Foster Garvey

Health Law Year in Review for 2025

2025 HEALTH LAW YEAR IN REVIEW

INTRODUCTION

Foster Garvey PC is pleased to publish its *Health Law Year in Review* for 2025. The health care legal landscape experienced significant change over the past year, reflecting new developments in public policy, technology, legislation and regulatory interpretations. A new administration, legislators, courts and administrative agencies addressed a wide range of issues—from oversight and enforcement to innovation and access—against a backdrop of economic pressure and evolving care delivery models.

This *Health Law Year in Review* examines a few developments that meaningfully influenced health care stakeholders during the year. It focuses on legislative and regulatory actions, enforcement initiatives and judicial decisions that carry practical implications for healthcare providers. Rather than cataloging every change, the review highlights certain shifts likely to affect compliance obligations, strategic planning and risk management.

Across these developments, several patterns became evident. Regulators continued to refine their approaches to fraud and abuse enforcement, reimbursement integrity and data protection, while courts weighed challenges that may reshape long-standing interpretations of health laws. At the same time, innovation—including digital health tools, artificial intelligence and alternative payment arrangements—prompted ongoing efforts to adapt existing legal frameworks to new realities.

Looking ahead, health care organizations must navigate an environment defined by both regulatory complexity and opportunity for growth. This publication is intended to serve as a practical resource, offering insight into some of the year's most consequential developments nationally and within Washington state and identifying areas where further legal developments are likely in the months to come.

Please reach out to the Foster Garvey health care attorneys with questions or specific concerns.

Disclaimer: This publication is solely for educational purposes and should not be construed as legal advice.

2025 HEALTH LAW YEAR IN REVIEW

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I. **Fraud and Abuse Updates**: Nationally and regionally, government agencies continue to make health care fraud and abuse a top enforcement priority. Agencies that enforce fraud and abuse laws, including the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) and U.S. Department of Justice (DOJ), have dedicated significant resources to investigating and prosecuting suspect financial arrangements between hospitals and physicians and between laboratory organizations and physicians. Enforcement agencies have also focused on wound care services and skin substitutes as well as genetic testing. This section provides a high-level overview of the OIG and DOJ's enforcement priorities and activities in 2025 including examples of a few enforcement cases involving the federal Anti-Kickback Statute ("AKS"), the physician self-referral law (Stark law) and the False Claims Act("FCA").

a. **Presidential Memorandum, Eliminating Waste, Fraud and Abuse in Medicaid.** President Trump's memorandum directs HHS Secretary Kennedy to "take appropriate action to eliminate waste, fraud and abuse in Medicaid, including by ensuring Medicaid payments rates are not higher than Medicare…." One of the practices the memorandum targeted was state directed Medicaid provider taxes or state-directed payments that have legally been used to maximize federal dollars to fund state Medicaid programs.
b. **DOJ Criminal Div., Memorandum Fight Against White Collar Crime.** The memorandum from the head of the DOJ's Criminal Division sets forth the division's key priority for investigating and prosecuting white-collar crimes (e.g., fraud and abuse) involving health care and federal health care programs.
c. **OIG Recovered Billions from Enforcement:** The OIG reported to Congress that it expected to recover $5.71 billion in investigative receivables and $533.2 million in auditable receivables for the 2025 reporting period.[1] In addition to monetary recoveries, the OIG enforcement efforts included 1,577 civil and criminal actions and exclusion of 2,839 individuals and entities from participating in federal health care programs (e.g., Medicare, Medicaid, TRICARE). OIG attributed its ability to fight fraud to its use of "cutting-edge technology" and "advanced data analytics" as well as employing specialized experts and professionals (investigators, auditors, evaluators, data scientists, attorneys) to investigate, evaluate and prosecute fraudulent schemes and activities. OIG continues to prioritize its

[1] HHS-OIG publishes its Spring and Fall Semiannual Report to Congress covering the October 1, 2024, through September 30, 2025, reporting period.

resources based on programs and activities that present the highest risk for illegal schemes.

d. **DOJ Recovers over $6.8 Billion in Settlements/Judgment in 2025:** The DOJ reported recovering over $6.8 billion in FCA recoveries in the fiscal year ending September 30, 2025. These recoveries represent the highest in a single year in the history of the FCA. Out of this total amount, $5.7 billion in recoveries is directly from the health care sector including hospitals and other medical facilities and physicians. DOJ highlighted its success through vigorous enforcement and the increased role of whistleblowers. As to the latter, DOJ reported another record-breaking year of *qui tam* (i.e., whistleblower) actions totaling 1,297. $5.3 billion of all recoveries related to whistleblower settlements and judgments. DOJ continued to emphasize its commitment to incentivizing and rewarding self-disclosures, cooperation and remedying non-compliance with effective remedial measures. Over the last year, DOJ entered into several settlements where the defendant's cooperation reduced penalties or damages in connection with resolving the cases. Finally, DOJ expressed its commitment to fighting fraud as part of the Trump administration's policy objectives and deploying FCA to safeguard taxpayer dollars. In early January of 2026, DOJ announced a new National Fraud Enforcement Division aimed at centralizing and vigorously combating fraud affecting federal programs and federally funded benefits.

e. **U.S. Attorney's Office, E.D. WA Continues to Aggressively Prosecute Health Care Fraud:** In November of 2024, the U.S. Attorney Office for the Eastern District of Washington (EDWA) announced its continued and increased number of health care fraud prosecutions in the last few years. The Trump administration appointed a new U.S. Attorney for EDWA who continues to aggressively pursue health care fraud and abuse claims such as:

   i. **$2.8 million dollar settlement** with an urgent care clinic for allegedly fraudulent billing for polymerase chain reaction (PCR) diagnostic testing that was part of a predetermined panel taken from a single patient specimen and billed separately (i.e., unbundling). The allegations also involved billing for panel tests that were more expensive and not medically necessary.
   ii. **A jury verdict** against a physician for participating in a telemarketing health care fraud scheme. The scheme involved billing Medicare for genetic tests and durable medical equipment (DME) that were not medically necessary. The physician signed orders for individuals he never spoke to or treated.
   iii. **$120,000 settlement** with a physician for allegedly prescribing controlled substances for non-legitimate purposes or outside the usual course of his professional practice. Over an eight-year period, the physician allegedly

ordered 1,400 prescriptions of certain addictive-controlled substances (e.g., opioids, benzodiazepines, etc.) to 13 patients in violation of the Controlled Substances Act and FCA.

iv. **Guilty plea** by a physician for adulterating and misbranding medical devices with the intent to defraud or mislead. The plea involves purchasing CPAP and BIPAP devices that were recalled, modifying the devices, and then using the devices in a sleep clinic and billing Medicaid under the false pretense that they were devices in good working order.

f. DOJ National Health Care Fraud Takedown. The DOJ operation led to hundreds of criminal and civil charges, significant asset seizures and preventive measures to protect Medicare and Medicaid programs. Some of the highlights are:

- **324 defendants charged**, including 96 licensed medical professionals, across 50 federal districts and 12 state AG offices.
- **Over $14.6 billion in intended loss** linked to fraudulent schemes.
- **$245 million seized** in cash, luxury vehicles, cryptocurrency, and other assets.
- **CMS prevented $4 billion** in fraudulent payments and revoked billing privileges for 205 providers.
- **Civil actions:** 20 defendants charged for $14.2 million; settlements with 106 defendants totaling $34.3 million.
- **AI-driven fraud:** $703 million scheme using fake recordings and stolen Medicare data; $44.7 million seized.
- **Fraudulent wound care:** $1.1 billion in false claims involving unnecessary amniotic allografts targeting elderly patients.
- **CMS statement:** Emphasized proactive fraud prevention through advanced data analytics and real-time monitoring.
- **Telemedicine and Genetic Testing Fraud:** 49 defendants charged with the submission of over $1.17 billion in allegedly fraudulent claims to Medicare from various schemes involving telemedicine and genetic testing.

g. Federal Anti-Kickback Statute (AKS) Updates:

i. **Laboratory Arrangement with Lab, Marketers and Physicians Subject to $6 Million AKS Settlement:** The government alleged that referring physicians received kickbacks from marketers in the form of managed service organization (MSO) investment distributions. The marketers included employees of the performing lab. The government also alleged that the lab paid physicians other types of disguised kickbacks such as consulting fees and process and handling fees. The government

also alleged that the submission of these tainted claims to federal health care programs violated the False Claims Act.

ii. **Physician Sentenced for Receiving $100 Payments for Medically Unnecessary Brain Scans:** The arrangement involved a mobile medical diagnostic company paying the physician $100 for each transcranial doppler (TCD) scan ordered by the physician and the use of false diagnoses to order the unnecessary TCD scans, which were then falsely submitted to Medicare for reimbursement.

iii. **Lab Granting Physician Free Access to Laboratory Information System ("LIS") Subject of Self-Disclosure:** The free remuneration allegedly paid by the laboratory and subject to the disclosure and settlement was for providing free access to its LIS so the physician could submit claims for the professional component of certain diagnostic testing. The $100,000 settlement involved alleged violations of the Civil Monetary Penalties Law.

iv. **Hospital Self-Discloses Providing Physicians Free Prior Authorization Services:** The hospital agreed to pay $100,000 after disclosing that it allegedly paid improper remuneration to certain physicians in the form of free prior authorization services.

v. **Offering Free Inventory Management Services to Physicians is the Subject of an AKS Settlement.** Besse Medical entered into a $1.67 million settlement with the government for allegedly providing a free inventory management system to certain medical providers to induce them to purchase certain expensive drugs from Besse Medical.

h. Federal Physician Self-Referral Law (Stark) Updates:

i. **Hospital Payments to Oncology Practices for Services Not Performed Subject to Stark and Kickback Settlement:** A hospital agreed to a $6.8 million settlement relating to three contracts with an oncology group for certain professional services including consulting services for a cancer center and developing and managing a radiation therapy service line. Despite being paid millions of dollars by the hospital to perform these services, it is alleged the group failed to perform or document its services. After these agreements expired, the group continued to receive payments from the hospital for the same services. The settlement resolved allegations that the hospital violated the Anti-Kickback Statute, Stark and False Claims Act.

i. Federal False Claims Act (FCA) Updates:

i. **DOJ-HHS False Claims Act Working Group** . This DOJ-HHS working group was formed to advance the Trump administration's priority of combatting health care fraud. In addition to maximizing collaboration between agencies to expedite investigations, they intend to use new technology to enhance data mining for identifying potential fraud. The priority enforcement areas include:
   1. Medicare Advantage;
   2. Kickbacks related to drugs, medical devices, DME and other products paid for by federal healthcare programs;
   3. Barriers to patient access to care, including violations of network adequacy requirements; and
   4. Manipulation of EHR systems to drive inappropriate utilization of Medicare covered products and services.

ii. **CMS Rolls Out Aggressive Strategy for Auditing Medicare Advantage Plans.** CMS reported that the federal government's prior audits suggest Medicare Advantage Plans ("Plans") may overbill the federal government $17 billion annually. To combat this potential fraud and abuse related to risk-adjusted payments based on the diagnosis (i.e., capitated payments), CMS's new audit plan will increase the volume of audits from 60 Plans each year to all eligible Plans using enhanced technology and workforce expansion.

iii. **Medically Unnecessary Wound Care Services Subject to $45 Million Dollar Settlement:** The government alleged that a wound management company encouraged its physicians to perform debridement procedures as frequently as possible, regardless of medical necessity, using pressure, training, and financial incentives. It also alleged that the organization's electronic health record and billing systems were configured to consistently bill Medicare for the highest-reimbursed surgical procedure and generate false documentation to justify those charges. According to the allegations, the scheme was directed by the organization's leadership and carried out by senior management. The settlement resolves allegations that the billing practices violated the FCA.

iv. **Family Practice Physician Gets Hit with $1.4 Million Judgment in Connection With P-Stim Reimbursement Claims:** The judgment obtained against a family physician involves the submission of claims to Medicare for treating pain using auricular stimulation (P-Stim) devices. The device was used by the family physician for essentially performing electrical acupuncture, which is not reimbursable by Medicare. Nevertheless, the provider submitted claims using codes for an

implantable neurostimulator device. The use of incorrect billing codes was part of the basis for this FCA judgment.

v. **Sale of Health IT Software to Government Containing Security Vulnerabilities Subject of $9.8 Million FCA Settlement:** The government asserted that when a health IT vendor sold to the federal government genomic sequencing systems with known cybersecurity vulnerabilities, it made false representations regarding its compliance with certain cybersecurity standards (e.g., NIST). It was also alleged that the vendor neglected cybersecurity by not adequately integrating it into software design and development, under-resourcing product security efforts and failing to fix design flaws that created cybersecurity vulnerabilities in its systems. As a result of these alleged false representations, the government alleged that the health IT vendor violated the FCA.

vi. **Largest Long-Term Care Pharmacy Gets Hit with FCA Award Over $948 Million Dollars:** The underlying claim was that Omnicare fraudulently dispensed drugs without valid prescriptions to patients in assisted living facilities. While the original FCA award was just over $135 million dollars, the FCA allow for three times the assessed damages to be awarded against a defendant. The court imposed $542 million dollars in statutory penalties for each false claim submitted to federal health care programs.

II. Privacy and Security.

The health care industry continues to be a high-value target of threat actors who continue to cause disruption and harm to all aspects of the health care industry. Due to significant privacy and security risks imposed by cyberattacks, government enforcement agencies continue to impose fines and take other corrective action against health care organizations to ensure the confidentiality, integrity and availability of PHI. At the end of the Biden administration, HHS-OCR also proposed a rule requiring modernization of cybersecurity programs with new advances in technology and adoption of certain cybersecurity best practices, methodologies and procedures. This section will provide a high-level overview of some privacy and security legal updates that may impact many health care providers.

a. HIPAA Updates

i. **Cybersecurity Deficiencies Continue to Be the Most Common Enforcement Area:** In 2025, the most common enforcement action resulting in fines and/or settlements involved non-compliance with the HIPAA Security Rule. The enforcement actions were against a wide range of HIPAA covered entities and business associates (e.g., billing, collection

and consulting services). The fines ranged from $10,000 to $3,000,000. Common corrective actions imposed by a settlement include requiring the covered entity and/or business associate to undertake remedial actions such as:

1. Conducting an accurate and thorough risk analysis to determine the potential risks and vulnerabilities to ePHI;
2. Implementing a written risk management plan to address and mitigate security risks and vulnerabilities identified in the risk analysis;
3. Developing, maintaining and revising privacy/security policies and procedures; and
4. Training workforce members on HIPAA policies and procedures.

ii. **HIPAA Security Rule Proposed Revisions:** Despite widespread industry opposition to HHS-OCR proposed rule to strengthen the HIPAA Security Rule, the Trump administration has not withdrawn the proposed rule. The rule may be finalized in 2026.

iii. **HHS-OCR Reproductive Health Care HIPAA Privacy Rule Found Unlawful:** In 2024, HHS-OCR issued a final rule strengthening HIPAA protections around disclosures of PHI involving legal reproductive health care services. A Federal court vacated the rule in 2025. The Trump administration did not appeal the court decision or seek to enforce the rule.

iv. **Substance Use Disorder Records (Part 2) Final Rule**: The final rule aims to make certain 42 CFR Part 2 ("Part 2") regulatory requirements consistent with HIPAA. Part 2 regulatory amendments address patient consent requirements, permitted and restricted use of Part 2 records, segregation of Part 2 records, penalties for violations, and breach notification. While the final rule was published in 2024, the effective date of the rule is February 16, 2026, including required changes to the HIPAA Notice of Privacy Practices of covered entities.

b. Washington:

i. **WA AGO Data Breach Report 2025:** The Washington Attorney General's Office (AGO) reports that 2025 was the second straight year where the number of data breach notices sent to affected residents exceeded the state's population. More specifically, AGO received notice of 209 separate data breach incidents affecting over 8 million

Washingtonians. The vast majority of data breaches involved ransomware attacks, which is consistent with federal data breach metrics. Four out of the five largest data breaches involved health care entities. AGO also reported suing T-Mobile for violating the Washington Consumer Protection Act for failing to adequately secure the personal information of Washington residents.

III. **Hospital Updates.** Federal and state laws applicable to hospitals continue to change at a rapid pace along with enforcement priorities with new federal and state administrations in 2025. Below are a few regulatory changes and/or enforcement trends in 2025 affecting hospitals:

a. **Hospital Price Transparency:** As discussed in a prior Foster Garvey PC Legal Alert, the Trump administration announced its intention to promote price transparency by requiring the meaningful disclosure to consumers of actual prices of items and services, not estimates, and making enforcement a priority. The 2026 Hospital Outpatient Prospective Payment System final rule specifies the requirements for public disclosure of the actual dollar amounts of hospital items and services. The effective date for these changes is January 1, 2026, but CMS is delaying enforcement for three months . States like Washington have adopted similar laws. For example, by July 1, 2027, Washington will require that hospitals comply with the federal hospital transparency requirements that existed on January 1, 2025, and submit annually to the Washington State Department of Health (DOH) the hospital charges that must be disclosed under federal law. DOH is considering regulations to clarify certain requirements under this law.

b. **Hospital at Home Services (WA):** In 2024, Washington provided a pathway for hospitals with certain federal waivers to operate hospital-at-home programs. In 2025, hospitals that want to add hospital-at-home services must submit an application to DOH and obtain approval to operate the program.

c. **Hospital Medical Record Retention Requirement Changes:** Hospitals are now required to retain medical records for 26 years from the date the record was created. The law is subject to certain exclusions and conditions, but generally these requirements apply for records in existence and retained by the hospital on July 27, 2025.

d. **WA Hospital Charity Care Law Updates:**

i. **WA AGO Settles with Hospital Requiring Refunds to Patients:** Confluence Health refunded over $1.8 million, including 12% interest, to 4,729 patients after the AGO found the hospital system failed to refund payments from patients who were later approved for charity care. The investigation, which began in 2024 and reviewed Confluence's practices

dating back to 2021, ended with an agreement that closes the case without litigation and requires Confluence to comply with the Consumer Protection Act and provide charity care in compliance with charity care law going forward.

ii. **WA DOH Rulemaking:** DOH continued to go through the notice and comment period for accepting proposed amendments to draft charity care rulemaking language. The rulemaking process will continue into 2026.

IV. **Other Legal and Compliance Updates.** One of the most challenging issues with working in the health care industry is keeping abreast of statutory and regulatory updates and enforcement actions. This section provides an overview of a few of the more significant developments.

a. **H.R.1 also known as the "One Big Beautiful Bill Act" (OBBA):** This legislation has significant financial ramifications for health entities. As applicable to health care, the law reforms Medicaid program operations, enhances oversight capabilities and establishes new accountability measures for Medicaid and the Children Health Insurance Program (collectively referred to as "Medicaid"). Together with other CMS priorities, these reforms will, among other things, affect how Medicaid is administered and reimbursed. A few highlights of the legislation include:

i. Redetermining eligibility for Medicaid beneficiaries more frequently;
ii. Reducing state Medicaid costs;
iii. Restricting federal payments to prohibited entities (e.g., abortion clinics);
iv. Restricting and/or phasing down of certain health care-related taxes on providers, which have increased the federal government's share of Medicaid funding;
v. Requiring budget neutrality for Medicaid Section 1115 demonstrations and waiver projects;
vi. Modifying cost-share requirements for certain individuals under Medicaid, thereby requiring states to impose cost-sharing on certain care, items or services as determined by the state; and
vii. Appropriating $10 billion annually for establishing a Rural Health Transformation Program.

Some provisions of OBBA became effective in 2025, while other will become effective at varying times in the next few years. Part of this legislation is being challenged legally, and one or more stays have been issued by federal courts halting or temporarily halting parts of the law. It is

expected that the Trump administration will appeal any adverse actions or stays to the OBBA in 2026.

b. Patient Dumping Enforcement.

i. **EMTALA Settlements**

1. **Inappropriate Transfer Leads to $100,000 Settlement:** A medical facility entered into a settlement agreement for allegedly transferring a patient when the benefits of the transfer did not outweigh the risks. An on-call surgeon did not evaluate the patient and provide stabilizing treatment within the capabilities of the hospital but instead ordered the patient's transfer.
2. **Psychiatric EMTALA Violations Still an Enforcement Priority:** A hospital entered into a $200,000 settlement for failing to perform a medical screening exam of two patients with potentially psychiatric emergency conditions.
3. **Refusing to Accept an Appropriate Transfer Results in $150,000 settlement:** In two separate cases, a hospital attempted to transfer a patient to another hospital that had oral maxillofacial surgical (OMFS) specialists within its capabilities, but the OMFS specialist would not accept the transfers. The reason for refusing to accept the transfer was due to the claim that the OMFS specialist did not treat new trauma facial fractures and there was a closer facility with physicians that could perform stabilizing care.
4. **Free Standing ED Failed to Provide Stabilizing Treatment:** A patient presented to a free-standing ED and was diagnosed with an emergency medical condition. Despite having a specialist on-call, and access to specialized clinical services to stabilize the patient, the ED providers discharged the patient with instructions to go to a different medical facility for specialist care.
5. **Hospital Failed to Screen a Patient for Capacity to Make Decisions:** A geriatric patient presented with history of dementia and significant psychiatric health conditions. Despite this history, including being assigned an Emergency Severity Index of 3, he was neither promptly seen nor monitored. The patient was permitted to leave without determining whether he had the capacity to make informed decisions. The hospital entered into a

$119,942 settlement to resolve allegations that it failed to perform a medical screening exam.

c. **False Representations Under Physician Payment Sunshine Act Subject to Criminal Sentence:** The CEO of a medical device company plead guilty for one count of false statements to CMS for directing his employees to report payments made to surgeons as consulting fees knowing the surgeons were not performing such services. The CEO knew the Physician Payment Sunshine Act required him and the company to accurately report payments to these surgeons thereby forming the basis for the false statement.

d. **HHS to "Crackdown" on Information Blocking:** To promote patients access to their health information, HHS announced in September of 2025 it will take enforcement action against health care entities that engage in information blocking. The specific enforcement action to be taken under the Information Blocking Rules includes:

    1. Imposing authorized "disincentives" (e.g., loss of certain incentive payments) for providers;
    2. Imposing civil monetary penalties up to $1 million per violation on health IT developers or health information networks; and
    3. Terminating certification and banning from the ONC Health IT Certification Program developers of ONC "certified" products.

e. **Medical Debt Reporting in Washington State:** Health care providers including hospitals are now prohibited from reporting a patient's medical debt to consumer credit agencies and noncompliance is a violation of Washington's Consumer Protection Act.

f. **HHS-OIG's Oversight of Billing for Remote Patient Monitoring in Medicare:** Remote patient monitoring assists providers to better manage certain health conditions, including chronic conditions. As technology continues to improve and support more effective care for patients, remote patient monitoring grew to over $500 million dollars in 2024. Due to the anticipated increased use of remote monitoring and Medicare expenditures, OIG recommends increased monitoring to prevent fraud, waste and abuse. OIG developed certain measures to identify potentially inappropriate remote billing practices for further investigation, auditing and/or scrutiny.

g. **Private Equity in Health Care Under the Microscope.** Several West Coast states (Washington, Oregon and California) actively sought to restrict or more closely monitor private equity investments in health care. For example, Washington enacted a health care entity registry that will allow regulators to understand and monitor the business structure, funding and contractual arrangements of health care entities in Washington. It also includes the status and future changes of ownership, control or affiliation with private equity investment. Private equity investment will continue to receive significant scrutiny in health care as regulators focus on restricting or monitoring the risk private equity deals are perceived to pose to health outcomes, safety or quality of care.

h. **Gender Affirming Care is Under Attack.** In an effort to limit gender affirming health care services to adolescents in states like Washington where it is permitted, Secretary Kennedy, on December 18, 2025, signed a declaration declaring that practitioners performing "sex-rejecting procedures on minors" are performing services outside of recognized professional health care standards. CMS will also be issuing a notice of proposed rulemaking that adds a Medicare condition of participation prohibiting hospitals from performing "sex-rejecting procedures on minors." The Washington Attorney General, along with 19 other states, filed a lawsuit challenging HHS's authority to issue the declaration and engage in rulemaking that will prohibit the delivery of transgender health care services to minors. Prohibiting and/or restricting transgender health care services nationally will continue to be a priority for the current administration and subject to ongoing litigation in 2026.

i. **AI Evolving Regulatory Landscape.** As health care entities continue to explore AI as a solution for reducing costs, creating efficiencies and improving care, certain states have begun regulating AI. To limit state regulation of AI, President Trump issued an Executive Order (EO) in December 2025 intended to ensure a "minimally burdensome national policy framework for AI." To implement this EO, the Federal Communications Commission (FCC) must take certain action that may include issuing a rule that preempts states from regulating AI. Approximately 23 attorneys general, including Washington's Attorney General, submitted a reply comment to the FCC opposing such action. Regulation of AI is expected to be litigated in the courts in 2026 as the federal government and states jockey for the regulation of AI. In addition to these regulatory developments, health care entities may be subject to existing laws and regulations related to utilizing AI, including but not limited to HIPAA and applicable state privacy laws.

j. Greenlighting the Use of Medical Cannabis and Psilocybin:

i. **Cannabis Gets the Green Thumb of Approval (Rescheduling Cannabis):** The process for rescheduling medical marijuana from a Schedule I to a Schedule III controlled drug started during the Biden administration, but President Trump issued an Executive Order on December 18, 2025, directing the U.S. Attorney General to expeditiously complete this process. Rescheduling medical marijuana to a Schedule III may facilitate increased access to this treatment nationwide and reduce the strict administrative burdens currently in place to perform this type of medical research.

ii. **Magic Mushrooms in Treating PTSD Gains Ground:** While psilocybin is still classified by federal and Washington state law as a Schedule I controlled substance, some states have loosened regulatory oversight for mental health treatment purposes. Washington's legislature previously authorized the Health Care Authority to create a Psilocybin Work Group and the University of Washington Department of Psychiatry and Behavioral Sciences has been charged with implementing a psilocybin therapy services pilot program. On December 19, 2025, the Washington Medical Psilocybin Act was introduced in the Senate (SB 5921).

k. Medical Research Potpourri.

i. **Upheaval in the Medical Research Field:** Biomedical research in 2025 was marked with massive uncertainty and upheaval as the new administration set sight on higher education, including reducing financial support for medical research. For example, National Institute of Health (NIH) grants totaling nearly $3.8 billion were terminated.[2] NIH is also limiting indirect costs to 15% across all research institutions, which is projected to cut $6.5 billion from federally funded research support.[3] While many of these funding cuts are subject to ongoing litigation, which includes a First Circuit Court of Appeals affirming a lower court stay, it is expected that there will be a decline in financial support for biomedical research in 2026.[4] To restore federal funding involving alleged violations of federal non-discrimination laws around gender identity or diversity and

[2] *See* AAMC, The Impact of federal actions on academic medicine and the U.S. Health Care System.
[3] *Id.*; NIH Supplemental guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Reports.
[4] Fact Sheet: President Donald Trump Stops Wasteful Grantmaking (Aug. 7, 2025)(describing executive order).

inclusion activities or antisemitism, some institutions of higher education entered into settlements with the federal government.[5]

ii. **WA Hospital Pays Over $10 Million Related to Clinical Research Studies:** Swedish Health Services self-disclosed billing federal health care programs for items and services provided to patients participating in clinical trials that should have been paid for by the study sponsor or been provided free.

iii. **$15 Million Dollar False Claim Settlement Related to Research Misconduct:** Over a ten-year period, Dana-Farber Cancer Institute was alleged to have falsified research data thereby making materially false statements and certifications to NIH in violation of the False Claims Act. Dana-Farber admitted that certain NIH-funded journals contained misrepresented and/or duplicated data. As a result of its cooperation during the investigation and remedial action, Dana-Farber received credit under the DOJ's cooperation guidelines to receive more favorable settlement terms such as less severe penalties.

l. Antitrust Updates

i. **Federal Antitrust Enforcement and Updates:** Under the Biden administration, the FTC adopted a rule banning certain noncompete agreements. This rule was ultimately stayed by federal courts but was then abandoned by the FTC under the Trump Administration. Although the FTC appears to oppose a broad ban on non-compete agreements, the Chair of the FTC sent letters to several large health care employers and staffing firms warning them that noncompete agreements must be narrowly tailored. The FTC stated that a top enforcement priority will be unreasonable noncompete agreements that harm healthcare markets by restricting patient choices, particularly in rural areas. Under current federal law, the FTC will investigate unfair methods of competition involving noncompete agreements. Many states, including Washington,[6] also have laws applicable to noncompete agreements, including particular remedies and penalties when violations are found to have occurred.

m. Immigration Regulatory and Enforcement Updates: One of the biggest policy changes with the Trump administration has been in the area of immigration. The

[5] *See* Agreement with federal government to restore Brown research funding, resolve compliance reviews.
[6] Chapter 49.62 RCW.

Trump administration has aggressively pursued removing illegal immigrants from the United States and has significantly restricted the granting of visas. These two policy changes have significantly affected health care providers as discussed below.

i. **Health Care Facilities Are No Longer Protected From ICE Enforcement:** One of the Trump administration's first acts was to rescind the Biden administration's guidelines prohibiting ICE from engaging in immigration enforcement activities in or near "sensitive areas" such as health care facilities. Thus, ICE now has the authority and has engaged in immigration enforcement activities in health care facilities. Some states, including Washington, had laws in place (Keep Washington Working Act or KWWA) that prohibit or restrict state and local agencies from participating in the enforcement of federal immigration law. The KWWA also requires health care facilities to adopt certain model policies published by the AGO to ensure compliance with this law or to notify the AGO if the facility refused to adopt the model policies. Litigation surrounding the KWWA and/or withholding federal funding for states with similar laws should be closely monitored in 2026.

ii. **Visas:** Effective January 1, 2026, at 12:01 a.m. EST, in line with Presidential Proclamation 10998 on "Restricting and Limiting the Entry of Foreign Nationals to Protect the Security of the United States," the Department of State is fully suspending visa issuance to nationals of 19 countries – Afghanistan, Burma, Burkina Faso, Chad, Republic of the Congo, Equatorial Guinea, Eritrea, Haiti, Iran, Laos, Libya, Mali, Niger, Sierra Leone, Somalia, South Sudan, Sudan, Syria and Yemen – and to individuals traveling on any travel documents issued or endorsed by the Palestinian Authority, for all nonimmigrant and immigrant visa categories with limited exceptions.

iii. **H-1B Visas:** On September 19, 2025, President Trump issued a Proclamation, *Restriction on Entry of Certain Nonimmigrant Workers*, an important initial step to reform the H-1B nonimmigrant visa program. Under the Proclamation, new H-1B petitions filed at or after 12:01 a.m. eastern daylight time on September 21, 2025, must be accompanied by an additional $100,000 payment as a condition of eligibility. The Proclamation applies to new H-1B petitions filed on behalf of

beneficiaries who are outside the United States and do not have a valid H-1B visa. The Proclamation does not apply to any previously issued and currently valid H-1B visas, or any petitions submitted prior to 12:01 a.m. eastern daylight time on September 21, 2025. The Proclamation also does not apply to a petition filed at or after 12:01 a.m. eastern daylight time on September 21, 2025, that requests an amendment, change of status, or extension of stay for an alien inside the United States where the alien is granted such amendment, change or extension.

iv. **H-1B Lottery:** The Department of Homeland Security is amending regulations governing the H-1B work visa selection process to prioritize the allocation of visas to higher-skilled and higher-paid aliens to better protect the wages, working conditions and job opportunities for American workers. The new rule replaces the random lottery for selecting visa recipients with a process that gives greater weight to those with higher skills. Under the new system, each H-1B registration will be assigned a weight based on the Occupational Employment and Wage Statistics (OEWS) wage level corresponding to the proffered wage for the position. The OEWS wage levels range from Level I (entry-level wages) to Level IV (highest wage level). The higher the wage level, the greater probability of selection, as described below:
    - Registrations at wage level IV will be entered into the selection pool four times;
    - Registrations at wage level III will be entered three times;
    - Registrations at wage level II will be entered two times; and
    - Registrations at wage level I will be entered once.