HEALTHCARE LAW UPDATE

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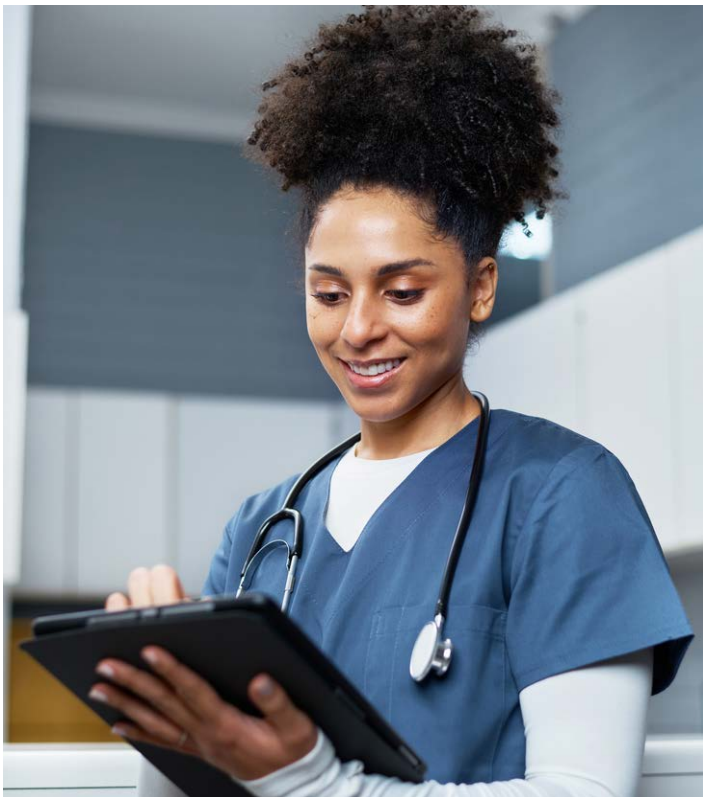

STATE UPDATE

Covid 19 Waivers for Advanced Practice Nurses and Physician Assistants Set to Expire

On February 13, 2026, Governor Mikie Sherrill signed Executive Order No. 13, extending the COVID-19 State of Emergency declared in former Governor Murphy's Executive Order No. 103 (2020) for the limited purpose of providing certain health care professionals more time to finalize joint protocols and delegation agreements with supervising physicians, requirements that were previously waived for the duration of the State of Emergency. The State of Emergency, previously set to expire at 5:00 p.m. on February 16, 2026, will now expire at 5:00 p.m. on April 2, 2026, and full compliance is required by such date.

Healthcare providers and facilities should ensure full compliance with scope of practice, supervision, and collaborative practice requirements that were previously not enforced during the State of Emergency. In particular, providers and facilities should be aware of the following:

1. The temporary waiver that permitted APNs to prescribe and order medications and devices without a joint protocol with a collaborating physician will expire. APNs must return to full compliance with the statutory requirements for practice, including maintaining a joint protocol with a collaborating physician for prescriptive authority.
2. The temporary waiver that permitted Physician Assistants (PAs) to practice without a delegation agreement and physician supervision will expire. PAs must return to full compliance with the statutory requirements for practice, including maintaining a delegation agreement with a supervising physician.
3. Providers practicing in New Jersey under a temporary or foreign license will need to transition to a full New Jersey license in order to continue practicing.

The extension of the State of Emergency gives the New Jersey Legislature additional time to consider Senate Bill 2996, introduced on January 13, 2026 to expand the scope of practice for APNs, before the temporary supervision waivers expire. If passed, Senate Bill 2996 would allow certain experienced APNs to practice independently of a collaborating physician. In particular, the Bill would permit APNs who have completed 24 months or 2,400 hours of licensed, active, advanced nursing practice to practice without a joint protocol with a collaborating physician. In addition, APNs-Anesthesia who have completed 24 months or 2,400 hours of licensed, active, advanced nursing practice would be authorized to practice without any requirement for supervision by a physician and without any requirement that the APN-Anesthesia enter into joint protocols with a physician.

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Waivers for Telemedicine Prescribing of Controlled Substances Expire

Beginning February 16, 2026, all New Jersey licensed providers are required to conduct an in-person physical examination prior to prescribing Schedule II controlled dangerous substances to patients, with limited exceptions. This comes as a result of then Governor Phil Murphy signing Executive Order 415, which terminated the COVID-19 State of Emergency in New Jersey, and with it, waivers that permitted the prescribing of Schedule II controlled dangerous substances via telemedicine without an in-person physical examination. Providers may still prescribe such substances via telemedicine, but may only do so after an initial in-person examination, and there must be subsequent in-person visits with the patient every three months that the patient is being treated with the Schedule II controlled dangerous substance. Notably, when prescribing stimulants to minor patients under the age of 18, such as those used to treat ADHD, an in-person examination is not required if the provider is using interactive, real-time, two-way audio and video technologies and the provider obtains a written consent for the waiver of in-person requirements from the minor's parent or guardian.

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New Jersey Department of Health Streamlines Licensing of Outpatient Facilities

On January 17, 2026, the New Jersey Department of Health, in conjunction with the New Jersey Department of Human Services, announced the adoption of significant regulatory reforms establishing a single, integrated licensure framework for outpatient health care facilities. Previously, if a facility offered primary care, mental health, and addiction services in a single location, three separate licenses were required. Additionally, under the old framework, providers were required to maintain separate medical records when a patient received physical and behavioral health services. The following changes will be included once the new rules take effect:

- Single Integrated License: Outpatient facilities may provide primary care, mental health, and substance use disorder services under one consolidated license, replacing the prior requirement for multiple, separate licenses.
- Unified Medical Records and Shared Space: Facilities may maintain integrated patient records and utilize shared clinical space without needing separate entrances or distinct physical areas for different service lines.
- Medications for Opioid Use Disorder: Under the new rules, a Department of Health waiver that increased access to Medications for Opioid Use Disorder (MOUD) treatment is made permanent.
- Reproductive Care: The requirement of a staff OB/GYN to provide essential care is removed under the new rules.

The new rules are designed to streamline oversight, reduce administrative burden, and promote integrated delivery of primary care, behavioral health, and addiction services. In particular, outpatient facilities, including Federally Qualified Health Centers (FQHCs), outpatient mental health and substance use disorder providers, and licensed primary care clinics will benefit from the new rules. The

new rules were to take effect upon publication in the New Jersey Register, but have been put on hold due to Governor Mikie Sherrill's Executive Order No. 7, instituting a 90-day pause on the proposal and adoption of new state agency rules and regulations.

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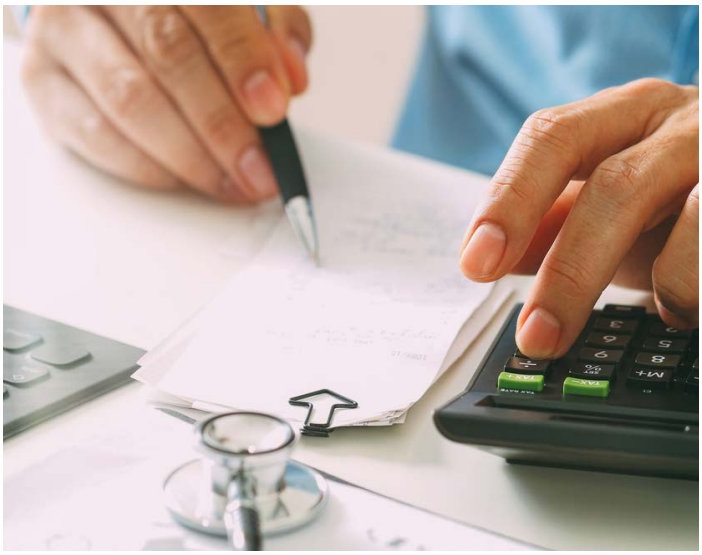

FEDERAL UPDATE

OIG Issues Favorable Advisory Opinion on Cost-Sharing Waivers for Commercially Insured Patients

On January 13, 2026, the United States Department of Health and Human Services, Office of Inspector General (OIG) issued Advisory Opinion 26-01, approving a proposal by a manufacturer of a screening test for colorectal cancer to waive any cost-sharing obligations for commercially insured patients, concluding that the proposal would not violate the Federal Anti-Kickback Statute (AKS) or the Beneficiary Inducements Civil Monetary Penalty (CMP) provisions.

Although colorectal cancer screening tests are recommended by the U.S. Preventive Services Task Force (USPSTF), the manufacturer's specific test is not yet included in its recommendations. As a result, many commercial insurers impose cost-sharing on patients who receive the test, while similar tests included in the USPSTF recommendations are covered without cost-sharing. Under the proposed arrangement, the manufacturer would waive cost-sharing for all eligible commercially insured patients who receive the test and do not otherwise qualify for its financial assistance program. The waiver would apply uniformly and would not be tied to other healthcare items or services. The manufacturer certified it would not shift any related costs to Federal health care programs. The proposed arrangement would end once the USPSTF updates its recommendations to include the test.

The OIG determined that the proposed arrangement would not violate the AKS or implicate the CMP because it would involve no offer or transfer of remuneration to induce the purchase of items or services reimbursable by a Federal health care program or to influence Medicare or State health care program beneficiaries to select the manufacturer for such items or services. The OIG also emphasized that the manufacturer would not provide remuneration to ordering prescribers. The OIG noted that this proposed arrangement differs from problematic arrangements that "carve-out" referrals of Federal health care program enrollees or business that disguise remuneration through the payment of amounts related to non-Federal health care program business.

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DOJ Reports Record $6.8 Billion in False Claims Act Recoveries, Driven Largely by Healthcare Enforcement

On January 16, 2026, the U.S. Department of Justice (DOJ) announced that False Claims Act recoveries totaled $6.8 billion in fiscal year 2025, the highest annual total on record and more than double the $2.9 billion recovered in fiscal year 2024. Approximately $5.7 billion of the $6.8

billion total arose from healthcare-related settlements and judgments. Notably, the government secured a $1.6 billion verdict against Johnson & Johnson related to the promotion of HIV medications for alleged unapproved uses, and obtained $289 million from CVS Caremark in connection with claims involving alleged overbilling under Medicare Part D.

The federal False Claims Act remains one of the government's primary civil enforcement tools for addressing fraud involving federal funds, especially considering the scale of federal healthcare program spending. The statute enables the government to seek treble damages and significant per-claim penalties from parties that knowingly submit, or cause the submission of, false or fraudulent claims for payment from the United States. According to the DOJ, enforcement activity in fiscal year 2025 focused heavily on the healthcare sector, including managed care, pharmaceutical pricing and marketing, and medically unnecessary services.

While large pharmaceutical and healthcare organizations continue to be prominent enforcement targets, the DOJ emphasized that liability under the False Claims Act extends across the healthcare industry, including to hospitals, physician groups, and other providers. The record-setting recoveries underscore the government's ongoing scrutiny of billing, coding, and reimbursement practices, and underscore the need for healthcare stakeholders to maintain strong compliance, monitoring, and internal auditing programs to reduce enforcement risk.

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Key Healthcare Reforms Enacted as Part of 2026 Federal Spending Law

On February 3, 2026, President Donald Trump signed the Consolidated Appropriations Act of 2026, a $1.2 trillion government funding package that ended a brief government shutdown and enacted two significant healthcare policy reforms. Most notably, the Act extends pandemic-era Medicare telehealth flexibilities for two additional years, pushing the expiration date to December 31, 2027. This extension preserves uninterrupted access to telehealth services for Medicare beneficiaries while Congress continues to evaluate permanent policy options.

The Act also introduces substantial federal oversight of pharmacy benefit managers (PBMs) aimed at enhancing transparency and accountability. Among the Act's key provisions, PBMs must pass through 100% of manufacturer rebates to Medicare plans to help reduce costs for both the program and its beneficiaries, and Medicare Part B compensation to PBMs may no longer be tied to the list price of prescription drugs. In addition, the Act requires PBMs to report detailed data on drug pricing, rebates, and utilization, and allows certain audits of rebate records. The Act also requires PBMs to disclose if they are steering patients to affiliated pharmacies and provide the costs for drugs at those pharmacies.

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Supreme Court Holds State Affidavit of Merit Requirements Inapplicable in Federal Medical Malpractice Cases

On January 20, 2026, the United States Supreme Court issued a unanimous decision in Berk v. Choy, holding that state "affidavit of merit" requirements do not apply to medical malpractice actions filed in federal court. The case involved a Florida resident who sued Delaware healthcare providers, including a physician and a hospital, alleging negligent treatment of an ankle injury. Delaware law, similar to that of many states, including New Jersey, requires malpractice plaintiffs to submit an affidavit from a qualified medical professional attesting that the claim has merit. After lower courts dismissed the case for failure

to meet this requirement, the Supreme Court reversed, finding that Federal Rules of Civil Procedure 8 and 12 govern the initiation of lawsuits in federal court and require only a "short and plain statement of the claim," not an expert certification.

For healthcare providers and clinicians, the decision means that plaintiffs able to access federal court, most commonly through diversity jurisdiction where the parties reside in different states, may proceed without satisfying state affidavit of merit requirements that often serve as an early screening tool against frivolous claims. Although the ruling does not alter the substantive standards governing malpractice liability, it removes a procedural barrier that previously led to early dismissal of some cases. Commentators have noted that the decision may encourage forum shopping by plaintiffs seeking to avoid state-imposed requirements, potentially increasing the number of malpractice cases that proceed in federal court.

The broader impact on malpractice litigation, however, may be limited. Most medical malpractice actions involve in-state parties in state court, where affidavit of merit statutes would remain fully enforceable. Federal jurisdiction for malpractice claims will continue to be limited to cases involving diversity of citizenship and the applicable jurisdictional threshold. Nonetheless, healthcare providers should be aware that, in matters eligible for federal court, plaintiffs may face fewer procedural hurdles at the outset, an important distinction that could influence litigation strategy and forum selection.

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President Trump's "Great Healthcare Plan"

On January 15, 2026, President Donald Trump called on Congress to enact The Great Healthcare Plan, a broad reform framework targeting four core areas: prescription drug pricing, insurance premiums, insurer accountability, and healthcare price transparency. The proposal seeks to reduce prescription drug costs by codifying the Administration's Most-Favored-Nation pricing model, with the goal of ensuring Americans do not pay more for medications than patients in comparable foreign markets. The plan also contemplates making certain drugs available over the counter to promote competition and improve consumer access, while advancing additional measures aimed at promoting transparency in pharmaceutical pricing.

To address rising insurance costs, the plan proposes redirecting billions of dollars in federal subsidies from insurers directly to eligible individuals, enabling consumers to purchase coverage that is best suited to their needs. The plan also calls for funding a cost-sharing reduction program intended to stabilize out-of-pocket expenses. In addition, the plan would impose new transparency requirements on insurers, including public reporting of profits derived from premiums, medical loss ratios, claim denial rates, and average wait times for routine care, measures designed to strengthen accountability for both consumers and providers.

The plan further expands federal price transparency efforts by requiring all providers participating in Medicare or Medicaid to prominently display pricing and fees at their place of business. The proposal builds

on transparency regulations promulgated during President Trump's first term, which applied primarily to hospitals and insurers, by extending similar obligations across the broader healthcare system. According to the Administration, if enacted, the Great Healthcare Plan would represent a significant continuation of the Administration's efforts to promote affordability, competition, and informed healthcare decision-making.

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LEGISLATIVE AND REGULATORY UPDATE

Governor Sherrill Institutes 90 Day Pause on the Proposal and Adoption of New Regulations

On January 23, 2026, Governor Mikie Sherrill issued Executive Order No. 7, which places a 90-day hold on the proposal or adoption of new rules by New Jersey state agencies. The purpose of this Order is to give the new Administration time to review pending regulations and ensure they align with its policy priorities, particularly regarding economic growth and regulatory simplification. The Order allows agencies to flag proposed rules that might impact public health, safety, court compliance, or federal funding, and the Governor may lift the hold for those specific rules. Importantly, the Order does not create any legal rights for regulated parties and cannot be used to challenge government action.

Bill Introduced to Prohibit Mid-Contract Reimbursement Reductions

Assembly Bill No. 3257, pre-filed for the 2026 legislative session, would prohibit health insurance carriers from reducing reimbursement rates to network healthcare providers during the term of an existing contract. If enacted, the prohibition would apply to contracts entered into or renewed on or after the Bill's effective date.

Standardized Reimbursement for Evaluation and Management Services Proposed

Senate Bill No. 3264, introduced on February 2, 2026, would require health insurance carriers in New Jersey to use the federal resource-based relative value scale (RBRVS) when setting reimbursement rates for certain medical evaluation and management services. The Bill specifically targets billing codes appended by "modifier 25," which indicates a significant, separately identifiable service beyond another procedure performed the same day. The Bill would apply to insurance companies, HMOs, and the State and School Employees' Health Benefits Programs.

Bill Introduced to Require Mental Health First Aid Training for School Personnel

Senate Bill No. 3301, introduced on February 2, 2026, would require school psychologists and school counselors in New Jersey to complete a mental health first aid training course during their first year of employment and at least once every three years thereafter. The training, which must consist of at least eight hours of instruction, would

cover topics such as recognizing signs of mental illness and substance use, risk factors, and intervention strategies for helping students in crisis. The Department of Education, in consultation with the Department of Human Services, would be responsible for establishing or approving the training program.

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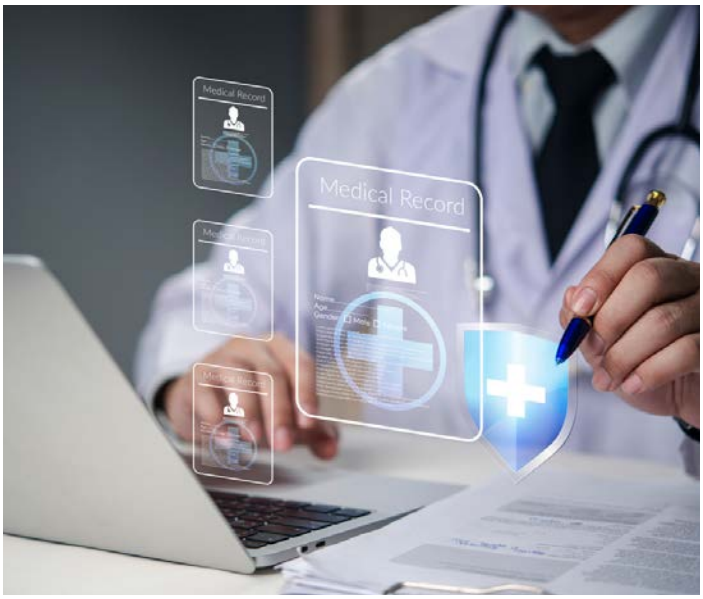

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HIPAA CORNER

OCR's Risk Analysis Initiative Going Strong

On February 19, 2026, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) issued a press release in which the OCR announced the settlement of its 11th enforcement action in OCR's Risk Analysis Initiative. The settlement resolved an OCR investigation of an Illinois substance use disorder treatment provider for potential HIPAA violations relating to a successful email phishing attack. Through the attack, the threat actor accessed electronic protected health information (ePHI) through a workforce member's email account, impacting 1,980 patients.

OCR concluded that the provider had failed to conduct an accurate and thorough risk analysis to determine the potential risks and vulnerabilities to the confidentiality, integrity, and availability of the ePHI the provider holds, as required by the HIPAA Security Rule. Pursuant to the resolution agreement entered into between the provider and the OCR, the provider agreed to pay a monetary penalty of $103,000, plus enter into a corrective action plan under which the provider must conduct a complete and thorough risk analysis, develop and implement a risk management plan, develop policies and procedures and provide workforce training.

- In its press release, the OCR recommended that HIPAA covered entities and business associates implement steps to mitigate or prevent cyber-threats, including:
- Identify where ePHI is located in the organization, including how ePHI enters, flows through, and leaves the organization's information systems.
- Periodically conduct, and update as needed, a risk analysis and develop and implement risk management measures to address identified risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI.
- Ensure audit controls are in place to record and examine information system activity.
- Implement regular review of information system activity.
- Utilize mechanisms to authenticate users seeking access to ePHI.
- Encrypt ePHI in transit and at rest to guard against unauthorized access to ePHI when appropriate.
- Incorporate lessons learned from incidents into the organization's overall security management process.
- Provide workforce members with regular HIPAA training that is specific to the organization and to the workforce members' respective job duties.

Required Updates to Notice of Privacy Practices

As we reported in our February 11th Healthcare Law Alert, HIPAA covered entities were required to update their Notice of Privacy Practices by February 16, 2026 to include certain protections to substance use disorder treatment information. We also reported on the OCR's "landmark" civil enforcement program and OCR's ability to bring enforcement actions against organizations that fail to protect SUD treatment records as required under HIPAA and 42 CFR Part 2. As with OCR's risk analysis initiative, we expect the OCR will place a heavy emphasis on investigating complaints relating to breaches of SUD treatment information and records.

If you need assistance with your organization's privacy and security

ATTORNEY **SPOTLIGHT**

Get to know the faces and stories of the people behind the articles in each issue. This month, we invite you to meet Members **Shannon Carroll** and **Jonathan Walzman**.

SHANNON CARROLL

In your opinion, what is the most pressing legal issue currently facing the healthcare industry?

The most pressing issue is the growing use of technology and artificial intelligence in healthcare. There is a lot of potential to use the tools effectively, especially in the areas of public health and preventive care. These new opportunities must be analyzed with strong consideration of the critical privacy and security concerns that can arise with their use.

What personal qualities or skills do you think are most important for a healthcare attorney to cultivate, both professionally and personally?

Flexibility. In transactions, litigation and compliance, a healthcare attorney needs to be able to understand the client's goals and challenges they are facing and provide strong legal guidance. During the representation, there will always be curveballs, a good attorney must be flexible in order to respond most effectively to quickly changing circumstances.

JONATHAN J. WALZMAN

In your opinion, what is the most pressing legal issue currently facing the healthcare industry?

One of the most pressing legal issues facing the healthcare industry is the dramatic pace of consolidation across the industry, especially as private equity investment, provider consolidation, and hospital system acquisitions of physician practices reshape the market. These trends raise complex legal questions around regulatory compliance, antitrust risk, and reimbursement structures, and they often require detailed analysis state corporate practice of medicine rules and fraud and abuse laws. As regulators increasingly scrutinize these transactions, the potential for new federal and state guidance or enforcement action is high, making it critical for counsel to stay ahead of emerging regulatory trends. Helping clients structure deals that balance growth objectives with compliance and risk management, while at the same time trying to anticipate how evolving enforcement priorities and potential new regulations may impact healthcare transactions, has become a central legal challenge.

What personal qualities or skills do you think are most important for a healthcare attorney to cultivate, both professionally and personally?

A successful healthcare attorney needs strong judgment and the ability to see both the legal and business implications of a decision, particularly in complex transactions. Clear communication is essential. Clients value practical, understandable advice that helps them make informed choices, not just technical legal analysis. Equally important are adaptability and intellectual curiosity, given how quickly healthcare law evolves. And perhaps most importantly, empathy and patience go a long way, as healthcare clients are utilizing their attorneys' advice to make decisions that directly affect patient care, their workforce, the long-term viability of their organizations, and ultimately their own livelihoods.

On February 25, Healthcare Law Member **Lani Dornfeld** and Labor & Employment Member **Jay Sabin**, co-presented "Effective Strategies for Managing AI In The Workplace—Part Two, The Solution—Building an AI Governance Structure." This webinar focused on practical guidance for developing written AI use policies, implementing effective governance frameworks, and training teams to manage AI responsibly. Save the Date for Part Three on March 25th.

On February 18, Healthcare Law Member **Lani Dornfeld** and Labor & Employment Member **Jay Sabin** issued a client alert entitled "AI Risks: Court Holds Attorney Client Privilege Waived By Client's Use of AI App."

On February 17, Healthcare Law Member **Lani Dornfeld** issued a client alert entitled "HIPAA Enforcement Agency Announces "Landmark Enforcement Program" for SUD Treatment Records—Take Action Now."

On February 13, Healthcare Law Member **Richard B. Robins** presented "NJ Employer Registration and Employee Separation Reporting" at Journey for Excellence Dental Study Club.

On February 11, Healthcare Law Member **Lani Dornfeld** issued a client alert entitled "Healthcare Providers Must Update Their Notice of Privacy Practices by February 16, 2026."

On February 12, Healthcare Law Associates **Rebecca Falk** and **Cynthia Liba** represented Brach Eichler at the Chemed Medicine + Ethics Conference.

On February 10, Brach Eichler announced its newest office location in Alpharetta, Georgia.

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