are eligible. "This is no longer something that's just limited to a narrow handful," says Harry Nelson, a health care attorney and author of "The United States of Opioids: A Prescription for Liberating a Nation in Pain." In his home*

*state of California, Nelson estimates that about a third of people are covered by Medicaid.*

[Read the full article](#)

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## **Top-ranked Healthcare Law Firm Nelson Hardiman Elevates Sarvnaz “Miriam” Mackin to Partner**

[Nelson Hardiman](#) is proud to announce that [Sarvnaz “Miriam” Mackin](#) has been elevated to partnership. Miriam is a key member of the firm’s Litigation, Administrative, and Regulatory practices and represents a range of clients including individual healthcare practitioners and healthcare organizations in matters encompassing licensing and compliance issues to complex litigation. Miriam has also applied her litigation and regulatory experience in assisting as outside counsel to medical staffs in peer review matters, disciplinary hearings, and drafting/revising medical staff bylaws and policies.

“Miriam is a star in every sense of the word. Her work ethic, her deep intelligence, and her savvy in solving clients’ problems are vital to our firm and have earned the confidence of our clients,” said the firm’s Founder, [Harry Nelson](#). “It is no mistake that clients trust her in high stakes matters, whether it is defending and advising them on fraud and abuse-related matters, patient safety issues, privacy and data security-related challenges, or healthcare business

litigation.”

Miriam’s dedication to assisting those in the healthcare field extends beyond the office. Engaged with organizations such as Women in Health Administration and the National Health Law Program, Miriam has built strong connections within the healthcare community and has a true appreciation for developing nimble and innovative strategies. “If the past year has taught us anything, it is that healthcare providers and organizations and the laws and regulations that guide the healthcare field are a vital component in ensuring the health and safety of our families and communities,” says Miriam. “I enjoy being able provide guidance to those individuals and organizations which enables our clients to continue doing their jobs and achieve their goals with the least number of hurdles as possible.”

Fellow Partner Sara Hersh, says “Miriam is dedicated and focused in her work with a true sense of compassion for the unique needs of her clients. Miriam’s broad range of experience in regulatory, administrative, and litigation matters ensures clients will benefit from her well rounded and proactive approach while resolutely protecting their interests.

[Nelson Hardiman LLP](#) is the premier healthcare and life sciences firm in Los Angeles, serving healthcare and life science providers, investors, and organizations that need a hard-to-find level of quality advice on the most sensitive industry issues. The firm’s litigation practice specializes in defending fraud and abuse and whistleblower actions, government investigations, and other complex business disputes. Nelson Hardiman’s transactional group handles healthcare organization acquisitions, sales, investment, and financings, and Nelson Hardiman’s regulatory team advises on compliance with licensing, operational, and reimbursement issues across the full continuum of healthcare industry sectors, with expertise on Medicare and Medicaid requirements,

privacy and data security, FDA, and other regulatory matters. The firm has earned a singular position reputation nationally for its leadership in addressing issues in behavioral health and telehealth. More information about the firm is available at <https://www.nelsonhardiman.com> or at 310.203.2800.

[Press Release](#)

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# Major Payers Slow to React to AMA Attack on High-Deductible Plans

Partner [Rob Fuller](#) was interviewed by [health payer specialist](#) to discuss the nation's leading payers high-deductible health plans in the aftermath of the American Medical Association's indictment of the products and the growing crisis of affordable coverage.

## From the article:

*Because they are designed to have consumers pay between \$1,400 to \$7,000 for medical care before insurance kicks in, these types of plans can be "a very bad trap for the unwary," says Rob Fuller, attorney with Nelson Hardiman in Los Angeles and co-author of the book From ObamaCare to TrumpCare.*

*Fuller says that the plans exploded in popularity over the past 15 years as employers started asking for a lower-cost benefit. But the crisis of affordability, rendered more sharply by the pandemic, is leading to calls for change.*

Read Full Article: [Major-Payers-Slow-to-React](#)

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# With no federal COVID-19 liability shield, states go it alone

Co-Founder and Managing Partner [Harry Nelson](#) was interviewed by [TechTarget](#) to provide commentary regarding the absence of a federal COVID-19 liability shield for states.

Congress has not enacted a COVID-19 liability shield, leaving states to craft their own policies. But the risk to employers from these lawsuits is still muddy.

## From the article:

*Georgia's COVID-19 shield states, for instance, that someone can sue for "gross negligence," meaning the operators of the business "were reckless and departed in an extreme way from what the standard was," said Harry Nelson, a healthcare attorney and founder and managing partner of Nelson Hardiman LLP.*

*Nelson supports a middle ground on shields and believes they can be structured in a way that makes it easier for businesses to reopen, but also "still ensure [they are] not a get-out-of-jail-free card."*

[Read the full article](#)

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# Nelson Hardiman Welcomes Alan J. Sedley as Senior Counsel

[Alan J. Sedley](#), former general counsel of two California hospital health systems, has joined the law firm of Nelson Hardiman, LLP as Senior Counsel. “We are thrilled to add an attorney with the wealth of healthcare experience that Alan brings,” said Managing Partner [Harry Nelson](#). “Alan brings not only expertise, but also leadership that will strengthen our firm and extend support to our clients.”

Sedley’s addition marks the firm’s ongoing growth and extension into Orange County, where he is based. “I am honored and delighted to join Nelson Hardiman,” said Mr. Sedley. “It is a pleasure to be part of the best team of healthcare lawyers in the State.” Nelson Hardiman was recently recognized by [U.S. News & World Report](#) for yet another year as a “Tier 1 Law Firm for Healthcare and Regulatory Compliance Law”.

At Nelson Hardiman, Alan will draw on three decades of experience, including service as corporate in-house general counsel to two large California hospital health systems. As a hospital general counsel, Alan advised on numerous health system corporate matters, and managed transactions, litigation, regulatory compliance and operational processes at the hospitals. In his private practice and as outside counsel, Alan regularly advises and represents hospitals, health systems, physicians and other health professionals, ambulatory surgical centers and multi-specialty medical groups in their oft-challenging operational issues, addressing the traditional business and legal concerns within the context of the healthcare marketplace. Alan has pursued a specialized focus and offers highly experienced and dedicated counsel to large

medical group and hospital medical staffs on issues relating to medical staff credentialing, privileging, physician recruitment, peer review analyses arising from suspected practitioner clinical deficiencies or disruptive conduct, and peer review body and committee investigatory processes. He provides detailed guidance on peer review hearing procedures as well as statutory reporting requirements. A civil litigator for the past thirty-five years, Alan has successfully litigated dozens of lawsuits in federal court on behalf of DSH hospitals and GME academic medical centers against the Centers for Medicare and Medicaid, alleging misapplication of rules and regulations during the course of computing hospital reimbursement payments.

About Nelson Hardiman

[Nelson Hardiman LLP](#) is the premier healthcare and life sciences firm in Los Angeles, serving healthcare and life science providers, investors, and organizations that need a hard-to-find level of quality advice on the most sensitive industry issues. The firm's litigation practice specializes in defending fraud and abuse and whistleblower actions, government investigations, and other complex business disputes. Nelson Hardiman's transactional group handles healthcare organization acquisitions, sales, investment, and financings, and Nelson Hardiman's regulatory team advises on compliance with licensing, operational, and reimbursement issues across the full continuum of healthcare industry sectors, with expertise on Medicare and Medicaid requirements, privacy and data security, FDA, and other regulatory matters. The firm has earned a singular position reputation nationally for its leadership in addressing issues in behavioral health and telehealth. More information about the firm is available at <https://www.nelsonhardiman.com> or at 310.203.2800.

[Press Release](#)

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# Nelson Hardiman Recognized by U.S. News & World Report's "2021 Best Law Firms in America" for Health Care Law

Nelson Hardiman was awarded a Tier 1 ranking in Health Care and Administrative/Regulatory Law by the [U.S. News & World Report's "2021 Best Law Firms in America."](#)

Firms included in the 2021 Edition of U.S. News-Best Lawyers "Best Law Firms" are recognized for professional excellence with consistently impressive ratings from clients and peers. To be eligible for a ranking, a firm must first have a lawyer recognized in The Best Lawyers in America®, which recognizes the top 5% of private practicing lawyers in the United States. Achieving a tiered ranking signals a unique combination of quality law practice and breadth of legal expertise.

Earlier this year, Nelson Hardiman Partners, [Mark Hardiman](#), [Aaron C. Lachant](#), [John A. Mills](#), and [Harry Nelson](#) were named to the 2021 Best Lawyers in America List.

This year marks the tenth consecutive year that Harry Nelson was recognized and the sixth consecutive year that Mark Hardiman was recognized by Best Lawyers. Mark, Harry, and John Mills were nominated for their specialty in Healthcare Law. Aaron Lachant was selected for both Healthcare Law and Litigation and John Mills was selected for Healthcare Law and Administrative/Regulatory Law. For the first time, Harry was recognized by Best Lawyers for leadership in focusing on COVID-19.

For the first time in the history of Best Lawyers, Partner [Kathryn F. Edgerton](#) and Attorney [Katherine Bowles](#) were named in the inaugural edition as Best Lawyers: Ones to Watch (2021). These awards are recognitions given to attorneys who are earlier in their careers for outstanding professional excellence in private practice in the United States.

“The 2021 rankings are based on the highest lawyer and firm participation on record, incorporating 8.3 million evaluations of more than 110,000 individual leading lawyers from more than 22,000 firms. “For the 2021 ‘Best Law Firms’ publication, the evaluation process has remained just as rigorous and discerning as it did when we first started 11 years ago.” says Phil Greer, CEO of Best Lawyers. “This year we reviewed 15,587 law firms throughout the United States – across 75 national practice areas – and a total of 2,179 firms received a national law firm ranking. We are proud that the ‘Best Law Firms’ rankings continue to act as an indicator of excellence throughout the legal industry.”

[Press Release](#)

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## **Harry Nelson on Spectrum News: Supreme Court Hears Challenge to Affordable Care Act**

[Harry Nelson](#) was interviewed on Spectrum News Founding Partner Harry Nelson was interviewed on Spectrum TV News1 to discuss the Supreme Court’s hearing of the newest challenge to the

Affordable Care Act and the idea of severability that Justice Brett Kavanaugh mentions.

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