

HEALTHCARE YEAR IN REVIEW

AHLA Annual Meeting

June 30, 2025

Robert Homchick, Davis Wright Tremaine LLP
Kim Harvey Looney, K&L Gates LLP
Cindy Wisner, Trinity Health

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The New Administration is off to the Races

Executive Orders
New Leaders
Employee Layoffs
Grants terminated
Programs Cut
Big Beautiful Bill?



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17+ Inspector Generals Fired

- Including: HHS IG Christi Grimm
- Feb 12, 2025: Eight of the terminated IGs sue seeking declaration that their firings were “legal nullities”



The Rise and Fall/Decline of DOGE/ Elon

- DOGE jump started the Trump Administration’s efforts to shrink the size of Government
- Initial promise to trim \$1 Trillion from the Federal Budget
- On the ground, DOGE prompted a large number of terminations and cancelled programs
- Fiscal impact difficult to gauge
- June 2025 Elon’s Exit–
 - But DOGE lives on....



RFK, Jr
Secretary of HHS

Make America Healthy Again

Proposed **Administration for Healthy America**

Primary Care

HIV/AIDS

Mental Health

Maternal and child health

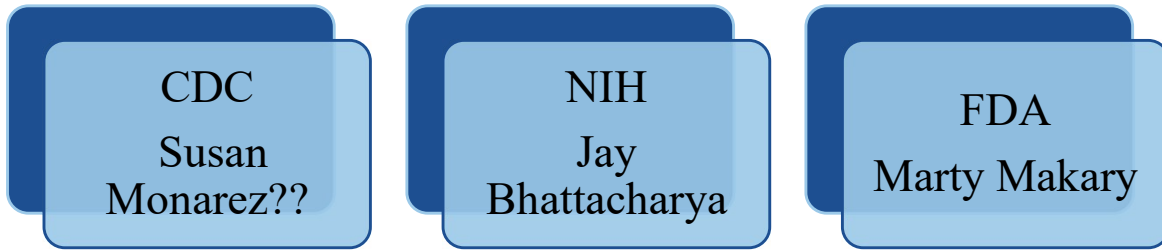
Environmental Health

Rural Health

Healthcare workforce



Other Agencies: New Leaders, New Direction



Other Agencies: New Direction



The Big Beautiful Bill

BBB includes tax cuts, border security funds and boosts defense spending

Social programs cut to offset impact on Deficit

So far, Medicare and Social Security mostly off limits

Medicaid, ACA and other social programs cut

House Version of BBB

- Reduces ACA subsidies & shortens enrollment period
- Imposes work requirements, increases copays and limits provider taxes

Senate Version of BBB

- Proposes deeper cuts to Medicaid
- Stricter work requirements and limits on provider taxes
- **BUT**— Senate Parliamentarian deemed limits on provider taxes and stricter Medicaid eligibility checks inappropriate for inclusion in reconciliation bill

A crystal ball sits on a small pedestal, held by two hands. Inside the crystal ball, various currency symbols (dollar, euro, yen, pound) are visible, suggesting a focus on financial matters.

What will happen next?

Public Health

Make America Healthy Again



Senate confirms Dr. Oz as CMS administrator in 53-45 party-line vote

By Dave Muoio

Mehmet Oz, M.D., is now the head of more than 160 million Americans' health coverage, and enters the role at a time of major upheaval for the agency and its parent department.



RFK Jr. and MAHA agenda divide country but vaccines have widespread support: Poll

Health Secretary Robert F. Kennedy's overall approval rating sits at 51 percent, though the party breakdown shows a big divide between Democrats and the GOP.

B Bloomberg Law News
https://news.bloomberglaw.com :
RFK Jr. Draws Worries He'll Limit Abortion Despite Past ...
14 hours ago — Robert F. Kennedy Jr.'s approach to abortion policy under the Trump administration is a lingering question for reproductive rights watchers ...

Elon Musk's team at the Department of Government Efficiency have turned their attention to CMS, gaining access to systems and technology

KENNEDY | MAHA



Nov 09, 2024

Kennedy Ready to Make America Healthy Again

Robert F. Kennedy Jr. is ready to lead a transformative mission to overhaul America's public health system. With a...



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Administration for a Healthy America

Check out Sessions 44 & 45

HHS Announces Transformation to Make America Healthy Again

Washington, D.C. — March 27, 2025 — HHS announced dramatic restructuring responding to President Trump's Executive Order, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative."

- 1) **Save taxpayers \$1.8 billion per year** through a reduction in workforce of about 10,000 full-time employees, when combined with HHS' other efforts, including early retirement and Fork in the Road, the restructuring results in a total downsizing from 82,000 to 62,000 full-time employees. Note: Mr. Kennedy acknowledged April 3 that around 20% of the 10,000 dismissed HHS employees may be reinstated. Dismissals included 3,500 FDA employees, 2,400 CDC employees, 1,200 NIH employees and 300 CMS employees
- 2) **Streamline functions**. Currently, 28 divisions of the HHS contain many redundant units. Restructure will consolidate into 15 new divisions, including a new Administration for a Healthy America (AHA) & centralize core functions, e.g. Human Resources, Information Technology, Procurement, External Affairs, and Policy. Regional offices reduced from 10 to 5.
- 3) Implement new HHS priority of **ending America's epidemic of chronic illness by focusing on safe, wholesome food, clean water, and the elimination of environmental toxins**
- 4) **Improve Americans' experience with HHS** by making the agency more responsive and efficient, while ensuring that Medicare, Medicaid, and other essential health services remain intact.



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Executive Order 14212 of February 13, 2025



The White House (.gov)

<https://www.whitehouse.gov/uploads/2025/05> PDF

[WH-The-MAHA-Report-Assessment.pdf](#)

May 16, 2025 – The Executive Order establishing the MAHA Commission directed the study of any potential contributing causes to the childhood chronic disease ...

This report—Make Our Children Healthy Again: Assessment—is a **call to action**.

The purpose of this report is radical transparency about our current state to spur a conversation about how we can build a world – together – where:

... ☐ **The American healthcare system thrives when disease is prevented and reversed**, not just “managed” in a sick-care system.

... ☐ The next ten years see **a revolution in living standards and prosperity**, while we understand how to better manage the increased threats to our children’s health that come from industrialization.

America will begin reversing the childhood chronic disease crisis during this administration by getting to the truth of why we are getting sick and spurring pro-growth policies and innovations to reverse these trends.

These concerning trends persist despite decades of federal investment in nutrition standards, physical activity campaigns, chemical risk assessments, and clinical quality initiatives. Still, childhood chronic disease continues to rise. To Make Our Children Healthy Again, we must go further.

Strategy due August 12, 2025



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Unhealthy Diets



Most Americans blame the food industry for the nation's chronic health problems, echoing arguments Kennedy has long made against “Big Food,” according to the results of the [NBC News Decision Desk Poll](#) released June 16.

Estimated 90 percent of the \$4.5 trillion annual cost of US health care is spent on medical care for chronic conditions for many of these conditions, diet is a major risk factor. Unhealthy diets are linked to poor health outcomes – More than nine in ten people in the US eat less than the recommended amounts of fruit and vegetables and consume too much sodium, saturated fat, and calories

Diet-related chronic conditions disproportionately affect historically underserved populations, with reduced access to healthy, safe, and affordable food playing an important role

Updating the 2025-2030 Dietary Guidelines USDA Secretary Rollins and HHS Secretary Kennedy are collaborating to update the 2025 - 2030 Dietary Guidelines for Americans.

•Goals for the 10th Edition of the Guidelines include:

•**Easy to read:** Make it concise and user-friendly so everyone can read it.

•**Available quickly:** Aiming to release the new edition ahead of the December 2025 deadline.

•**MAHA-focused:** Will be a nationally recognized vehicle to promote MAHA priorities to improve nutrition for all Americans and reduce the burden of chronic disease. The 10th Edition milestone provides an opportunity for HHS to support healthy eating and Make America Healthy Again.



[What Is ‘Food Is Medicine,’ Really? Policy Considerations On The Road To Health Care Coverage](#)
Colin M. Schwartz et al.

FOOD IS MEDICINE



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Federal Assistance Pauses

Check out Session 7



| 02.03.25 | Second judge blocks Trump's funding freeze; Federal health agencies purge data

January 31, 2025

[Trump's federal assistance 'pause': Judge delays order, states confirm Medicaid portal disruptions](#)

Though the administration said Tuesday that Medicaid would not be caught up in a hold on federal program payments, industry groups and legislators say that portals in all 50 states are down. This comes as other questions remain on whether Monday's ambiguous memo will interrupt clinical research, community health centers, suicide prevention, state infectious disease surveillance and other government-backed efforts. On Wednesday, the Office of Management and Budget (OMB) distributed a new internal memo rescinding a hold that threw much of the country's federal funding recipients into a panic.

In February 2025, district judge [John J. McConnell Jr.](#) McConnell cited evidence that the Trump administration "continued to improperly freeze federal funds and refused to resume disbursement of appropriated federal funds".

February 3, 2025

ACL UPDATES



Notice of Court Order

You are hereby advised that a [temporary restraining order](#) has been entered in the case of *New York et al. v. Trump*, No. 25-cv-39-JJM-PAS (D.R.I.), ECF No. 50 (Jan. 31, 2025). You are receiving this Notice pursuant to the Court's directive that notice of the order be provided "to all Defendants and agencies and their employees, contractors, and grantees by Monday, February 3, 2025, at 9 a.m."

This case challenges an alleged "pause" of certain Federal financial assistance, related to OMB Memorandum M-25-13, *Temporary Pause of Agency Grant, Loan, and Other Financial Assistance Programs* (Jan. 27, 2025) ("OMB Memo"). Although that OMB Memo was rescinded on January 29, 2025, the plaintiffs in the above-referenced case allege that the funding pause directed by the OMB Memo is still in effect, including because of recently issued Executive Orders by the President.

In response, the Court has entered a temporary restraining order prohibiting certain actions by the Defendants in the case, which is effective immediately. All Defendants—including their employees, contractors, and grantees—must immediately comply with the Court's Order. For complete details and terms of the Court's Order, please refer to pages 11 and 12 of the Order.



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BECKER'S
HOSPITAL REVIEW

Courts' Reactions to CUTS

Bloomberg
Law

Health Law & Business News

Trump administration's cuts to scientific research grants for focusing on gender and diversity, equity and inclusion are illegal and vacated, a federal judge in Massachusetts ruled from the bench Monday June 16, 2025.

"This represents racial discrimination and discrimination against America's LGBTQ community. That's what this is," said Judge William G. Young of the US District Court for the District of Massachusetts. "I would be blind not to call it out. My duty is to call it out."

Attorneys general from 16 states filed a federal lawsuit April 4 that challenged the Trump administration's termination of NIH research grants. The lawsuit argued that the cuts jeopardize public health and disrupt studies on maladies such as Alzheimer's disease and substance abuse.

- Kennedy said during an April 9 interview with CBS News that he was "not familiar" with the \$11 billion cuts to local and state programs that oversee mental health, childhood vaccination, addiction and infectious disease



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5 states where NIH funding cuts would hit hardest: Report

BECKER'S
CLINICAL LEADERSHIP

The Science & Community Impacts Mapping Project [shows](#) a breakdown of the effects proposed National Institutes of Health funding cuts could have at a national, state and county level developed by researchers from several universities, including University of Maryland, University of Pennsylvania and Georgia Institute of Technology, using data from NIH grants in 2024.

On April 4, a federal judge [issued](#) a permanent injunction to block the policy, siding with universities and state attorneys general who argued the cuts would cause irreparable harm and violate federal law.

Five states set to see the largest funding cuts and associated job losses, per researchers' map:

- **California**: \$2.28 billion in funding cuts and 9,836 jobs lost
- **New York**: \$1.77 billion in cuts and 7,645 jobs lost
- **Massachusetts**: \$1.55 billion in cuts and 6,713 jobs lost
- **Pennsylvania**: \$1 billion in cuts and 4,423 jobs lost
- **Texas**: \$856 million in cuts and 3,698 jobs lost

More than 500 counties are estimated to lose at least \$6.25 million in funding. About half of U.S. counties may see losses of at least \$250,000, the map shows.

BECKER'S
HOSPITAL REVIEW

June 19, 2025 Below is a state-by-state breakdown of NIH grant funding losses, offering a snapshot of where grant terminations are being felt the most.

1. Massachusetts — \$1,274,165,191
2. New York — \$487,367,224
3. North Carolina — \$466,815,638
4. California — \$214,912,854
5. Texas — \$98,966,858

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ASSOCIATION

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Communication and Website Disruptions

BECKER'S
HOSPITAL REVIEW

Doctors for America has filed a **lawsuit** against the Office of Personnel Management and other federal health agencies **for removing webpages from healthcare websites**. Feb. 4 news release by Public Citizen Litigation Group lawsuit includes CDC, FDA and HHS for removing a "broad range of health-related data and other information used every day" by health professionals and researchers based on the APA and Paperwork Reduction Act of 1995

On January 21, 2025 officials on President Donald Trump's team directed federal health agencies to pause external communications, including health advisories and scientific reports, *The Washington Post* reported Jan. 21, citing anonymous sources

- The directive does not specify an end date and applies to data updates on the CDC website, public health news releases from the National Center for Health Statistics, and the CDC's morbidity and mortality weekly report
- Reports that had been scheduled included updates on the H5N1 avian influenza virus outbreak, the *Post* reported

The Washington Post
Democracy Dies in Darkness

Trump Administration Halted Health Agency Communications



BECKER'S
PHYSICIAN LEADERSHIP

Federal Health Agencies Take Down Webpages To Comply With Trump Administration Orders On Gender Identity, Diversity

[Reuters](#) reported the CDC "and other federal health agencies on Friday took down webpages with information on HIV statistics and other data to comply with Trump administration orders on gender identity and diversity, raising concerns among physicians and patient advocates." According to Reuters, "CDC webpages that appear to have been removed include statistics on HIV among transgender people and data on health disparities among gay, lesbian, bisexual and transgender youth."

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HHS Communication Freeze



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Washington, D.C. 20201

TO: Heads of Operating Divisions Head
Heads of Staff Divisions

THROUGH: Wilma M. Robinson, Ph.D., Deputy Executive Secretary

FROM: Dorothy A. Fink, MD, Acting Secretary

DATE: January 21, 2025

SUBJECT: Immediate Pause on Issuing Documents and Public Communications – ACTION

As the new Administration considers its plan for managing the federal policy and public communications processes, it is important that the President's appointees and designees have the opportunity to review and approve any regulations, guidance documents, and other public documents and communications (including social media). Therefore, at the direction of the new Administration and consistent with precedent, I am directing that you immediately take the following steps through February 1, 2025:

1. Refrain from sending any document intended for publication to the Office of the Federal Register until it has been reviewed and approved by a Presidential appointee. Please note that the Office of the Executive Secretary (Exec Sec) withdrew from OFR all documents that had not been published in the Federal Register to allow for such review and approval.
2. Refrain from publicly issuing any document (e.g., regulation, guidance, notice, grant announcement) or communication (e.g., social media, websites, press releases, and communication using listservs) until it has been reviewed and approved by a Presidential appointee.
3. Refrain from participating in any public speaking engagement until the event and material have been reviewed and approved by a Presidential appointee.

4. Coordinate with Presidential appointees prior to issuing official correspondence to public officials (e.g., members of Congress, governors) or containing interpretations or statements of Department regulations or policy. Nothing in this guidance is intended to limit an employee's personal correspondence with members of Congress or other third parties, including an employee's whistleblower protected communications.
5. Notify Exec Sec promptly of any documents or communications that you believe should not be subject to the directives in paragraphs 1-4 because they are required by statute or litigation; affect critical health, safety, environmental, financial, or national security functions of the Department; or for some other reason. Please provide the title, a brief summary, the target release date, and the rationale for expedited release to your Exec Sec Policy Coordinator.

The President's appointees intend to review documents and communications expeditiously and return to a more regular process as soon as possible.

If you identify any actions taken inconsistent with these requests, please know they shall not be considered impliedly ratified. These items should be immediately withdrawn or rescinded to deem them as void and without effect.

Thank you for your assistance in ensuring a smooth transition consistent with our nation's democratic principles.

Dorothy A. Fink, MD, Acting Secretary



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Modern
Healthcare

A CRAIN FAMILY BRAND

April 08, 2025 05:00 AM | 6 HOURS AGO

Tariffs

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Tariffs may force hospitals to ration supplies and cut services

Providence expects President Donald Trump's initial tariffs to increase its costs by \$10 million to \$25 million per year

Renton, Wash.-based Providence Health previously estimated that the tariffs could increase costs by \$10 million to \$25 million annually. The estimate was shared in response to the initial announcement of reciprocal rates. Moreover, a January survey of 200 healthcare industry experts found that 82% expect tariff-related import expenses could drive up hospital and health system costs by 15% within the next six months.

President Trump also said April 8 that pharmaceutical imports will soon face "major tariffs," after drug imports evaded the first round of tariffs.

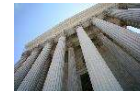
Uncertainty around potential pharmaceutical tariffs is one factor driving up the cost of marketplace coverage in 2025, according to [KFF](#). Multiple insurers, including UnitedHealthcare plans in New York, Maryland and Oregon, and Independent Health have cited tariffs on pharmaceuticals as one reason behind their requests for higher premiums in 2026, KFF analysts wrote June 16.



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Developments in International & National Public Health

- Bird Flu, Measles and Covid 19
- Health Equity
- Public Health Crises
 - Autism
 - Gun Violence?
 - Climate
- Access to Care
 - OCR, Discrimination and 1557
 - Behavioral Health
 - Maternal Health
- Post-Dobbs/Reproductive Health



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Avian Influenza (Bird Flu)

EXPLORE THIS TOPIC

H5 Bird Flu: Current Situation

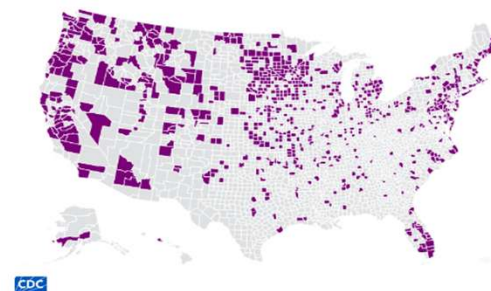
Centers for Disease Control and Prevention | CDC (.gov)
<https://www.cdc.gov/bird-flu/situation-summary>

13,225 wild birds detected as of 6/11/2025 | Full Report ; 51 jurisdictions with bird flu in wild birds ; 174,804,048 poultry affected as of 6/13/2025

While the current public health risk is low, CDC is watching the situation carefully and working with states to monitor people with animal exposures.

Counties Affected

Instructions: Counties that have reported bird flu outbreaks are marked in purple. On the map, select a state that has an outbreak to zoom in. More information is available about the outbreak by hovering over with the mouse (desktop) or tapping (mobile) the affected county.
[Download Data](#) [Excel](#)



JANUARY 7, 2025

What Does First U.S. Bird Flu Death Tell Experts about Disease Severity?

Louisiana has reported the first U.S. fatality from avian influenza. Most of the country's human cases have been mild

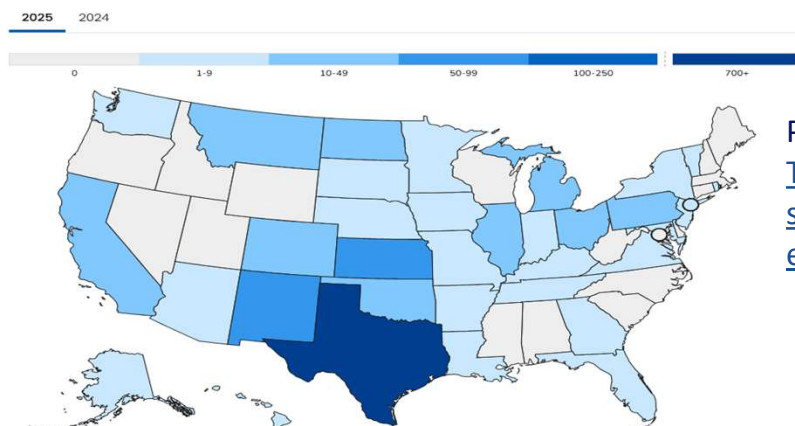


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Map of measles cases in 2024 & 2025

as of June 12, 2025



Measles (Rubeola) >

Measles is one of the most contagious diseases and can be dangerous in babies and young children. The best protection against measles is the MMR vaccine.

PBS: [Amid measles outbreak, Texas lawmakers vote to make school vaccine exemptions easier](#)



Latest Covid 19 Updates: Vaccine and Paxlovid



New COVID Variant NB.1.8.1 'Nimbus' Now Driving 37% of Cases in US: Know These Symptoms

In May, the [World Health Organization](#) classified NB.1.8.1 as a "variant under monitoring" due to its rapid spread and mutations

CDC ended its COVID-19 vaccine recommendations for pregnant people & healthy children, and the FDA will no longer approve new COVID shots for healthy adults

- Updated COVID-19 vaccines are now required to undergo placebo-controlled clinical trials prior to approval, which could limit access to shots.
- Experts say it's shortsighted to exclude pregnant people and children from the list of recommended groups who should get vaccinated against COVID-19.

[PAXLOVID™ \(nirmatrelvir tablets; ritonavir tablets\)](#)
For Patients
([paxlovidinformation.com](#))

Through December 31, 2024, eligible patients qualified for free Paxlovid through the [PAXCESS program](#).



Before throwing out at-home COVID-19 tests, check the FDA's website to confirm ...

Did you know that there are several over-the-counter (OTC) COVID-19 tests that have extended expiration dates? If you have at-home OTC COVID-19 tests with extended expiration dates, they can be used beyond the expiration date that is printed on the box.



Milestone: COVID-19 five years ago



30 December 2024 Statement Five years ago on 31 December 2019, WHO's Country Office in China picked up a media statement by the Wuhan Municipal Health Commission from their website on cases of 'viral pneumonia' in Wuhan, China. ... At WHO, we went to work immediately as the new year dawned. WHO employees activated emergency systems on 1 January 2020, and informed the world on 4 January. By 9-12 January, WHO had published its first set of comprehensive guidance for countries, and on 13 January, we brought together partners to publish the blueprint of the first SARS-CoV-2 laboratory test. ... Read about WHO's actions in this [interactive timeline](#).

U.S. Removed from WHO on 1-20-2025 CDC Ordered to Stop working with WHO 1-27-2025



Mr. Trump signed an executive [order](#) Jan. 20 removing the U.S. from the World Health Organization due to "the organization's mishandling of the COVID-19 pandemic that arose out of Wuhan, China, and other global health crises, its failure to adopt urgently needed reforms and its inability to demonstrate independence from the inappropriate political influence of WHO member state," according to the order.

The order will also review, revoke and replace the 2024 U.S. Global Health Security Strategy.

... January 27, 2025 NEW YORK (AP) — U.S. public health officials have been told to stop working with the World Health Organization, effective immediately.



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PBS NEWS RFK Jr. names 8 vaccine panel replacements, including a critic of COVID vaccines

[HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP](#)

Health Secretary Robert F. Kennedy Jr. announced eight new picks two days after removing all 17 of the prior members of the Advisory Committee on Immunization Practices. The panel makes vaccine recommendations to the CDC, including when and how often children and adults should get them.



You had posted the criticism of my choice by Senator Cassidy and a claim that I had promised Senator Cassidy not to change the vaccine panels. That's not true," Kennedy said during an interview on Fox News' "The Story with Martha MacCallum."
"What I told Senator Cassidy is that I would allow him to put one of his candidates on, which we're going to do," he said of the ACIP panel.

The Affordable Care Act's (ACA) guarantee of no-cost preventive services is under legal threat in Kennedy v. Braidwood.

Health care providers: Visit the [Vaccine Communication Resources for Health Care Providers page](#).
Public health professionals: Get resources in easy-to-download zip files by visiting the [Communication and Print Resources for Public Health](#).



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Health Equity in 2025



Check out Session 41



The Health Equity Roadmap is a framework to help hospitals and health care systems chart their own paths toward transformation — thus becoming more equitable and inclusive organizations.

AHA 2025 Accelerating Health Equity Conference

Accelerating Health Equity Conference May 19 - 22, 2025 | Atlanta Registration is Open!



Centers for Medicare & Medicaid Services

[Health Equity - Office of Health Equity - CDC](#)

CMS Health Equity Conference 2025 CMS Health Equity Conference: Building a Healthier America, held April 23-24, 2025

The CMS Health Equity Award winner recognizes organizations who have demonstrated a strong commitment to health equity by reducing disparities affecting vulnerable populations



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Autism Epidemic Action

On April 15, 2025, Secretary Kennedy held a [press conference](#) on the latest CDC data showing an alarming increase of autism.

[According to the data](#), autism prevalence in the U.S. has increased from 1 in 36 children to 1 in 31. Better diagnostics alone do not account for this sharp increase. Secretary Kennedy is taking action to treat autism as the public health emergency it is.



President Trump has tasked me with identifying the root causes of the childhood chronic disease epidemic -- including autism. At Wednesday's press conference, I shared new data from [@CDCgov](#)

Autism and Developmental Disabilities Monitoring Network survey. Autism prevalence in the U.S. has increased from 1 in 36 children to 1 in 31. We will find the root cause of this epidemic and Make America Healthy Again.



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Gun Violence in the NEWS



1 injured in HonorHealth hospital shooting

A security guard was injured in a shooting at HonorHealth Scottsdale (Ariz.) Shea Medical Center on March 2, police confirmed. March 3rd, 2025

Ophthalmologist identified as Georgia shooting suspect

Retired ophthalmologist Jay Berger, MD, was taken into custody Oct. 29 following a stand-off with Atlanta police. October 31st, 2024

Inmate shot, killed by officer in Georgia hospital

A 31-year-old man was shot and killed by an officer in Washington County Regional Medical Center in Sandersville, Ga., April 23, after what local officials describe as an attempted escape from correctional officers. April 24th, 2024

Family of guard killed in shooting sues Legacy Health for negligence

A wrongful death lawsuit has been filed in the fatal July 2023 shooting at Legacy Good Samaritan Hospital in Portland, Ore. November 13th, 2024



MORE Gun Violence in the NEWS



1 injured in shooting at Michigan Corewell hospital

One employee was injured in a shooting at Corewell Health Beaumont Troy (Mich.) Hospital March 20. The Troy Police Department said in a live briefing it responded to reports of gunfire in the parking garage around 7:08 a.m. Lt. Ben...March 20th, 2025

1 injured in New York hospital shooting

A patient in the emergency department at Catholic Health's Mercy Hospital in Buffalo, N.Y., sustained a self-inflicted gunshot wound March 9, according to a March 10 health system statement shared with Becker's. March 10th, 2025

OSHA opens investigation into UPMC hospital shooting

The Occupational Safety and Health Administration is investigating a Feb. 22 shooting at UPMC Memorial Hospital in York, Pa., that left two dead and five wounded, an agency spokesperson confirmed to Becker's. March 5th, 2025

UPMC hospital reopens ICU after shooting

UPMC Memorial Hospital in York, Pa., has reopened its intensive care unit following a Feb. 22 shooting that left two dead and five wounded. February 27th, 2025

Patient fires police officer's gun inside Jefferson hospital ED: Reports

An in-custody patient reportedly fired shots inside the Jefferson Cherry Hill (N.J.) Hospital emergency department, according to local media outlets September 3rd, 2024



Gun Violence is a Public Health Crisis?

<https://www.whitehouse.gov/ogvp/>

HealthDay News — HHS has removed the 2024 surgeon general's advisory on gun violence from its website.

"HHS and the Office of the Surgeon General are complying with President Trump's Executive Order on Protecting Second Amendment Rights," HHS spokesman [Andrew Nixon](#) said in an email to CNN. (The advisory, released in June by Surgeon General Dr Vivek Murthy, had called gun violence a public health crisis.)

Luigi Mangione pleads not guilty to murder charges in killing of UnitedHealthcare CEO
The suspect accused of fatally shooting UnitedHealthcare CEO Brian Thompson pleaded not guilty on Dec. 23 to state charges of terrorism and murder. December 23, 2024

MONEYWATCH
Who was Brian Thompson, the UnitedHealthcare CEO shot dead in Manhattan?



Brian Thompson, 50, the CEO of UnitedHealthcare, was shot to death Dec. 4 outside the New York Hilton in Midtown Manhattan



Was established under the Biden administration to coordinate a whole-of-government approach to gun violence



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JANUARY 13, 2025

Climate and Health: 2024 Year in Review

From [Day One](#) of this Administration, President Biden and Vice President Harris have recognized the climate crisis as a crucial public health priority. This recognition stems from the major, current, and demonstrated risks of events such as heat waves, as well as the large, well-documented co-benefits of reducing emissions, such as improved air quality.

The Biden-Harris Administration has advanced progress in the area of climate and health in a robust, ambitious, coordinated fashion.

The accomplishments listed [Climate and Health: 2024 Year in Review](#) | OSTP | The White House showcase how this Administration has uplifted the health co-benefits of ambitious climate action.

This Administration has driven the health care industry in sustainable directions, protected public health and health care delivery from climate impacts, and improved the [state of science and technology](#) to address this massive challenge.



Home Topics In depth Secretary-General Media

AUDIO HUB

Climate emergency is a health crisis 'that is already killing us,' says WHO

11 June 2025 [Health](#)

With 2024 confirmed as the hottest year on record, the World Health Organization (WHO) has issued a stark warning: the climate crisis is also a health crisis – and it's already claiming lives.

Europe is warming faster than any other WHO region, and the impact on people's health is growing more severe. From rising death rates to increasing climate-related anxiety, nearly every health indicator linked to climate has worsened in recent years.



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NEW Director of HHS Office of Civil Rights



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Office for Civil Rights

June 4, 2025

HHS Announces Paula M. Stannard as Director of the Office for Civil Rights

Director Paula Stannard is appointed to enforce the nation's civil rights laws and advance compliance with health information privacy and security authorities

The U.S. Department of Health and Human Services ("HHS"), Office for Civil Rights ("OCR") announces the appointment of Paula M. Stannard as Director of the Office for Civil Rights. In this role, Director Stannard is the Department's chief officer and adviser to Secretary Robert F. Kennedy, Jr. concerning the implementation, compliance, and enforcement of Federal health information privacy, security, and breach notification rules under the Health Insurance Portability and Accountability Act (HIPAA) as well as Federal civil rights, conscience, and religious freedom laws in HHS' jurisdiction.



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HHS.gov

<https://www.hhs.gov/civil-rights/fs-sex-discrimination>

Section 1557 Compliance 2025 Due Dates

Part B Application. Final Section 1557 has **staggered effective dates**—and 1557 now applies to recipients of Medicare Part B payments because the preamble to the 2024 Rule states HHS is changing its interpretation to include any providers who accept Part B patients (now deemed to be recipients of federal financial assistance.)

Policies, Procedures and Notice of Availability. Covered entities have until **July 5, 2025** to comply with the Final Rule's policies and procedures and notice of availability requirements. The Final Rule provides tables that outlines the effective **dates** of specific provisions. [Federal Register : Nondiscrimination in Health Programs and Activities](#)

Patient Care Decision Support Tools. HHS' position is patient care decision support tools, including the use of clinical algorithms and other AI tools also violates Section 1557 may be used to discriminate. Accordingly, Section 92.210(b) requires a covered entity to make reasonable efforts to identify patient care decision support tools used in its health programs and activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.



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HHS.gov

<https://www.hhs.gov/civil-rights/fs-sex-discrimination>

Use of Patient Care Decision Tools

Section 92.210(c) requires that for each patient care decision support tool identified in paragraph (b), a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.

As of May 2025, covered entities must satisfy an “ongoing duty to make reasonable efforts to identify uses of patient care decision tools” that use input variables that measure race, color, national origin, sex, age, or disability.

As summarized by HHS OCR, these tools include those used at the individual patient level or at the population health level, and these tools may be used by healthcare actors for patient screening, risk analysis, clinical diagnosis, clinical decision-making, and treatment planning.

Note: The regulation now uses the term “patient care decision tool,” rather than the former proposed term “clinical algorithm.”



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MEDPAGETODAY®

VA Bylaws Update and The Guardian story



The VA is vigorously disputing a news story claiming that new policy allows physicians and other medical staff to decline to treat patients based on political party or marital status. VA has asked ... to retract it," a VA spokesperson said in an email to MedPage Today. "Any media outlets that repeat the story are spreading disinformation."

The story claims that individual workers are now free to decline to care for patients "based on personal characteristics not explicitly prohibited by federal law."

The story also says that under the new policy, doctors and other medical staff can be barred from working at VA hospitals based on their marital status, political party affiliation, or union activity. The VA spokesperson said these claims were "false," noting that "Federal law prohibits that, and VA will always follow federal law."

The VA spokesperson acknowledged that the VA did recently update its bylaws "to ensure compliance with White House executive orders, such as the order on Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government." But, the spokesperson added, "These updates will have no impact whatsoever on who VA treats or who works at VA."



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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

January 10, 2025

Protecting Civil Rights and Access to Health Care

By Melanie Fontes Rainer, Director for Office for Civil Rights

OCR's Rules:

- [Section 1557 of the Affordable Care Act Final Rule](#)
- [HIPAA Privacy Rule to Support Reproductive Health Care Privacy Final Rule](#)
- [Section 504 of the Rehabilitation Act of 1973 Final Rule](#)
- [Health and Human Services Grants Regulation Final Rule](#)
- [Confidentiality of Substance Use Disorder Patient Records Final Rule](#)
- [Safeguarding the Rights of Conscience Final Rule](#)
- [Proposed HIPAA Security Rule](#)



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

February 3, 2025

HHS' Civil Rights Office Acts Swiftly to Combat Anti-Semitism

OCR Opens Compliance Reviews of Four Medical Schools over Protests Taking Place during Their 2024 Commencement Ceremonies

Language and Physical Access - Excerpt from 1-10-2025 listserve posting: People with disabilities would share their stories with me about a hospital that denied them a companion in the emergency room, or how they worked so hard to get accessible medical equipment for their wheelchairs to have an MRI, only to face staff that day who did not know how to use it. Time and again, I heard about appointments canceled because no interpreter was available for a person whose primary language is not English. Or children being forced to interpret for their family member.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

Civil Rights – Maternal Health & Language Access Resolutions

January 16, 2025

HHS Office for Civil Rights and Cedars-Sinai Enter Into Mutual Agreement to Advance Civil Rights and Improve Maternal Health for All

Agreement Takes Important Steps in Addressing Racial Disparities in Maternal Health Outcomes by Ensuring That Black Women and Other Women of Color Have Access to Treatment During the Full Course of Their Care

OCR initiated a compliance review of Cedars-Sinai in response to public reports indicating that racial bias in healthcare decision making and treatment contributed to the death of Kira Johnson, a Black maternity patient who died approximately 10 hours after delivering her son at Cedars-Sinai Medical Center.

January 17, 2025

HHS Office for Civil Rights Reinforces State Medicaid Agencies' Obligations Under Civil Rights Laws

HHS OCR resolved 27 matters to reinforce State Medicaid agencies obligations under certain civil rights laws. "Today's actions reaffirm OCR's deep commitment to helping states ensure that eligible individuals with LEP and individuals with disabilities are provided with meaningful language access and effective communication to ensure they do not experience an otherwise unnecessary lapse in coverage due to communications from state agencies about Medicaid eligibility redeterminations that enrollees do not understand."



May 15, 2025 **Enforcement** of the 2024 final regulations under the Mental Health Parity and Addiction Equity Act (MHPAEA) has been **suspended** due to litigation by The ERISA Industry Committee. In response, the US Departments of Labor, Health and Human Services, and Treasury announced that they **will not enforce the new rule until the case is resolved, plus an additional 18 months**. This enforcement relief applies only with respect to those portions of the 2024 Final Rule that are new in relation to the 2013 final rule.

(Updated on July 3rd, 2024) [Approaches in Implementing the Mental Health Parity and Addiction Equity Act of 2008: Best Practices from the States | SAMHSA Library](#)
library.samhsa.gov/product/approaches-implementing-mental-health-parity-and-addi...

April 17th, 2023 (Updated on May 8th, 2025) [2025 Mental Health Awareness Month Toolkit | SAMHSA](#)
www.samhsa.gov/about/digital-toolkits/mental-health-awareness-month/toolkit

SAMHSA's Office of Behavioral Health Equity (OBHE)

The Office of Behavioral Health Equity (OBHE) advances behavioral health equity by reducing disparities in racial, ethnic, LGBTQIA+, and other under-resourced communities across the country by improving access to quality services and supports that enables all to thrive, participate, and contribute to healthier communities.

Medicare Enrollment Increased Visits To Primary Care Providers But Not Mental Health Care Providers, 2014–21

[Donghoon Lee](#) and [Jing Li](#)
[AFFILIATIONS](#) ▾

PUBLISHED: JANUARY 2025 No Access

<https://doi.org/10.1377/hlthaff.2024.00666>

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Abstract

Medicare enrollment increases provider visits among older adults; however, it remains unclear whether this increase is uniform across all types of providers. Using data from the 2014–21 Medical Expenditure Panel Surveys, we examined the effect of Medicare enrollment on office and outpatient visits across providers, using a regression discontinuity design. We found that Medicare enrollment at age sixty-five led to a 14 percent increase in visits to primary care providers and a 31 percent increase in visits to other providers, with the former more prominent among Medicare Advantage enrollees. In contrast, there was no change in visits to mental health care providers. Our study highlights the heterogeneous effects of Medicare enrollment on health care use across different types of providers. Strengthening partnerships across providers, especially between primary care and mental health care providers, could be one way to improve mental health care use among new Medicare enrollees.

Mental Health Parity

 HealthAffairs

ACKNOWLEDGMENTS Research reported in this article was supported by the National Institute on Aging, National Institutes of Health (Grant No. K01AG066946 to Jing Li).

[Medicare Enrollment Increased Visits To Primary Care Providers But Not Mental Health Care Providers, 2014–21 | Health Affairs](#)

Access to Care Deaf and Hard of Hearing



January 2025 GAO-25-106978 HEARING DETECTION AND INTERVENTION Program Connects Deaf or Hard of Hearing Infants and Children to Services, but Actions Needed to Improve Access

What GAO Recommends

GAO is making two recommendations to HRSA:

- (1) require state Early Hearing Detection and Intervention (EHDI) programs to set performance goals that can be used to measure progress in addressing any identified disparities in access for underserved populations; and
- (2) assess the results of state EHDI programs' access disparities performance and use it to inform future plans.

HHS agreed with these recommendations.



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No-Cost Preventive Health Services

Check out Session 39

The Supreme Court recently heard oral arguments in *Kennedy v. Braidwood*, a case that could upend no-cost coverage for dozens of preventive health services under the Affordable Care Act. (April oral arguments)

At the heart of the case is whether the U.S. Preventive Services Task Force has the constitutional authority to mandate insurance coverage without cost-sharing.

V-BID Center Director, Mark Fendrick, M.D., who helped craft the ACA's preventive care provision, warned that millions could lose access to vital services like cancer screenings, mental health evaluations, and cardiovascular disease prevention.

"When Americans face out-of-pocket costs, many skip essential preventive care," Fendrick said, adding that the potential rollback could have devastating public health and equity consequences. A decision is expected in June or July.

New Bipartisan U.S. Senate Bill Seeks to Eliminate Out-of-Pocket Costs for Childbirth

The bipartisan [Supporting Healthy Moms and Babies Act](#) was introduced in the Senate, aimed to reduce the high cost of childbirth in the U.S. The bill would require private insurance companies to fully cover all childbirth-related expenses — from prenatal care and ultrasounds to delivery, postpartum care, and mental health treatment — without any co-pays or deductibles. Medicaid, which insures roughly 41 percent of American births, [already covers these costs](#).



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POST- Dobbs: Supreme Court and State Court Actions, State Laws

[AHLA - Reproductive Health Law Hub](#)



Supreme Court Review of EMTALA and State Law Preemption
State Actions Re Abortion Pills

State Abortion Bans

Other State Actions

[Reproductive Health and Shield Laws: Latest Developments](#)

12/27/2024 Podcast Episode State of Texas v. HHS September 2024

Texas' attorney general recently filed a civil lawsuit against a New York physician for prescribing medication abortion pills via telehealth to a woman in Texas. Natalie Birnbaum, State Legal and Policy Director, RHITES, and Krusheeta Patel, Associate, Manatt Phelps & Phillips LLP, discuss this first open challenge to abortion shield laws and the intersection of telehealth, abortion access, and interstate licensure pathways for U.S. providers.

Three additional lawsuits were filed:

State of Missouri v. U.S. Department of Health and Human Services January 2025

State of Tennessee v. HHS January 2025

Purl, M.D. v. HHS October 2024

Check out Session 17



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Breaking News:

HIPAA Privacy Rule to Support Reproductive Health Care Privacy VACATED

In an earlier high-profile case, Kacsmayk attempted to order the U.S. Food and Drug Administration to rescind its decades-old approval of mifepristone, one of two drugs used to terminate early pregnancies and treat miscarriages. That decision was eventually returned by the U.S. Supreme Court to a lower court for consideration.

Officials in Texas have already attempted to investigate women who left the state, which has a near-total abortion ban and other abortion-related laws, to terminate a pregnancy.

[Texas judge strikes down federal health privacy rule for legal abortion care | News From The States](#)

Case 2:24-cv-00228-Z Document 111 Filed 06/18/25 Page 1 of 1 PageID 52159

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

CARMEN PURL, *et al.*,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

2:24-CV-228-Z

JUDGMENT

The Court GRANTED Plaintiffs' Motion for Summary Judgment and DENIED Defendants' Motion to Dismiss for Lack of Jurisdiction. Accordingly, the HIPAA Privacy Rule to Support Reproductive Health Care Privacy at 89 Fed. Reg. 32976 is VACATED per 5 U.S.C. Section 706(2), except its modifications to 45 C.F.R. Section 164.520. But the provisions at 45 C.F.R. Section 164.520(b)(1)(ii)(F), (G), and (H) are VACATED per 5 U.S.C. Section 706(2). This case is therefore DISMISSED with prejudice. Judgment is rendered accordingly.

SO ORDERED.

June 18, 2025

MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE



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Reproductive Rights – 2025 Executive Order

On January 24, 2025, President Trump issued an [Executive Order](#), titled "Enforcing the Hyde Amendment," revoking President Biden's two Executive Orders [14076](#) (July 8, 2022) and [14079](#) (August 3, 2022) that federally protected access to reproductive healthcare services.

President Trump's Executive Order [leaves access to reproductive healthcare services to the states](#).

President Biden's first reproductive healthcare Executive Order directed HHS to expand access and ensure women receive emergency medical care and strengthen the protection of sensitive information related to reproductive healthcare services and bolster patient-provider confidentiality.

President Biden's second reproductive healthcare Executive Order directed federal agencies to address barriers to healthcare access, particularly for marginalized and underserved communities, and to promote public awareness of reproductive healthcare services and rights.



Abortion NEWS from



Health Law Weekly

Montana Supreme Court Says 20-Week Abortion Ban Violates State's Constitution 06/13/2025

CMS Nixes EMTALA Guidance on Abortion Services 06/06/2025

Missouri Supreme Court Walks Back Injunctions Blocking Abortion Restrictions 05/30/2025

DOJ Urges Court to Dismiss States' Challenge to Abortion Pill Access 05/09/2025

U.S. Court in Texas Allows Generic Manufacturer GenBioPro to Intervene in Abortion Pill Challenge 05/02/2025

FDA Commissioner Says No Plans to Restrict Mifepristone Access 04/25/2025

Idaho Judge Says "Non-Negligible" Risk of Death Triggers "Medical Emergency" Exception to State's Abortion Law 04/18/2025

U.S. Court in Illinois Says Condition on Conscience Shield Law Requiring Abortion Discussion Violates Free Speech 04/11/2025

Woman Sues California Hospital Alleging Failure to Provide Emergency Abortion Care Violated State Law 04/04/2025



Abortion Pill Challenge June 2024

USA Today: **Abortion advocates, opponents agree on one thing about SCOTUS ruling: The fight isn't over**

AP AP News
Unanimous Supreme Court preserves access to abortion pill mifepristone



AHLA Podcast 2/21/25

[Top Ten 2025: Medication Abortion Cases to Watch](#)

[FDA v. Alliance for Hippocratic Medicine](#)

US Supreme court issued its decision June 13 in the challenge to access to a pill commonly used in abortion known as mifepristone. The ["abortion pill,"](#) as it's commonly referred to, is used in up to 50% of abortions in the United States.

A group of doctors challenged the Food and Drug Administration's more recent approvals of mifepristone in 2016 and 2021 that expanded access to the drug by letting clinicians other than physicians prescribe it, and let patients receive the pill by mail.

Held: Plaintiffs lack Article III standing to challenge FDA's actions regarding the regulation of mifepristone. Pp. 5–25.



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Abortion Pill Challenge June 15, 2025



📺 CBS NEWS · 10d · on MSN

[FDA to "review the latest data" on mifepristone. What could it mean for access to the abortion ...](#)

AP AP NEWS · 5d · on MSN

[Louisiana lawmakers pass bill targeting out-of-state doctors who prescribe and mail abortion pills](#)

The Washington Post · 12d · on MS

[Maine will let abortion-pill prescribers keep their names off labels](#)

📺 The Center Square · 4d · on M

[DOJ staffer charged with capital murder in abortion pill case](#)

(The Center Square) – Another abortion-related arrest has been made in Texas, this time for capital murder by a Department of Justice staffer working for the Trump administration.

Abortion, with some exceptions, is illegal in Texas. In recent months, several individuals have been arrested for performing illegal abortions or operating illegal abortion facilities, The Center Square [reported](#). Local entities were also [sued](#) for facilitating "abortion tourism" using taxpayer money in violation of state law, prompting the Texas legislature to act, The Center Square [reported](#).



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Louisiana grand jury indicts New York doctor over mailing abortion pills into state

Forbes, US News and CNN report:

By the first half of 2024, 10% of abortions in the U.S. were a result of receiving abortion pills in the mail

Medication abortion accounted for nearly two-thirds of all abortions in the US in 2023 (Medication abortions are safe until 10 weeks into pregnancy)

Abortion rates have risen since the Dobbs decision

"The sharpest increases were seen in states bordering ban states, where abortions increased by 37% from 2020 to 2023," according to Guttmacher.org

A Louisiana grand jury on January 31, 2025 Friday indicted a doctor from New York on charges of prescribing abortion pills that were forced upon a pregnant minor, a first-of-its-kind criminal case.

Local news reports indicate that a grand jury in Port Allen, Louisiana, indicted Dr. Margaret Carpenter, her practice, Nightingale Medical, and the minor's mother, who prosecutors say coerced her daughter into a medication abortion.

Prosecutors say that the pregnant minor's mother obtained the abortion drugs mifepristone and misoprostol online from Carpenter, who shipped the medications to Louisiana where abortion is illegal.

District Attorney Tony Clayton told local news outlet WAFB that the child was "told by the mother that she had to take the pills or else," and when she took the medication, she began to hemorrhage. Although it is unclear how far along she was in her pregnancy, the victim was admitted to the emergency room and lost her pregnancy.

Abortion Issues in the Courts & States

News 5 Cleveland WEWS

Republican lawmakers in Ohio to propose total abortion and IVF ban

Gothamist

Supreme Court orders NY to reconsider religious exemptions to abortion...

The Times

Suspected gunman Vance Boelter had 'hit list of abortion activists'

CBS News

Doctors say strict abortion laws in Texas put pregnant women and their physicians at serious risk

The Independent

Fewer than half of young men believe abortion should be legal, poll finds

Christian Post

Gallup finds record gap between men, women on whether abortion is morally acceptable

Supreme Court to Hear Case on New Jersey Subpoena to Anti-Abortion Pregnancy Centers

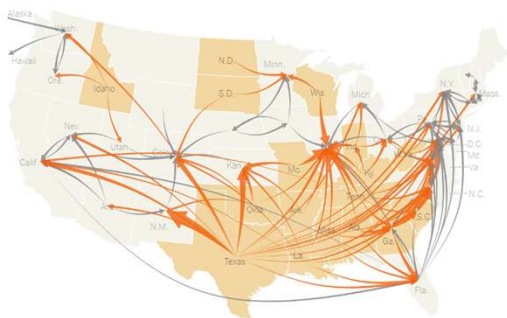
May the centers pursue a First Amendment challenge to a state subpoena seeking donor information?

Access to Abortions will be determined by the States

The New York Times

171,000 Traveled for Abortions Last Year. See Where They Went.

By Molly Cook Escobar, Amy Schoenfeld Walker, Allison McCann, Scott Reinhard and Helmut Rosales
June 13, 2024



[171,000 Traveled for Abortions Last Year. See Where They Went. - The New York Times](#)

KFF The independent source for health policy research, polling, and news.

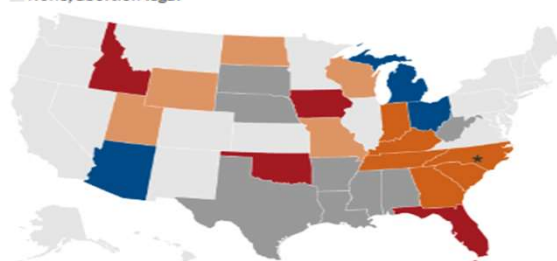
Reproductive Rights and Abortion Litigation Tracker

Status of Abortion Litigation in State Courts, as of June 6, 2025

Status of Litigation

- Concluded, ban in effect
- Concluded, ban permanently blocked
- Ongoing, ban in effect
- Ongoing, ban temporarily blocked
- None, abortion banned
- None, abortion legal

[Abortion in the United States Dashboard | KFF](#)



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Abortion Bans

Tracking Abortion Laws Across the Country

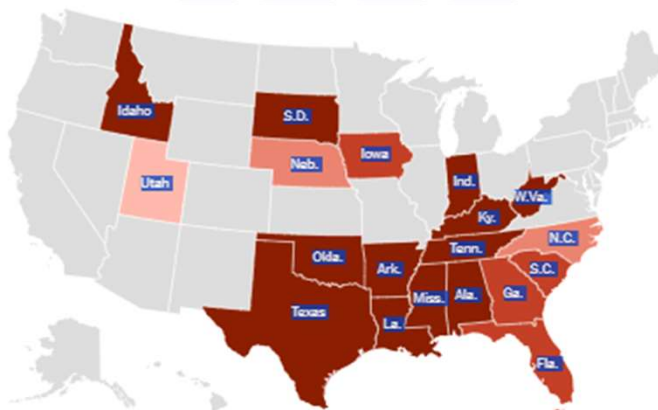
By Allison McCann and Amy Schoenfeld Walker

Updated May 29, 2025 at 12:24 p.m. E.T.

[Abortion Laws Across the Country: Tracking Bans and Protections by State - The New York Times](#)

Where abortion bans are in effect

Full ban Six weeks 12 weeks 18 weeks

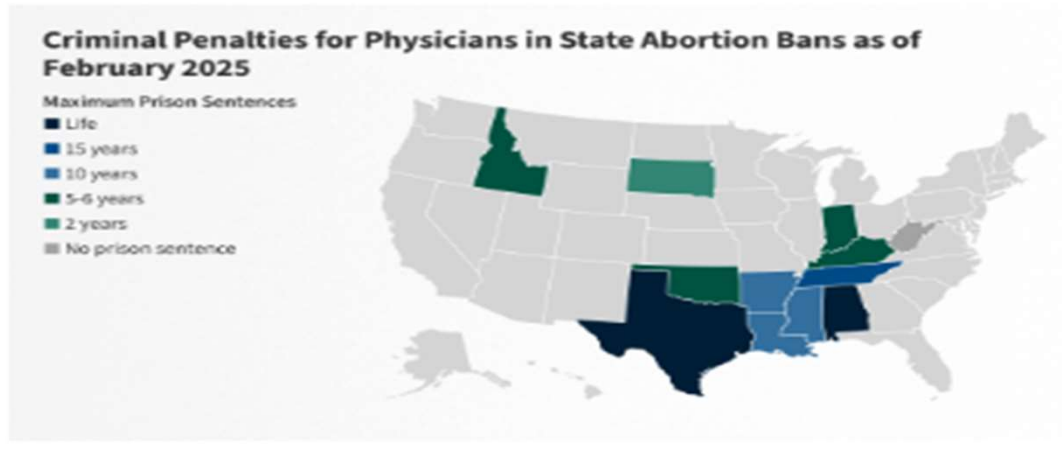


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Criminal Penalties for Physicians in State Abortion Bans

[Abortion in the United States](#)
Dashboard | KFF

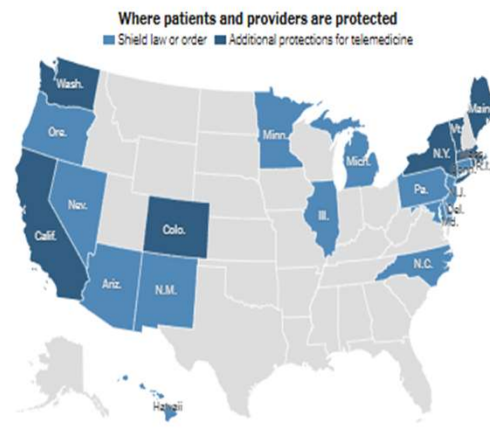
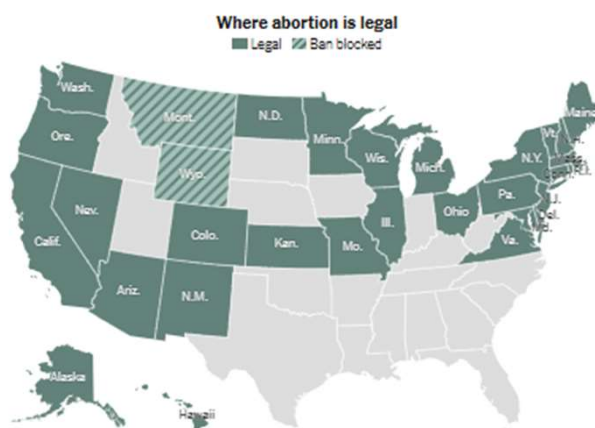


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Where Abortions are Legal

Eight states have gone even further by enacting [telemedicine shield laws](#), which aim to protect doctors and others who prescribe and send abortion pills in the mail to patients located in states with bans.



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Health Law Weekly Articles

[Montana Supreme Court Says 20-Week Abortion Ban Violates State's Constitution](#)

06/13/2025

[CMS Nixes EMTALA Guidance on Abortion Services](#) 06/06/2025

[Missouri Supreme Court Walks Back Injunctions Blocking Abortion Restrictions](#) 05/30/2025

[DOJ Urges Court to Dismiss States' Challenge to Abortion Pill Access](#) 05/09/2025

[U.S. Court in Texas Allows Generic Manufacturer GenBioPro to Intervene in Abortion Pill Challenge](#) 05/02/2025

[FDA Commissioner Says No Plans to Restrict Mifepristone Access](#) 04/25/2025

[Idaho Judge Says "Non-Negligible" Risk of Death Triggers "Medical Emergency" Exception to State's Abortion Law](#) 04/18/2025

[U.S. Court in Illinois Says Condition on Conscience Shield Law Requiring Abortion Discussion Violates Free Speech](#) 04/11/2025

[Woman Sues California Hospital Alleging Failure to Provide Emergency Abortion Care Violated State Law](#) 04/04/2025



Access to Care is Changing Site of Care is Changing

Hospital Closures

Rural Emergency Hospital

Hospital at Home

HealthCare.gov Enrollment

Extended Telehealth



Becker's has reported on 16 hospital and emergency department closures in 2025 (Becker's reported on 25 hospital and emergency department closures in 2024)

1. Moulton, **Ala.**-based Lawrence Medical Center permanently **shuttered** its emergency department on May 23.
2. Upland, **Pa.**-based Crozer Health **closed** its Crozer-Chester Medical Center in Upland on May 2.
3. Crozer Health **closed** its Ridley Park, **Pa.**-based Taylor Hospital on April 26. Around 2,651 employees across two Crozer hospitals and its other facilities were laid off from April 25 to May 2.
4. Mid Coast Medical Center Trinity (**Texas**) **closed** April 25, after attempting to secure facility long-term sustainability and financial stability for months.
5. Heritage Valley Kennedy Hospital in Kennedy Township, **Pa.**, will **shutter** on June 30 due to reduced insurance reimbursements and declining patient volume.
6. Insight Hospital and Medical Center Trumbull in Warren, **Ohio**, **paused** its inpatient, outpatient and emergency room services March 27 for the foreseeable future amid ongoing bankruptcy and financial disruptions from former owner Dallas-based Steward Health Care.
7. East **Ohio** Regional Hospital, a 140-bed healthcare facility in Martins Ferry, **closed** March 20.
8. **St. Louis-based** Homer G. Phillips Memorial Hospital's board of directors voluntarily surrendered its hospital license March 17 to the Missouri Department of Health and Senior Services and **closed**.
9. Brewer, **Maine**-based Northern Light Health has shared plans to close Northern Light Inland Hospital in Waterville and its associated services and clinics on May 27.
10. Ascension St. Elizabeth in **Chicago** closed in mid-February prior to Ontario, Calif.-based Prime Healthcare's acquisition of it and eight other St. Louis-based Ascension hospitals in Illinois.
11. **New York City-based** Mount Sinai's Beth Israel closed April 9 after months of legal back and forth with the Community Coalition to Save Beth Israel Hospital to keep the hospital open.
12. Irving, **Texas**-based Christus Health shuttered its Christus Santa Rosa Hospital-Medical Center in San Antonio on April 25, and consolidate care to nearby system hospitals.
13. **Washington, D.C.**-based United Medical Center closed April 15 and laid off 485 employees. The closure will be timed with the opening of Washington, D.C.-based Cedar Hill Regional Medical Center, which will start seeing patients April 15.
14. Orlando (**Fla.**) Health shuttered Rockledge Hospital and four hospital-based outpatient departments on April 22.
15. Moulton, **Ala.**-based Lawrence Medical Center will end inpatient and emergency services by mid-2025. The hospital entered a financial partnership with Huntsville (Ala.) Hospital Health System that will see the hospital shift to an outpatient-only model.
16. Pauls Valley, **Okl.**-based Valley Community Hospital closed Jan. 8. The 43-bed facility had reopened in 2021 after shuttering for three years. It was also forced to end online rumors of closure in January 2024 after multiple complaints led to the closure of its laboratory and relocation of laboratory services to Norman (Okla.) Regional Hospital.

Ohio health system to pay \$2.1M settlement after abrupt hospital closure (in 2022)



January 23, 2025 Cleveland-based University Hospitals will transfer the former UH Bedford (Ohio) Hospital site, along with more than 11 acres and buildings, to the city of Bedford and pay \$2.1 million as part of a settlement stemming from the hospital's abrupt **closure** in 2022, cleveland.com reported Jan. 22.

The agreement, approved by **Bedford City Council**, ends a nearly three-year legal dispute over University Hospital's decision to end inpatient, surgery and emergency services at the hospital in August 2022. Staffing shortages created "unprecedented challenges" for University Hospitals according to the news release announcing the closure.

In July 2022 to optimize limited resources, UH reached the decision to consolidate inpatient, surgical and emergency department services in its East Market to facilities at UH Ahuja, Geauga, Lake West, TriPoint, Beachwood, Geneva and Conneaut medical centers.

Rural Hospitals at risk



Rural providers on edge as Congress eyes \$1T in healthcare cuts

Rural healthcare providers foresee major problems if Congress follows through on plans to slash Medicaid and health insurance exchange spending.



- Across the US, the rural health safety net remains under intense pressure. Since 2010, 182 rural hospitals closed or converted to an operating model that excludes inpatient care.

- According to our newest analysis (Feb 2025), 46% of rural hospitals are in the red, and 432 are vulnerable to closure.



Feb 12, 2025 — Arkansas (50%) has the highest percentage of rural hospitals at risk of closure, followed by Mississippi (47%) and Kansas (47%).

Over 100 rural hospitals have stopped delivering babies over the past 5 years, and less than half of all rural hospitals still have labor and delivery services [The Crisis in Rural Health Care – Saving Rural Hospitals](#) [705 hospitals at risk of closure, state by state](#)



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Rural Emergency Hospital and Hospital at Home



[New Medicare Designation Could Prevent Closure of Struggling Rural Hospitals - National Conference of State Legislatures \(ncsl.org\)](#)

36 Rural Emergency Hospitals



Hospital-at-home 2.0: Where health systems are headed next June 18, 2025

According to health system leaders who spoke with *Becker's*, this "Hospital-at-Home 2.0" era will focus on scaling daily admissions, broadening patient eligibility, and preparing for potential shifts in federal reimbursement.

Providers see hospital-at-home growth potential in cancer care

Mayo Clinic, Mount Sinai and Huntsman Cancer Institute are delivering services from chemotherapy to imaging in cancer patients' homes.



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HealthCare.gov Enrollment 2025

HealthCare.gov

Expiration of ACA Subsidies Projected To Increase Premium Costs Significantly

HL HEALTH LAW ASSOCIATION | Health Law Daily

6/18/25 KFF Health News reports that supplemental ACA subsidies put in place during the pandemic “are in place only through Dec. 31. Without enhanced subsidies, Affordable Care Act insurance premiums would rise by more than 75% on average, with bills for people in some states more than doubling, according to estimates from KFF.”

Upward Of 44M People Have Been Covered By ACA Initiative, Report

Says: AHLA Health Law Daily HealthLawDaily@ahla.bulletinhealthcare.com>

Jan 17, 2025 [Healthcare Finance News](#) says, “Upward of 44 million people, or 16.4% of the non-elderly U.S. population, have been covered by an Affordable Care Act initiative, including health plan enrollment and Medicaid expansion, finds a new KFF [report](#).” .., “KFF attributed much of the marketplace growth since 2020 to enhanced subsidies under the American Rescue Plan Act in 2021, which were renewed through 2025 by the Inflation Reduction Act.”

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Telehealth.HHS.gov

Telehealth Extension

Check out Session 26

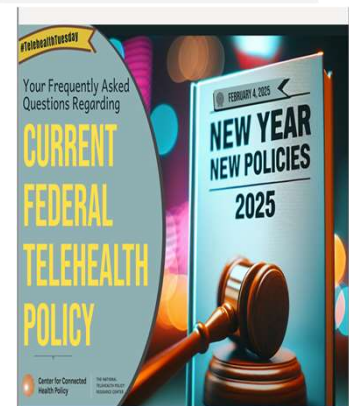
Permanent Medicare changes

- [Federally Qualified Health Centers \(FQHCs\)](#) and [Rural Health Clinics](#) (RHCs) can serve as a distant site provider for behavioral/mental telehealth services
- Medicare patients can receive telehealth services for behavioral/mental health care in their home
- There are no geographic restrictions for originating site for behavioral/mental telehealth services
- Behavioral/mental telehealth services can be delivered using audio-only communication platforms
- Rural Emergency Hospitals (REHs) are eligible originating sites for telehealth

Sources: [Consolidated Appropriations Act, 2021](#) (PDF), [Consolidated Appropriations Act, 2022](#) (PDF), [CMS CY 2022 Physician Fee Schedule](#) (PDF), [CMS CY 2023 Physician Fee Schedule](#) (PDF)



Center for Connected Health Policy | THE NATIONAL TELEHEALTH POLICY RESOURCE CENTER



HL AMERICAN HEALTH LAW ASSOCIATION

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Telehealth.HHS.gov

Telehealth Extension



Medicare payment policies

Read the latest on the Centers for Medicare & Medicaid Services (CMS) coverage for telehealth.

On this page:

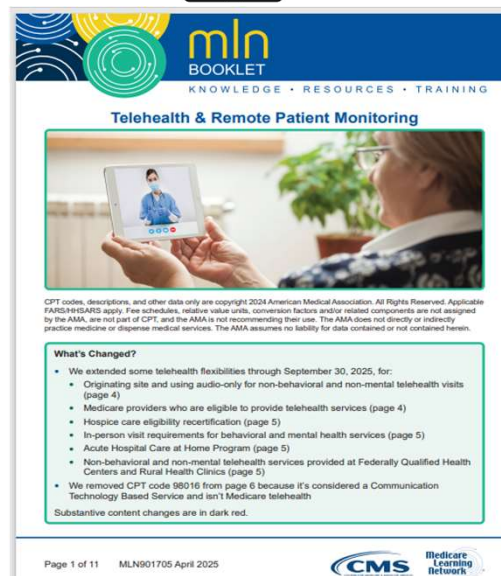
- [Telehealth policy updates](#)
- [Permanent telehealth policy](#)



Recent legislation authorized an extension of many of the Medicare telehealth flexibilities that were in place during the COVID-19 public health emergency through September 30, 2025.

In late April, the [Centers for Medicare and Medicaid Services](#) updated its [Medicare Learning Network \(MLN\) Telehealth and Patient Monitoring Booklet](#) to reflect recent policy changes made in compliance with [H.R. 1968—the Continuing Resolution](#) (March 2025).

Expired Medicare Coverage Waivers. Did not extend the flexibilities that expired December 31, 2024



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Telehealth Access Updates



Telehealth.HHS.gov

Licensing across state lines

The ability to deliver health care services across state lines varies based on state regulations.



Federation of State Medical Boards

<https://www.fsmb.org/news/may-15-2025>

PDF



Lawsuit challenging NJ licensure requirements dismissed

May 15, 2025 – The court rejected these claims, ruling that: The Commerce Clause does not apply because the law treats in-state and out-of-state.

More information:

- [Cross-State Licensing](#) – National Policy Telehealth Resource Center
- [Licensure Compacts](#) – National Policy Telehealth Resource Center
- [Out-of-State Telehealth Provider Policies](#) (PDF) – National Policy Telehealth Resource Center

K Hosted on MSN · 5h

[For California Farmworkers, Telehealth Visits With Mexican Doctors Fill a Gap](#)

The MiSalud app enables Spanish-speaking users in the U.S. to meet virtually with ...



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Telemedicine and Safe Prescribing



January 16, 2025, the Drug Enforcement Administration (DEA) announced two final rules and a proposed rule for telemedicine flexibilities.

DEA Extended the Pandemic-Era Telehealth Prescribing Flexibilities Through 2025. The Drug Enforcement Administration (DEA) **has officially extended the pandemic-era telehealth prescribing flexibilities for controlled substances for an additional year, now set to expire on Dec. 31, 2025.** Two final rules include expanded ability to prescribe buprenorphine and continuity of care for Veterans Affairs patients. These rules will only apply if a patient has never been seen in-person by the prescribing medical provider *and* the patient is being prescribed controlled medication.

“The DEA received a record 38,000 comments on its proposed telemedicine rules. We take those comments seriously and are considering them carefully,” said Administrator Milgram. As a result of the comments and listening session, DEA has now made significant revisions to the draft rules. The two final rules are a result of the temporary rules to prescribe medications via telemedicine that were adopted during the COVID-19 public health emergency. A third temporary [extension of COVID-19 Telemedicine Flexibilities](#) extended the temporary rule until December 2025.



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§ 1307.41 Temporary extension of certain COVID-19 telemedicine flexibilities for prescription of controlled medications

- (a) ... The authorization granted in [paragraph \(b\)](#) of this section expires at the end of December 31, 2025.
- (b) During the period May 12, 2023, through December 31, 2025, a DEA-registered practitioner is authorized to prescribe schedule II-V controlled substances via telemedicine, as defined in [21 CFR 1300.04\(i\)](#), to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in [paragraph \(c\)](#) of this section are met.
- (c) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to [paragraph \(b\)](#) of this section if all of the following conditions are met:
- (1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;
 - (2) The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in [42 CFR 410.78\(a\)\(3\)](#);
 - (3) The practitioner is:
 - (i) Authorized under their registration under [21 CFR 1301.13\(e\)\(1\)\(iv\)](#) to prescribe the basic class of controlled substance specified on the prescription; or
 - (ii) Exempt from obtaining a registration to dispense controlled substances under [21 U.S.C. 822\(d\)](#); and
 - (4) The prescription is consistent with all other requirements of [21 CFR part 1306](#).

[\[88 FR 30042\]](#), May 10, 2023, as amended at [88 FR 69882](#), Oct. 10, 2023; [89 FR 91257](#), Nov. 19, 2024]



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Home Healthcare Telehealth Post-Covid



Telehealth Use by Home Health Agencies Before, During, and After COVID-19 22 May 2025 <https://doi.org/10.1111/1475-6773.14645>

Funding: Research reported in this publication was supported by the National Institute on Aging of the National Institutes of Health under Award Number R01AG078840.

Principal Findings By 2019, prior to COVID-19, 183 (23%) of HHAs used telehealth, increasing to 446 (56%) by 2021. Growth occurred mainly in virtual visits. Of those HHAs adopting telehealth, 96 (19%) discontinued use later in the pandemic. Key concerns were about the appropriateness of the patient population and reimbursement.

Conclusions Patterns of adoption and discontinuation suggest that COVID-19 interrupted the innovation diffusion process of telehealth into home health. Telehealth's future will depend on information about **cost-effectiveness and Medicare reimbursement policies.**



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Fraud & Abuse, Part 1



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Fraud & Abuse, Part 1 Topic Team



- Laura Laemmle-Weidenfeld, *Jones Day*
- Brian Roark, *Bass, Berry & Sims PLC*
- Brad Robertson, *Bradley Arant Boult Cummings LLP*
- Gavin Keene, *Davis Wright Tremaine, LLP*

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The Numbers . . .

OIG Efforts Yield \$7.1B in Expected Recoveries/Receivables in FY24

- Recoveries up from \$3.16B in FY23
- OIG brought 1548 civil and criminal enforcement actions
- OIG excluded 3,234 individuals and entities from participation
- Spring Report to Congress shows upward trend for first six months of FY25

DOJ Recovers \$2.9B from False Claims Act Cases in FY24

- Recoveries up slightly from \$2.78B FY23
- 57% of FY24 recoveries from health care cases
 - Note that total continues a downward trend
- Record setting 979 new qui tam cases filed
- Total 1,402 new cases filed (15% increase over FY23)



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Criminal Healthcare Fraud Enforcement

Prosecuting Offices

- DOJ Criminal Division, Health Care Fraud Unit
- US Attorneys
- Medicaid Fraud Control Units

May 2025 DOJ Memo

- May 12, 2025, memo from DOJ's Criminal Division highlights 10 "high-impact" areas as enforcement priorities
- #1 on the list: Waste, fraud, and abuse, including **health care fraud** and federal program and procurement fraud...

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Hospital Indicted for Conspiring to Bill for Unnecessary Surgeries

- In January of 2025, Chesapeake Regional Medical Center (CRMC) was indicted in E.D. of Virginia for conspiring with a physician (Dr. Perwaiz) to defraud federal healthcare programs by performing unnecessary surgeries and elective inductions without medical justification
- Government alleges that CRMC employees were aware of Dr. Perwaiz's actions and allowed them, prioritizing profits over patient care
- Dr. Perwaiz was arrested in 2019 and subsequently convicted of performing medically unnecessary surgeries
- From 2010 to 2019, CRMC allegedly received about \$18.5M in reimbursement from the procedures performed by Dr. Perwaiz



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Enforcement Trends: Covid-19

- **Since its creation in 2021**, the *COVID Fraud Enforcement Task Force* has seized over \$1.4 billion in COVID-19 relief funds
 - Charged over 3,500 defendants with crimes in federal districts across the country
 - Secured over 650 civil settlements totaling more than \$500M in recoveries
- Key Areas of Enforcement:
 - Improper sale or distribution of Covid 19 Over the Counter (OTC) Kit Products
 - Pathogen Panel Testing
 - Improper use of Paycheck Protection Program (PPP) funds
 - Improper claims to HRSA
 - E.g., the Uninsured Program
 - Improper use of CARES Act funds

COVID Criminal Enforcement

- Owner of a Chicago laboratory convicted of participating in a fraudulent COVID-19 testing scheme. Sentenced to 7 years in prison– restitution and forfeiture of \$6.8M [DOJ 6/20/25](#)



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COVID-19 Enforcement

• Covid FCA Cases

- **Dr. Samad Khan** agreed to pay **\$3.5M** to resolve FCA allegations related to billing COVID-19 Uninsured Program for E&M services not furnished [DOJ 5/30/25](#)
- **Vault Medical Services** agreed to pay **\$8M** to resolve FCA allegations that it submitted false claims for COVID testing under the Uninsured Program for patients who had insurance [DOJ 4/23/25](#)
- The U.S. District Court entered default judgments against **Provista Health** and **Patrick Britton-Harr**, its owner and operator, totaling over **\$26M** for violations of the FCA. The labs allegedly offered unnecessary respiratory pathogen panel tests to nursing home patients [DOJ 1/15/25](#)
- US Attorney S.D.N.Y. brought FCA lawsuit against **LabQ, Dart Medical and CEO** for improperly billing for COVID-19 tests provided to uninsured persons. [DOJ 6/13/24](#)
- **CityMD** agreed to pay over **\$12M** to resolve FCA allegations arising out of false claims for COVID-19 testing to the Uninsured Program for individuals who had health insurance [DOJ 6/7/24](#)

• COVID Audits:

- June 2025 OIG report –11 of 30 Hospitals did not comply with Provider Relief Fund requirements-- \$63M unallowable expenditures

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Enforcement Trends: Managed Care

Follow the \$....

- In 2024, 54 % of eligible Medicare beneficiaries (32.8 Million individuals) enrolled in a Medicare Advantage Plan
- Payments to MA plans during 2024 were \$462 billion– 55% of total Medicare Spending
- In 2025, MA enrollment projected to reach 57% of Medicare eligible beneficiaries



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Enforcement Trends: Managed Care

Focus on Marketing Practices

- In September 2024, *Oak Street Health* agreed to pay **\$60M** to resolve allegations that it violated the AKS by paying third-party insurance agents to contact MA eligible beneficiaries and refer them to Oak Street's primary care clinics.
- In December 2024, MA plan, *MMM Holdings, Inc.*, agreed to pay **\$15.2M** to resolve allegations that it distributed gift cards to administrative assistants of providers in exchange for referrals to the plan.
- In December 2024, OIG issued a **Special Fraud Alert**, warning of an increase in abusive marketing practices involving payments from MA plans to providers for MA plan marketing and payments from providers to agents and brokers for referring Medicare enrollees to a particular provider.



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Enforcement Trends: Managed Care

Focus on Marketing Practices

- **U.S. ex rel Shea v. eHealth, Inc. et al**, No. 21-cv-11777-DJC, (D. Mass.)
 - In a 217-page complaint unsealed May 1, 2025, the U.S. intervened in qui tam action against Aetna, Elevance and Humana alleging the insurers paid hundreds of millions in illegal kickbacks to brokers in exchange for influencing enrollments into their Medicare Advantage plans
 - The government's complaint asserts that by making illegal payments — often disguised as "marketing" or "sponsorship" payments-- the insurer defendants made, or caused to be made, material false claims to the government
 - Humana and Aetna also accused of discriminating against disabled beneficiaries
-

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Managed Care Fraud: Risk Adjustment

• Focus on Risk Adjustment Practices

- In December 2024, *Independent Health Association* agreed to pay up to **\$98M** to settle allegations that it submitted invalid diagnosis codes to increase risk adjustment payments.
- In March 2025, *Seoul Medical Group* and related parties agreed to pay approximately **\$62M** for allegedly submitting false diagnosis codes to increase MA payments.
- In March 2025, a special master recommended granting United Health's motion for summary judgment in risk adjustment fraud case brought by DOJ, finding that government's case was "devoid of evidence." **U.S. ex rel. Poehling v. UnitedHealth Group, Inc.**, 2025 WL 682285 (C.D. Cal. Mar. 3, 2025).
- **OIG Issued Reports** in September 2024 that EmblemHealth, HealthAssurance, and Humana exaggerated severity of MA members' illnesses to increase risk adjustment payments
- **CMS** recently announced that every MA plan will be audited for Payment Years 2018 to 2024 and going forward
 - **CMS** will also take action on OIG audit results

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Enforcement Trends: Managed Care



- **Criminal Enforcement ?**
- **WSJ reported UnitedHealth Group is under criminal investigation for Medicare Advantage fraud**
 - *The Wall Street Journal*
May 14, 2025
- Exact charges unknown



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Enforcement Trends: Lab Testing



- DOJ continues to pursue a steady stream of laboratory testing cases
- Cases often allege that the lab wrongfully induced or influenced the ordering of the test –AKS violations –and/or that the tests were medically unnecessary
 - **Physicians Toxicology Laboratory**, paid **\$4.4M** to settle allegations that it violated FCA by causing physicians to order medically unnecessary urine drug testing and hormone testing that it billed to Medicare. [DOJ 1/3/25](#)
 - **Precision Toxicology** paid **\$27M** to settle allegations that it billed for medically unnecessary urine drug tests and for providing free items to doctors who agreed to refer testing to the company. [DOJ 10/2/24](#)
 - Several **health care providers** and **lab marketers** paid **\$1.9M** to settle allegations that they received kickbacks for referrals to a South Carolina lab. Dr. **Gerald Congdon** and his medical practices paid **\$400K** for allegedly receiving kickbacks disguised as office space rental and phlebotomy payments in exchange for ordering testing. **Omar Hussain** and his marketing company paid **\$818K** for allegedly receiving commissions from the lab based on the volume and value of Medicare and TRICARE testing that they arranged for and recommended. [DOJ 3/6/25](#)

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Enforcement Trend: Controlled Substances Act

- Government interest in controlled substances enforcement is reflected in DOJ pursuit of FCA based on Controlled Substances Act (CSA) violations
 - Cases highlight FCA risks to DEA registrants
- July 2024, Rite Aid agreed to pay almost **\$410M** to settle FCA allegations that it dispensed opioids in violation of the CSA
- December 2024, US intervened in FCA lawsuit against CVS alleging that the pharmacy repeatedly sought reimbursement for opioid prescriptions in violation of the CSA
- December 2024, Food City pharmacies paid **\$8M** to settle FCA allegations that it dispensed opioids and other substances in violation of CSA
- Government also continuing CSA enforcement:
 - June 2024 OptumRX agreed to pay **\$20M** to settle CSA charges arising out of mail order pharmacy operations
 - Sacred Heart Rehab and CEO **\$1M** settlement for failure to comply with dispensing and recordkeeping requirements of CSA
 - Pending Investigation of Asante Rogue Medical Center arising out of alleged diversion of fentanyl

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Emerging: Civil Rights Fraud Initiative

- On [May 19](#), DOJ announced the Civil Rights Fraud Initiative, which will use the federal False Claims Act to pursue claims against recipients of federal funds that knowingly violate federal civil rights law
- Initiative follows a series of executive orders related to “illegal DEI [diversity, equity and inclusion]”
- This Initiative will be co-led by the Civil Division Fraud Section and the Civil Rights Division–
 - all 93 US Attorney Offices require to identify a responsible AUSA



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New OIG Compliance Guidance

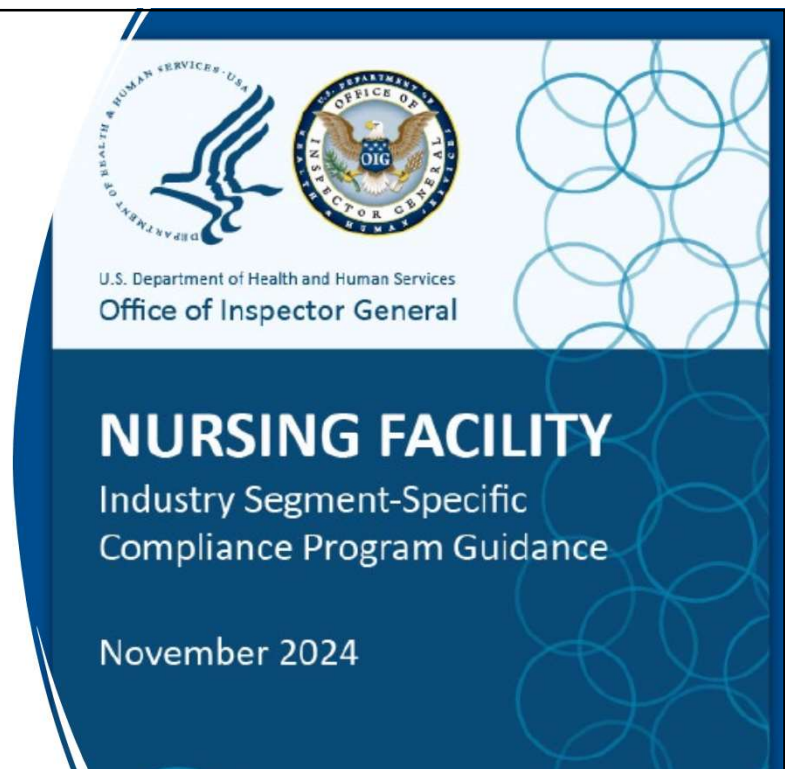
November 6,
2023

- Office of the Inspector General has started to update its Compliance Program Guidance (CPG)
- New guidance will be published on OIG Website
- The New Guidance:
 - Maintains the 7 elements from the historic guidance but provides more detail
 - Emphasizes the “Tone at the Top” and importance of a well-functioning Compliance Committee
 - Integrates Quality and Compliance
- OIG plans to issue additional industry segment specific CPGs--

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Nursing Home ICPG

- The Nursing Home Industry specific Compliance Program Guidance was issued in November 2024
- Focus on assisting facilities in identifying risks and implementing effective compliance and quality programs to mitigate risks.
- ICPGs in the works: Medicare Advantage, Hospital, Clinical Lab



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DOJ: Corporate Compliance



- **Focus, Fairness, and Efficiency in the Fight Against White-Collar Crime** (May 2025)
 - Directs prosecutors to focus on ten high-impact areas, including waste, fraud, and abuse in health care fraud, procurement fraud, and federal program fraud
 - Expands **DOJ Whistleblower Awards Pilot Program**
 - Whistleblowers can receive financial rewards in exchange for submission to DOJ of information about corporate crime
 - Applies to violations related to crimes involving private healthcare benefit programs, supplementing DOJ's *qui tam* program that targets crimes involving public healthcare programs
- DOJ Criminal Division issued **Memorandum on Selection of Monitors in Criminal Division Matters** (May 2025)
 - Raises bar for imposing monitors; expect to see fewer going forward
 - Requires cost and budget limitations, removes DEI in monitor selection
- DOJ Criminal Division revised its **Corporate Enforcement and Voluntary Self-Disclosure Policy** (May 2025)
 - Criminal Division *will* decline if company voluntarily self-discloses, fully cooperates, timely remediates, and there are no aggravating circumstances

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Administrative False Claims Act

Administrative FCA signed into law Dec 23, 2024

Replaces the Program Fraud Civil Remedies Act

Agency Inspector Generals may pursue administrative FCA actions for single damages up to \$1M

Act provides for 2X damages and per claim penalties

Agencies directed to amend regulations to incorporate by June 23, 2025*



*The Railroad Retirement Board (RRB) became the first to [publish](#) final rule changes on June 16, 2025 (20 CFR Part 355)

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The False Claims Act



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Constitutional Challenges to the Qui Tam provisions of the FCA



- Justice Thomas’s dissent in ***U.S. ex rel. Polansky v. Executive Health Resources, Inc.***, 599 U.S. 419 (2023) [raised](#) “serious constitutional questions” about the *qui tam* provisions of the FCA, including their potential inconsistency with Article II and the Appointments Clause.
- ***U.S. ex rel. Zafirov v. Florida Medical Associates, LLC***, 2024 WL 4349242 (M.D. Fla. Sept. 30, 2024) Florida District Court adopted the reasoning of the *Polansky* dissent, holding that the *qui tam* provisions of the FCA violated Article II and the Appointments Clause
 - DOJ and Relator appealed; fully briefed and currently awaiting oral argument to be scheduled in 11th Circuit
- See also ***U.S. ex rel. Montcrief v. Peripheral Vascular Assocs., PA***, 133 F.4th 395 (5th Cir. 2025) (full panel remanded case for new trial but separate concurrence noted that *qui tam* provisions were unconstitutional).

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Wisconsin Bell: Definition of Claim (and another Polansky concurrence)

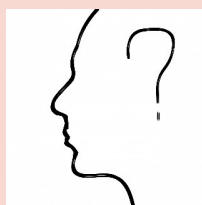
- **Wisconsin Bell v. United States ex rel. Health (Feb. 21, 2025).** SCOTUS ruled unanimously that the FCA may apply even when fraud is committed against a private administrator of a government-funded program (e.g., FCC's E-Rate). The decision clarifies the definition of "claim" under the FCA.
 - In concurrence, Justices Thomas and Kavanaugh reiterated sentiment expressed in *Polansky* that the FCA's qui tam provision raises constitutional questions under Art. II.

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Supervalu's Impact on FCA Litigation

In *Supervalu*, SCOTUS rejected the objective reasonableness test for determining scienter under the FCA

- Defendant's subjective intent is key –not what a hypothetical reasonable person could have believed



Aftermath of Supervalu

- More difficult for defendants to use the FCA scienter requirement as a basis for dismissal (focus on defendant's subjective beliefs create questions of fact)
- *United States ex rel. Miller v. Reckitt Benckiser Group PLC*, 698 F. Supp. 3d 889 (W.D. Va. 2023)
- *United States v. Walgreen Co.*, – F. Supp. 3d —, 2024 WL 150959 (W.D. Va. Jan. 13, 2024)
- *United States ex rel. Behnke v. CVS Caremark Corp.*, 2024 WL 1416499 (E.D. Pa. Apr. 2, 2024).

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FCA: *Escobar's* Materiality Test and Government Knowledge

U.S. ex rel. Holt v. Medicare Medicaid Advisors, Inc., 115 F.4th 908 (8th Cir. Sept. 13, 2024)

Insurance broker's alleged failure to follow Medicare Advantage marketing regulations was not material to CMS's contract with MA plan sponsors where no regulation expressly conditions payment on compliance, and CMS's authority to sanction carriers for violations is discretionary.

U.S. ex rel. Askari v. PharMerica Corp., No. 23-909-CV, 2024 WL 1132191 (2d Cir. Mar. 15, 2024)

Affirmed dismissal for failure to adequately allege materiality because, "[e]ven if the judgments of [a local U.S. Attorney's office] were indicative of the government's Medicare payment decisions," relator did not plead that a recent action filed by the U.S. Attorney involved a scheme similar to that alleged by relator, and "the CMS Medicare Fraud Handbook's general discussions of fraudulent billing do not establish with particularity that the government would have refused to reimburse Defendants' claims if it had been aware of their dispensing arrangements."

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FCA Materiality

U.S. ex rel. Wheeler v. Acadia Healthcare Co., Inc., 127 F.4th 472 (4th Cir. Feb. 3, 2025)

- 4th Circuit reversed D.Ct dismissal, holding that Acadia's failure to provide therapy and counseling to patients in addiction treatment program was material to the government's decision to pay.

U.S. ex rel. Montcrief v. Peripheral Vascular Assocs., P.A., 133 F.4th 395 (5th Cir. Mar. 28, 2025)

- Affirmed jury verdict on grounds that materiality finding was supported by evidence at trial that Medicare would not have paid the relevant claims if it had known it was being billed for incomplete procedures.
- Affirmed D.Ct decision declining to extend FCA's scienter requirement to the materiality element in express certification case.



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Materiality: CVS PBM Subsidiary overcharged Medicare by at least \$95M

- June 25, 2025, District Court E. District of Penn ruled in a qui tam FCA lawsuit that a PBM inflated Medicare Part D drug prices to offset higher costs in other lines of business. ***US ex rel Behnke v. CVS Caremark Corp***, No.14-cv-824 (E.D. PA)
- Dist. Ct, applying ***Escobar***, found that the misrepresentation of drug prices were material noting that if CMS had known of Caremark's guaranteed average pricing terms and the corresponding mismatch with reported prices such knowledge would have had a likely effect on CMS's payment decisions.
- Overcharges of \$95M may be trebled
- Court did not rule on whether CVS knowingly concealed its conduct
- Ordered Briefing on reverse false claims act liability



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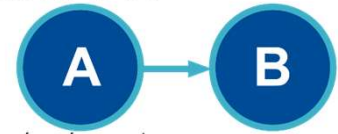
FCA and AKS: “But For” Causation

- Affordable Care Act added provision to FCA providing that claims “**resulting from**” AKS violation were false claims
- Courts initially permitted a weaker causal link: ***U.S. ex rel. Greenfield v. Medco Health Sols., Inc.***, 880 F.3d 89 (3d Cir. 2018), which found a violation of AKS and FCA so long as a kickback payment was made anywhere in the causal chain.



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FCA and AKS: “But For” Causation



- But courts increasingly require “but for” causation:
 - **United States v. Regeneron Pharms., Inc.**, 128 F.4th 324 (1st Cir. 2/18/2025)
 - “Resulting from” language typically must be construed to require but-for causation, and court found “no reason to deviate” from that approach.
 - Held that the plain language of the AKS provision established “a separate track” for establishing FCA/AKS liability in addition to pre-2010 false certification-based cases.
 - **United States ex rel. Martin v. Hathaway**, 2023 WL 2661358 (6th Cir. 3/28/2023), cert. pet. filed 8/11/23 (govt must prove the claim would not have been submitted absent the illegal kickbacks)
 - **U.S. ex rel. Cairns v. D.S. Medical LLC**, 42 F.4th 828 (8th Cir. 7/26/2022) (govt must prove claims “would not have included particular ‘items or services’ absent the illegal kickbacks”)
- Increasingly lopsided circuit split (1C, 6C, & 8C v. 3C) now ripe for Supreme Court resolution?

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FCA: Public Disclosure Bar

- 9th Cir reversed PDB dismissal of claims against Express Scripts finding that the Army Times article did not address practices substantially similar to those alleged. **U.S. ex rel. 3729, LLC v. Evernorth Health, Inc.**, 2025 WL 383801 (Feb. 4, 2025).
- 9th Cir rev’d PDB dismissal because “the scattered qualifying public disclosures each contain a piece of the puzzle, but none shows the full picture.” **Silbersher v. Valeant Pharms. Int. Inc.** 89 F.4th 1154 (9th Cir. 2024)
- D. Ct granted PDB dismissal where alleged improper arrangements had been described in news article and relator added no information that was independent of or added to that disclosure. **Omni Healthcare Inc. v. North Brevard County Hosp. Dist.**, 2024 WL 4235850 (Sep. 19, 2024).
- D. Ct holds PDB dismissal is moot if DOJ opposes. **U.S. ex rel. Marcus v. BioTek Labs, LLC**, 2023 WL 374334 (M.D. Fla. Jan. 24, 2023).

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AKS and FCA – Excessive Fines Considerations

Grant v. Zorn, 107 F.4th 782 (8th Cir. 2024)

- Relator alleged that sleep lab physician up coded E&M codes. After bench trial, court found in Relator's favor on some claims.
- 764 false claims. Actual damages of \$86,332. Trebled to \$258,996. Per-claim penalties of \$12,537 per claim, which totaled \$7,669,525.
- Citing Excessive Fines Clause, district court reduced total award to \$6,733,896, which was 26x amount of treble damages and 78x amount of actual damages.
- On appeal, 8th Circuit held this amount violated Excessive Fines Clause.
- **Must use compensatory damages amount as baseline.**
- Double-digit multiplier was disproportionate where only relatively small amount of economic loss and no evidence of danger to health and safety of others.
- Remanded with instruction to recalculate penalties with single-digit multiplier.

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FCA – Excessive Fines Considerations

U.S. ex rel. Taylor v. Healthcare Assocs. of Texas, LLC, 2025 WL 624493 (N.D. Tex. Feb. 26, 2025).

- Defendants allegedly submitted: “incident to” claims without appropriate documentation; claims by providers not eligible to bill Medicare; and for services performed by medical assistants instead of qualified providers.
- Jury found HCAT liable for submitting 21,844 false claims, resulting in \$2,753,642 in actual damages. Relator sought judgment for \$8,260,926 in trebled damages and \$449,653,800 in civil penalties.
- Court held that FCA penalties are “fines” subject to Eighth Amendment’s Excessive Fines Clause.
- Even minimum penalty was 100x actual damages and “grossly out of alignment with the ratios in similar cases.”
- Held that a civil penalty to actual damages ratio of 3:1 was the maximum allowable here and imposed civil penalty of \$8,260,926.

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FCA: Medical Necessity

SETTLEMENTS:

- **Diopsys Inc.** agreed to pay **\$14.25M** to settle allegations that it billed for unnecessary vision testing by utilizing its NOVA device for tests not approved by the FDA. [DOJ 3/28/25](#)
- **Precision Toxicology** paid **\$27M** to settle allegations that it billed for medically unnecessary urine drug tests and for providing free items to doctors who agreed to refer testing to the company. [DOJ 10/2/24](#)
- **Acadia Healthcare Company Inc.** agreed to pay **\$19.85M** to settle allegations that it billed for medically unnecessary inpatient behavioral health services that did not meet state and federal requirements. [DOJ 9/26/24](#)

CASES:

- **The Grand Health Care System and 12 Affiliated Skilled Nursing Facilities** to Pay **\$21.2M** to resolve claims that they billed for therapy services that were medically unnecessary or did not occur. [DOJ 7/10/24](#)
- **United States v. Femcreek Cardiology, P.A.**, No. 19-cv-164 (E.D.Pa.) Intervened claims that Femcreek billed the government for medically unnecessary coronary artery disease and peripheral artery disease procedures – still pending.
- **United States v. Philadelphia Vascular Inst. LLC**, No. CV 18-5458 (E.D.Pa.) Intervened claims that Philadelphia’s practices performed medically unnecessary invasive vascular procedures—including multiple angiograms on some patients and intravenous ultrasounds on every Medicare patient – still pending.
- **United States v. Premier Medical, Inc.**, No. 6:18-cv-165 (D.S.C.) Intervened claims that Premier billed federal health care programs for medically unnecessary genetic testing –

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Ninth Circuit Weighs in on First-to-File Bar

- In **Marcia Stein et al. v. Kaiser Foundation Health Plan Inc. et al.** (Sept 25, 2024), the Ninth Circuit Court of Appeals overruled circuit precedent by finding that the FCA’s first-to-file bar is not jurisdictional.
- The court’s ruling revived the whistleblower’s *qui tam* suit that accused Kaiser of defrauding Medicare Advantage through false diagnosis codes, reversing the district court’s decision that dismissed the complaint based on the first-to-file bar.
- The impact of the court’s decision is that defendants now bear the burden of persuading courts to toss FCA actions under the first-to-file bar, rather than being entitled to dismissal if a claim has already been filed.
- The decision brings the Ninth Circuit in line with the Courts of Appeals for the First, Second, Sixth and District of Columbia circuits. The Fourth, Fifth, and Tenth Circuits hold that the first-to-file bar is jurisdictional.

FCA Settlements

- **Creative Hospice** and its owner paid **\$9.2M** to settle FCA allegations that they paid kickbacks to Medical Directors in exchange for referrals. [DOJ 6/11/25](#)
- **Omniceil** has agreed to pay **\$4.3M** to settle allegations that it fraudulently overcharged the VA for medical products and software [DOJ 6/11/25](#)
- **Fresno Community Hospital d/b/a CHS** and its technology partner, Physicians Network Advantage, paid **\$31.5M** to settle FCA lawsuit based on AKS and Stark Law violations arising out of the assistance provided to local physicians for their EHR-related expenses. Support was both linked to referrals and inconsistent with the requirements of the EHR donation Stark exception and AKS safe harbor. [DOJ 5/14/25](#)
- **Gilead** agreed to pay a total sum of **\$202M** to settle allegations that it offered and paid kickbacks in the form of honoraria payments, meals, and travel expenses to healthcare practitioners who spoke at or attended Gilead speaker events to induce them to prescribe Gilead HIV Drugs in violation of the AKS and FCA. [DOJ 4/29/25](#)
- **Seoul Medical Group** agreed to pay \$60.5M to resolve allegations that it submitted false diagnosis codes for two spinal conditions to inflate Medicare Advantage Payments [DOJ 3/26/25](#)
- **Diopsys, Inc.** agreed to pay up to **\$14.25M** to settle allegations that it caused providers to submit false claims for medically unnecessary vision testing [DOJ 3/28/25](#)

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FCA Settlements



- **Pfizer** on behalf of its wholly-owned subsidiary Biohaven Pharmaceutical, agreed to pay **\$60M** to resolve allegations that Biohaven knowingly caused the submission of false claims to Medicare and other federal programs by paying kickbacks to health care providers to induce prescriptions of Biohaven's drug Nurtec. [DOJ 1/24/25](#)
- **St. Vincents Catholic Medical Centers** agreed to pay **\$29M** to resolve allegations that it knowingly retained erroneously inflated capitated payments received from the Department of Defense. [DOJ 2/14/25](#)
- **Health Net Federal Services** and **Centene Corporation** agreed to pay **\$11.3M** to settle allegations that they falsely certified compliance with cybersecurity requirements relating to a TriCare contract [DOJ 2/18/25](#)
- **University of Colorado** agreed to pay **\$23M** to resolve allegations that it automatically coded claims for emergency services at the highest E&M level without regard to the severity of the patient's condition. [DOJ 11/12/24](#)
- **Oroville Hospital** paid **\$10.25M** to resolve allegations related to billing for medically unnecessary admissions, payments to physicians that took into account the volume of inpatient admissions and false diagnosis codes [DOJ 12/12/24](#)
- **Acadia Healthcare** agreed to pay **\$19.9M** to settle allegations that it admitted patients who were not eligible for inpatient treatment, prolonged inpatient stays, and lacked adequate staffing [DOJ 9/26/24](#)
- **Dunes Surgical Hospital** agreed to pay **\$12.76M** to resolve FCA allegations that it violated the AKS and Stark Law by (i) providing free and below fair market value clinic space, supplies, and employees to an anesthesia practice; and (ii) making significant financial contributions to a nonprofit affiliate of a referring physician group. [DOJ 9/15/24](#)

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FCA Settlements

- **Dunes Surgical Hospital** agreed to pay **\$12.76M** to resolve FCA allegations that it violated the AKS and Stark Law by (i) providing free and below fair market value clinic space, supplies, and employees to an anesthesia practice; and (ii) making significant financial contributions to a nonprofit affiliate of a referring physician group. [DOJ 9/15/24](#)
- **Dr. Gray** and her practice, **Center for Health & Wellbeing** in San Diego, agreed to pay **\$3.8M** to settle FCA allegations relating to claims for services that were not covered by either disguising the rendering provider or misrepresenting the service. [DOJ 10/11/24](#)
- **Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc.** agreed to pay **\$425M** to resolve allegations that Teva paid kickbacks via co-pay assistance foundations in violation of the Anti-Kickback Statute (AKS) and False Claims Act [DOJ 10/10/24](#)
- **Dr. Eric Troyer** and his practice have agreed to pay **\$626K** to the government to resolve FCA allegations arising out of their involvement in laboratory kickback schemes [DOJ 10/9/24](#)
- **Texas Hospital CEO** Jeffrey Madison, paid **\$5.3M** to resolve allegations that the hospital paid illegal funds to physicians for laboratory referrals. [OIG 10/2/24](#)
- **Bournewood Health Systems and Bournewood Hospital** agreed to pay between **\$5.5M-6.5M** to settle allegations that it provided free sober housing to substance use recovery patients enrolled in state and federal health care programs to induce patients to participate in the hospital's partial hospitalization program. [DOJ 10/1/24](#)

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FCA Settlements

- **Ra Medical Systems**, a medical device company, and two physicians, paid over **\$8M** to resolve FCA allegations arising out of kickbacks paid to physician to induce the use of Ra Medical's DABRA laser.
- **Oak Street Health** agreed to pay **\$60M** to resolve allegations that it violated the AKS and FCA by paying kickbacks to third-party insurance agents in exchange for recruiting patients to Oak Street primary care clinics.
- **Walgreens** paid **\$106M** to resolve allegations that it billed government programs for prescriptions it never dispensed.
- **St. Peter's Health** paid nearly **\$11M** to settle alleged FCA violations stemming from conduct by an oncologist who submitted fraudulent claims to government programs for up-coded cancer treatment services and who double-billed office visits to boost his own salary. Note St. Peter's voluntarily disclosed conduct to government.
- **United Seating & Mobility** paid **\$13.5M** to resolve FCA allegations that it submitted claims for custom wheelchairs to the federal health care programs that were not properly ordered by medical professionals. Note defendant voluntarily disclosed conduct to the government.

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FCA Settlements

- **National Interventional Radiology Partners** and its founder and CEO paid **\$8.8M** to resolve FCA and Anti-Kickback Statute violation allegations that they illegally paid physicians for referrals to clinics established to surgically treat patients with Peripheral Arterial Disease. [DOJ 8/20/24](#)
- **Intrepid**, a nationwide home health provider, agreed to pay **\$3.85M** to resolve allegations that it violated the FCA by submitting claims for home healthcare services and hospice services furnished to patients who did not qualify. [DOJ 8/20/24](#)
- **Orange Medical Care** paid \$600K to settle FCA lawsuit based on allegations that its physician owners billed for services furnished by APPs or PAs not enrolled in Medicare/Medicaid and physicians who had no involvement or supervision in treatment. [DOJ 8/19/24](#)
- **Humana** agreed to pay \$90 million to settle a declined case alleging that it submitted fraudulent bids to CMS for Medicare Part D prescription drug contracts. [DOJ 8/16/24](#)
- **DaVita Inc.**, a kidney dialysis provider, agreed paid **\$34M** to settle allegations that it violated the FCA through the illegal kickback payments to induce referrals to DaVita's dialysis centers and DaVita Rx, a former subsidiary that provided pharmacy services for dialysis patients. [DOJ 7/18/24](#)

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Payer, Plans, and Managed Care

June 2025
Kim Harvey Looney
K & L Gates, LLP

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Thank You to the Efforts of the Payer, Plans, and Managed Care Topic Team:

Alexis Boaz, Epstein Becker Green
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Kevin Malone, Epstein Becker Green
Christopher Smith, Epstein Becker Green
William Walters, Epstein Becker Green
Emma Pelkey, Epstein Becker Green
Lorin Melanson, Epstein Becker Green



Medicare Advantage and Part D Final Rule CY2025

89 Fed Reg. 30448 (April 23, 2024)

- Improve access to behavioral health care by adding several behavioral health provider types to Medicare Advantage network adequacy requirements.
- Provide more flexibility for Part D plans to more quickly substitute lower-cost biosimilar biological products for their reference products.

Medicare Advantage and Part D Final Rule CY2025

89 Fed Reg. 30448 (April 23, 2024)

A Texas federal court has temporarily paused implementation of the following finalized changes to agent/broker compensation and administrative payments:

- Broadening the definition of “compensation” to capture certain administrative expenses of agents and brokers and removing the ability of plans to make separate administrative payments to individual agents and brokers;
- Making a one-time increase of \$100 to compensation payments to individual agents and brokers to account for the shift in administrative costs.
- Standardize the commission payments that plans may make to independent agents and brokers for beneficiary enrollments.
- Improve transparency on the effects of prior authorization on underserved communities by requiring an annual health equity analysis



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Medicare Advantage and Part D Final Rule CY2025

Improve Medicare Special Needs Plans (SNPs)

- Creating a new exception to the Time and Distance Standards under the general network adequacy requirements (§ 422.116) for Facility-based Institutional SNPs (I-SNPs) to allow a plan to submit documentation proving that it is unable to successfully establish a contract with a provider OR provide access to specialists through telehealth and cover in-person, out-of-network services at in-network cost sharing levels
- Limiting “D-SNP look-alike” plans further by lowering the threshold of Medicaid-eligible plan enrollees required for CMS to contract with plans not operating as D-SNPs to 60 percent over 2 years
- Capping out-of-network cost sharing for D-SNP PPO plans starting in 2026
- Capping out-of-network cost sharing for other enumerated services, including chemotherapy, skilled nursing care, home health, and durable medical equipment



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Medicare Advantage and Part D Final Rule CY2025

Improve Medicare Special Needs Plans (SNPs)

Instituting 4 changes to special enrollment periods for dually eligible individuals which would restrict the ability of these beneficiaries to select a plan outside of the annual enrollment period unless that plan is a PACE plan or a highly integrated or fully integrated dual eligible (HIDE/FIDE) SNP with exclusively aligned enrollment, while continuing to allow dually eligible individuals to disenroll in any month, by:

1. Replacing the current quarterly Special Enrollment Period (SEP) with a once-per-month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a stand-alone prescription drug plan



Medicare Advantage and Part D Final Rule CY2025 (cont.)

Improve Medicare Special Needs Plans (SNPs)

2. Creating a new integrated care SEP to allow dually eligible individuals to elect an integrated D-SNP on a monthly basis
3. Limiting enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO)
4. Limiting the number of D-SNP plan benefit packages an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO



Medicare Advantage and Part D Proposed Rule CY 2026

89 Fed. Reg. 99340 (December 10, 2024)

- Potential guardrails for the use of artificial intelligence (AI) to protect access to health services
- Coverage of anti-obesity medications under the Medicare Part D and Medicaid programs
- Broadened marketing definitions to expand CMS oversight of Medicare Advantage (MA) and Part D communications materials and activities
- Prohibition on the marketing of supplemental benefit amounts and of the mechanisms for delivering supplemental benefits (e.g., debit cards)
- Efforts to ensure equitable access to behavioral health services
- Changes regarding MA provider directory data
- Improvements relating to Star Ratings.



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No Surprises Act Updates

The Previously Proposed Changes to the Independent Dispute Resolution (IDR) “Operations” Have Not Yet Been Finalized (89 Fed Reg. 3896)

- Would streamline IDR process and address backlog by standardizing information required from payors at the outset of the billing interaction with out-of-network providers.
- Would adjust specific timelines and steps of the Federal IDR process and add additional flexibility to the batching rules.



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No Surprises Act Updates (cont.)

Enforceability of IDR Awards in Court

- Courts are split on the issue of whether providers can have awards obtained through the NSA IDR process enforced in court.
- A federal judge ruled June 12, 2025, that Independent Dispute Resolution (IDR) awards cannot be enforced in court through a final judgment because the No Surprises Act does not create a private right of action. *Guardian Flight LLC v. Health Care Serv. Corp.*, (N.D. Tex.) No. 3:23-CV-1861
- Other federal courts have enforced IDR awards in actions brought by providers. *GPS of New Jersey M.D., P.C. A/S/O.T.U. v. Horizon Blue Cross & Blue Shield* (D.N.J.) No. 2:22-cv-06614



No Surprises Act Updates (cont.)

TMA Litigation Continues in the 5th Circuit, including a government win

- On Oct. 30, 2024, the 5th Circuit reversed the *TMA III* decision that had invalidated certain guidance and regulatory provisions for Qualifying Payment Amount (QPA) calculations.
- HHS issued guidance confirming plans will need to calculate the QPAs in good faith using the requirements remaining in effect after both the 5th Circuit and *TMA III* decisions, but HHS plans to exercise enforcement discretion at least until Aug. 1, 2025.
- On May 30, 2025, the 5th Circuit granted the plaintiff's request to vacate the 5th Circuit's 2024 decision and conduct en banc review to consider overturning of the appellate panel's decision to uphold the government's methodology for determining QPAs.



No Surprises Act Updates (cont.)

Elevance Health Lawsuit

- Elevance Health (parent company of BCBS of Georgia) filed lawsuit May 27, 2025 against billing company HaloMD and 2 hospital based physician groups
- Alleged exploiting federal arbitration established under NSA
- Submitting thousands of ineligible disputes through the Federal IDR process
- Disputes falsely certified as eligible and structured to maximize payments well above market rates
- Nearly 70% of disputes that resulted in payment to providers allegedly not qualified for arbitration
- Between January 2024 and April 2025: \$5.9M in improper payments and arbitration fees
- HaloMD: Payors routinely apply a code that forces providers to file under both state and federal IDR statutes to preserve eligibility – payors don't want to resolve disputes fairly, independently and efficiently



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Affordable Care Act Updates Revocation of Executive Orders

Executive Order 14009 of January 28, 2021 (Strengthening Medicaid and the Affordable Care Act).

An executive order issued by Biden that led to longer enrollment periods for Affordable Care Act Plans and increased funding for parties helping people to enroll in ACA insurance. These measures, along with increased government subsidies that lowered premiums, are credited with significant increases in ACA enrollment.

Executive Order 14087 of October 14, 2022 (Lowering Prescription Drug Costs for Americans).

Another Biden executive responsible for CMMI creating 3, not-yet-implemented, drug pricing models aimed at capping out-of-pocket costs for generic drugs, expediting FDA approvals, and reducing costs of cell and gene therapies. The future of drug pricing models is unclear.



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Affordable Care Act Updates

Becerra v. Braidwood Management, Inc.

At issue:

Whether the court of appeals erred in holding that the structure of the Task Force violates the Appointments Clause, U.S. Const. Art. II, § 2, Cl. 2, and in declining to sever the statutory provision that it found to unduly insulate the Task Force from the HHS Secretary's supervision.

April 21: the Supreme Court heard arguments in *Braidwood v. Becerra*, a case challenging the ACA's preventive services coverage requirement.

- Following arguments, the Court ordered a supplemental briefing on the authority of the HHS Secretary to appoint Task Force members. Issue hinges on the word "convene" in the Task Force authorizing statute.

What's next:

A decision is expected by July of this year.



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Drug Price Containment

Inflation Reduction Act (P.L. 117-169)

Medicare Drug Price Negotiation Program

Permits direct price negotiation for certain high-expenditure, qualifying single-source drugs without generic or biosimilar competition.

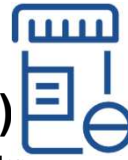
Aug. 2024: following inaugural price negotiations between the federal government and selected drug manufacturers for price applicability year (PAY) 2026, CMS issued the maximum fair price (MFP) for each of the first 10 selected drugs and explanations of its determination of the MFP for each drug

CMS proposed and finalized guidance for PAY 2027 negotiations, which also included information to assist manufacturers effectuate the MFPs in PAY 2026 and 2027 using Medicare Transaction Facilitators



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Drug Price Containment Inflation Reduction Act (P.L. 117-169)



January 20, 2025: President Trump issued an Executive Order rescinding a Biden Executive Order that had created three drug pricing experiments.

April 15, 2025: President Trump issued an Executive Order aimed at lowering drug prices. The EO:

- orders the HHS Secretary to work with Congress to abolish the "Pill Penalty".
- orders the HHS Secretary to propose guidance on the Medicare Drug Price Negotiation Program for 2028 and the effectuation of the negotiated maximum fair price for 2026 through 2028.
- directs OMB to make recommendations on reducing Part D premiums.

April 14, 2025 Executive Order (cont.)

- directs the HHS Secretary to develop a payment model to test methods for obtaining more value for high-cost drugs under Medicare.
- requires a survey of hospital outpatient department acquisition costs for covered outpatient drugs to determine whether Medicare payment should be adjusted.
- directs the OMB and HHS Secretary to make recommendations regarding accurate payment of Medicaid drug rebates, promoting innovation in Medicaid payment and providing support to states to manage drug spending.

April 14, 2025 Executive Order (cont.)

- requires that grants to health centers be conditions on making insulin and injectable epinephrine to certain low-income patients at or below acquisition cost.
- call for proposed regulations to shift drug administration away from hospital outpatient departments to physician office setting.
- requires an FDA report with recommendations to accelerate generic approvals and biosimilars, and to improve the process for reclassifying prescription drugs as OTC drugs.
- requires steps to streamline and improve state drug importation.
- requires a report on recommendations to reduce drug manufacture anti-competitive behavior.

Drug Price Containment Inflation Reduction Act (P.L. 117-169)



CMS issued guidance to implement the components of the Part D Redesign—most of which went into effect starting on Jan. 1, 2025

CMS will accept comments to the Draft CY 2026 Part D Redesign Program Instructions until Feb. 10, 2025, which builds on the Final CY 2025 Program Instructions to provide guidance on changes to the Part D benefit

Medicare Prescription Payment Plan gives Part D enrollees the option to pay out-of-pocket prescription drug costs in monthly payments over the course of the plan year. Program participants will pay \$0 to the pharmacy for covered Part D drugs and will instead be billed monthly for any cost sharing incurred.

Part One Guidance – Issued Aug. 21, 2023, and published the final guidance on Feb. 29, 2024, to outline operational requirements for Part D plans, including identifying enrollees likely to benefit from the program, the opt-in process, participant protections, and data collection to evaluate the program.

Part Two Guidance - Issued Feb. 15, 2024, for public comment and published the final guidance on July 16, 2024, to outline implementation issues, such as enrollee outreach and education, pharmacy processes, and operational considerations

Part D Manufacturer Discount Program replaced the Coverage Gap Discount Program as of Jan. 1, 2025. CMS issued its Revised Part D Manufacturer Discount Program Final Guidance on Dec. 20, 2024

Drug Price Containment Inflation Reduction Act (P.L. 117-169)



May 12, 2025: President Trump issued an Executive Order on most-favored nation drug pricing.

- The EO requires the Secretary of Commerce and US Trade Representative to address foreign practices that result in Americans disproportionately paying for R&D.
- The EO requires facilitating manufacturers directly selling drugs to consumers at MFN prices.
- Within 30 days HHS must communicate MFN price targets to manufacturers.
- If there is no significant progress towards MFN pricing.
- The EO requires MFN pricing rulemaking.
- The EO call for possible expansion of personal drug importation.
- The EO call for more enforcement action to address high drug prices:
 - Enforcement actions against anti-competitive practices.
 - Review of drug and precursor material exports that may contribute to global price discrimination.
 - Review of drug approvals to ensure safety, effectiveness and proper marketing with potential modifications and revocations.



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Drug Price Containment Oversight of Pharmacy Benefit Managers (PBMs)



Federal Regulation of PBMs

Federal PBM reform ultimately did not pass, but would have:

- 100% pass through of rebates to sponsors
- Prohibited spread pricing for Medicaid
- Required detailed drug spending data

July 2024: FTC report with substantial superficial criticisms, finding:

- Increasing vertical integration and consolidation of PBMs
- Integration/consolidation allowed PBMs to influence what drugs are available & at what prices
- Integration/consolidation allowed PBMs to favor their own pharmacies over unaffiliated pharmacies.

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Drug Price Containment Oversight of Pharmacy Benefit Managers (PBMs)



January 2025: Second FTC report finding that the large PBMs:

- Marked up generic specialty drugs at their affiliated pharmacies by hundreds and thousands of percent
- Pushed the most profitable specialty generic drugs to their affiliated pharmacies
- Generated significant income from spread pricing
- Were connected to double-digit compound annual growth rates in plan sponsor spending and patient cost sharing

April 14, 2025: 39 State Attorneys General sent a letter to Congress urging passage of a law banning PBMs from owning and operating pharmacies.

April 15, 2025: President Trump Executive Order.

- The EO calls for recommendations to reevaluate the role of PBMs in the pharmaceutical value chain.
- The EO calls for proposed regulations to improve employer health plan fiduciary transparency as to direct and indirect compensation received by PBMs.



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Drug Price Containment Oversight of Pharmacy Benefit Managers (PBMs)



PBM Litigation

- **January 2025:** The Oklahoma Attorney General sued Caremark in Oklahoma's PBM Administrative Court for reimbursing pharmacies below acquisition costs.
- **February 2025:** The Texas Attorney General issued an opinion that Texas state PBM laws apply self-funded ERISA plans.
- **April 2025:** The Teamsters filed suit against Arkansas, asserting that a regulation forcing health plans to turn over information about PBM negotiated reimbursement rates violates ERISA.
- **April 2025:** A TN federal court ruled that Tennessee's any willing pharmacy requirement was preempted by ERISA.
- **April 2025:** The Michigan Attorney General sued Express Scripts and Prime Therapeutics for forming an unlawful agreement to suppress reimbursement rates to independent pharmacies.
- **April 2025:** The FTC paused its lawsuit against Caremark, Express Scripts and OptumRx for engaging in anticompetitive and unfair rebating practices that have artificially inflated the list price of insulin.
- **May 2025:** Express Scripts filed suit to overturn the Arkansas law banning PBMs from owning pharmacies.



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Drug Price Containment Oversight of Pharmacy Benefit Managers (PBMs)



State Regulation of PBMs

- Pennsylvania passed a bill limiting patient steering, prohibiting mail order requirements and limiting clawbacks.
- A new Arkansas insurance regulation requires PBMs to pay NADAC minimums with a dispensing fee adjustment.
- New York passed a law prohibiting PBM gag clauses.
- New York promulgated regulations strengthening PBM oversight, including limiting patient steering, PBM audits, and pharmacy network terminations
- Massachusetts passed a law requiring PBMs to obtain licenses.
- Generally, state oversight over PBMs is increasing every year, including the creation of state pricing boards that limit the cost of drugs with implications for PBMs
- Arkansas passed a law, effective January 1, 2026, banning PBMs from owning pharmacies.

Nondiscrimination in Health Care Section 1557 Final Rule

- **Effective July 5, 2024, with certain provisions phased in on longer timeframes – final upcoming deadlines July 5, 2025**
- Broader reach: Expands the nondiscrimination requirements to direct and indirect recipients of federal financial assistance, including Medicare Part B funds, health insurance issuers that receive federal financial assistance, and the state and federal insurance marketplaces
- Clarifies nondiscrimination based on “sex” includes sex characteristics (including intersex traits), pregnancy or related conditions, sexual orientation, gender identity, and sex stereotypes
 - Nationwide injunction expanding definition of discrimination based on “sex”
- Suite of operational requirements: Section 1557 - Coordinator, notices, policies, and training

Nondiscrimination in Health Care (cont.)

Section 1557 Final Rule (cont.)

- Focus on language access for individuals and companions with limited English proficiency (LEP), and effective communication for individuals and companions with disabilities
- Upcoming deadlines: Policies and Procedures (§ 92.8), and Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11) both due by **July 5, 2025**
- Numerous other nondiscrimination provisions, including for telehealth, and “patient care decision support tools,” which includes any automated or non-automated tool, mechanism, method, or technology (AI or clinical algorithms) used to support decision-making to provide care for patients

Nondiscrimination in Health Care (cont.)

Section 504 Final Rule - Effective July 8, 2024

Updated for the first time in nearly 50 years and provides robust protections, such as:

- Accessibility standards for web, mobile, and kiosks, as well as medical diagnostic equipment
- Prohibits measures that discount the value of life extension based on disability to deny or afford an unequal opportunity
- Prohibits discrimination against qualified individuals with disabilities in the child welfare system
- Requires programs/activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities

Nondiscrimination in Health Care (cont.)

Final Rules under Title II of the ADA for state and local governments:

- Web Content and Mobile Apps (effective 6.24.24)
- Accessibility of Medical Diagnostic Equipment (effective 10.8.24)

2025 Impacts to the Section 504 Final Rule

- On May 16, 2025, in a process that does not adhere to notice and comment rule-making under the Administrative Procedures Act, the Department of Energy issued a rule rescinding the new construction requirements located in 10 CFR 1040.73. The rule is effective July 15, 2025, unless met with “significant adverse comments.”
- We understand the Trump Administration is planning further steps to weaken the disability antidiscrimination changes, especially those related to gender dysphoria.



Nondiscrimination in Health Care (cont.)

State Litigation Against the 504 Final Rule

- In September 2024, seventeen states collectively filed a lawsuit against the U.S. Department of Health and Human Services (HHS) challenging the constitutionality of Section 504.
- In April 2025, the 17 state plaintiffs dropped the constitutional challenge, but continue to argue that gender dysphoria is not a disability.
- Disabilities rights advocates remain on alert to legal proceedings and regulatory actions against transgender people with disabilities.



Mental Health Parity and Addiction Equity Act

- The MHPAEA requires covered health plans to ensure that beneficiaries have access to benefits that are designed and delivered in a manner that doesn't discriminate against individuals with mental health (MH) conditions or substance use disorders (SUD)
- On September 9, 2024, the Tri-Departments published **final rules** to implement the requirements for plans and issuers to create and document **comparative analyses for non-quantitative treatments limits** that were added to the MHPAEA statute as part of the Consolidated Appropriations Act of 2021
 - Comparative analyses must include data on the comparative impact of Nonquantitative Treatment Limitations (NQTLs), and plans must take reasonable action to address any material differences in access to MH/SUD benefits compared to M/S benefits that result from the application of NQTLs



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Mental Health Parity and Addiction Equity Act (cont.)

- The final rules also:
 - Define “mental health conditions” to include autism and other intellectual and developmental disabilities
 - Require coverage for “meaningful benefits” for all covered MH/SUD conditions
 - Require health plan sponsors to identify a named fiduciary to certify that they have engaged in a prudent process to select and monitor their service providers involved in creating their NQTL analyses
- On January 17, 2025, the ERISA Industry Committee (ERIC) filed a lawsuit to challenge the new regulations as violating the Administrative Procedure Act



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Mental Health Parity and Addiction Equity Act (cont.)

- The Tri-Departments' *2024 Report to Congress* summarizes enforcement that occurred prior to the new final rules (under the statute)
 - Key focuses for enforcement were benefit exclusions (e.g. for autism treatments) and provider network adequacy and reimbursement
 - CMS also indicated new focus on prescription drug formularies for Marketplace plans

Mental Health Parity and Addiction Equity Act (cont.)

The 2024 Report includes a settlement agreement with a plan using the Cigna provider network that includes the most stringent corrective action plan seen to date, including requirements for the plan to:

- Create extensive new standards for network adequacy
- Update its plan terms to better educate members about their right to receive out-of-network services at in-network coverage and cost-sharing where the network does not meet the updated network adequacy standard
- Create its own supplemental networks for MH/SUD facilities
- Create a website to direct members with MH/SUD needs to Collaborative Care Model providers
- Expand access to telehealth for MH/SUD
- Send an RFI to competing TPAs to evaluate whether they offer more robust networks for MH/SUD providers

Mental Health Parity and Addiction Equity Act

Federal Enforcement in 2025

- Federal Regulators will not enforce the 2024 Rule
 - Statute and 2013 Rule continue to apply
 - Plans can refer to FAQ 45 and Self-Compliance Tool
- New federal guidance will be forthcoming
 - Next step is NPRM to amend/replace 2024 Rule
 - Departments to give quarterly status updates
- Private litigation is not slowing down
 - Most cases dismissed or settled at pleading stages
 - Handful of large class actions are ongoing

Health Information and Technology



Patient Identification Disclosure Concerns

January 31, 2025
Health Law Weekly

Preparing for ICE Enforcement: Key Considerations for In-House Counsel

This Feature Article is brought to you by AHLA's In-House Counsel Practice Group. On January 21, 2025, Acting Secretary of the Department of Homeland Security, Benamine Huffman, rescinded the "Biden Administration's guidelines for Immigration and Customs Enforcement (ICE) and Customs and Border Protection enforcement actions that thwart law enforcement in or near so-called 'sensitive' areas." As a result of Acting Secretary Huffman's directive, hospitals, physicians' offices, clinics, and other medical or mental health care providers may find themselves dealing with ICE, CBP, or other federal law enforcement officials at their facilities, requesting access to patients, patient family members, employees, or records, which may include protected health information (PHI)

Department of Homeland Security, *Statement from a DHS Spokesperson on Directives Expanding Law Enforcement and Ending the Abuse of Humanitarian Parole*, Jan. 21, 2025, <https://www.dhs.gov/news/2025/01/21/statement-dhs-spokesperson-directives-expanding-law-enforcement-and-ending-abuse> (last accessed Jan. 29, 2025)

HR Becker's Hospital Review · 2d

[CMS directed to turn over Medicaid data to immigration officials: Report](#)

"Medicaid is not, and cannot be, a backdoor pathway to subsidize open borders," CMS Administrator Mehmet Oz, MD, previously said. "States have a duty to uphold the law and protect taxpayer funds. We are putting them on notice — CMS will not allow federal dollars to be diverted to cover those who are not lawfully eligible."

Shared data includes the immigration status of Medicaid enrollees in California, Illinois, Washington state and Washington, D.C.



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Stargate to revolutionize AI's physical and virtual framework

JUN 02

[FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People](#)

FDA today launched Elsa, a generative Artificial Intelligence (AI) tool designed to help employees—from scientific reviewers to investigators—work more efficiently. This innovative tool modernizes agency functions and leverages AI capabilities to better serve the American people.

Check out Sessions 5, 11, 22 & 40

January 21, 2025 Three technology firms — OpenAI, SoftBank, and Oracle — will create **Stargate** Stargate was described by President Trump as the "largest AI infrastructure project in history," beginning with a \$100 billion investment, with projections to scale up to \$500 billion Stargate's formation comes shortly after President Trump rescinded former President Joe Biden's 2023 executive order which sought to monitor and regulate AI risks



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AI Scribes and Messages – large language models



Duke debuts frameworks to assess ambient AI tools

In two newly published studies, Duke researchers introduced evaluation frameworks aimed at measuring how well large language models — the AI systems behind many automated note-taking and patient messaging tools — perform in real-world medical settings.

- intended to give health systems, software developers and regulators practical ways to test AI tools before and after deployment

The research was published in *npj Digital Medicine* and the *Journal of the American Medical Informatics Association*. **16K hours saved: Ambient AI scribes at Kaiser Permanente**

- first framework, named SCRIBE, was created to assess ambient digital scribes
- second study focused on AI models built into Epic's EHR system that help providers draft responses to patient messages

June 13, 2024 **16K hours saved: Ambient AI scribes at Kaiser Permanente**

Between October 2023 and December 2024, 7,260 Permanente Medical Group physicians used the [technology](#), which transcribes medical visits and generates EHR notes, for about 2.5 million patient encounters, according to a June 10 news release.

UnitedHealth has 1,000 AI use cases

Payers are moving forward with AI

UnitedHealth Group has 1,000 uses for AI technology currently in production across its insurance, care delivery and pharmacy businesses, [The Wall Street Journal](#) reported May 5.

The applications are split between generative AI and more traditional AI and are being used to **transcribe clinician visits, help with claims processing and support chatbots**, according to the report.

Increasing Adoption of Generative AI, While Prioritizing Accuracy and Trust Generative AI is Enhancing Operational Agility and Member Outcomes

Generative AI (GenAI) is changing how healthcare payers operate.... GenAI is changing the game for payers. How are they doing it?

- 59% are partnering with vendors to build custom solutions
- 24% are developing in-house (a heavy lift)
- 17% are opting for off-the-shelf products

[The 2025 Landscape: Key AI Trends Shaping Healthcare Payers' Ecosystem Today](#)

AI debate: Is AI Good, Bad or Biased?



CALIFORNIA ATTORNEY GENERAL'S LEGAL ADVISORY ON THE APPLICATION OF EXISTING CALIFORNIA LAWS TO ARTIFICIAL INTELLIGENCE

Supervision of AI Tools in Healthcare Settings • SB 1120 (Becker) requires health insurers to ensure that licensed physicians supervise the use of AI tools that make decisions about healthcare services and insurance claims. (Health & Saf. Code, § 1367.01; Ins. Code, § 10123.135.) Approved by Governor September 28, 2024 Filed with Secretary of State September 28, 2024



What hospitals can learn from FQHCs using AI to fight burnout + expand access
Whitepapers: Making AI work at scale: Key strategies from leading systems

REPORT
2024 Generative AI in Professional Services

Generative AI (GenAI), once a futuristic concept, is here and reshaping the professional landscape across service industries like legal, tax and accounting, risk and fraud, and government. Since its debut in late 2022, platforms like ChatGPT and advancements like GPT-4 have demonstrated disruptive potential, enabling the rapid creation of high-quality content with heightened accuracy. While adoption isn't yet widespread, more than half of professionals believe they should use GenAI in their daily work — and they're already planning for the specialized tools that will create this reality.

In this report, we explore how these professionals perceive the use of generative AI in their workplace, how and to what level they are using and integrating it into their processes, and perceptions of the future of work in an environment in which generative AI has made its presence felt.

81% of respondents said GenAI can be applied to their work, while fewer (54%) said they believe GenAI should be applied to their work.

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AI Concerns



Nurses across US to rally over AI safeguards

On Jan. 16, 2025 thousands of registered nurses will hold marches, protests and rallies to demand the hospital industry ensure safe staffing levels and artificial intelligence safeguards, a Jan. 14 National Nurses United news release [said](#).

"Patient advocacy is at the core of what we do as nurses," Nancy Hagans, RN, president of NNU, said in the release. "That's why we're demanding safe staffing and protections against untested technologies such as AI. We see the harm that these cost-cutting schemes cause our patients on a daily basis."

In 2024, the union [released](#) guiding principles for AI implementation and shared its deep concerns that the current implementation of AI was "reckless."

In a 2024 survey of over 2,300 registered nurses and NNU members, the union [found](#) that 60% of nurses did not trust their employer to implement AI with patient safety as the first priority. The survey also found that nurses repeatedly reported that their assessments of patients did not match assessments from AI tools.



FDA concerns re AI listed in JAMA

FDA Commissioner Robert Califf, M.D., and other senior FDA officials published a "Special Communication" in [JAMA](#) (October 15, 2024) describing FDA's concerns with the use of AI in medical product development, clinical research, and clinical care. [FDA Perspective on the Regulation of Artificial Intelligence in Health Care and Biomedicine | Artificial Intelligence | JAMA | JAMA Network](#)

FDA concerns:

- (1) potential uses of AI in clinical trials, such as employing "digital twins" to generate simulated clinical records;
- (2) AI in medical devices; and
- (3) privacy considerations regarding the use of AI in clinical research.



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Strategic Plan Provides a Roadmap for AI in Health Care, Human Services, and Public Health

January 2025 HHS has released its Artificial Intelligence (AI) Strategic Plan, setting a vision for how AI can revolutionize health care, human services, and public health. This comprehensive roadmap outlines the department's commitment to trustworthy, ethical, and equitable AI use.

Key highlights included:

1. Catalyzing health AI innovation and adoption to unlock new ways to improve people's lives
2. Promoting trustworthy AI development and ethical and responsible use to avoid potential harm
3. Democratizing AI technologies and resources to promote access
4. Cultivating AI-empowered workforces and organization cultures to effectively and safely use AI

[HHS Artificial Intelligence Strategic Plan | HealthIT.gov](#)

Not Found

The requested URL was not found on this server.

Apache/2.4.52 (Ubuntu) Server at www.healthit.gov Port 80

HHS Artificial Intelligence Strategic Plan

Artificial Intelligence (AI) at HHS

Together with our partners in academia, industry and government, HHS will leverage artificial intelligence (AI) capabilities to solve mission challenges and gain new insights into complex problems while ensuring that our solutions are ethical, effective, and secure.

Resources

Learn about AI-focused laws, regulations, and past work.

We're sorry, but there is no www.hhs.gov page that matches your entry. Possible reasons:

- The page may have been moved,
- It no longer exists, or
- The address may have been typed incorrectly.

OIG's Information Blocking Investigations

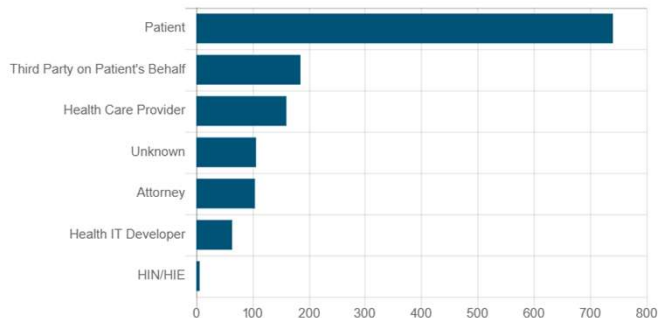
Note: OIG has six years to impose civil monetary penalties (CMPs) on an actor found guilty of information blocking

The Cures Act authorizes the HHS OIG to [investigate](#) any claim of information blocking
[Information Blocking Claims: By the Numbers | HealthIT.gov](#)
Stats below for April 5, 2021 – May 31, 2025

Information on submissions received through the Report Information Blocking Portal²

Total number of information blocking portal submissions received	1,321
Total number of possible claims of information blocking	1,241
Total number of submissions received that did not appear to be claims of potential information blocking ³	80

Claims Counts by Types of Claimant

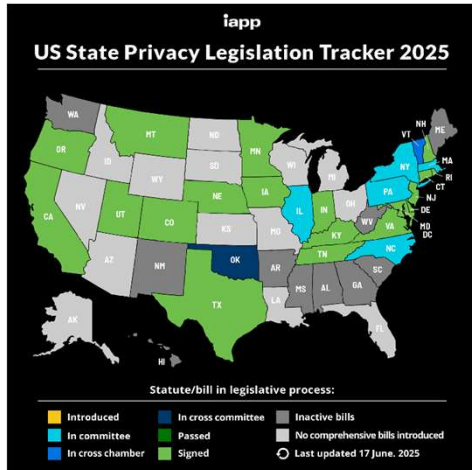


State Privacy Laws & Biometric Information Privacy



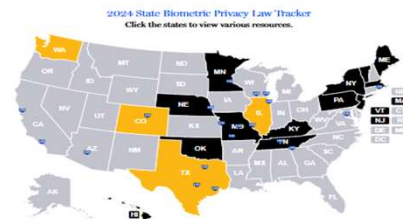
State-level momentum for comprehensive privacy bills is at an all-time high

States Addressing Biometric Information Privacy



Tracking U.S. state biometric privacy legislation.

Illinois, Texas, and Washington have passed legislation regulating private entities' collection and use of biometric information. In 2024, more states are introducing similar bills that address biometric privacy issues. Our interactive map tracks those bills. Click the states to learn more and if you have questions, contact [Jedrej Kowalski](#) or [David Shapiro](#). If you would like to receive updates on these bills and other privacy news, please subscribe to our [privacy blog](#). If you would like to track broad state consumer privacy bills, visit our [2024 State Privacy Law Tracker](#). If you would like to track state children's privacy bills, visit our [2024 State Children's Privacy Law Tracker](#).



HUSCHBLACKWELL



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Cookies in E-Commerce: Personal Jurisdiction



[Ninth Circuit Court of Appeals](#) on April 21, 2025 issued a ruling likely to impact privacy litigation for e-commerce platforms.

In [Briskin v. Shopify, Inc.](#), the Court held that Shopify could be sued in California because it allegedly engaged in tortious actions that deliberately targeted the plaintiff, a California resident even though it is headquartered in Canada.

Shopify conceded that its geolocation technology allowed it to know that Briskin's device was located in California when it installed cookies on Briskin's device; and (2) Briskin's complaint alleged that Shopify used the data gathered by its cookies to compile consumer profiles and then sold them without the consumer's knowledge or consent.

<https://cdn.ca9.uscourts.gov/datastore/opinions/2025/04/21/22-15815.pdf>



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ClearBlue in the Clear: Home Pregnancy Test Company Wins Dismissal of Pixel Wiretapping Suit

California court dismissed on multiple grounds suit challenging the use of website pixels by Clearblue, a company that offers home pregnancy and fertility test kits. *Saedi v. SPD Swiss Precision Diagnostics d/b/a Clearblue*, 2025 WL 1141168 (C.D. Cal. Feb. 27, 2025).

Roz Saedi, a California resident, alleged she visited Clearblue's website in September 2022 to research and purchase a fertility product.

Shortly thereafter, Saedi claims that she saw advertisements on a personal social media account for the same product she had viewed on Clearblue's website.

She alleged wiretapping in violation of the California Invasion of Privacy Act ("CIPA") and the federal Wiretap Act and an intrusion upon seclusion under California common law.

Plaintiffs filed first amended complaint in March and parties reached a confidential individual settlement of the case in May. Court set order to show cause regarding dismissal if the parties have not finalized the settlement/dismissal by July 11.



ClearBlue in the Clear: Home Pregnancy Test Company Wins Dismissal of Pixel Wiretapping Suit

Saedi v. SPD Swiss Precision Diagnostics d/b/a Clearblue, 2025 WL 1141168 (C.D. Cal. Feb. 27, 2025). Cal Court granted Clearblue's motion to dismiss each of the plaintiff's claims.

- **CIPA Claim Barred by One-Year Statute of Limitations** Plaintiff brought her claim in August 2024, nearly two years after the purported collection of her data in September 2022. Plaintiff alleged "general knowledge that the Website collected [her] information," which the Cal Court held "is sufficient to provide constructive notice of the Privacy Policy" disclosing the alleged data collection practices.
- **Federal Wiretap Act Claim Barred by Party Exemption** Federal Wiretap Act's party exemption barred plaintiff's claim because Clearblue, "as the owner of the Website," was "party to the communications" allegedly intercepted. Crime exception did not apply because (i) the plaintiff conceded that Clearblue is not a covered entity under HIPAA, and (ii) failed to satisfy "the requirement that the alleged criminal or tortious purpose is 'independent of the interception itself.'"
- **No Intrusion by Party to Communication** "No 'intrusion' for purposes of an invasion of privacy claim." Relevant question - whether Clearblue—and not any third party—intruded upon the plaintiff's alleged communications. Clearblue could not "logically intrude into communications to which they are a party."



Pixel and Meta Class Actions



HIPAA Journal
https://www.hipaajournal.com › university-rochester...

University of Rochester Medical Center Settles Pixel Lawsuit

Jun 4, 2025 · University of Rochester Medical Center Settles Pixel Lawsuit for \$2.85M



Ferooot
https://www.feroot.com › blog

Pixel Tracking Violations Cost US Healthcare \$100M+

2 days ago · 2024: Escalating Stakes Penalties soared to \$50.61M across six cases, driven by massive class-action settlements. Advocate Aurora Health ...

•2024: Escalating Stakes

Penalties soared to \$50.61M across six cases, driven by massive class-action settlements. Advocate Aurora Health paid \$12.25M for exposing 3 million patients' data via Meta Pixel, while Mass General Brigham's \$18.4M settlement addressed cookie and pixel tracking violations. The FTC's \$7M fine against Cerebral underscored the risks for telehealth platforms sharing data with ad networks.

•2025: Ongoing Fallout

Early 2025 saw \$15.76M in settlements, including HealthPartners (\$6M) and University of Rochester Medical Center (\$2.85M). With claims periods extending into mid-2025 and ongoing lawsuits against providers like Kaiser Permanente, more penalties loom on the horizon. [Pixel Tracking Violations Cost US Healthcare \\$100M+](#)



claimdepot.com
https://www.claimdepot.com › settlements › lb-pixel-settlement

LifeBridge Health \$2M Pixel Class Action Settlement

Dec 3, 2024 · If you logged into the LifeBridge Patient Portal at least once between May 13, 2020 and July 25, 2023, you may be eligible to claim compensation from a class action settlement...



claimdepot.com
https://www.claimdepot.com › settlements › ghp-pixel-settlement

\$6 Million Group Health Plan Pixel Settlement - claimdepot.com

Jan 5, 2025 · If you visited the HealthPartners and Virtuwel websites between January 1, 2018, and November 10, 2023, you may be eligible to claim a monetary award from a class action...



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Health Care Targeted for Cyber Attacks



ConsumerAffairs



Health care had more cyberthreats last year than any other critical infrastructure industry, according to the FBI's 2024 [Internet Crime Report](#) released April 23. A total of 444 reported incidents impacted health care, comprised of 238 ransomware threats and 206 data breach incidents. Only critical manufacturing had more ransomware incidents, with 258, but fewer data breaches, with 71. The report also found that ransomware groups with the most FBI complaints in 2024 included Akira, LockBit and RansomHub.

hhs.gov
https://hhs.gov/hhs/cyber
HHS Cyber Gateway

Connecting the Healthcare and Public Health (HPH) Sector with specialized healthcare specific cybersecurity information & resources from across the U.S. Department of Health and Human ...

Cyberattacks continued to be the primary cause of data breaches. Specificity regarding the attack in breach notices declined.

Check out Session 13



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Cyberattacks in the News

Bloomberg Law

Health Data Breach Class Actions Surge as Cyberattacks Climb

[Shields Health Care Group reaches settlement in data breach class action](#) June 5, 2025
[OrthoMinds class action alleges data breach compromised orthodontics patient info](#) May 29, 2025
[\\$1.1M WellNow Urgent Care data breach class action settlement](#) May 23, 2025
[Yale New Haven Health announces massive data breach affecting 5.5M patients](#) May 23, 2025
[Planned Parenthood data breach exposed 1.6M patients' info, class actions claim](#) May 22, 2025
[DaVita sued after data breach allegedly exposed 20TB of dialysis patient info](#) May 12, 2025

[Data Breach Archives](#)



Check out Sessions 13 & 20

LEADING THE DAY: Suit filed following cyberattack



A CLASS-ACTION LAWSUIT HAS BEEN filed against Kettering Health after last month's cyberattack and data breach.

The lawsuit was filed by a law firm in Montgomery County Court.

THE ATTACK, WHICH WAS BELIEVED TO be caused by ransomware, limited the network's ability to access certain patient care systems across the organization.

The complaint claims Kettering Health should have been well aware of the dangers of potential cyberattacks, the law firm Wright & Schulte said.

KETTERING HEALTH SAYS PATIENTS NOW have limited access to MyChart and that all surgeries have resumed, including scheduling for elective procedures.

Patients should be able to see upcoming appointments, schedule new appointments, view prescriptions and test results, order refills and message their providers.



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Ransomware Attack

Change Healthcare, a subsidiary of UnitedHealth Group, said 1-16-2025 it has "substantially" [completed](#) identifying and notifying individuals affected by the Feb. 21 ransomware attack



According to 2024 year-end earnings [report](#):

\$3.09 billion: Total impact
\$2.2 billion: Direct response costs
\$867 million: Business disruptions
\$2.60: Total impact per share of UnitedHealth Group
1%: Year-over-year decline in revenue for Optum Insight
\$9.03 billion: Direct [loans](#) to affected healthcare providers
\$4.5 billion: Loans that were repaid



Ransomware Attack Against Change Healthcare Exposed Data On 190M People, UnitedHealth Says

[Modern Healthcare](#) reported, "A ransomware attack against Change Healthcare last year exposed data on a record-breaking 190 million people, parent company UnitedHealth Group reported Friday." This is "90 million more people than the company, which operates Change Healthcare through its Optum subsidiary, disclosed to federal regulators in October. It also amounts to 55% of the U.S. population



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OCR Response to Change Healthcare Cyberattack

The webpage updates address questions OCR has received concerning who is responsible for performing breach notification to HHS, affected individuals, and where applicable the media. Specifically, the FAQs make clear that:

Covered entities affected by the Change Healthcare breach may delegate to Change Healthcare the tasks of providing the required HIPAA breach notifications on their behalf.

Only one entity – which could be the covered entity itself or Change Healthcare – needs to complete breach notifications to affected individuals, HHS, and where applicable the media.

If covered entities work with Change Healthcare to perform the required breach notifications in a manner consistent with the HITECH Act and HIPAA Breach Notification Rule, **they would not have additional HIPAA breach notification obligations.**

The new and updated FAQs on the Change Healthcare Cybersecurity Incident may be viewed at: <https://www.hhs.gov/hipaa/for-professionals/special-topics/change-healthcare-cybersecurity-incident-frequently-asked-questions/index.html>.

The HHS Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information may be found at: https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf.

OCR is committed to enforcing the HIPAA Rules that protect the privacy and security of peoples' health information. Guidance about the Privacy Rule, Security Rule, and Breach Notification Rules can also be found on OCR's website.

If you believe that your or another person's health information privacy or civil rights have been violated, you can file a complaint with OCR at <https://www.hhs.gov/ocr/complaints/index.html>.



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January 7, 2025

2024 HIPAA Accomplishments and Wrap-Up

By Melanie Fontes Rainer, OCR Director

2024 was a historic year filled with tremendous activities and accomplishments for OCR on Health Insurance Portability and Accountability Act of 1996 (HIPAA) rulemakings, enforcement actions, conferences, webinars, videos, and newsletters for the health care sector on HIPAA privacy and cybersecurity.

Rulemaking

For the first time in OCR's history, OCR issued three HIPAA rulemakings in one year

In February, OCR published a [final rule](#) on the Confidentiality of Substance Use Disorder Patient Records

In April, OCR published a [final rule](#) modifying the HIPAA Privacy Rule to support reproductive health care privacy

In December, OCR issued a [proposed rule](#) to modify the HIPAA Security Rule to strengthen cybersecurity in health care. The proposed rule would require covered entities and their business associates to better protect individuals' electronic protected health information against both external and internal threats

Enforcement

OCR completed 22 HIPAA enforcement actions (2nd highest in OCR history) and collected over \$9.9 million in settlements and civil money penalties. HIPAA issues resolved included ransomware, phishing, health information left unsecured on the internet, impermissible access to electronic PHI, reproductive health information impermissibly disclosed, and untimely patient access to PHI

Cybersecurity Resources

OCR published cybersecurity resources including a [video](#) on ransomware and the HIPAA Security Rule that analyzes trends that OCR is seeing in ransomware investigations. OCR also published two cybersecurity newsletters and held two webinars to support the two final rules

Check out Session 20



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HIPAA Security Rule To Strengthen the Cybersecurity of Electronic Protected Health Information



About HHS Programs & Services Grants & Contracts Laws & Regulations

Office for Civil Rights

The Department's Office for Civil Rights seeks to update HIPAA Security Rule for the first time since 2013 On December 27, 2024 HHS OCR issued a proposed rule to improve cybersecurity and better protect the U.S health care system from a growing number of cyberattacks (Federal Register on January 6, 2025) This document has a comment period that ends in 03/07/2025.

[HIPAA Security Rule Notice of Proposed Rulemaking to Strengthen Cybersecurity for Electronic Protected Health Information | HHS.gov](https://www.federalregister.gov/public-inspection/2024-30983/health-insurance-portability-and-accountability-act-security-rule-to-strengthen-the-cybersecurity-of)
NPRM is at: <https://www.federalregister.gov/public-inspection/2024-30983/health-insurance-portability-and-accountability-act-security-rule-to-strengthen-the-cybersecurity-of>



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HIPAA Security Rule Proposed Updates



About HHS Programs & Services Grants & Contracts Laws & Regulations

Office for Civil Rights



<https://ncvhs.hhs.gov/wp-content/uploads/2024/10/Presentation-Full-Committee-Meeting-September-20-2024-Noonan.pdf>

Tim Noonan, deputy director of health information privacy, updated the status of the NPRM at the Virtual 42nd National HIPAA Summit. Noonan confirmed OCR has received [4,745 comments](#) on the proposed Security Rule update

Noonan advised OCR will work within HHS, as with any rulemaking, on what future actions to take

Noonan also confirmed that the long-awaited [third phase of HIPAA compliance audits](#) commenced in December 2024 and involves audits of 50 HIPAA-covered entities and business associates, specifically looking at the most important Security Rule provisions for hacking and ransomware attack prevention.

Noonan explained that between 2020 and 2024, hacking incidents increased by 30% and there was a 45% increase in ransomware attacks on the healthcare sector, with 81% of all data breaches reported to OCR last year due to hacking.



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HIPAA Security Rule Proposed Updates

OCR proposed the rule in response to growing cyber threats impacting regulated entities and follow the plan for improving the cybersecurity of critical infrastructure ([Biden-Harris Administration's National Cybersecurity Strategy](#)). The proposed rule



- * removes the distinction between “required” and “addressable” implementation specifications (“required” implementation specifications must be implemented)
- * sets specific requirements for incident response including written procedures to restore the loss of certain relevant electronic information systems and data within 72 hours
- * proposes updates to definitions and other implementation specifications adds specific compliance time periods
- * updates requirements for Business Associates, including requiring confirmation at least once every 12 months from Business Associates showing that they have employed technical safeguards required by the Security Rule to protect ePHI by a subject matter expert and a written certification that analysis has been performed and is accurate.
- * requires improved cybersecurity protections and safeguards for individuals’ ePHI by requiring documentation, security measures, compliance audits and inventories by HIPAA Covered Entities and Business Associates
- * adds notification required from Business Associates of activation of contingency plans
- * requires greater specificity in the security risk analysis and a detailed written risk assessment
- * Business Associate requirements would extend to subcontracted Business Associates



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FTC Data Breach News + Attention Economy



[FTC Finalizes Order with GoDaddy over Data Security Failures](#) (May 21, 2025)

The [FTC alleged in January 2025](#) that despite claiming it provides “award-winning security,” GoDaddy failed to implement standard data security tools and practices to protect customers’ websites and data. For example, it failed to use multi-factor authentication, monitor for security threats, and secure connections to its consumer data. These failures led to several data breaches that allowed bad actors to gain unauthorized access to customers’ websites and data. The FTC also alleged that the company deceived users about its compliance with the EU-U.S. and Swiss-U.S. Privacy Shield Frameworks.

[FTC Hosted June 4 Workshop on The Attention Economy: How Big Tech Firms Exploit Children and Hurt Families](#))

We need only look at our families and lives and communities to glimpse the wreckage our digital age is leaving behind. And we need only be honest that sometimes, products themselves can be harmful. [Commissioner Meador's Attention Economy Workshop Keynote](#)



NOTE: Financial institutions are required to notify the Federal Trade Commission about any security breach that involves the information of 500 customers or more. The breach must be reported no later than 30 days after it is discovered.



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Reports (privacy breach impacting > 500) Currently Under Investigation by OCR

794 CASES LISTED CURRENTLY
UNDER INVESTIGATION 6/15/2025

Breach Report Results							
Expand All	Name of Covered Entity	State	Covered Entity Type	Individuals Affected	Breach Submission Date	Type of Breach	Location of Breached Information
>	Blue Shield of California	CA	Business Associate	1543	06/06/2025	Unauthorized Access/Disclosure	Other
>	Sensata Technologies, Inc. Health and Welfare Benefit Plan	MA	Health Plan	15600	06/05/2025	Hacking/IT Incident	Network Server
>	AffirmedRx PBC	KY	Business Associate	1089	06/05/2025	Unauthorized Access/Disclosure	Paper/Films
>	Rankin Corporation	MI	Business Associate	48592	06/02/2025	Hacking/IT Incident	Network Server
>	Cumberland County Hospital Association	KY	Healthcare Provider	36659	06/02/2025	Hacking/IT Incident	Other
>	Ocuco Inc.	FL	Business Associate	240961	05/30/2025	Hacking/IT Incident	Network Server
>	CareOregon, Inc.	OR	Health Plan	1786	05/30/2025	Unauthorized Access/Disclosure	Paper/Films
>	Oliver Street Dermatology Management LLC	TX	Business Associate	13717	05/30/2025	Hacking/IT Incident	Network Server
>	Horizon Blue Cross Blue Shield NJ	NJ	Health Plan	781	05/30/2025	Unauthorized Access/Disclosure	Network Server
>	Next Step Healthcare LLC	MA	Healthcare Provider	12090	05/30/2025	Hacking/IT Incident	Network Server
>	Missouri Department of Conservation	MO	Health Plan	10280	05/30/2025	Hacking/IT Incident	Network Server
>	Northwestern Community Services Board	VA	Healthcare Provider	21856	05/29/2025	Hacking/IT Incident	Network Server
>	Gateway Community Services, Inc.	FL	Healthcare Provider	34498	05/29/2025	Hacking/IT Incident	Network Server
>	Erlanger Health	TN	Healthcare Provider	3371	05/28/2025	Hacking/IT Incident	Network Server
>	The Smith Institute for Urology	NY	Healthcare Provider	2283	05/28/2025	Unauthorized Access/Disclosure	Desktop Computer
>	Covenant Surgical Partners, Inc.	TX	Business Associate	88809	05/28/2025	Hacking/IT Incident	Network Server
>	Cahaba Center for Mental Health	AL	Healthcare Provider	501	05/27/2025	Hacking/IT Incident	Email
>	NHPP Physical Medicine and Rehabilitation	NY	Healthcare Provider	1353	05/23/2025	Unauthorized Access/Disclosure	Other
>	Sports Physical Therapy, Occupational Therapy and Rehabilitation Services of the North Shore, P.L.L.C.	NY	Healthcare Provider	6195	05/23/2025	Unauthorized Access/Disclosure	Other

**U.S. Department of Health and Human Services
Office for Civil Rights
Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information**



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Reports (privacy breach impacting > 500) Archive

6162 cases listed on the
Archive Page 6/15/2025

This page archives all resolved breach reports and/or reports older than 24 months.

Breach Report Results							
Expand All	Name of Covered Entity	State	Covered Entity Type	Individuals Affected	Breach Submission Date	Type of Breach	Location of Breached Information
>	Langdon Prairie Health	ND	Healthcare Provider	1152	04/18/2025	Unauthorized Access/Disclosure	Email
>	Highland Rivers Behavioral Health	GA	Healthcare Provider	2253	04/15/2025	Hacking/IT Incident	Network Server
>	Charleston Area Medical Center	WV	Healthcare Provider	67413	02/14/2025	Hacking/IT Incident	Email
>	Insurance ACE/Humana Inc.	KY	Health Plan	8553	02/09/2025	Unauthorized Access/Disclosure	Paper/Films
>	Infays Public Services, Inc. ("Infays")	MD	Business Associate	2985	01/31/2025	Unauthorized Access/Disclosure	Network Server
>	Square Medical Group, LLC	MA	Healthcare Provider	2383	01/15/2025	Unauthorized Access/Disclosure	Email
>	Veterans Health Administration	DC	Healthcare Provider	1847	01/13/2025	Unauthorized Access/Disclosure	Paper/Films
>	Heritage Health Care	OH	Healthcare Provider	12162	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Washington Inc. ("Court House Manor")	OH	Healthcare Provider	2489	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Warren Inc. ("Warren Manor")	PA	Healthcare Provider	2709	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Wapaltoneta Inc. ("Wapaltoneta Manor")	OH	Healthcare Provider	1862	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Van Wert Inc. ("Van Wert Manor")	OH	Healthcare Provider	1604	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Sweden Valley Inc. ("Sweden Valley Manor")	PA	Healthcare Provider	1788	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Shawnee Inc. ("Shawnee Manor")	OH	Healthcare Provider	4395	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Rosalwin Inc. ("Rosalwin Manor")	OH	Healthcare Provider	1208	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Piqua Inc. ("Piqua Manor")	OH	Healthcare Provider	2969	01/09/2025	Hacking/IT Incident	Network Server
>	HCF of Perryburg Inc. ("Manor at Perryburg")	OH	Healthcare Provider	2704	01/09/2025	Hacking/IT Incident	Network Server

**U.S. Department of Health and Human Services
Office for Civil Rights
Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information**



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Patient Access fines

Mental Health Center, Health Insurer, Health System, Long Term Care, Psychotherapy, Lab, Primary Care, Dental Practices

53 cases
22 cases in 2024

HHS Office for Civil Rights Settles HIPAA Case Against Memorial Healthcare System Over Patient Access to Records

This settlement marks the 52nd enforcement action in the OCR Right of Access Initiative

January 15, 2025 HHS OCR announced a settlement with South Broward Hospital District d/b/a Memorial Healthcare System (Memorial Healthcare System), a Florida health system, concerning a potential violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The settlement resolves litigation resulting from an investigation about a complaint alleging a lack of timely access to an individual's protected health information (PHI).

OCR's investigation determined that Memorial Healthcare System failed to provide timely access within 30 calendar days. Memorial Healthcare System has agreed to pay \$60,000.

[HHS Office for Civil Rights Settles HIPAA Case Against Memorial Healthcare System Over Patient Access to Records](#) - January 15, 2025

Currently, a total of twenty states have passed comprehensive data privacy laws. Application varies -- [each state requires a "right to access" for that state's consumers](#) (often requiring access initiation via website).

[Frequently Asked Questions for Professionals](#) Content created by Health Information Privacy Division. Content last reviewed May 30, 2025.



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HHS Office for Civil Rights Imposes a \$200,000 Penalty Against Oregon Health & Science University for Failure to Provide Timely Access to Patient Records

53rd Case
Right of Access

The civil monetary penalty marks OCR's 53rd HIPAA Right of Access enforcement action to advance patient access to medical records.

Today, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), announced a \$200,000 civil monetary penalty against Oregon Health & Science University (OHSU), a public academic health center and research university, for violating an individual's right to timely access her medical records through a personal representative.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) [Privacy Rule's "Right of Access" provisions](#) require that individuals or their personal representatives have timely access to health information requested from a HIPAA covered entity (health plans and most health care providers) within 30 days, with the possibility of one 30-day extension and for a reasonable, cost-based fee. OCR enforces the HIPAA Privacy Rule, which establishes national standards to protect individuals' medical records; sets limits and conditions on the uses and disclosures of protected health information; and gives individuals certain rights, including the right to timely access and to obtain a copy of their health records.

"The HIPAA Privacy Rule requires that individuals and their personal representatives receive timely access to their medical records," said OCR Acting Director Anthony Archeval. "A covered entity's responsibility to provide timely access continues, even when a covered entity contracts with a business associate to respond to HIPAA right of access requests."

OCR initiated an investigation of OHSU based on a complaint filed in January 2021 from the individual's personal representative – the second complaint OCR received on this matter. In September 2020, OCR resolved the first complaint (received in May 2020) when OCR notified OHSU of its potential noncompliance with the Privacy Rule Right of Access provisions. Although OHSU provided part of the requested records in April 2019, OHSU did not provide all of the requested records until August 2021, which was nearly a year after OHSU received OCR's September 2020 letter, and sixteen months after the first request for records in April 2019. OCR's investigation found that OHSU failed to take timely action in response to the right of access requests.



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Resolution Agreements and Civil Money Penalties

A resolution agreement is a settlement agreement signed by HHS and a covered entity or business associate in which the covered entity or business associate agrees to perform certain obligations and make reports to HHS, generally for a period of three years. During the period, HHS monitors the covered entity's compliance with its obligations. A resolution agreement may include the payment of a resolution amount. If HHS cannot reach a satisfactory resolution through the covered entity's demonstrated compliance or corrective action through other informal means, including a resolution agreement, civil money penalties (CMPs) may be imposed for noncompliance against a covered entity.

Ransomware, Cybersecurity, Security Rule, Phishing

- [HHS Office for Civil Rights Settles HIPAA Ransomware Cybersecurity Investigation with Comstar, LLC](#) - May 30, 2025
- [HHS Office for Civil Rights Settles HIPAA Security Rule Investigation with a Florida Health Care Provider \[PDF, 126 KB\]](#) - May 28, 2025
- [HHS Office for Civil Rights Settles HIPAA Cybersecurity Investigation with Vision Upright MRI](#) - May 15, 2025
- [HHS Office for Civil Rights Settles HIPAA Ransomware Cybersecurity Investigation with Neurology Practice \[PDF, 245 KB\]](#) - April 25, 2025
- [HHS Office for Civil Rights Settles Phishing Attack Breach with Health Care Network for \\$600,000 \[PDF, 232 KB\]](#) - April 23, 2025
- [HHS Office for Civil Rights Settles HIPAA Ransomware Cybersecurity Investigation with Public Hospital \[PDF, 228 KB\]](#) - April 17, 2025
- [HHS Office for Civil Rights Settles HIPAA Security Rule Investigation with Northeast Radiology \[PDF, 369 KB\]](#) - April 4, 2025
- [HHS' Office for Civil Rights Settles HIPAA Security Rule Investigation with Health Fitness Corporation \[PDF, 210 KB\]](#) - March 21, 2025



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Resolution Agreements and Civil Money Penalties

16 Resolution Agreements in 2024 and 15 to date (May 30) in 2025

[HHS Office for Civil Rights Settles with Health Care Clearinghouse, Inmediata Health Group, Over HIPAA Impermissible Disclosure](#) (12-10-2024)

OCR uncovered the breach investigating a 11-16-2018 HIPAA complaint that ePHI was online. OCR confirmed the allegations and established that 1,565,338 individuals' ePHI was accessible to the public online from May 16, 2016 to January 23, 2019, indexed by search engines. Inmediata confirmed the online exposure of names, birth dates, home addresses, claims data, diagnosis/disorders, other treatment details, and Social Security numbers.

[HHS Office for Civil Rights Settles with Holy Redeemer Family Medicine Over Disclosure of Patient's Protected Health Information, Including Reproductive Health Information](#) (11-26-24)

HRFM impermissibly disclosed the protected health information to a prospective employer of Complainant without first obtaining a valid authorization.



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HIPAA News Releases & Bulletins

[HIPAA News Releases](#) ^{Sunset} [HHS.gov](#)

To view HIPAA News Releases & Bulletins from 2015 to January 19, 2025, visit the [HIPAA News Archive](#).



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HHS Office for Civil Rights Settles HIPAA Ransomware Cybersecurity Investigation with Comstar, LLC

MAY 30, 2025 | PRESS RELEASE

HHS Office for Civil Rights Settles HIPAA Security Rule Investigation with a Florida Health Care Provider

MAY 28, 2025 | PRESS RELEASE

OCR initiated the investigation following its receipt of a complaint in October 2018 (complainant alleged after receiving treatment at a BayCare facility, she was contacted by an unknown individual who had photographs of her printed medical records, as well as a video of someone scrolling through her medical records on a computer screen. Investigation determined credentials used to access the complainant's medical record belonged to a non-clinical former staff member of a physician's practice, which had access to BayCare's electronic medical records for the continuity of common patients' care. OCR's investigation found BayCare potentially violated multiple HIPAA Security Rule requirements

HHS Office for Civil Rights Settles HIPAA Cybersecurity Investigation with Vision Upright MRI

MAY 15, 2025 | PRESS RELEASE

The settlement resolves an OCR investigation concerning the breach of an unsecured server containing the medical images of 21,778 individuals.



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Ransomware Settlements and Fines 13th Ransomware & 9th Risk Analysis



HHS Office for Civil Rights Settles HIPAA Ransomware Cybersecurity Investigation with Comstar, LLC

Settlement Marks OCR's 13th Ransomware Enforcement Action and 9th Enforcement Action in OCR's Risk Analysis Initiative

Today, the U.S. Department of Health and Human Services ("HHS"), Office for Civil Rights ("OCR") announced a settlement with Comstar, LLC ("Comstar"), a Massachusetts company that provides billing, collection, and related services to non-profit and municipal emergency ambulance services, concerning potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule. The settlement resolves an OCR investigation concerning a ransomware breach that affected 585,621 individuals.

OCR initiated an investigation after receiving Comstar's breach report, dated May 26, 2022, that an unknown actor had gained unauthorized access to Comstar's network servers on March 19, 2022. Comstar did not detect the intrusion until March 26, 2022. Ransomware was used to encrypt Comstar's network servers and the ePHI of approximately 585,621 individuals was affected. At the time of the breach, Comstar was a business associate of over 70 HIPAA covered entities. The type of ePHI impacted was clinical, including medical assessments and medication administration information. OCR's investigation determined that Comstar failed to conduct an accurate and thorough risk analysis to determine the potential risks and vulnerabilities to the ePHI that it holds.



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Deletion of ePHI held by Business Associate



HHS Office for Civil Rights Settles HIPAA Security Rule Investigation with USR Holdings, LLC Concerning the Deletion of Electronic Protected Health Information

Settlement resolves multiple Security Rule failures

January 8, 2025 HHS OCR announced a \$337,750 settlement with USR Holdings, LLC, a business associate in Florida, under the [HIPAA Security Rule](#).

OCR initiated an investigation following the receipt of a breach report filed by USR in February 2019, which reported that from August 23, 2018, through December 8, 2018, a database containing the ePHI of 2,903 individuals was accessed by an unauthorized third party/parties who were able to delete ePHI in the database.

OCR's investigation found potential violations of the HIPAA Security and Privacy Rules, including failures to conduct an accurate and thorough risk analysis to determine the potential risks and vulnerabilities to ePHI in its systems; to regularly review its information system activity; and to establish and implement procedures to create and maintain retrievable exact copies of ePHI.

The resolution agreement and corrective action plan may be found at: <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/usr-holdings-llc-ra-cap/index.html>

[HHS Office for Civil Rights Settles HIPAA Security Rule Investigation with USR Holdings, LLC Concerning the Deletion of Electronic Protected Health Information](#) - January 8, 2025



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Data Collection and Reporting

Check out Session 44



The Public Health Data Strategy (PHDS) addresses gaps in public health data, reduces the complexity of data exchange, helps the nation promote health equity, provides timely and actionable data and improves health outcomes for all.

88% Nation's emergency department visits available for situational awareness, most within 24 hours.

700,000 Anonymized commercial lab tests received per day, covering 167 conditions.

69% Of deaths from provisional mortality data received within 10 days, up from 11%.

[Allstate faces national class-action lawsuit over data collection](#)

for allegedly unlawfully collecting and selling data from more than 45 million consumers to raise premiums. **The class action brought its claims under the Federal Wiretap Act, the Computer Fraud and Abuse Act and invasion of privacy** The consumer class action follows [Attorney General Ken Paxton's enforcement action against Allstate and its subsidiary Arity LLC under the Texas Data Privacy and Security Act](#), filed Jan. 13, 2025 in Texas.



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TEFCA



Over 1,000 Hospitals Connect to TEFCA with Epic Nexus
June 2, 2025 The Epic community continues to lead the way to universal, secure, nationwide health data exchange.



More than 1,000 hospitals and 22,000 clinics using Epic's software are now connected to a federally backed health information network. The organizations are live on the Trusted Exchange Framework and Common Agreement, or TEFCA, a government-led initiative launched in 2022 to create a nationwide standard for sharing electronic health data. Epic announced the milestone in a June 2 news release.

TEFCA was established under the bipartisan 21st Century Cures Act and aims to make patient data more accessible across different health systems — a longstanding challenge in the U.S., where hospitals often operate on siloed IT infrastructure. Epic's participating hospitals and clinics are connected through its own Qualified Health Information Network, Epic Nexus, which was designated a federal QHIN in 2023.

TEFCA and other EHR vendors and data custodians -- [Will TEFCA Transform U.S. Health Data Exchange Forever? | HealthPoint](#)



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PRESS RELEASE



United States Sues Telehealth Providers and Executives for Unfair and Deceptive Conduct

May 8, 2025 — More than \$5 Million in Refunds Sent to Consumers as a Result of the FTC's Action Against Cerebral over Deceptive Cancellation Practices.

Cerebral, Inc. has agreed to an order that will restrict how the company can use or disclose sensitive consumer data and require it to provide consumers with a simple way to cancel services to settle FTC charges that the telehealth firm failed to secure and protect sensitive health data.

On June 10, 2024, the U.S. Justice Department announced that together with the [Federal Trade Commission](#), it filed an amended complaint (May 31) against [telehealth company](#) Cerebral Inc., and its founder and several executives. Alleged Privacy Violations: Intentionally deployed [online tracking technologies across its website in conflict with](#) own express claims that its services were "private" or "confidential," and that it would not disclose user data to third parties without the users' consent. Also alleged executives violated the FTC Act by causing Cerebral employees to [falsely impersonate patients on online review sites](#), post fictitious reviews praising the company's services and suppress authentic, negative reviews of the company.



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Medical Staff, Credentialing, and Peer Review

June 2025

Kim Harvey Looney
K&L Gates LLP



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Thank You to the Efforts of the AHLA Year in Review Medical Staff, Credentialing, and Peer Review Topic Team:

Alexis Angell, Polsinelli
Avery Schumacher, Epstein Becker Green
Hilary Velandia, Conner & Winters



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Criminal Indictments Based on Clinical Care – Tracking a Trend?

- **Perceived Trend:** Increase in criminal prosecutions involving physicians and other professionals for clinical decisions; increased media attention around same
- **Context:** Often tied to allegations of fraud, purposeful patient harm, or gross negligence; employing/contracting entity involvement in aftermath
 - Ohio physician charged and later acquitted of 14 murder charges in connection with fatal patient overdoses; physician filed a defamation suit against the hospital system's parent company, court entered a directed verdict for the defense in June 2025
 - Iowa LPN sentenced to 2 years in prison in April of 2025, for felony wanton neglect of a nursing home resident, for failing to suction an 87-year-old man's airway despite repeated requests from colleagues. CNA involved filed suit against the nursing home in April 2025 for unlawful termination, citing retaliation for quality-of-care reports to regulators.
- **Significance for Medical Staffs:** Underscores the importance of robust credentialing and peer review, and proactive institutional responses to red flags; also raises considerations around culture and education (this is a topic of interest among clinicians)



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Criminal Indictment of Hospital

- A VA hospital (CRMC) was criminally indicted Jan. 8, 2025, by a federal grand jury for conspiracy to defraud the U.S. and healthcare fraud. HOSPITALS ARE RARELY CRIMINALLY CHARGED.
- The charges stem from the hospital's involvement with [former] OB/GYN J. Perwaiz, to whom the hospital granted privileges from 1984 – 2019, despite knowing his privileges had been terminated at another hospital for performing unnecessary surgeries, and that he was convicted of two federal felonies in 1996. From 2010 to 2019, the hospital allegedly received ~\$18.5 million in public payor reimbursements for procedures performed by the OB/GYN.
- The OB/GYN was convicted of federal healthcare fraud and sentenced to 59 years in prison. Evidence at trial proved he tricked patients into hysterectomies by falsifying diagnoses, he sidestepped Medicaid's 30-day waiting period for elective sterilization by backdating forms, and would regularly induce patients into early labor to ensure he could perform the delivery and receive the reimbursement.
- The indictment alleges that the hospital knew the OB/GYN was inducing early deliveries and that he performed sterilization procedures without valid consent forms, but allowed him to proceed, and routinely allowed the OB/GYN to deviate from scheduling policies for non-emergency cases.
- **Medical Staff Takeaway:** Hospitals have a legal and ethical obligation to act on known red flags during the credentialing and privileging process. The CRMC indictment illustrates that knowingly allowing an unfit physician to continue practicing can expose the institution itself to criminal liability.



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NPDB Reports – Voluntary Agreement Not to Exercise Privileges

Maneckshana v. Baystate Health Inc., No. CV 24-30097-MGM (D. Mass. Apr. 16, 2025)

- A transplant surgeon agreed to voluntarily refrain from exercising clinical privileges at a hospital after quality concerns were raised. The hospital later submitted an NPDB report, stating the surgeon posed “a danger to the public.” The surgeon sued, alleging violation of the Health Care Quality Improvement Act (HCQIA), and defamation based on the NPDB report.
- The U.S. District Court in Massachusetts dismissed the HCQIA claim, holding, as *courts consistently have*, that HCQIA does not create a private right of action. It also dismissed the defamation claim, finding the hospital immune under HCQIA because the report was not shown to be knowingly false, and the surgeon failed to plead facts to overcome immunity.
- **Medical Staff Takeaways:** HCQIA is a shield, not a sword. Physicians cannot sue under HCQIA, it provides immunity for peer reviewers, not rights for those reviewed. So long as the hospital doesn’t knowingly submit false information, it is protected from defamation claims under federal law. Statements in NPDB reports should be fact-based and supportable.



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NPDB Reports – Separation Agreement

Hoedt v. Vanderbilt Univ., No. 3:24-CV-00310 (M.D. Tenn. Feb. 12, 2025)

- Employed physician had his clinical privileges summarily suspended and later signed a separation agreement (from employment) instead of pursuing a medical staff hearing under the bylaws. He later sued the hospital, alleging breach of contract due to alleged inaccurate NPDB reports, claiming reputational and career harm.
- The hospital argued that the separation agreement’s release language barred the physician from suing.
- The U.S. District Court in Tennessee denied the hospital’s motion to dismiss, and held that the release was not broad enough to waive the physician’s right to sue over the alleged reporting misconduct.
- **Medical Staff Takeaways:** Separation agreements must be precise. Broad waivers and releases may not cover claims related to NPDB reporting, especially if those claims involve facts arising after the agreement is signed, or if ambiguous.



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NPDB Reports – Locums Physician

Madera v. Taos Health Sys., Inc., No. 1:22-CV-00285-MLG-SCY (D.N.M. Feb. 19, 2025)

- A locum tenens physician, sued the hospital after his clinical privileges were revoked following complaints of disruptive conduct and patient care concerns. The hospital filed an NPDB report, prompting claims of defamation and interference with business opportunities.
- The U.S. District Court in NM dismissed the physician's defamation claims, finding the hospital immune under HCQIA, which protects reports to the NPDB absent knowledge of falsity. One statement in the report was false (that the locums agency dropped him), but the hospital didn't know it was false at the time.
- The physician's claims based on intentional interference with economic relations were allowed to proceed. The court found HCQIA immunity inapplicable, as the hospital failed to provide notice and a hearing before revoking credentials and submitting the NPDB report.
- **Medical Staff Takeaways:** NPDB reports should be fact-checked, narrowly tailored, and avoid internal assumptions (e.g., about third party action). Even for temporary providers, if privileges are adversely affected, hospitals must comply with medical staff due process rights, or risk exposure to tort claims. HCQIA does not protect actions when due process requirements are not met.



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NPDB Reports – Forced Resignation

Lakatos v. Fla. IPS, No. 24-CV-21357 (S.D. Fla. Apr. 29, 2025)

- A physician treating COVID-19 patients claimed he was coerced into resigning after prescribing an unapproved treatment plan and posting a patient case on Instagram. He alleged the health system told him that if he didn't resign, they would file a damaging NPDB report. The physician sued, asserting several claims.
- U.S. District Court in Florida allowed the breach of contract claim to proceed, finding the physician had sufficiently alleged that his resignation was not voluntary, and thus could constitute a constructive termination in violation of his employment contract.
- **Medical Staff Takeaways:** Using the threat of NPDB reporting as leverage in employment disputes may undermine the hospital's legal protections and create exposure. If a physician alleges coercion tied to threats of NPDB reporting, courts may find that a resignation was not truly voluntary, potentially triggering breach of contract liability.



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Credentialing Inquiries – Reference Releases

Rushing v. Wood Health Co., LLC, No. 3:24-CV-845 (N.D. Ohio Mar. 31, 2025)

- A physician alleged that two hospitals engaged in racial discrimination and retaliation, claiming: (1) the first hospital (where he trained) mistreated him during residency; and (2) the second hospital terminated his employment because he refused to sign a reference release form required to contact the first hospital. The physician argued that signing the release would undermine his claims against the first hospital.
- U.S. District Court in Ohio dismissed all claims, finding that the factual allegations were insufficient to support a discrimination or retaliation claim. Noted the second hospital's inability to obtain a reference was an adequate and non-discriminatory reason for termination. The court reviewed the release form and found it would not have compromised his legal claims.
- **Medical Staff Takeaways:** Hospitals are entitled to decline employment when a candidate refuses to authorize references, so long as this is applied consistently. Release forms for references should be neutral, limited in scope, and legally reviewed to ensure they don't chill future claims; doing so increases defensibility in litigation.



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Court Intervention in Medical Staff Proceedings

Solomon v. Med. Exec. Comm. of Morriston Med. Ctr., No. A-0436-23 (NJ Ct. App. Aug. 8, 2024).

- The appellate court reversed a lower court's decision to intervene in a medical staff hearing and order the hearing panel apply a standard of proof different than the one in the medical staff bylaws.
- The bylaws required that a hearing panel uphold the MEC's recommendation if the MEC's evidence showed its recommendation was reasonable and warranted, unless the physician presented clear and convincing evidence that the recommendation was arbitrary, capricious, not supported by credible evidence, or contrary to law.
- The physician asserted bylaws improperly shifted a burden to the physician that would be nearly impossible to meet and that the MEC should have to prove its case by a preponderance of the evidence.
- The lower court had imposed a standard of proof from caselaw rather than the standard in the bylaws. The appellate court held the intervention prevented review of a complete record and that the standard from the caselaw did not apply.
- **Medical Staff Takeaways:** Courts will generally defer to the procedural and evidentiary rules established in bylaws, so long as they are fair and not contrary to law. Courts will usually require the administrative process to play out before stepping in.



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Discrimination – MEC Request for Physician Psych Evaluation

Byrnes v. St. Catherine Hospital, No. 2:21-cv-02086 (D. Kan Sep. 5, 2024)

- After a physician made late-night allegations of sexual harassment and improper care against a colleague, the Medical Executive Committee (MEC) requested that he undergo a psychological evaluation. The MEC later rescinded the request. The physician was later terminated and sued under the Americans with Disabilities Act (ADA), alleging that the hospital perceived him as impaired and discriminated against him on that basis.
- The U.S. District Court in Kansas dismissed the ADA claim, holding that a request for psych evaluation was not enough to show the hospital viewed the physician as impaired. Also found insufficient evidence that the physician's termination was because of a perceived impairment, noting that subsequent quality and professionalism concerns supported the decision.
- **Medical Staff Takeaways:** A request for psychological evaluation is not itself ADA discrimination, especially if made in response to concerning behavior, and rescinded or reconsidered appropriately. Medical staffs should ensure that requests for evaluation are grounded in observable conduct, not speculative assumptions. Strong documentation of independent concerns is key.



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Peer Review Privilege for Grand Rounds Conference Materials

Van Houwelingen v. Milton S. Hershey Med. Ctr., No. 1:22-CV-01388 (MD.. Pa. Aug. 21, 2024).

- The U.S. District Court for the Middle District of Pennsylvania denied a patient's motion to compel a hospital to provide a grand rounds PowerPoint presentation sections discussing care relevant to the patient's malpractice claim.
- Plaintiffs asserted the grand rounds presentation was not privileged because CME credits were offered for the presentation and it was intended to educate the entire dermatology department.
- The court held the portion of the grand rounds presentation met the definition of peer review and was privileged under Pennsylvania law, although it was not reviewed by a group entitled "peer review committee" because the conference was solely open to professional health care providers and the purpose of that part of the presentation was to evaluate the care and improve future care.
- **Medical Staff Takeaways:** While materials utilized in grand rounds and M&M conferences generally aren't considered to be protected by state peer review privileges, hospitals should assess the structure and sufficiency of quality review processes, and educational quality activities should align with the state peer review statute, to maximize protection.



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Peer Review Privilege for Resident Files

Stull v. Summa Health Sys., 2024-Ohio-5718.

- The Supreme Court of Ohio considered whether Ohio's peer-review privilege protects residency files from discovery in medical negligence lawsuits, in the context of a claim involving a resident's alleged improper intubation (a matter of first impression for this Court).
- The plaintiff requested the resident's complete file. The hospital claimed peer review privilege and submitted an affidavit in support of its position. The lower courts held the affidavit alone was insufficient to establish privilege and ordered disclosure of the full file.
- The Court held that the privilege may apply to a hospital's residency files, but an affidavit alone is insufficient to establish the privilege. Instead, trial courts must conduct an in-camera review of requested files to determine whether they are protected.
- **Medical Staff Takeaway** – Hospitals should assess the structure and sufficiency of resident quality review processes, and resident review committees should align with the state peer review statute, to maximize protection.



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Performing ASC Procedures without License

- Two men face charges for performing procedures at New World Medical and Mystic Cosmetic Surgery without a license
 - Practicing medicine without a license
 - Unlicensed medical practice and causing injury as an unlicensed health provider
- One man previously accused of botched procedure that led to woman losing nipple, now faces allegations of disfiguring another patient during procedure. Man allegedly posed as cosmetic surgeon to bank employee who discovered him on Instagram.
- Florida Department of Health issued emergency suspension of surgical center's license in May 2025



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Fraud & Abuse, Part 2



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Fraud & Abuse, Part 2 Topic Team:

- Darby Allen, *Davis Wright Tremaine LLP*
- Travis Lloyd, *Bass, Berry & Sims PLC*
- Matthew Westbrook, *Proskauer Rose LLP*
- Tim Gonzalez, *RivkinRadler*



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Alert: Stark and Loper Bright



- The Stark statute was originally enacted in 1992 and significantly expanded in 1995:
 - **Ambiguities Abound**
- CMS has issued several sets of regulations and the agency's interpretation of the law has evolved significantly over time
- **Loper Bright** directs courts not to defer to agency's interpretation simply because the statute is ambiguous....
 - Anticipate shift in focus from the regulations to the statutory text
- **United States ex rel. Kyer v. Thomas Health System** (S.D.W.Va.), defendants filed a motion to dismiss a Stark-based FCA lawsuit.
 - Both parties briefed the motion relying on arguments derived from the Stark regulations. In late September the district court, *sua sponte*, ordered the parties to file supplemental briefs to address the impact of *Loper Bright*, describing the regulations as "complex, nuanced, and potentially beyond Congress's intent."
 - Court dismissed case in November on other grounds, without addressing the parties' *Loper Bright* arguments.

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**Disturbing
Trend: Stark
Based FCA
Lawsuits**



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Historic Stark Settlement: Community Health Network



- Community Health Network paid **\$345M** to settle allegations it violated the Stark Law by paying specialists in excess of FMV.
 - Qui tam relator former CFO/COO
 - CHN also entered into a Corporate Integrity Agreement
- CHN allegedly paid cardiologists, cardiothoracic surgeons, vascular surgeons, neurosurgeons and breast surgeons well above market, with bonuses tied to referrals, as part of a scheme designed to generate downstream referrals to hospital network.
- Valuation firms engaged but Community allegedly provided incorrect information and, in some instances, ignored indications that physician compensation exceeded FMV.
- *December 2024*, CHN entered into a separate **\$145M** settlement to resolve remaining claims in which the government did not intervene.

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Stark Settlement: Saint Peter's Health



- August 2024, Saint Peter's Health, a non-profit system based in Montana, paid **\$10.8M** to resolve allegations related to a single employed medical oncologist.
- Matter arose out of a voluntary disclosure and includes two basic allegations:
 - Physician upcoded E/M claims and improperly billed for services that weren't significant, separately identifiable services
 - System paid physician based on these false claims (i.e., credited physician with wRVUs), which caused compensation to be above FMV
- On the same day the settlement agreement was signed, DOJ brought a civil enforcement action under the FCA against the physician.

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Slide 195

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DOJ Sues Erlanger: Stark Physician Compensation

- **U.S. ex rel. Sullivan v. Erlanger Health System**, No. 1:21-cv-00219 (W.D.N.C.)
 - May 2024, DOJ announced its intention to intervene in an FCA lawsuit against Erlanger alleging that the health system paid physicians above FMV in violation Stark and AKS.
 - The lawsuit alleges that Erlanger made compensation decisions based on financial metrics that tracked physicians' expected referral patterns and their impact on the financial performance.
 - Erlanger paid outside physician groups sham directorships, to induce referrals.
 - Erlanger allegedly ignored internal compliance concerns raised about these practices.
 - Relators are the former chief compliance officer and former chief financial officer.

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CMS Advisory Opinion 2025-1:

Favorable opinion regarding relocation of physician-owned hospital

- **Background:** ACA amended the “whole hospital” exception to the Stark law to limit the creation of new physician-owned hospitals (while grandfathering those up and running at the time, with limits on the aggregate number of beds, operating rooms, and procedure rooms).
- **Proposal:** Physician-owned hospital proposed to locate the entire hospital approximately 8 miles from current location and to add an emergency department at the new location, which would be in the same community. No change in the aggregate number of beds, operating rooms, and procedure rooms. No change in legal entity, provider number, or name/branding.
- **Analysis:** CMS framed the question as whether the hospital, following the relocation, would be the same hospital that had physician ownership and a provider agreement on Dec. 31, 2010. Analysis focused on a non-exhaustive list of factors described in a 2023 proposed rule, including (1) whether state license would remain the same; (2) whether hospital would participate under same Medicare provider agreement; (3) whether tax ID or ownership would change; (4) whether community or patient base served by hospital would change; and (5) whether scope of services would change.
- **Conclusion:** Because the hospital checked almost all the boxes (per CMS, the addition of the emergency room would not “substantially alter the overall scope of services”), CMS concluded the hospital would remain the same hospital and issued a favorable opinion.

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AKS: “Willfulness”—

- **U.S. ex rel Hart v. McKesson Corporation**, 96 F.4th 145 (2nd Cir. March 12, 2024). Hart alleged that McKesson provided two business management tools to its customers without charge, in exchange for those customers’ commitments to purchase drugs from McKesson, allegedly in violation of the AKS.
 - District Court dismissed FCA claims holding Hart failed to allege sufficient facts to suggest McKesson acted “willfully” as required by AKS.
 - Second Circuit affirmed: *“We hold that the district court correctly concluded that to act “willfully” under the federal AKS, a defendant must act knowing that its conduct is in some way unlawful, and that Hart failed to plead sufficient facts to meet that standard.”*
 - SCOTUS: Cert Denied
- **U.S. v. Donofrio** – (5th Cir. May 20, 2025)
 - Fifth Circuit upheld Donofrio’s conviction under the AKS for conspiracy and kickbacks tied to pharmacogenetic testing-reinforcing that “knowing and willful” solicitations remain an essential element of conviction
 - Fifth circuit is committed to a traditional willfulness standard in criminal AKS cases – requiring knowledge and intent, consistent with “bad purpose.”
- **U.S. v. Sorensen** – (7th Cir., April 2025)
 - High-profile reversal – Seventh Circuit overturned a conviction of DME Company Owner where payments were made to marketing/advertising firms rather than clinicians.
 - Emphasized Prosecutors must prove inducement – that recipients had “fluid, informal power and influence” over healthcare decisions.
 - In other words, payments to non-decision makers may fall outside liability if they don’t influence clinical judgment.

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AKS: “Willfulness”— Circuit Split

- **Split on definition of “willfulness” under AKS**
 - **Fifth Circuit – (US v. St. Junius)** - Requires only intentional commission of the act, not knowledge of illegality. Although, **US. v. Donofrio** suggests a shift toward the higher scienter threshold in criminal AKS cases, aligning it more closely with the 2nd, 9th and 11th circuits.
 - **Second Circuit (Hart), Eleventh Circuit (US v. Sosa)** - Requires knowledge of illegality.
 - **Eighth Circuit (US v. Jain)** – lies in between - willfulness requires only knowledge that the defendant’s conduct was *wrongful*, rather than proof that he knew it violated a known *legal* duty.

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AKS & Marketing

U.S. v. Sorensen (7th Cir 2025)



- Mark Sorensen was convicted of AKS violations arising out of the marketing practices of his DME Company, SyMed
 - SyMed paid third parties to place advertising targeting patients
 - Patients could respond to the ads by providing information that was used to generate prefilled, unsigned prescriptions– those Rx were sent to patients’ physicians
 - Physicians decided whether to sign the order– if signed brace shipped, Medicare billed
- April 14, 2025, 7th Cir reversed Sorensen’s conviction
 - Insufficient evidence that Payees leveraged any influence or power over healthcare decisions
 - 80% of prescriptions never signed
 - Court Concluded: “[while] physicians and nonphysicians may exert formal or informal influence on patient’s choice of health care providers” that was not the case in this instance as the physicians clearly retained independent decision-making authority over patient care.

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AKS: Corruption Element/Inducement



- A series of cases brought by drug manufacturers and pharmaceutical coalitions have argued that patient assistance programs should not be held to violate the AKS absent a showing of **corrupt intent**
- All of these cases start with an advisory opinion request
 - The OIG issues a negative opinion and the requestor sues in Federal Court challenging the OIG’s interpretation of the law
 - Two cases the courts have sided with the Government
 - Pfizer v. HHS (2nd Cir, July 25, 2022)
 - Pharmaceutical Coalition for Patient Access (4th Cir Jan 23, 2025)
 - One case still pending
 - **Vertex Pharmaceuticals v. HHS–**
 - Vertex sought Advisory Opinion that its patient assistance program did not induce purchase or ordering of its drugs-- OIG orally disagreed
 - D.C. District Court upheld OIG’s interpretation on March 31, 2025 – Vertex Appealing

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AKS Discount Safe Harbor

- December 2024, Kansas District Court issued an opinion with a detailed analysis of the discount safe harbor and statutory exception to the Anti-Kickback Statute
 - ***United States ex rel Schroeder v. Hutchinson Regional Medical Center et al***, Case No. 2:2017-cv-02050 (D. Kan)
- Safe Harbor and Exception provide independent grounds for protection
- District Court's order addresses the provision on no-charge devices, device bundling, required seller documentation, and required reporting of discounts by a cost-reporting purchaser



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60-Day Rule: The Statute



Providers, suppliers, Medicaid MCOs, MAOs, and PDP sponsors that receive an **overpayment** must report and return it and provide notice of the reason for the overpayment to the agency or appropriate contractor



Overpayment = "any funds that a person receives or retains under Title XVIII (Medicare) or Title XIX (Medicaid) to which the person, after applicable reconciliation, is not entitled under such title"



Deadline for reporting and returning:

- 60 days after the overpayment was identified for claims; or
- The date any corresponding cost report is due, if applicable

204

60-Day Rule: Updated Regulations

- Eliminated the reasonable diligence and quantification standards and replaced them with the FCA scienter standard - an overpayment is identified if a provider or supplier has actual knowledge, acts in deliberate ignorance, or acts in reckless disregard of the overpayment.
- Regulations now state repayment of an identified overpayment can be suspended for up to 180 days to allow provider/supplier to complete a good faith investigation of related overpayments and submit a combined refund.
 - Previous commentary suggesting that complex investigations may extend beyond 6 months was eliminated, but consider when an overpayment is identified in complex investigations like a potential Stark Law violation
- Abandoned proactive compliance activity standard from 2016 preamble focusing instead on FCA scienter standard.



205

OIG Advisory Opinions (07/24 – 06/25)

Life Sciences

- Proposed arrangements involved pharmaceutical manufacturers, a publicly-traded biotechnology company, and a manufacturer of a medical device-based therapy.
- Two favorable opinions ([24-05 \(split opinion\)](#), [24-13](#)) – Financial assistance for transportation, lodging, and meals to patients and caregivers relating to patients' receipt of cell, tissue, and/or gene therapies.
- Two unfavorable opinions ([24-06](#), [24-05 \(split opinion\)](#)) – Fertility services for patients receiving gene therapies. OIG acknowledged that, while these therapies hold significant promise to improve health outcomes, OIG currently lacks sufficient data to assess their fraud and abuse risk to issue favorable opinions.

206

OIG Advisory Opinions
(07/24 – 06/25)

Life Sciences (cont.)

- [24-12](#) – Approving a pharmaceutical manufacturer’s sponsorship of a program that includes genetic testing, genetic counseling, and disease-state awareness education relating to an ultra-rare genetic condition, despite no available safe harbor or Beneficiary Inducement CMP exception available.
- [25-04](#) – Disapproving a medical device company’s proposal to pay the costs its customers would otherwise incur for a third-party to screen and monitor the medical device company for exclusion from Federal health care programs and to ensure compliance with other legal requirements.

207

OIG Advisory Opinions
(07/24 – 06/25)

Life Sciences (cont.)



Free Drugs and Vaccines!

- [24-11](#) – Approving a pharmaceutical manufacturer’s proposal to provide **free meningococcal vaccines** to patients prescribed a drug that treats rare disorders but significantly increases the risk of serious and life-threatening meningococcal infections in patients treated with the drug.
- [25-01](#) – Approving a pharmaceutical manufacturer’s provision of **free access to a drug** to patients meeting financial, among other, eligibility criteria and that do not have adequate coverage (including under Medicare) for the drug, despite no applicable safe harbor. OIG also noted that the provision of the free drug does not even implicate the Beneficiary Inducements CMP because a pharmaceutical manufacturer was the offeror.

208

OIG Advisory Opinions
(07/24 – 06/25)

Patient Assistance Programs (a/k/a PAPs)

- OIG has long recognized that PAPs can provide important safety net assistance to patients, especially patients who cannot afford their cost-sharing obligations for prescription drugs.
 - See, e.g., [24-02](#).
- [24-07](#) is yet another favorable advisory opinion relating to proposed PAPs operated by non-profit organizations.

209

OIG Advisory Opinions
(07/24 – 06/25)

Others

- [24-08](#) – Disapproving a proposal by a company that contracts with CMS to offer Parts C and D and Employer Group Waiver Plans to share a percentage of its savings with certain groups to which it provides coverage through Employer Group Waiver Plans.
- [24-09](#) – Approving a municipal corporation's proposal to begin billing patients' health insurance plans and waiving any patient cost-sharing amounts for treatment-in-place emergency medical service without any associated ambulance transport when the municipal corporation has historically not done so.

210

OIG Advisory Opinions
(07/24 – 06/25)

Others (cont.)

- [24-10](#) – Approving a global distributor of medical and dental supplies' proposal to expand its customer loyalty program to allow program members to earn points from qualifying purchases that can be used towards future purchases from the distributors' subsidiaries, despite the proposal not fitting squarely into the discount safe harbor.
 - See also [19-06](#) – Approving a supermarket's proposal to expand its customer loyalty program to allow customers to earn rewards points on out-of-pocket costs paid for pharmacy purchases.

211

OIG Advisory Opinions
(07/24 – 06/25)

Others (cont.)

- [25-02](#) – Approving a community health center's (created under Section 330 of the Public Health Act) proposal to identify individuals needing primary care services during their receipt of social services, informing such individuals about the availability of the primary care services, and scheduling services at the community health center or referring them elsewhere.
- [25-03](#) – Approving a proposal for an MSO and an affiliated PC to enter into an arrangement with telehealth providers to lease employees and to provide certain administrative services.

212

Self-Disclosure Resolutions (7/24 – 6/25)

Health Care Fraud Self-Disclosures: \$41.4M

- **Kadlec Regional Medical Center** – Paid **\$8.9M** to resolve allegations that it submitted claims for inpatient hospital stays that did not meet coverage criteria under the two-midnight rule and for intravenous hydration administration for hospital outpatients in the ED that did not meet coverage criteria.
- **Capital Cardiology Associates** – Paid **\$2.8M** to resolve allegations that it falsely represented the rendering provider on claims to Federal health care programs when the services were performed by non-enrolled providers.

HHS Grant and Contractor Fraud Self-Disclosures

- **Altarum Institute** – Paid **\$262,000** to resolve allegations that its former employee reported inaccurate time and effort spent working on Agency for Healthcare Research and Quality awards and falsely documented clinic interaction data for use in an evaluation study.



213

Affirmative CMPs and Exclusions (7/24 – 6/25)

Affirmative CMPs: \$6.6M

- 10 EMTALA resolutions – **\$1.6M** Total Settlement Amounts
- Hospitals and physicians allegedly failed to provide appropriate medical screening and stabilizing treatment and to accept appropriate transfers.

Affirmative Exclusions

- 11 individuals and entities – **167** Total Years
- **Assure Neuromonitoring, Assure Holdings, and Alex De Jesus, MD**, all defaulted on their payment obligations under a settlement agreement with the Federal government and, thus, have been excluded until such default is resolved.



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Health Care Liability and Litigation

**June 30, 2025
Kim Harvey Looney
K&L Gates LLP**

Thank You to the AHLA Year In Review Health Care Liability and Litigation Topic Team:

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Sahar Tirmizi, Epstein Becker Green



States Fight Back Against HHS

Numerous states are pushing back against U.S. Department of Health and Human Services (HHS) agency restructuring that threatens \$11 billion for public health efforts related to infectious diseases and vaccines.

State of Colorado et al. v. U.S. Dep't of Health and Human Services, D.R.I., No. 1:25-cv-00121



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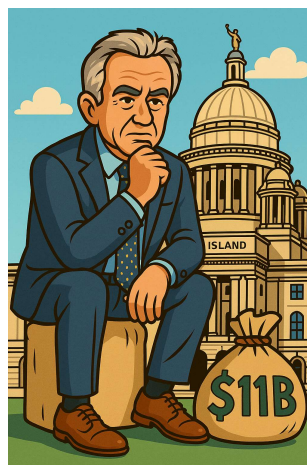
A similar, concurrent case has been filed in D.C. to stay the federal funding freezes.



217

Question Presented

Did HHS violate the Administrative Procedure Act when it terminated \$11 billion of public health funding that was originally appropriated during the COVID-19 pandemic but has since been repurposed for immunization access, infectious disease tracking, and emergency preparedness?



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Factual and Procedural Background

- HHS awarded the public health grants during the COVID-19 pandemic. It terminated the grants this year and claimed that, since the pandemic is over, there is no longer a need to distribute the funds.
- 23 states and the District of Columbia are suing HHS to distribute the \$11 billion in public health funds.

April 1, 2025

States file in the U.S. District Court for the District of Rhode Island to halt HHS's funding freeze on public health grants. The states claim the funds were arbitrarily frozen.

April 3, 2025

District Court Judge Mary McElroy grants a temporary block on the freezes and finds a strong likelihood of success on the merits, irreparable harm, and the balance of equities and public interest favoring the states.

May 16, 2025

After a more extensive review of the record and preliminary hearings, Judge McElroy extends the temporary injunction.



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Why It Matters



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- If the \$11 billion of public health funding is cut, states will struggle to fund programs that track infectious disease, ensure access to vaccines, strengthen emergency preparedness, and provide mental health and substance abuse services.
- This implicates downstream impacts on vaccine manufacturers, health providers, and the state health departments.



220

Opioid Crisis: The Sackler Family Bankruptcy Saga UPDATE



Sackler Family, Purdue Pharma Propose New \$7.4B Agreement

- June 2024: U.S. Supreme Court overrules bankruptcy settlement deal involving Purdue Pharma and Sackler family
 - Why: Did not want Sackler family to get immunity from opioid lawsuits without filing for bankruptcy themselves, at least against claimants who had not agreed to settle with them
- New settlement offer: 7.4B
 - Sackler – \$6.5B over 15 years
 - Purdue - \$900M up front
- 55 states and territories agreed to settle
- Sackler's ownership of Purdue ended and barred from making, selling, or marketing drugs in the U.S.
- Funds to support opioid addiction treatment, prevention and recovery programs over next 15 years

Health Care Entities Eliminating DEI Face Greater Risk of Civil Rights Lawsuits Under ACA's Sec. 1557 or Title VII

While the Trump administration threatens to withdraw federal funding and launch investigations into health care entities, **little about the law concerning diversity, equity, and inclusion (DEI) has changed yet.**

In response, health care institutions are renaming, eliminating, or ramping up their DEI programs.

Elimination could lead to increased legal risk. Common civil rights lawsuits allege sex or race discrimination under Title VII of the Civil Rights Act of 1964 ("Title VII") for health care employees or the Affordable Care Act's (ACA's) Sec. 1557 for patients. There is also risk under the False Claims Act for entities that fail to comply with Trump's Executive Order.



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Compounding of GLP-1 Drugs

- There has been a large increase in patients and providers turning to unapproved versions of GLP-1 drugs for weight loss.
- The Food and Drug Administration (FDA) does not review these drugs for safety, effectiveness, or quality before they are marketed.
- Risks of using compounded drugs:
 - Drug quality problems
 - Contamination
 - Too little or too much active ingredient
 - Patient injury or death
 - Civil and criminal liability for the pharmacy (e.g., the New England Compounding Center meningitis outbreak)
- FDA concerns with compounded GLP-1 drugs:
 - Multiple reports of adverse events related to dosing errors
 - Over 392 reports with compounded semaglutide
 - Over 215 reports with compounded tirzepatide
 - Salt forms of drugs
 - Illegally marketed versions of the drugs



Disclaimer: AI-Generated Image

The Battle over GLP-1 Drugs



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Drug Manufacturers vs. Pharmacists

- Drugmakers could not keep up with the demand for obesity drugs, so compounding pharmacies began creating their own versions of the drugs in 2022.
- Drugs can only be compounded if they are on the FDA's shortage list.
- In the summer of 2024, many drug manufacturers, including Eli Lilly, declared that their drugs are no longer in short supply.
- The FDA agreed and removed these drugs from the shortage list in the fourth quarter of 2024.
- In late 2024, the Outsourcing Facilities Association (OFA), a group of large-scale compounders, sued the FDA for removing these drugs from the shortage list, claiming they are still in short supply.
- Eli Lilly joined the OFA lawsuit on January 2, 2025, claiming it could not rely fully on the FDA to defend its interests in this case.
- This case will be the first step in determining whether compounding pharmacies can continue to manufacture and sell compounded obesity drugs in the United States.
- FDA determined that the semaglutide injection shortage ended on February 21, 2025, but that FDA would not take action against state-licensed pharmacy of physician compounding until April 22, 2025 and outsourcing facilities until May 22, 2025.



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ANDA Process: an Epinephrin Case Study

Regulatory Background

- Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C. § 355(j)) allows the submission of an **Abbreviated New Drug Application (ANDA)** to market a generic version of a previously approved drug product.
- An ANDA must show that the new generic drug:
 - has the same active ingredient(s), dosage form, route, strength, and conditions of use as the brand-name drug; and
 - is bioequivalent to the listed (reference) drug.
- ANDA applicants do not need to repeat full clinical trials required for new drug applications (NDAs).
- Section 505(j)(7) requires the FDA to maintain a list of approved drugs, published in the **Orange Book**.
- A drug is **removed from the Orange Book** if it was withdrawn for reasons related to safety or effectiveness.



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Epinephrin Case Study: Regulatory Actions Timeline

- **July 29, 2014:** NDA 205029 is approved for epinephrine 1 mg/mL IV prefilled syringe held by BPI Labs, LLC.
- **May 29, 2024:** BPI Labs informs the FDA it was discontinuing the product. The FDA moves the product to the "Discontinued Drug Product List" in the Orange Book.
- **March 29, 2025:** Alembic Pharmaceuticals Ltd. submits a citizen petition on (Docket No. FDA-2025-P-1021).
- **March 29 – June 2, 2025:** The FDA reviews the petition under 21 CFR § 10.30.
- **June 2:** The product was **not withdrawn for safety or effectiveness reasons**.
- If the product meets regulatory requirements, the FDA may not withdraw approval of this ANDA product, and other like-ANDAs may be approved.



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U.S. Supreme Court Addresses State Restrictions on Health Care for Transgender Persons



United States v. Skrmetti, No. 23-477,
2025 WL 1698785 (U.S. June 18, 2025)

Question Presented

Does a Tennessee bill prohibiting all medical treatments intended to allow “a minor to identify with, or live as, a purported identity inconsistent with the minor’s sex” or to treat “purported discomfort or distress from a discordance between the minor’s sex and asserted identity,” violate the equal protection clause of the 14th Amendment?



Factual Background

- A Tennessee law, known as SB1, prohibits doctors from prescribing puberty blockers and hormone therapy to affirm the gender identity of transgender teens, but allows those same treatments for other purposes.
- The bill also prohibits doctors from performing surgery to affirm the gender identity of transgender teens, an issue that the U.S. Supreme Court (SCOTUS) did not take up.
- Tennessee has defended the law by arguing that it is exercising its power to regulate the practice of medicine for all youth, without distinguishing based on a patient's sex.
- Three transgender teenagers and their parents filed suit, arguing that the law violates the equal protection clause of the 14th Amendment.

Timeline of Updates

■ August 27, 2024

The parties file their briefs.

■ September 3, 2024

Many amicus briefs are filed supporting the parties' petitions, including those from California and 20 other states, the American Psychological Association, the American Bar Association, the NAACP, various anti-LGBTQ groups, and others.

■ December 4, 2024

SCOTUS hears oral arguments.

Timeline of Updates (cont.)

■ February 7, 2025

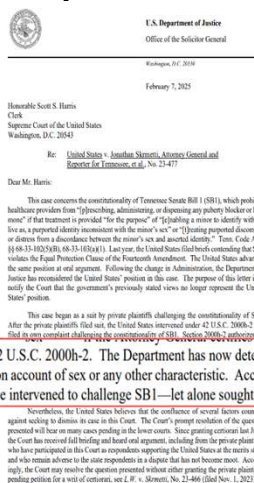
The U.S. Department of Justice (DOJ) under the Trump administration files a letter with SCOTUS reversing the position taken in its briefing. DOJ did not request dismissal of the case.

■ June 18, 2025

SCOTUS upholds Tennessee's ban on gender-affirming care for transgender youth.

Key takeaways:

- The majority wrote: "We afford States wide discretion to pass legislation in areas where there is medical and scientific uncertainty. The fact the line might have been drawn differently at some points is a matter for legislative, rather than judicial, consideration."
- The majority declined to rule on whether transgender status is a protected class.



CMS Rescinds Biden-Era Guidance on Emergency Abortions

- **Rescinded Biden-era memorandum:**
As of May 29, 2025, the Centers for Medicare & Medicaid Services (CMS) has withdrawn its July 11, 2022, guidance directing emergency departments to provide abortions as stabilizing treatment under the Emergency Medical Treatment and Labor Act (EMTALA), regardless of state abortion ban.
- **New administration stance:** The current CMS stated the prior guidance “do[es] not reflect the policy of this Administration.”
- **Side effects:** Though EMTALA itself remains in force, the Center for Reproductive Rights warns that the guidance will exacerbate existing confusion amongst practitioners in states with abortion bans.



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State Ban on Transgender Youth Medical Care

June 18, 2025 WASHINGTON – An ideologically divided [Supreme Court](#) upheld [Tennessee’s ban on gender-affirming care](#) for minors. The court’s six conservative justices upheld the ban, and the three liberals dissented



CNN · 1h · on MSN

Supreme Court upholds Tennessee’s ban on gender-affirming care for trans...



Roll Call · 1h

Supreme Court upholds Tennessee youth transgender care ban



AP NEWS · 2h · on MSN

Supreme Court upholds Tennessee’s ban on gender-affirming care for minors, a...



The Boston Globe · 2h

Supreme Court upholds Tenn. ban on gender-affirming care for...



Access to Care in the Courts

Supreme Court Hears Case on Youth Transgender Care

The court's conservative majority seems poised to uphold Tennessee's ban on gender-affirming medical treatments for minors.

The case is a challenge to a Tennessee law that bans gender-affirming medical treatments for transgender adolescents

HHS Facing New Challenge To Federal Rule Prohibiting Health Care Discrimination Against Transgender People

[Bloomberg Law](#) (5/31) "The Department of Health and Human Services is facing a new legal challenge from 15 states over a federal rule prohibiting health-care discrimination against transgender people." The lawsuit "joins two others filed in recent weeks over the HHS' rule on Section 1557 of the Affordable Care Act.

On Friday April 26, 2024, OCR issued a final rule under Section 1557 of the Affordable Care Act (ACA) **advancing protections against discrimination in health care.** [Section 1557 of the Patient Protection and Affordable Care Act | HHS.gov](#)

Gender-affirming care – US Supreme Court to assess requests for certiorari (May 2024)

Three cases involve constitutional challenges brought against state prohibitions on providing gender-affirming care to minors: [United States v. Skrmetti, L. W. v. Skrmetti](#), and [Jane Doe 1 v. Kentucky ex rel. Cameron](#). Last year, Tennessee and Kentucky were among a group of more than 20 states that enacted laws that prohibit giving transgender youths under the age of 18 medical treatment to align their appearance with their gender identity. [Restrictions on gender-affirming medical care – and assault weapons – SCOTUSblog](#)

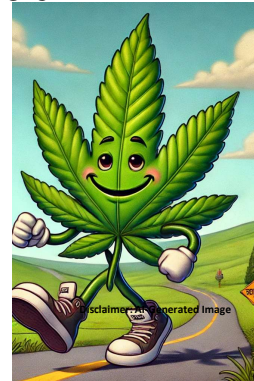


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Marijuana Reclassification A Long and Winding Road...

Since 1970, marijuana has been classified as a Schedule I drug, meaning it is considered to have no acceptable medical use and the highest potential for misuse. This classification has posed a barrier to medical use and research studies, because Schedule I drugs have restrictive regulations on storage, security, and reporting that make creating effective studies more difficult.

Advocates have been pushing for its reclassification for years, and the Biden administration began a process in 2024 to reschedule marijuana to a Schedule III drug.



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Marijuana Reclassification – What’s Next?

However, that process was halted in January 2025 when an Administrative Law Judge granted some parties leave to file an interlocutory appeal challenging the refusal to remove the Drug Enforcement Administration (DEA) as the proponent of the proposed rule to reschedule marijuana.

For now, the rescheduling process has halted. The hearings originally set for January 2025 were cancelled and have yet to be rescheduled.

There is no statutory deadline for the DEA to complete the rescheduling process, so the current pause could extend indefinitely.



Johnson & Johnson’s Rebate System Proposal Timeline



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August 23, 2024: Johnson & Johnson (J&J) announces its intention to move to a rebate pricing model for two of its drugs (Stelara and Xarelto) beginning in October 2024.

September 17, 2024: HRSA issues a letter stating that J&J’s rebate system would violate Section 340B(a)(1) of the Public Health Service Act.

September 19, 2024: J&J makes clear it would continue with the “unapproved rebate proposal for sales of certain covered outpatient drugs to particular covered entities.”

September 30, 2024: HRSA issues a final warning threatening to terminate J&J’s participation in the 340B Program and initiate a referral to the HHS Office of Inspector General if the rebate program were implemented.

- J&J dropped the implementation of rebate pricing the same day.

Response to the Rebate System Rejections

J&J filed a lawsuit on November 12, 2024, against HRSA, alleging that “HRSA’s attempts to bar J&J from bringing transparency to the 340B Program through implementation of the Rebate Model are fundamentally at odds with the 340B statute, the Administrative Procedure Act, and HRSA’s own stated program integrity goals.”

- *Johnson & Johnson Healthcare Sys. Inc. v. Becerra*, No. 1:24-cv-03188 (D.D.C. filed Nov. 12, 2024)

J&J asked the court to declare the HRSA letters purporting to bar the adoption of the rebate program unlawful, set them aside, and enjoin HRSA from commencing any enforcement action against J&J arising from the implementation of the rebate model.

- *This case is still ongoing.*

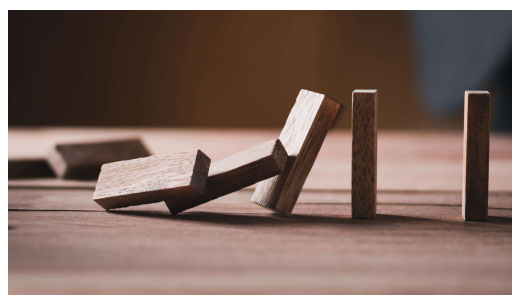


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Domino Effect

Other drug manufacturers have filed lawsuits on similar grounds, and HRSA has generally prevailed.

- Eli Lilly (*Eli Lilly & Co. v. Kennedy*, No. 24-cv-03220 (D.D.C. filed Nov. 14, 2024))
- Bristol Myers (*Bristol Myers Squibb Co. v. Kennedy*, No. 24-cv-03337 (D.D.C. filed Nov. 26, 2024))
- Sanofi (*Sanofi-Aventis U.S. LLC v. Kennedy*, No. 24-cv-0396 (D.D.C. filed Dec. 16, 2024))
- Novartis (*Novartis Pharm. Co. v. Kennedy*, No. 25-cv-00117 (D.C. Cir. Filed May 21, 2025))
- Kalderos (*Kalderos Inc. v. United States of America* No. 21-cv-02608 (D.D.C. filed October 6, 2021))



In a Memorandum Opinion, the D.C. District Court found that “HRSA did not act contrary to law by requiring the plaintiffs to obtain approval before implementing their proposed rebate models.” (*Eli Lilly & Co. v. Kennedy*, No. 1:24-cv-03220-DLF, ¶308,611 (D.D.C. May 15, 2025))



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SCOTUS to Address Planned Parenthood Medicaid Coverage



Medicaid

Kerr v. Planned Parenthood South Atlantic,
U.S. No. 21-1275 (cert. granted Dec. 18, 2024)

Question Presented

Does the Medicaid Act's
“any qualified provider”
provision unambiguously
confer a private right upon a
Medicaid beneficiary to
choose a specific provider?

In other words, may states
restrict Medicaid recipients
from choosing providers
who perform abortion care?



Statutory Background

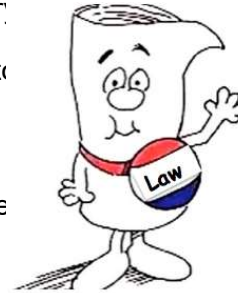
42 U.S.C. 1396-1: States create Medicaid plans and submit them to the HHS Secretary for approval and disbursement of funds.

42 U.S.C. 1396c: If the Secretary finds that a state has failed to “comply substantially” with the Medicaid Act’s requirements in the plan’s administration, the Secretary may withhold all or part of the state’s funds until “satisfied that there will no longer be any such failure to comply.”

42 U.S.C. 1396a(a)(23)(A): Plans “must” allow “any individual eligible for medical assistance” to obtain “assistance from any [provider] *qualified* to perform the service . . . who undertakes to provide” it.

- **42 U.S.C. 1396a(a)(4)(A), (39), (41), (77); 1396a(p); 1396a(kk)(8)(B)(ii)**
- **42 C.F.R. 1002.201; 1002.213**

S.C. Code Ann. Regs. 126-404; 126-1500: South Carolina gives Medicaid providers the right to a hearing before an exclusion, suspension, or termination decision and offers an administrative appeal to anyone “possessing a right to appeal.”



Factual Background

South Carolina deemed abortion clinics unqualified to provide family planning services, terminated their enrollment agreements, and denied future enrollment applications from them in 2018, following S.C. Code Ann. § 43-5-1185, which prohibits the use of funds to pay for abortions.

- The governor reasoned that “the payment of taxpayer funds to abortion clinics, for any purpose, results in the subsidy of abortion and the denial of the right to life.”

Planned Parenthood South Atlantic and Julie Edwards, a Medicaid client, sued in the District of South Carolina and subsequently moved for a preliminary injunction.

- *Planned Parenthood S. Atlantic v. Phillips*, No. 21-1043 (4th Cir. Mar. 29, 2021).



Decisions Below



The district court granted Edward's motion for a preliminary injunction and chose not to analyze Planned Parenthood's right to the same relief.

- The court held that § 1396a(a)(23)(A) *did* create a private right of action, enforceable through § 1983.

On appeal, the Fourth Circuit affirmed, holding that:

- (1) "Congress's intent to create an individual right enforceable under § 1983 in the free-choice-of provider provision is unambiguous," and
- (2) "the provision's mandate . . . bars states from excluding providers for reasons unrelated to professional competency."

South Carolina then asked SCOTUS to resolve the circuit split over "[w]hether Medicaid recipients have a private right of action . . . to challenge a state's determination that a specific provider is not qualified to provide certain medical services."

- While that petition was pending, the district court granted summary judgment to the plaintiffs and directed them to submit a draft order granting a permanent injunction.
- The district court permanently enjoined the director and his successors from "terminating or excluding" Planned Parenthood from South Carolina's Medicaid program based on its abortion activities.



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***Gonzaga University v. Doe*, 536 U.S. 273 (2002) & *Health & Hospital Corp. of Marion County v. Talevski*, 599 U.S. ____ (2023)**

Gonzaga: The 2002 decision holding that the creation of individual rights requires clear and unambiguous terms, which FERPA's confidentiality provisions did not contain:

- "Unless Congress speaks with a clear voice, and manifests an unambiguous intent to confer individual rights, federal funding provisions provide no basis for private enforcement by § 1983." 536 U.S. at 280.

Talevski: The 2023 decision in which SCOTUS held that courts are expected to "employ traditional tools of statutory construction" to decide whether a right has been unambiguously conferred. 599 U.S. at 183:

- All Justices agreed that there is a "demanding bar" and "significant hurdle" to find "rights-creating language." *Id.*

In *Medina v. Planned Parenthood*, South Carolina used the ambiguity created between *Gonzaga* and *Talevski*—in conjunction with older, conflicting cases that are still good law—to request "guidance on the appropriate test for determining whether a federal statute is privately enforceable under Section 1983."

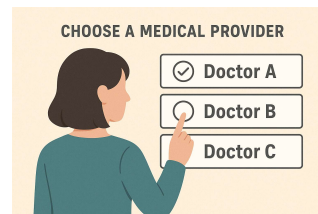
- Courts continue to apply the cases that were functionally overruled by these cases (*Blessing* and *Wilder*), leading the Sixth, Seventh, and Ninth Circuits to hold that the Medicaid Act's "any qualified provider" provision creates privately enforceable rights, while other circuits disagreed.



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SCOTUS Upholds Right to Enforce Medicaid's "Free Choice of Provider" Provision

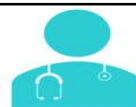
- **Return to District Court:** The case is remanded to the district court to determine if South Carolina's exclusion of Planned Parenthood complies with Medicaid's provider qualification rules.
- **Medicaid Rights Enforceable Under § 1983:** SCOTUS reaffirmed that Medicaid beneficiaries have a private right of action under 42 U.S.C. § 1983 to enforce the "free choice of provider" provision in Medicaid, reaffirming individual enforcement under Spending Clause programs.
- **Provider Exclusions:** States must base Medicaid provider exclusions on objective, federally recognized criteria (e.g., medical licensing, fraud), not on moral or political grounds.
- **Expanded Federal Oversight:** This decision enhances federal constraints on states' Medicaid authority, particularly limiting their ability to disqualify providers for lawful services such as abortion or gender-affirming care.
- **Broader Legal Impact:** The ruling increases legal vulnerability for state policies excluding providers based on ideology and deters exclusionary tactics by exposing states to potential § 1983 litigation.



§ 1983 Reaffirmed as Tool to Enforce Spending Clause Programs

Some Justices and commentators have questioned whether there is a private right of action under 42 U.S.C. § 1983 for Spending Clause statutes such as Medicaid. This decision indicates that when the statutory text is rights-creating, beneficiaries may sue.

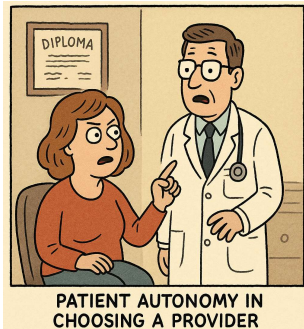
- Reinforces *Talevski's* trajectory: Federal spending statutes are not categorically exempt from private enforcement.
- Opens the possibility that other Medicaid provisions—such as access to EPSDT services, transportation, or timely processing—might be litigated under § 1983.
- Creates a doctrinal pathway for challenging state noncompliance in areas where CMS has been silent or inconsistent.



Structural Protection for Reproductive Health Providers

This ruling *does not constitutionalize a right to reproductive health care services*, but it does protect providers who offer certain legal reproductive services.

- Planned Parenthood and similar providers cannot be categorically excluded from Medicaid networks solely due to their association with abortion or controversial services.
- The ruling affirms that being a lawful provider is enough to trigger protection under the "any qualified provider" clause.
- The decision also prevents state defunding strategies that attempt to sidestep federal law by redefining "qualification" in pretextual ways.



Protection of patient autonomy: SCOTUS reinforced that the Medicaid “free choice of provider” provision safeguards beneficiaries’ right to choose trusted health care providers, making that choice judicially enforceable, not merely aspirational.

Emphasis on continuity of care: The decision highlights that preserving access to familiar providers is critical for effective care, particularly in sensitive areas such as reproductive, mental, and preventive health services.

Challenges to state waiver attempts: States such as Texas, Arkansas, Tennessee, and Missouri have sought to obtain Section 1115 waivers or use executive actions to exclude providers. This ruling undermines the validity of waivers based on ideological rather than clinical criteria.

Impact on federal oversight and CMS standards: The decision may prompt CMS to adopt stricter standards when evaluating state waiver requests to ensure compliance with federal Medicaid protections.

Broader health equity and access implications: The ruling affirms that Medicaid is a federally enforceable entitlement, not just a funding mechanism. It may have far-reaching effects in rural and underserved areas, where excluding even a single provider could mean losing all access to care.



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42 U.S.C. § 1983 Held as Inapplicable to Enforce Medicaid’s “Free Choice of Provider” Provision

Medicaid patients now lack the right to challenge a state’s exclusion of a provider in federal court via 42 U.S.C. § 1983.



States gain broad discretion

- States may now define “qualified provider” with minimal judicial oversight.
- Medicaid beneficiaries have no enforceable right to challenge exclusion decisions via 42 U.S.C. § 1983.

Impact on access to care

- Planned Parenthood and similar providers may be at risk of losing Medicaid funding or having to challenge qualified provider determinations.
- Millions of low-income patients, particularly reproductive-age women, may lose access to care.
- Preventative services such as cancer screenings, STI testing, and contraception are increasingly vulnerable to state-level exclusion decisions.



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Systemic Consequences and Legal Takeaways

Broader policy implications:

- The ruling opens the door for more states to exclude providers based on politics.
- CMS may face pressure to approve waivers excluding providers such as Planned Parenthood.
- Existing state efforts in Texas, Arkansas, Missouri, and others are now legally reinforced.

Provider and legal system impact:

- Patients can no longer sue to enforce Medicaid's free-choice provision with 42 U.S.C. § 1983 as their vehicle to do so.
- Providers face limited, state-controlled appeal processes with no federal remedy.
- The Medicaid statute's enforceability has been significantly narrowed.

Key takeaways for health lawyers:

- The *Medina* decision fundamentally reshapes Medicaid enforcement.
- States now hold extensive authority to define qualified providers, while patients and providers are left without meaningful legal recourse.
- This ruling sets a precedent with national implications for access, equity, and health system accountability.



251

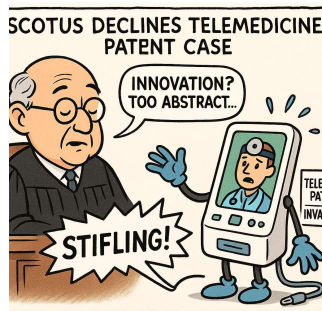
SCOTUS Declines to Revisit Telemedicine Patent Eligibility

Audio Evol. Diag. Inc. v. U.S. (No. 24-806)

Cert. denied 6/6/25

SCOTUS **denied** review of a Federal Circuit decision finding telemedicine patents invalid as “abstract ideas” under the *Alice* framework.

- AED sued the federal government, alleging infringement by telemedicine tools used at U.S. Department of Veterans Affairs facilities.
- Lower courts found patents in question **ineligible** under §101 of the Patent Act.



Disclaimer: AI-Generated Image



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Contested Legal Standards and Implications for Health Tech



Disclaimer: AI-Generated Image

AED argued its invention was **not** abstract, but a tangible, electronic diagnostic machine.

- AED warned that “ongoing confusion over” patent eligibility law has “**stifled innovation.**”

While the U.S. Solicitor General urged SCOTUS not to hear this case, he stated that if cert. were granted, the government would argue that the relevant claims **are** patent-eligible.

- The government still believes that uncertainty “has had deleterious consequences, and that clarification by this court would be useful.”

Digital health innovators will continue to face uncertainty and hurdles under §101 of the Patent Act.

Pressure mounts for Congress, the U.S. Patent and Trademark Office, and SCOTUS to clarify patent-eligibility standards.



253

CMS Withdraws Notice of Appeal



- UnitedHealth received a downgraded quality score
- UnitedHealth sued CMS claiming that its quality score was downgraded on an arbitrary and capricious assessment of how its call center handled a single phone call from a CMS test caller that lasted less than 10 minutes
- CMS ordered by U.S. District Court for Eastern District of Texas to recalculate UnitedHealthcare’s Star rating without consideration of disputed call
- CMS filed notice that it planned to appeal, and a few days later withdrew its notice to appeal
- **NOTE:** CMS is facing at least a half-dozen lawsuits over its 2025 Medicare Advantage star ratings. Alignment Healthcare filed a complaint Jan. 10 in federal court in Washington, D.C., alleging CMS and its contractors made “significant mistakes” in their handling of Alignment’s MA star ratings. Judge ruled against Florida Blue who sued arguing that CMS did not account for natural disasters in star ratings. Humana loses star rating appeal – April 15.



254

AIDS Organization Wins \$10M Antitrust Ruling against Prime Therapeutics

- Jan 17: Arbitrator determined Prime Therapeutics violated federal and state antitrust laws against AIDS Healthcare Foundation (AHF) and independent pharmacies
- AHF awarded more than \$10M and injunctive relief against Prime Therapeutics
- Prime Therapeutics engaged in horizontal price fixing with Cigna's pharmacy benefit manager (PBM), Express Scripts

NOTE: *Prime is a PBM owned by BCBS state plans with more than 20 million patients in its network affected by the collaboration*

Aronstein v. Kenvue



Aronstein v. Kenvue

- Class action brought in District Court in New Jersey by Plaintiff on behalf of consumers who purchased certain Band-Aid Bandages products for personal care purposes
- Johnson and Johnson and spinoff Kenvue key players for over 100 years in global bandages market
- Consistently market safety, quality and ongoing evaluation to ensure products manufactured with the highest standards and comply with most discerning regulatory standards
- Plaintiffs allege PFAs “forever chemicals” notorious for having adverse effects on humans and environment, are present in unsafe amounts in Band-Aid brand adhesive bandages
- Class members have suffered and will continue to suffer serious injury as result of Defendants’ failures
- January 22, 2025: Judge Michael Shipp of U.S. District Court for the District of New Jersey appointed E. Powell Miller as Interim Co-Lead Class Counsel



257

Amazon One Medical

- Amazon acquired One Medical (founded in 2005) for \$4B in February 2023
- 45-year-old began coughing up blood and was short of breath, with feet turning blue
- Video consultation with clinician at Amazon One Medical
- Advised to buy an inhaler
- Hours later collapsed and died in ER
- Allegation that Amazon should have recognized patient needed ER care
- Accused of lacking “adequately trained and qualified staff,” resulting in care that was “careless, reckless and negligent”



258

United Health Settlements

- Minnesota judge gave preliminary approval Jan 24 to UnitedHealth's agreement to pay \$69M to settle a class-action lawsuit alleging company prioritized its business relationship with Wells Fargo over concerns its 401(k) plan contained low-performing target-date funds
- Settlement reached Jan. 21 in Massachusetts to resolve 3 proposed class action lawsuits from members alleging that insurer wrongfully denied coverage for a specialized cancer treatment that plaintiff's claim is more effective but significantly more expensive than traditional radiation therapy
- Change Healthcare and BCBS of North Carolina agreed to pay \$1.7M on Jan. 2 to settle a class action lawsuit accusing them of using automated technology to send voice messages to individuals without their consent
- Settlement reached with U.S. DOL in October over allegations that it improperly denied claims for emergency room visits and urinary drug screenings for thousands of patients




259

TeamHealth Physicians Sue BCBS Texas

- Jan. 24: 3 TeamHealth-affiliated physician groups filed a lawsuit against BCBS of Texas, alleging that insurer breached its contract by improperly reducing reimbursements for emergency services.
- Plaintiffs claim BCBSTX implemented a new coding policy without proper notice, leading to significant financial losses
- BCBSTX introduced an "Emergency Department Evaluation and Management Services Coding Policy," effective October 2023, which allegedly allowed BCBSTX to review and potentially downgrade level of service billed resulting in lower reimbursements
- Providers allege 30 day notice not given, as required by contract; policy invalid and unenforceable, & violates ERISA (seeking \$4M in damages)



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Regulation, Accreditation, and Payment (including Medicare and Medicaid)



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Regulation & Payment Topic Team:

- Caitlin Forsyth, Davis Wright Tremaine
- Jeff Davis, Bass, Berry & Sims



262

On the horizon.... Medicaid Cuts?

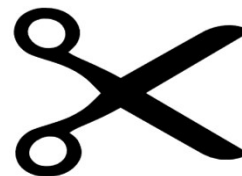
- According to updated Congressional Budget Office (CBO) cost estimates of the House's version of the "One Big Beautiful Bill Act", the Bill would cut gross Medicaid and CHIP spending by **\$863.4 billion** over the next ten years—Senate version of BBB proposes even higher cuts
- Separate updated CBO coverage estimates of the House-passed bill find that the Medicaid and CHIP provisions of the Bill would increase the number of uninsured individuals by 7.8 million by 2034.
- This does not include the impact of the ACA marketplace cuts included in both the House Energy and Commerce Committee and House Ways and Means Committee sections of the bill which would together increase the number of uninsured people by another 3.6 million in 2034.
- Because of interactions between different titles of the bill, CBO estimates find that the number of uninsured individuals overall would increase by a net 10.9 million in 2034.
- BUT: Senate Parliamentarian rejects some provisions of BBB



Georgetown University School of Public Policy, Center for Children and Families - <https://ccf.georgetown.edu/2025/05/27/medicaid-and-chip-cuts-in-the-house-passed-reconciliation-bill-explained/>

263

Cuts to Section 1115 Waiver Programs

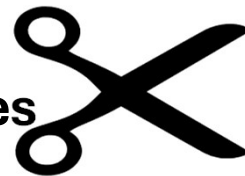


- On April 10, 2025, CMS issued a letter to State Medicaid Directors announcing its intention to not approve new or extend existing requests for federal matching funds for state expenditures for designated state health programs (DSHP) and designated state investment programs (DSIP), because "these programs were funded entirely without federal Medicaid funds prior to those approvals, and the addition of federal Medicaid funding does not render these programs as integral components of section 1115 demonstration programs."
- Examples given in the CMS letter of state programs deemed not "a prudent financial investment," by the federal government include one state's "grants to a labor union for the purpose of reducing the cost of providing health insurance, dental and vision benefits to certain childcare providers," and another state's funding of "a telehealth infrastructure grant program for healthcare providers to purchase equipment, high-speed internet access, and other infrastructure."

<https://www.medicaid.gov/resources-for-states/downloads/dshp-dsip.pdf>

264

CMS Proposed Rule on State Medicaid Taxes



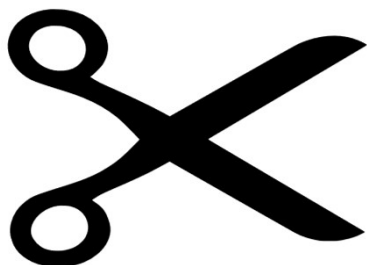
- On May 15, 2025, CMS released a proposed rule - “Preserving Medicaid Funding for Vulnerable Populations – Closing a Health Care-Related Tax Loophole.”
- CMS states that these arrangements allow states to benefit from a budget surplus to reinvest in unrelated programs—including the \$8.5 billion program in California to cover more than 1.6 million undocumented individuals.
- The proposed rule “is intended to address a loophole in a regulatory statistical test applied to State proposals for Medicaid tax waivers. The test is designed to ensure, as required by statute, that non-uniform or non-broad-based health care-related taxes, authorized under a waiver, are generally redistributive. The inadvertent loophole currently allows some health care-related taxes, especially taxes on managed care organizations, to be imposed at higher tax rates on Medicaid taxable units than non-Medicaid taxable units, contrary to statutory and regulatory intent for health care-related taxes to be generally redistributive.”

<https://www.federalregister.gov/documents/2025/05/15/2025-08566/medicaid-program-preserving-medicaid-funding-for-vulnerable-populations-closing-a-health>

<https://www.cms.gov/newsroom/press-releases/cms-moves-shut-down-medicaid-loophole-protects-vulnerable-americans-saves-billions>

265

2025 MPFS – 5th Year of Cuts



- CMS finalized a 2.83% reduction in the 2025 Medicare Physician Fee Schedule.
- Combined with CMS’s estimate that the costs of practice expenses will rise by 3.6% in 2025, physicians will see an effective cut in Medicare physician payment of 6.4%.
- The 2.8% cut went into effect on January 1, 2025.
- On January 31, a bipartisan group of 10 House members reintroduced a bill – The Medicare Patient Access and Practice Stabilization Act - to cancel the 2.83% cut and introduce a 2% increase. Senate introduced similar bill in June --- outcome unclear.
 - *Medicare payment rates have fallen by 29% over the last two decades, when adjusting for the costs of running a practice*
- **BBB** House version: proposes annual increases tied to MEI (Medicare Economic Index)—a measure of inflation in medical practice costs

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2025 MPFS – Caregiver Training

- New coding and payment for caregiver training for direct care services and supports.
- Topics of training could include techniques to prevent decubitus ulcer formation, wound dressing changes, infection control, special diet preparation, and medication administration.
- Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and support would focus on specific clinical skills (e.g., changing wound dressings). Training in these clinical skills would not fall into the categories of caregiver training services codes that currently exist.



267

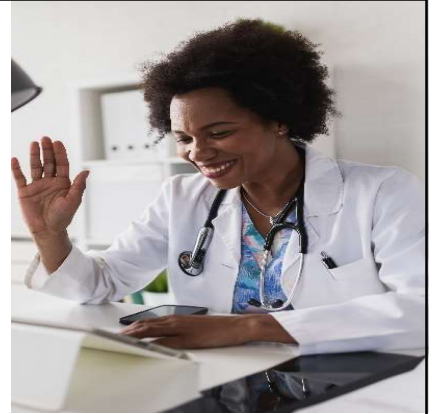
2025 MPFS - Telehealth

- Beginning January 1, 2025, an interactive telecommunications system may include two-way, real-time **audio-only communication** technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system, but the patient is not capable of, or does not consent to, the use of video technology.
- Through CY 2025, distant site practitioners will be permitted to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

268

Telehealth Originating Site Flexibilities Extended by Congress Through September 30

- Medicare Part B pays for **covered telehealth services included on the telehealth list** when furnished through an **interactive telecommunications system** and provided by an **eligible professional** to a patient at an **eligible originating site**.
- Originating site requirements were waived during the COVID-19 PHE but were set to go back into effect January 1, 2025. Section 2207 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended many of the COVID-19 telehealth flexibilities (including originating site flexibilities) through September 30, 2025.
- Absent further congressional action, effective October 1, 2025, eligible originating sites for telehealth services will be physician offices, hospitals, rural health clinics and other health care provider settings. The patient's home will be an eligible originating site only for limited types of services (e.g., home dialysis, treatment of a substance use disorder, treatment for a mental health disorder).



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2025 MPFS – Direct Supervision Using Live Video

Under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or other practitioner. Direct supervision requires the physician (or other supervising practitioner) to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service.

During the COVID-19 PHE, CMS changed the definition of "direct supervision" to allow a supervising practitioner to be immediately available through real-time audio/video technology. This definition was extended through 2024.

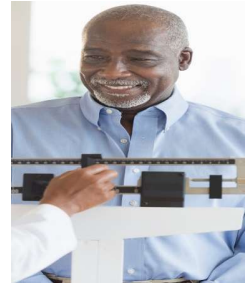
CMS extended the definition of "direct supervision" to include audio-visual communications technology through 2025.

270

2025 MPFS –

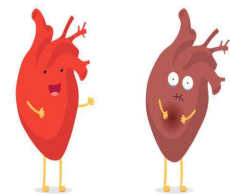
- **Advanced Primary Care Management**

- Established coding and payment under the PFS for a new set of APCM services described by HCPCS codes G0556, G0557 and G0558.
- APCM services combine elements of several existing care management and communication technology-based services. Communication technology-based services include virtual check-ins, remote evaluations of pre-recorded patient information and interprofessional consultations.
- Unlike existing care management codes, billing the new APCM codes will not require providers to meet and document time-based thresholds.



- **Cardiovascular Risk Assessment & Management**

- The CMS Innovation Center tested the Million Hearts® Model, which coupled payments for cardiovascular risk assessment with cardiovascular care management. The Model was found to reduce the rate of death by lowering heart attacks and strokes amongst Medicare fee-for-service beneficiaries.
- To incorporate lessons learned, beginning with CY 2025, CMS will pay for an Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment service and risk management services. The ASCVD risk assessment would be performed in conjunction with an E/M visit when a practitioner identifies a patient at risk for CVD who does not have a diagnosis of CVD.
- CMS will also pay for ASCVD risk management services that include service elements related to the ABCS of CVD risk reduction (aspirin, blood pressure management, cholesterol management, smoking cessation), for beneficiaries at medium or high risk for CVD.



 AMERICAN HEALTH LAW ASSOCIATION

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2025 MPFS – Behavioral Health

- Established separate coding and payment under the PFS describing safety planning interventions for patients in crisis, including those with suicidal ideation or at risk of suicide or overdose. Would take the form of an add-on G-code that would be billed along with an E/M visit or psychotherapy service when safety planning interventions are personally performed by the billing practitioner in a variety of settings.
- Created a monthly billing code to that requires specific protocols in furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter.
- Created six G codes to be billed by practitioners in specialties whose covered services are limited by statute to services for the diagnosis and treatment of mental illness (including clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors) to mirror current interprofessional consultation CPT codes used by practitioners who are eligible to bill E/M visits.



272

2025 MPFS – PTA and OTA Supervision

- Finalized a regulatory change to permit general supervision of physical therapist assistants and occupational therapy assistants by PTs in private practice and OTs in private practice for all applicable physical and occupational therapy services.
- [CMS](#) – *This finalized change will give PTPPs and OTPPs more flexibility in meeting the needs of beneficiaries and safeguard patient access to medically necessary therapy services, including those experiencing challenges accessing these services in rural and underserved areas, and it will align with general supervision of PTAs and OTAs by PTs and OTs who work in institutional providers.*



273

2025 OPPS

- CMS finalized an update to OPPS payment rates of 2.9% for hospitals and ASCs that meet applicable quality reporting requirements.
- [American Hospital Association](#) - *Medicare's sustained and substantial underpayment of hospitals has stretched for almost two decades, and today's final outpatient rule only worsens this chronic problem. The agency's final increase of less than 3% for outpatient hospital services will make the provision of care, investments in the health care workforce, and addressing new challenges, such as cybersecurity threats, more difficult. These inadequate payments will have a negative impact on patient access to care, especially in rural and underserved communities nationwide.*



274

2025 IPPS

Finalized 2.9% increase in payment rates for general acute care hospitals paid under the IPPS that successfully participate in the Hospital Inpatient Quality Reporting (IQR) program and are meaningful electronic health record (EHR) users.

American Hospital Association – “CMS’ payment updates for hospitals will exacerbate the already unsustainable negative or break-even margins many hospitals are already operating under as they care for their patients. The AHA is deeply concerned about the impact these inadequate payments will have on patient access to care, especially in rural and underserved communities.”

Finalized proposal to change the severity designation of the seven ICD-10-CM diagnosis codes that describe inadequate housing and housing instability from non-complication or comorbidity to complication or comorbidity, based on the higher average resource costs of cases with these diagnosis codes compared to similar cases without these codes.

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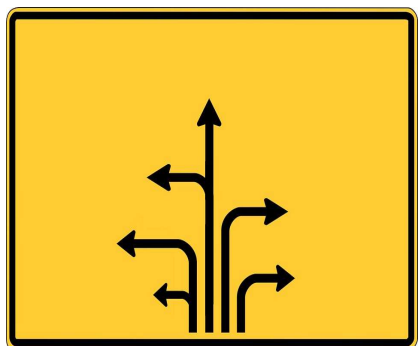
2026 Rulemaking Timeline

- 2026 MPFS
 - Proposed Rule Expected: July 2025
 - Final Rule Expected: November 2025
- 2026 OPFS
 - Proposed Rule Expected: July 2025
 - Final Rule Expected: November 2025
- 2026 IPPS
 - Proposed Rule Issued: April 2025
 - Comments Due: June 2025
 - Final Rule Expected: August 2025



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CMMI– New Direction



- Centers for Medicare & Medicaid Innovation (CMMI)
- New leader: Abe Sutton
- New Strategic Direction (announced May 2025)
 - Promote Evidence Based Prevention
 - Patient Empowerment
 - Drive Choice and Competition

277

CMMI: Changes to Model Portfolio



- On March 12 announcement: early termination of four models, not pursuing two previously-announced models, and reducing the size of awards under one model.
- Estimated savings of almost \$750 million by ending the selected models early.
- Models Identified to End Early (Original Performance Period)
 - Maryland Total Cost of Care (2019 – 2026)
 - Primary Care First (2021 – 2026)
 - ESRD Treatment Choices (2021 – 2027)
 - Making Care Primary (2024 – 2034)
- CMS is considering options to reduce the size of the Integrated Care for Kids awards (2020 – 2026)
- The CMS Innovation Center will no longer pursue two previously announced but not yet implemented models:
 - Medicare \$2 Drug List
 - Accelerating Clinical Evidence
- <https://www.cms.gov/newsroom/fact-sheets/cms-innovation-center-announces-model-portfolio-changes-better-protect-taxpayers-and-help-americans>

278

CMS Innovation Center – Transforming Maternal Health Model



- On December 15, 2023, CMS announced the new Transforming Maternal Health Model
- The Model will support participating state Medicaid agencies (SMAs) in the development of a whole-person approach to pregnancy, childbirth, and postpartum care.
- On January 6, 2025, CMS announced that 15 states have been selected to participate in the Model – Alabama, Arkansas, California, DC, Illinois, Kansas, Louisiana, Maine, Minnesota, Mississippi, New Jersey, Oklahoma, South Carolina, West Virginia and Wisconsin.
- Participating State Medicaid agencies will receive technical assistance to develop and implement the Model.
- In Model Year 3, state Medicaid agencies will use a portion of their funding to pay providers for care delivery transformation activities and data infrastructure.
- In Model Year 4, providers will be eligible for upside-only performance incentive payments. Anticipated performance measures include low-risk Cesarean delivery, timeliness of prenatal care, and screening for depression and follow-up.
- <https://www.cms.gov/files/document/tmah-payment-design-fs.pdf>

279

OIG – Need to “Monitor” Remote Patient Monitoring

- OIG issued report in September 2024 concluding that additional oversight of remote patient monitoring in Medicare is needed.
- Medicare broadly covers remote patient monitoring of health data for any chronic or acute condition.
- OIG’s findings demonstrate the need for additional oversight to ensure that remote patient monitoring is being used and billed appropriately.
- The use of remote patient monitoring in Medicare increased dramatically from 2019 to 2022. About 43 percent of enrollees who received remote patient monitoring did not receive all 3 components of it, raising questions about whether the monitoring is being used as intended.
- Medicare lacks key information for oversight, including who ordered the monitoring for the enrollee.



<https://oig.hhs.gov/documents/evaluation/10001/OEI-02-23-00260.pdf>

280

Supreme Court Ruling on DSH Calculations



- Congress provides several “hospital-specific rate adjustments” under the Medicare program, including the “disproportionate share hospital” (DSH) adjustment. The DSH provides enhanced Medicare payments to hospitals that serve an unusually high percentage of low-income patients.
- On April 29, 2025, the Supreme Court decided ***Advocate Christ Medical Center v. Kennedy***, which addressed the Medicare fraction’s numerator in the DSH formula, which counts “ ‘the number of patient days attributable to Medicare patients who are poor’ — i.e., those Medicare patients who are entitled to SSI benefits under subchapter XVI.
- SCOTUS held that for purposes of calculating the Medicare fraction in the formula for the DSH adjustment, an individual is entitled to SSI benefits when they are eligible to receive cash payment during the month of their hospitalization.
- The petitioners (which included more than 200 hospitals) argued that all patients who are enrolled in SSI during their hospitalization should be included in the DSH calculations.

281

9th Circuit Strikes Down Wage Index Adjustment

- Hospitals filed suit against HHS, claiming that HHS’s low wage index policy, which boosted wage index and thereby increased Medicare rates for lower-wage hospitals and reduced rates for all hospitals by a small percentage to maintain budget neutrality violated Medicare statutes.
- **Background** - *In 2020, the Secretary tinkered with the wage index by inflating the Medicare payment rates for the lowest quartile of hospitals—and paid for it by reducing payments to all the hospitals by a small percentage. The Secretary believed that boosting the wage index (and thus the payment rate) for lower-wage hospitals would help them recruit and retain medical staff in lower-income, and often rural, communities.*
- On December 11, 2024, Ninth Circuit held that low wage index policy violated Medicare statute’s wage index provision, and that policy was not allowed under Medicare statute’s exceptions and adjustments provision.
- *While the Secretary may have had a laudable goal in tilting the wage index in favor of the lower-wage hospitals, Congress did not empower him to do so. And under our system of separation of powers, neither good intentions nor pressing policy problems can substitute for an agency’s lack of statutory authority to act.*

Kaweah Delta Health Care District v. Becerra, 123 F.4th 939

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OPPS Payments for 340B Drugs



- April 15, 2025, Executive Order directed CMS to survey hospital drug acquisition costs and consider reducing Medicare Part B payments to hospitals based on survey data
- Question of whether CMS will attempt to reinstate payment reduction to hospitals for 340B drugs in place from 2018-2023
- In *AHA v. Becerra* (2022), the Supreme Court vacated the payment cuts on procedural grounds because CMS did not base the cuts on survey data

283

HHS Administration of 340B Program

- White House budget proposal released May 2025 outlines plans to move administration of 340B from HRSA to CMS
- Part of overall proposed HHS reorganization
- Unclear if proposal requires congressional approval

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340B: Manufacturers Target Contract Pharmacies

- To date, 38 drug manufacturers have restricted access to 340B pricing for drugs dispensed through contract pharmacies
- HRSA has attempted to take enforcement action against manufacturers for violating the 340B statute, and manufacturers have filed lawsuits against HRSA
- Four district court decisions appealed to three Circuit Courts

285

340B Contract Pharmacy Litigation

Third Circuit

In *Sanofi Aventus U.S., LLC v. HHS* (Jan. 30, 2023), the Third Circuit ruled in favor of the drug manufacturers in a single consolidated appeal by Sanofi, Novo Nordisk and AstraZeneca. The court held that Section 340B cannot be read to require manufacturers to deliver 340B drugs whenever and wherever covered entities demand—i.e., the law does not require delivery to an unlimited number of contract pharmacies.

DC Circuit

In *United Therapeutics Corporation v. Carole Johnson*, No. 21-5304 (May 21, 2024), the United States Court of Appeals for the District of Columbia Circuit affirmed the D.C. District Court, holding that manufacturer restrictions do not violate the 340B statute on their face, although recognized that more onerous restrictions could be prohibited and the restrictions at issue could be prohibited in particular circumstances.

Seventh Circuit

Appeal still pending in *Eli Lilly and Company v. HHS*, No. 21-3128

286

340B Program– The Rebate Debate

- Five drug manufacturers have proposed to offer 340B pricing through rebates instead of up-front discounts
- HRSA has informed manufacturers they may not implement a rebate model without prior approval, which has not been granted
- Manufacturers have filed five lawsuits against HRSA in the D.C. District Court challenging rebate proposal denials



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340B Rebate Court Decision and Expected Guidance

- On May 15, 2025, a D.C. District Court judge issued a decision in four of the five cases ruling primarily for the government:
- The Court ruled HRSA can require manufacturers to obtain prior approval before implementing rebate models
- HRSA must further consider whether to allow the manufacturer rebate proposals to proceed
- On June 1, 2025, HRSA submitted 340B rebate guidance to OMB for review

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White House Executive Order on Hospital Price Transparency

- Issued February 25, 2025
- Directed the Secretaries of the Departments of Labor, HHS, and Treasury to take action within 90 days to:
 - Require the disclosure of the actual prices of items and services, not estimates
 - Issue updated guidance or proposed regulatory action ensuring pricing information is standardized and easily comparable across hospitals and health plans
 - Issue guidance or proposed regulatory action updating enforcement policies designed to ensure compliance with the transparent reporting of complete, accurate, and meaningful data

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CMS Hospital Price Transparency RFI and Updated Guidance

- On May 22, 2025, CMS released a Request For Information (RFI) to meet the Executive Order requesting feedback on how to improve hospital price transparency compliance and enforcement
- On May 22, 2025, CMS issued guidance indicating that hospitals must encode a standard charge dollar amount in the machine-readable file (MRF) if it can be calculated and hospitals should no longer encode 999999999 (nine 9s) in the estimated allowed amount data element

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Hospital Price Transparency: New Rules

New Rules Effective January 1, 2025

- Machine readable file (MRF) must include drug unit and type of measurement for drugs,
- MRF must include any modifier(s) that may change the standard charge, including a description and how it would change the charge
- MRF must include an Estimated Allowed Amount

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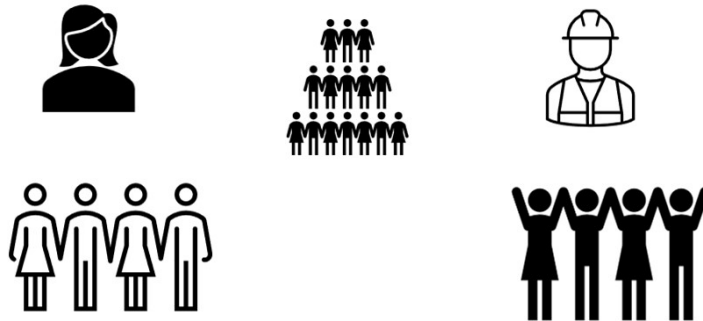


Hospital Price Transparency: Enforcement

- CMS has issued 27 civil monetary penalty (CMP) notices for non-compliance with price transparency rules
- 13 notices are under review
- <https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/enforcement-actions>

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Labor and Employment



Labor and Employment

Federal Employees

Strikes and Layoffs

Employee Engagement and Safety

Significant Court Cases

Disparate Impact Executive Order

Minimum Wage & State Pay Transparency

Healthcare Worker Shortages

Check out Sessions 27 & 31





Federal Employees & Labor Boards



Supreme Court allows Trump to fire members of independent agency boards — for now (May 2025)

Supreme Court granted the Trump administration's emergency request to fire the heads of two independent agencies, the National Labor Relations Board and the Merit Systems Protection Board.

As of May 12, 2025, the New York Times tracked more than 58,000 confirmed cuts, more than 76,000 employee buyouts, and more than 149,000 other planned reductions; cuts total 12% of the 2.4 million civilian federal workers.



INDEPENDENT

Federal employees say many government agencies at a standstill thanks to DOGE cuts: 'We are set up for failure'

June 17, 2025

After issuing the return to in-person work order, the White House offered federal workers buyouts for those who didn't want to end their remote arrangements, and also ordered a hiring freeze for all federal agencies, which was expected to remain in place for 90 days [Answers to Frequently Asked Return to In-Person Work Implementation Questions \(March 20, 2025\)](#)

Federal workers are still required to fill out DOGE 'five things' email despite Musk being long gone June 13, 2025



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STRIKES



BECKER'S
HOSPITAL REVIEW

In 2024, there were **359 work stoppages** — 356 strikes and three lockouts — across the U.S., with 36 occurring in the healthcare and social assistance industry, according to a [report](#) published Feb. 19 by the School of Industrial and Labor Relations at Cornell University and the University of Illinois School of Labor and Employment Relations.

In 2025, to date, there were **17 healthcare strikes** Nurses, hospital, mental health and nursing home staff and patient care staff and various nursing homes in California, Iowa, Louisiana, Michigan, Minnesota, New York, Oregon, Pennsylvania, Rhode Island are striking over workplace issues including safety, wages, and training

[Providence reaches tentative agreements with most striking providers 2-6-2025](#)

[KTVU FOX 2 on MSN - 56m](#)
[UCSF Benioff Children's Hospital workers on strike over 'integration plan'](#)

[The Butler Hospital strike is ongoing. Here's where negotiations stand](#)

<https://wisconsinexaminer.com>
[Nurses plan 5-day strike at Meriter hospital in Madison](#)



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Statistics and Layoffs in the News



45 hospitals, health systems cutting jobs -

June 13, 2025

6-6-2025

Health care added 62,000 jobs in May, higher than the average monthly gain of 44,000 over the prior 12 months.

In May, job gains occurred in hospitals (+30,000), ambulatory health care services (+29,000), and skilled nursing care facilities (+6,000).

Modern Healthcare
https://www.modernhealthcare.com/providers/mh...
Vanderbilt University Medical Center layoff 650 employees

1. Brattleboro (Vt.) Memorial Hospital eliminated six administrative positions. The layoffs affected the senior director of revenue cycle, director of radiology, outpatient specialty practice manager, a data scientist and two executive assistants, according to VT Digger.

2. Penn Highlands Healthcare, a nine-hospital health system based in DuBois, Pa., laid off about 36 positions across two hospitals. The layoffs affect Penn Highlands Connellsville (Pa.) and Penn Highlands Mon Valley in Monongahela, Pa., according to the Pittsburgh Post-Gazette. Twenty-six of the employees laid off were in nonclinical roles.

3. Fountain Valley, Calif.-based MemorialCare eliminated 58 roles and reclassified three others at its Long Beach (Calif.) Medical Center and Miller Children's and Women's Hospital, also in Long Beach. The affected positions include administrative and nonclinical roles, as well as jobs in interpreter services and respiratory care.

4. Middletown, N.Y.-based Garnet Health announced a restructuring plan that includes workforce reductions, outpatient service closures, and leadership changes. The changes will affect 42 employees — less than 1% of the organization's workforce — and include the discontinuation of certain consistently underused outpatient services.

5. Providence, a Renton, Wash.-based health system with 125,000 employees, has implemented a restructuring plan that will affect 600 full-time-equivalent positions across seven states. Affected roles are primarily in nonclinical, administrative functions. Leadership roles and some patient-care roles are also included.



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Layoffs, health systems & payers cutting jobs



Fierce Healthcare is tracking workforce changes across healthcare in 2025. Fierce Healthcare also has a [2024 tracker](#).

Examples of Layoffs:

June 12 Blue Cross Blue Shield of Michigan eliminates 600 positions, including 220 layoffs

June 10 Molina Healthcare lays off Virginia health plan employees

June 9 Prime Healthcare's post-acquisition consolidations cut over 100

June 9 Virginia Mason Franciscan Health lays over 116, with more roles affected

June 3 Hims & Hers lays off 68 employees

May 29 Carelon shuts down Ireland operations

May 29 Devoted Health trims workforce

May 28 PeaceHealth reduces workforce by 1%, freezes hiring

May 16 UCare trims 5% of workforce

May 12 Carle Health to begin laying off 612 employees amid health plans' shuttering

May 8 NewYork-Presbyterian Hospital cuts 1,000 employees

April 29 CVS scraps Aetna Carefree insurance plan, trims workforce by 55



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GALLUP® Beginning of the 2025 calendar year U.S. Employee Engagement Sinks to 10-Year Low

WORKPLACE JANUARY 14, 2025



Among the 12 engagement elements that Gallup measures, those that saw the most significant declines in 2024 (by three points or more in “*strongly agree*” ratings) include:

- **Clarity of expectations.** Just 46% of employees clearly know what is expected of them at work, down 10 points from a high of 56% in March 2020
- **Feeling someone at work cares about them as a person.** Currently, 39% of employees feel strongly that someone cares about them, a drop from 47% in March 2020
- **Someone encouraging their development.** Only 30% strongly agree that someone at work encourages their development, down from 36% in March 2020



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Employee Safety (CANDOR program)

The Centers for Medicare & Medicaid Services' (CMS) new Patient Safety Structural Measure — inaugurated Aug. 1 as part of its final rule for the fiscal year 2025 hospital inpatient prospective payment system — is an attestation-based measure indicating whether hospitals are prioritizing patient and employee safety.

The PSSM is an attestation-based measure indicating whether hospitals are prioritizing patient and employee safety. Hospitals are asked to attest to the use of 25 proven strategies and practices that support systemic and cultural improvements in safety. Included in the measure is the implementation of a communication and resolution program (CRP), such as CANDOR, consisting of the following elements:

- Harm event identification
- Open and ongoing communication with patients and families about the harm event
- Event investigation, prevention, and learning
- Care-for-the-caregiver
- Financial and non-financial reconciliation
- Patient-family engagement and ongoing support

Time is of the essence for hospitals. Mandatory reporting on the new measure starts with Calendar Year 2025, and—beginning in 2027—CMS will reduce payments to hospitals that have not submitted this data.



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National Labor
Relations Board

Captive Audience Meetings

In November 2024, the NLRB ruled in Amazon.com Services LLC, 373 NLRB No. 136, that mandatory meetings held by employers during work hours to share their views on unionization with employees (“captive audience” meetings) violate the National Labor Relations Act unless attendance is voluntary and without repercussions

12 states that have enacted laws designed to ban or restrict captive audience meetings: Alaska, California, Connecticut, Hawaii, Illinois, Maine, Minnesota, New Jersey, New York, Oregon, Vermont and Washington.



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2024-25 Significant Employment Decisions



FLSA In a unanimous decision, the Supreme Court reversed the District Court (bound by Fourth Circuit precedent) requirement that the employer establish entitlement to an exemption under the FLSA by “clear and convincing evidence. The Supreme Court cited three reasons for holding that the default evidentiary standard in civil litigation, preponderance of the evidence, applies when employers invoke FLSA exemptions. *EMD Sales v. Carrera*

Title VII The Supreme Court confirmed that a plaintiff alleging employment discrimination under Title VII cannot be held to a different, heightened evidentiary standard if they belong to a majority group *Ames v. Ohio Department of Youth Services*: Adjudicating Discrimination Claims of Members of ‘Majority’ Groups

ADA An unreasonable delay in providing an accommodation can support an Americans with Disabilities Act (ADA) claim, the Fifth U.S. Circuit Court of Appeals held, reversing the dismissal of a failure to accommodate suit. *Strife v. Aldine Independent School District*

Not yet decided: Can a former employee sue for discrimination under the ADA regarding post-employment benefits, despite no longer holding her job *Stanley v. City of Sanford, FL*



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Disparate Impact Executive Order



April 2025 “Restoring Equality of Opportunity and Meritocracy,” declares new federal policy “to eliminate the use of disparate impact liability in all contexts to the maximum degree possible to avoid violating the Constitution, Federal civil rights laws, and basic American ideals.”

According to the Order, disparate impact liability has hindered businesses from making hiring and other employment decisions based on merit and skill, their needs or the needs of their customers “because of the specter that such a process might lead to disparate outcomes, and thus disparate impact lawsuits.”

The Order directs all federal agencies, including EEOC and DOJ to deprioritize enforcement of all statutes and regulations to the extent they include disparate impact liability.

[Restoring Equality of Opportunity and Meritocracy – The White House](#)

Multiple executive orders rolled back DEI initiatives, including Order that required federal contractors to implement affirmative action programs and rescinding an Order that protected contract workers from discrimination based on sexual orientation and gender identity. The Office of Federal Contract Compliance Programs has been directed to stand down on enforcement of these previous Orders.



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WAGE AND HOUR DIVISION
UNITED STATES DEPARTMENT OF LABOR

Press Fact Sheet

Fact Sheet #17A: Exemption for Executive, Administrative, Professional, Computer & Outside Sales Employees Under the Fair Labor Standards Act (FLSA)

FLSA Minimum Wage and State Pay Transparency

UPDATE: More than a dozen states and DC have enacted pay transparency laws, requiring employers to disclose in postings for new jobs and internal promotions details such as pay ranges, benefits, bonus structures, and other compensation information. New laws in [Illinois](#) and [Minnesota](#) already took effect on January 1, 2025, with laws in [New Jersey](#), Vermont, and [Massachusetts](#) set to take effect later in the year.

On April 26, 2024, the DOL published a final rule, [Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees](#), implementing the exemption from minimum wage and overtime pay requirements for executive, administrative, and professional employees.

On November 15, 2024, the U.S. District Court for the Eastern District of Texas vacated the Department's 2024 final rule. Consequently, with regard to enforcement, the Department is applying the 2019 rule's minimum salary level of \$684 per week and total annual compensation requirement for highly compensated employees of \$107,432 per year.

Lawsuits regarding the 2024 final rule are currently pending in two other federal district courts, and the United States filed a notice of appeal from the November 15 decision. [Wages and the Fair Labor Standards Act | U.S. Department of Labor](#) (not updated as of 6-17-25)



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Workers' Conscience Rights

May 12, 2025 HHS Acts to Protect Health Care Workers' Conscience Rights

HHS' Office for Civil Rights Reviews a Hospital's Compliance with Federal Conscience Protections HHS OCR initiated a compliance review of a hospital to investigate the hospital's compliance with Federal law that safeguards conscience rights in health care – a Federal conscience protection statute known as the Church Amendments. OCR opened the review based on information that **ultrasound technicians employed by the hospital allegedly faced potential termination because they have religious objections to conducting ultrasounds in abortion procedures.**

OCR facilitates and coordinates the Department's enforcement of the Federal health care conscience protection statutes and religious nondiscrimination statutes... The investigation will examine whether the hospital, which is part of a larger health care system, accommodates its health care personnel who decline to perform or assist in the performance of abortion procedures contrary to their religious beliefs or moral convictions.

"The Department is committed to enforcement of our nation's laws that safeguard the fundamental rights of conscience and religious exercise," said Anthony Archeval, Acting OCR Director. "Health care professionals should not be coerced into, fired for, or driven out of the profession for declining to perform procedures that Federal law says they do not have to perform based on their religious beliefs or moral convictions."

This matter is **the second investigation of an entity's compliance with laws protecting the exercise of conscience that OCR has initiated during President Trump's second term.** **Today's announcement is part of a larger effort to strengthen enforcement of laws protecting conscience and religious exercise.**

OCR enforces Federal protections against discrimination based on conscience and religion in specific programs funded by HHS Federal financial assistance. For more information visit, <https://www.hhs.gov/conscience/your-protections-against-discrimination-based-on-conscience-and-religion/index.html>.

Healthcare Worker Shortage

McKinsey Health Institute

Closing the healthcare worker shortage gap could eliminate 7 percent of the global disease burden and add \$1.1 trillion to the global economy.

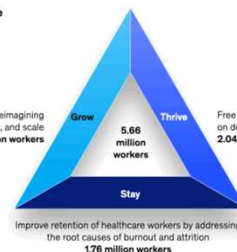
At a glance

- A global healthcare worker shortage of at least ten million is expected by 2030.
- Closing that shortage could avert 189 million years of life lost to early death and disability and boost the global economy by \$1.1 trillion.
- While known supply-side interventions that enable the workforce to grow, thrive, and stay can add about 5.6 million healthcare workers, this is not enough to close the gap. Closing it will require transforming healthcare service delivery—reimagining who provides healthcare, how services are delivered, and where care is accessed.

Scaling known interventions could reinforce the Healthcare Workforce Triangle to Grow, Thrive, and Stay.

Total impact on healthcare workers from reinforcing the healthcare triangle

Expand the talent pipeline by reimagining training program structure, timing, and scale
1.86 million workers



Free up healthcare workers' time to focus on delivering quality care to more patients
2.04 million workers

Improve retention of healthcare workers by addressing the root causes of burnout and attrition
1.76 million workers



McKinsey & Company

<https://www.mckinsey.com> › mhi › our-insights › heart...

Business Law, Transactions, and Governance

June 2025
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Significant Transactions



Rady Children's Hospital and Health Center and Children's HealthCare of California Merge

- Announced their plan to merge in December 2023.
- In November 2024, the California AG gave conditional approval for the merger.
- Merger closed on December 31, 2024.

Cencora Buys Retina Consultants of America

- Retina Consultants of America is a management services organization that operates a network of retina specialists.
- Deal closed on January 2, 2025, and bolstered Cencora's specialty drug business.

Arnot Health and Cayuga Health Unite as Centralus Health

- Systems merged on January 7, 2025, to create a five-hospital system with more than \$1 billion in annual revenue in upstate New York.
- New system will have more than 6,500 employees and serve a nine-county region.



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Significant Transactions (cont.)



HCA acquires Catholic Medical Center (Manchester, NH)

- HCA acquired Catholic Medical center on February 1, 2025.
- HCA is committed to maintaining the medical center's Catholic identity and has dedicated \$200 million in capital infusion to help modernize infrastructure and expand clinical services.

Community Health Systems sells two hospitals in Florida to Advent Health

- Signed definitive agreement to acquire ShorePoint Health – Port Charlotte and certain assets of ShorePoint Health-Punta Gorda in November 2024.
- ShorePoint Health – Punta Gorda sustained irreparable damage during Hurricanes Helene and Milton in Fall 2024 and had suspended patient operations.
- Transaction closed on March 1, 2025.



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Significant Transactions (cont.)



Cigna sells Medicare business to Health Care Service Corporation

- Cigna announced it would sell its Medicare Advantage, Part D Plans, Supplemental benefits, and CareAllies businesses to HCSC for \$3.7 billion in January 2024.
- Deal closed in March 2025.

Walgreens Boots Going Private

- Announced sale to private equity firm Sycamore Partners in March 2025.
- Walgreens shares have plummeted in value 80% over past 5 years.
- Total deal value anticipated at \$23.7 billion.

Prime Completes Acquisition of Eight Ascension Hospitals

- Signed a definitive agreement in July 2024.
- Transaction was the largest acquisition in the history of Prime and closed on March 1, 2025, for \$370 million.



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Significant Transactions (cont.)



Santa Clara (Calif.) County and San Jose, Calif.—based Regional Medical Center (part of HCA)

- Definitive agreement reached for \$150 million.
- 252-bed hospital to be integrated into Santa Clara Valley Healthcare system.
- Deal closed in April 2025.

General Catalyst's portfolio company Health Assurance Transformation (HATCo) to acquire Summa Health

- Signed definitive agreement in November 2024; Summa Health would convert to for-profit status and become a wholly-owned subsidiary of HATCo.
- Ohio AG gave conditional approval in June 2025. Summa and HATCo must meet 10 conditions, including transfer of additional \$15M in cash and \$15M in equity to surviving non-profit corporation.
- Transaction is still undergoing regulatory review and approval by the Ohio Department of Insurance, FTC, and other applicable authorities.



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Significant Transactions (cont.)



Penn Medicine acquires Doylestown Health

- Parties signed letter of intent to merge in January 2024.
- Acquisition closed on April 1, 2025, with Doylestown Health becoming Penn Medicine's seventh hospital.

Duke Finalizes Acquisition of Lake Norman Medical Center

- Duke completed its \$284 million acquisition of Lake Norman Regional Medical Center on April 1, 2025.
- The 123-bed acute care hospital will be renamed Duke Health Lake Normal Hospital.

Johnson & Johnson Acquires Intra-Cellular Therapies

- Acquisition adds CAPLYTA to J&J's portfolio, which treats adults with schizophrenia and bipolar depression
- Transaction closed for \$14.6 billion on April 2, 2025.



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Significant Transactions (cont.)



Northwell Health Completes Merger with Nuvance Health

- In February 2024, Northwell and Nuvance announced a strategic agreement to form a new integrated health system serving a population of more than 13 million.
- Deal closed in May 2025.

TidalHealth and Atlantic General Hospital Finalize Merger

- Atlantic General Hospital and TidalHealth signed a definitive agreement to merge on May 1, 2025.
- Merger will provide Atlantic General with access to an integrated EHR through Epic and enhance service coordination and care access.



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Significant Transactions (cont.)



UnitedHealth and Amedisys reach agreement to sell home health and hospice locations if merger is approved

- Entered into agreement in May 2025 to sell locations to BrightSpring Health Services (Louisville, KY) and Pennant Group (Eagle, ID).
- Sale is contingent on closure of UnitedHealth's acquisition of Amedisys, which had been held up due to anticompetitive concerns.

Emory Healthcare Acquires Houston HealthCare

- Systems signed letter of intent to combine in August 2024.
- Houston Healthcare based in Warner Robins, GA will add 282 beds across two hospital campuses to the Emory system.
- Deal closed on June 1, 2025, after receiving approval from Georgia AG.

Sanofi to Buy Blueprint Medicines Corporation

- Signed definitive agreement for \$9.1 billion in June 2025.
- Acquisition would expand portfolio in rare immunological diseases.
- Transaction is expected to close in third quarter of 2025.



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Significant Transactions (cont.)



Ascension Saint Thomas enters Joint Venture with PathPoint Health

- Partnership to open two facilities in June 2025 in Nashville and Murfreesboro, TN offering treatment for metabolic conditions, including obesity and diabetes.
- Services to be provided including nutrition planning, medical care, and lifestyle counseling.

Ascension Health to Acquire AMSURG Outpatient Centers

- AMSURG is an outpatient surgery management company with over 250 surgery centers nationwide.
- Agreement signed on June 17, 2025.



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Significant Transactions (cont.)

Surgery Partners

- Surgery Partners ended talks with Bain Capital on June 17, 2025 regarding a \$3.3 billion take-private proposal, saying it sees a stronger future as a public company

ChristianaCare to assume operations of 5 Crozer Health Outpatient Facilities

- Christiana Care submitted highest bid of \$50.3 million to acquire facilities in PA after bankruptcy or parent Prospect Medical Holdings

Caris Life Sciences Inc.

- Cancer-diagnostics test provider raised \$494.1 million in IPO in June 2025

Slide Insurance Holdings, Inc.

- Coastal-focused residential insurer raised \$408 million in IPO in June 2025



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Significant Transactions (cont.)

Google to Buy Security Firm Wiz

- Google's planned acquisition of cybersecurity company Wiz Inc. for \$32 billion being reviewed by Justice Department antitrust enforcers (June 2025)

Amazon

- Amazon healthcare business to be divided into six units after losing top health executives (June 16, 2025)

Baptist Memorial Healthcare (Memphis, TN) to acquire 96-bed hospital in Mississippi

- In May 2025, the Oktibbeha County Board of Supervisors approved Baptist Memorial Health Care as the preferred partner for OCH Regional Medical Center in Starkville, MS
- A formal agreement is expected to be signed around July 31, 2025, pending further due diligence and legal review



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Significant Transactions: Bankruptcy



Prospect Medical Holdings filed Chapter 11 in January 2025

- Company includes hospitals and affiliates in four states.
- Bankruptcy filing does not include subsidiaries in California, Texas and Arizona whose sale is pending to Astrana Health.
- Seeking approval to sell two facilities in Rhode Island and a Pennsylvania system.
 - Pennsylvania AG sued in October 2024 claiming mismanagement and negligence.
 - Bankruptcy filing may pause the suit.
- Prospect's attempt to sell 3 hospitals in Connecticut ran into legal challenges from the state and a May 2024 suit by Yale New Haven to terminate the deal.
- Previously majority-owned (2010-2022) by PE firm Leonard Green & Partners.
 - News reports indicate Prospect relied on value of real estate to finance payouts for investors, diverting funds from patient care to pay for expensive leases.

Significant Transactions: Bankruptcy (cont.)



23andMe Bankruptcy Triggers Privacy Concerns

- Filed for bankruptcy protection in March 2025
- TTAM Research Institute topped Regeneron's bid at \$305 million.
- TTAM is a non-profit led by the co-founder and former CEO of 23andMe
- Court-supervised sale requires compliance with 23andMe's privacy policies and applicable law
- 27 states and the District of Columbia have sued to stop the sale

Significant Transactions: Bankruptcy (cont.)

Steward Health—A Year After Filing

- Originally hoped to finalize sales within 3 months after filing in 2024
- In August 2024, a U.S. Bankruptcy Judge approved a \$245 million sale of Steward's nationwide physician network to Rural Healthcare Group.
- Other auctions and sales were delayed but as of May 2025, most hospitals have transitioned to new owners.
- Five hospitals have closed and two have reduced services.
- More than 2,400 workers have been laid off.
- Steward Health opposed requests from Justice Department's bankruptcy monitor and a group of doctors to convert its Chapter 11 case to trustee-supervised liquidation, saying they haven't shown a "substantial or continuing loss" to the estate



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Significant Transactions: Bankruptcy (cont.)



Heywood Healthcare emerges from bankruptcy

- Filed Chapter 11 in October 2023 citing workforce shortage, supplies chain issues, and low reimbursement rates.
- Two hospital system exited bankruptcy as a standalone entity in October 2024.

CarePoint Health exits Chapter 11 Bankruptcy

- Filed Chapter 11 in November 2024 citing insufficient state funding, reimbursement challenges, and an increase in hospital operating costs.
- In April 2025, judge approved Hudson Regional Hospital to take over operations of CarePoint's three hospitals.



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Significant Transactions: Bankruptcy (cont.)



Washington Regional Medical Center (NC) filed for Chapter 11 bankruptcy

- The 25-bed critical access hospital filed for bankruptcy in October 2024 to help the hospital restructure finances while ensuring patient care.
- Finance and restructuring experts have been brought in to help the hospital stabilize its financial position and improve operational efficiency.

WeightWatchers Cleared to Exit Ch. 11

- WeightWatchers secured Delaware bankruptcy judge's blessing to exit Chapter 11 on June 17, 2025 less than 2 months after filing case. Plan to cut \$1.15 billion in debt by swapping debt held by secured creditors for about 91% of equity in the reorganized firm. Existing shareholders to receive 9% of new equity



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Significant Transactions: Bankruptcy (cont.)



Rite Aid re-enters bankruptcy

- Previously filed for bankruptcy in October 2023 and exited bankruptcy in September 2024 after completing financial restructuring, including closing more than 100 stores.
- Restructured company filed for Chapter 11 in May 2025 and is seeking to sell substantially all of its assets.

Alabama Hospital files for bankruptcy

- Jackson Hospital and Clinic, a 344-bed nonprofit, has filed for Chapter 11 protection to allow it to implement financial restructuring and reorganize operations.
- Jackson Hospital received commitment for DIP financing from third-party Jackson Investment Group to facilitate bankruptcy process.
- Following court approval, DIP financing and cash generated from hospital's ongoing operations expected to support debtors.



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Transaction Trends: Bankruptcy

Trends

- Overall drop in healthcare bankruptcies in 2024 (after 10 consecutive quarters of increase).
- 79 cases filed in 2023; 57 in 2024.
- Increase in filings by clinics/physician practices and medical equipment cos.

Insolvency risks

- Continued pressure from labor and supply chain costs.
- Rural hospitals at risk in states with no Medicaid expansion.
- In 2024, high interest rates, inflationary pressures, the failure of Medicare and Medicaid reimbursements to keep up with rising costs, and the rollout of the No Surprises Act - contributing factors to Chapter 11 bankruptcy filings.
- Payor pressure – Medicare Advantage denials and little leverage in negotiating with commercial payors.
- Proposed Medicaid cuts could be disastrous for rural providers.



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Transaction Trends: Retail Healthcare Challenges

- Walmart Health closed all health centers and ceased virtual health services.
- Walgreen's closed 160 VillageMD clinics.
- Amazon announced restructuring of health care operations in June 2025 after executive departures.
- CVS closed dozens of pharmacies in Target stores and 25 MinuteClinic locations in Los Angeles.

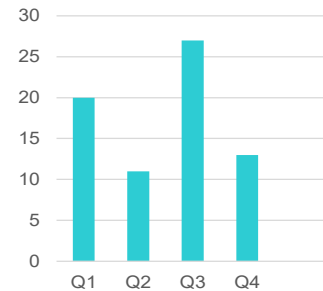


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Transaction Trends: Hospital M&A

- Hospital M&A continued strong in 2024, with a big jump in Q3. But Q1 2025 dropped to only 5 deals.
- Cross-market M&A activity is increasing.
- Increasing behavioral health, outpatient surgery and post-acute joint ventures.
- Many of Q3 transactions related to Steward's bankruptcy.
- Average seller size dropped from high of \$852 million in 2022 to \$492 million in 2024.

2024 Hospital M&A Deals Announced



HCA's Thoughts on M&A in 2025

- System capacity growth in 2025 primarily through “organic measures” according to Sam Hazen, CEO.
- Acquisition of Catholic Medical Center in New Hampshire will round out NH network and give broader and more productive Southern NH network.
- Expected capital expenditures between \$5B and \$5.2B in 2025, excluding acquisitions.
- Capital expenditures in 2024 were \$4.9B.

Transaction Trends: Private Equity

- Currently invested in about 460 hospitals
 - A third of those are in rural areas
 - Risks re: quality, reduction in services
- In 2024, PE firms sharply slowed serial acquisitions of smaller healthcare companies, largely due to increased FTC scrutiny and state regulations.
- PitchBook reports:
 - Drop in Q1 2025 health care deals – 94 announced vs 162 in Q4 2024
 - Decrease in health care as a percent of all PE and VC
 - 2024 had increased activity in health care IT and pharma
 - Infusion strongest category for health care services



Investigations into PE in Healthcare: Senate Budget Committee Bipartisan Staff Report

- In January of 2025, the United States Senate Budget Committee published the results of a bipartisan investigation examining the effects of private equity on the American healthcare system.
- The bipartisan report slams private equity's "detrimental effects" on hospitals.
- Senator Sheldon Whitehouse, D, RI: "Private equity has infected our health care system, putting patients, communities, and providers at risk."
- Investigators concluded that PE's financial model may pose "a threat to the nation's health care infrastructure, particularly in underserved and rural areas."
- This report concluded that the Committee's investigation highlighted significant concerns regarding the impact of PE ownership on the quality of care, patient safety, and the financial stability of hospitals throughout the United States.
- The Committee also states in its report that it has uncovered troubling patterns of prioritizing profits over patient health. These patterns include underinvestment in critical hospital infrastructure, understaffing, and the pursuit of financial gains through leveraged buyouts and dividend extractions in ways that it claims to be detrimental to patients and hospital operations.

Increased State-Level Review of Healthcare Transactions

- Many states have recently increased their review of healthcare transactions and investments, often requiring pre-closing notice and/or state approval of certain healthcare transactions. At least fifteen states (including California, Illinois, Massachusetts and New York) have enacted such laws.
- Numerous additional bills have been introduced or are expected in the current sessions of state legislatures, including Washington, Texas, Wisconsin and others.
- Some proposed legislation prohibits specific financial arrangements between PE and physicians, restricts control that can be exercised by MSOs, and limits use of stock transfer restriction and similar agreements.
- Laws allow designated state agencies (usually the state AG or health department) to review healthcare transactions to ensure they meet specific statutory criteria or involve certain healthcare entities. Some agencies' interpretations of the statutes make it challenging for entities to know whether they are regulated.



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PE as a Primary Intended Target of These Laws

- Investments and transactions involving PE appear to be one of the primary intended targets of these recent regulations. Some mandate disclosure of detailed information regarding any PE sponsor and/or a PE sponsor's other portfolio companies in addition to the portfolio at issue.
- Proponents of these regulations argue that the increased volume of transactions with private investment adversely impacts competition, cost, and patients, and that regulatory scrutiny is necessary to reduce the potential adverse impact and prevent violations of corporate practice of medicine prohibition principles.
- State-level agencies regulating PE transactions and investments express concern that the aim to secure high returns on investments conflicts with delivering affordable, accessible, and high-value healthcare to patients within their states.



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Counterpoint: Avalere Report

- In September of 2024, Avalere released a report on Medicare service use and expenditures across various physician practice affiliation models. According to this report, the share of physicians in PE-affiliated private practices is growing but remains a small share of physicians affiliated with hospitals or other corporate entities.
- The physician practice affiliation models analyzed by Avalere include unaffiliated private practices (or UPPs), private equity-affiliated private practice (PEAPP), corporate-affiliated practices, and hospital-affiliated practices.
- This report found that patients attributed to hospital-affiliated physicians are associated with the highest Medicare expenditures, followed (in order) by corporate, PEAPP, and then UPP.
- Also, the report found that, on average, total Medicare expenditures per beneficiary were lower for beneficiaries attributed to physician practices transitioning from UPP to PEAPP, regardless of the medical specialty involved.



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Canceled Transactions



Oregon Health & Science University (OHSU) and Legacy Health (Legacy) Cancel Merger

- OHSU and Legacy announced their merger in August 2023, which would have included a roughly \$1 billion, 10-year commitment from OHSU into primary- and community-based service investments.
- A community review board, charged with weighing whether the deal was in the public interest pursuant to Oregon's Health Care Market Oversight program, concluded that the transaction would likely lead to higher prices for care and recommended that state regulators block the transaction.
- OHSU and Legacy subsequently terminated the transaction as of May 5, 2025.



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Canceled Transactions (cont.)

Santiam Hospital (Santiam) and Samaritan Health Services (Samaritan) Abandon Merger

- The parties signed a definitive agreement to affiliate in October 2024 and sought approval from the Oregon Health Authority.
- Under the proposed agreement, Samaritan was to build a \$15 million medical office building and provide Santiam with \$10.5 million for capital expenses.
- Santiam and Samaritan announced their mutual decision to abandon their merger on May 29, 2025.
- Neither Santiam nor Samaritan gave a reason for the deal being called off.



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Canceled Partnerships



Baptist Health (Baptist) Terminates Long-Standing Partnership with University of Florida Health (UF Health)

- UF Health has provided pediatric services for Jacksonville-based Baptist Health's Wolfson Children's Hospital for several decades.
- In the first quarter of 2026, Nemours Children's Health will take over pediatric care at the hospital.
- UF Health said it was "surprised and disheartened" to learn that Baptist had "unilaterally decided to end its decades-long clinical collaboration."

Valley Medical Center (VMC) and the University of Washington School of Medicine (UW Medicine) End Their Strategic Affiliation

- VMC and Seattle-based UW Medicine partnered in 2011.
- The strategic affiliation will end, effective December 31, 2026.
- The decision was made unanimously by VMC's board of commissioners, with VMC currently exploring new partnerships that better align with its strategic priorities—focusing on access and the evolving needs of its patients and communities.



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Called off Negotiations



Adventist HealthCare (Adventist) Ends Talks to Acquire Howard University Hospital (HUH)

- Adventist began managing HUH under a Management Services Agreement (MSA) in February 2020, as an initial step towards a possible acquisition.
- Both parties mutually agreed on June 5, 2025, to end their partnership and phase out the MSA by February 2026, though no specific reason was provided for ending the acquisition talks.
- As the MSA winds down, operational control of HUH will transition back to Howard University.

Fairview Health Services (Fairview) Rejects Merger With Essentia Health (Essentia) and the University of Minnesota (UM)

- In late January 2025, UM and Essentia announced a plan to create a statewide nonprofit health system, including a \$1 billion investment over 5 years in UM's programs.
- On February 17, 2025, Fairview, which owns health care facilities on the UM's campus, said it was not interested in a merger with UM and Essentia because it wants



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Transactions Facing Uncertainty (cont.)



Prospect Medical Holdings (Prospect) and Yale New Haven (YNH) Deal Stalls

- Connecticut-based YNH is demanding revised terms for a \$435 million deal to acquire three Connecticut hospitals from Los Angeles-based Prospect.
- YNH sued in May 2024 to exit the deal, alleging that Prospect engaged in irresponsible financial practices and breached its contract by not paying rent and taxes on time.
- Prospect countersued, accusing YNH board members of waging a campaign to slow down the transaction and drive down the purchase price.
- YNH has called the deal "impossible" due to Prospect's failure to pay vendors on time, disinvestment in the facilities and record of mismanagement.
- The bidding process for a new buyer is underway, with three bidders expressing interest in acquiring Prospect's hospitals.



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State Oversight in Transactions



State Oversight Continues to Expand

- States are starting to enact legislation targeting health care transactions. 34 bills relating to health system consolidation and competition were enacted across 22 states in 2024:
 - Some focus solely on non-profit facilities;
 - Some on hospitals; and
 - Some apply to any health care transactions that satisfy certain criteria.
- State laws vary but generally:
 - Require 30-to-90-days' notice in advance of closing; and
 - Empower the AG or another state agency to undertake a review.

State Oversight in Transactions (cont.)



Examples of Expansion of State Oversight

- **California:** Non-profit health facility transactions and health care entity material change transactions
 - Cal. Corp. Code §§ 5914 & 5920b
 - Cal. Health & Saf. Code § 127500-127507.6
- **Connecticut:** Sale of non-profit hospitals: Health Care Institutions
 - Conn. Gen. Stat. §§ 19a-486 through 19a-486h
- **Indiana:** Required notice to AG of healthcare transactions over \$10 million
 - IN Code § 25-1-8.5-1—25-1-8.5-4, effective July 1, 2024.
 - HB 1666, effective May 6, 2025
- **Maryland:** Application to Maryland Health Care Commission required before acquisition of a nursing home
 - SB 1000, effective July 1, 2025.

State Oversight in Transactions (cont.)



Examples of Expansion of State Oversight (cont.)

- **Massachusetts:** Provider material change transactions
 - Mass. Gen. Laws Ch. 6D § 13, effective April 8, 2025.
 - House Bill 5159, effective April 8, 2025.
 - House Bill 1355
 - SB 868
- **Nevada:** Material change of group practices AND if the transaction will result in practice provider with >50 percent of services in market
 - AB 47
- **New Mexico:** Grants the attorney general authority to approve or deny healthcare mergers
 - SB 15

State Oversight in Transactions (cont.)

- **Illinois:** Require AG approval (written consent) when PE group or hedge fund provides any financing to covered transaction before transaction can take effect
 - SB 1998
- **Wisconsin:** Establish procedures for review, oversight, and transparency when healthcare entities propose to undergo material change transactions
 - AB 50

Federal Oversight in Transactions



New Federal Premerger Notification Requirements:

- On February 21, 2025, new 2025 Hart-Scott-Rodino Act (HSR Act) filing thresholds went into effect.
- Pursuant to the new thresholds, a transaction is subject to the reporting and waiting requirements of the HSR Act if:
 - The transaction value is greater than \$505.8 million, up from \$478 million; or
 - If:
 - (a) the transaction value is greater than \$126.4 million, up from \$119.5 million;
 - (b) one party has net sales or total assets of \$25.3 million or more, up from \$23.9 million; and
 - (c) a second party has net sales or total assets of \$252.9 million or more, up from \$239 million.

Trends in Deal Cancellations



- **Slower Start, Stabilization:** Healthcare M&A began 2025 with fewer deals than Q1 2024, but activity stabilized by March as the market adjusted to new economic and regulatory realities.
- **Economic & Regulatory Headwinds:** Interest rate hikes, inflation, new tariffs, increased labor costs, labor shortages, Medicaid reimbursement risks, and potential loss of premium tax credits have made investors more cautious, leading to some deal cancellations or delays.
- **Regulatory Scrutiny:** Increased state-level regulation—15 states with new or proposed "material transaction" laws and expanded antitrust pre-merger notification requirements—has added complexity, causing delays and, in some cases, deal terminations.
- **General Regulatory Uncertainty:** Heightened regulatory oversight, state-level restrictions, and administrative burdens have created uncertainty regarding business viability, leading to more rigorous diligence, deal restructuring, and, at times, deal withdrawals or terminations.

Trends in Deal Cancellations (cont.)

Digital Health & Health IT:

- Despite steady deal flow, shifting federal policies and regulatory uncertainty around virtual care have led to some deal cancellations or postponements.

Hospital & Health System Consolidation:

- Consolidation among hospitals and health systems remains ongoing, but some deals have been deterred, blocked or delayed by regulators.

Alternative Growth Strategies:

- Some hospitals and academic medical centers (AMCs) are increasingly seeking organic growth, strategic affiliations, and joint ventures as alternatives to, or incremental steps toward, full mergers.

M&A Lawyers Must Look Beyond Due Diligence on Buyer Fraud Claims

- Two recent Delaware Chancery Court cases highlight need for more strategic, comprehensive approach to negotiating fraud parameters in light of fraud claim risks buyers face. In common practice, fraud often connotes intentional deception: in Delaware minimum threshold for fraud is reckless misrepresentation.
- *Fortis Advisors*: J & J acquired Auris Health - \$3.4B upfront and \$2.35B in contingent earnout. Extracontractual statements by J & J that earnout milestone was “so certain to be met.” Auris’ former stockholders sued J & J for fraud, citing extracontractual statements, among other things. J & J argued that merger agreement barred fraud claims based on extracontractual statements. Delaware law requires express disclaimers of reliance to bar extracontractual fraud claims. J & J had disclaimed reliance on extracontractual representations by Auris, but court found Auris had made no such disclaimer and fraud claims against buyer allowed to proceed.

M&A Lawyers (cont.)

- *Cytotherapyx* sued Castle Creek for extracontractual fraud. *Cytotherapyx* received deal consideration from Castle Creek in the form of preferred stock, which *Cytotherapyx* intended to liquidate by redemption. *Cytotherapyx* sued Castle Creek for extracontractual fraud, alleging that Castle Creek's CEO assured it that certain obstacles to redemption had been removed. Court ruled in *Cytotherapyx* favor on motion to dismiss, citing that integration clauses alone were insufficient to bar extracontractual fraud claims without explicit disclaimers of reliance.
- Sophisticated sellers may push for extracontractual and reckless fraud exclusions, ensuring fraud disclaimers protect them unilaterally. To mitigate risk, consider whether buyers should insist that such fraud disclaimers apply reciprocally, protecting both parties.



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Corporate Practice of Medicine

California

- Lawsuit by American Academy of Emergency Physician Group in 2021 against Envision Healthcare Corporation alleging that Envision's use of friendly PC model violated California's prohibitions on lay ownership of medical practices. Case voluntarily dismissed in July 2024 after Envision left the State of California.
- 2024 bill passed in the California legislature; California Governor Gavin Newsom vetoed the bill; said Office of Health Care Affordability is the appropriate state entity to review the issues addressed by the legislation.
- Senate Bill (SB) 351 introduced – seeks to ensure that healthcare providers control clinical decisions, limit private equity influence, and reinforce prohibitions on corporate practice of medicine and dentistry. Would prohibit PE group from interfering in clinical decisions or controlling practice operations. PE groups and hedge funds cannot restrict providers from engaging in competitive activities or commenting on quality of care and professional practices.



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Corporate Practice of Medicine (cont.)

Oregon

- June 9, 2025: Oregon enacted Senate Bill 951, effective January 1, 2026, for all management services organization professional corporation (MSO-PC) structures created after June 9, 2025, with a 3-year grace period ending on January 1, 2029, for currently existing MCO-PCs.
- Prohibits professional medical entities from relinquishing control over their “assets,, business operations, clinical practices or decision or the clinical practices or decision of a physician.” Does not prohibit:
 - Selling, leasing, or assigning the right to possess corporate assets, inclusive of any leased or owned property, to an MSO
 - Supporting, advising, and consulting on all matters of the professional medical entity’s business operations, including accounting and budgeting, personnel, real estate and facilities management, and compliance support, for the benefit of the professional medical entity
 - Advising and providing direction to the professional medical entity related to its participation to value-based contracts, payer arrangements or vendor contracting

Corporate Practice of Medicine (cont.)

Massachusetts

- HB 2486 and SB 1628: An Act to Protect the Independence of Clinical Decision Making
- Implement statutory prohibition of corporate practice of medicine with narrow exceptions
- Provide guardrails around management services organization (MSO) relationships with physician practices to protect clinical decision making authority
- MSOs would not be allowed to own patient medical records, hire or fire any owner or clinician based on clinical competency, set parameters under which a practice enters into contractual relationships with clinicians for delivery of care, make final decisions regarding coding and billing procedures for patient care services, or approve the selection of medical equipment and medical supplies

Board Diversity



- Backlash has grown in recent years against DEI activities in many industries
- Attempts to regulate board diversity have been struck down
 - 5th Circuit vacated Nasdaq's board diversity rule in December 2024
 - Previously, courts had held California statutes AB 979 (mandating minimum numbers of directors from underrepresented communities) and SB 826 (mandating minimum numbers of female directors) unconstitutional under the equal protection clause of the California Constitution.
- President Donald Trump's first week in office: nixed discrimination protections

Antitrust

Antitrust Topic Team:

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- On December 18, 2023, the Antitrust Division of the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) finalized the new Merger Guidelines.
- These Guidelines replaced the 2010 Horizontal Merger Guidelines and 2020 Vertical Merger Guidelines.
- On February 18, 2025 the FTC published a press release stating that the FTC and DOJ's Joint 2023 Merger Guidelines are in effect and will serve as the framework for the FTC's merger-review analysis under the new administration.

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On June 27, 2023, the FTC announced significant proposed changes to the pre-merger notification form that parties to certain transactions must submit under the HSR Act.



On October 10, 2024, the FTC published its final changes to the HSR Form. The final rule was a paired-back version of what the FTC and DOJ presented for public comment in 2023.



The new HSR form took effect on February 10, 2025. The new rules increase the scope of information and documents required to be submitted under the HSR Act.

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- The antitrust agencies continue to promise strict enforcement of healthcare mergers.
- UnitedHealth Group/Amedisys: The DOJ, Maryland, Illinois, New Jersey, and New York sued to block UHG's acquisition of home health and hospice provider Amedisys on November 12, 2024. This litigation is ongoing with trial set for August 2025.
- As of late April 2025, the parties entered mediation discussions with federal and state plaintiffs. Mediation is ongoing.

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- Union Health/Terre Haute Regional Hospital: Originally announced in September 2023, Union Health sought state-level approval to acquire Terre Haute Regional Hospital pursuant to a Certificate of Public Advantage (COPA).
 - In September 2024, the FTC submitted a comment to the Indiana Department of Health (IN DOH) arguing that Union Health and Terre Haute are each other's most direct competitor and, "it is doubtful that the regulatory conditions imposed by the IN DOH [pursuant to the COPA agreement] would effectively mitigate all of the potential anticompetitive harms to patients in the Terre Haute area."
 - After initially announcing a decision to delay the acquisition and withdraw its COPA application, the parties filed a second COPA application in February 2025.
 - In May 2025, the FTC published a press release reaffirming its opposition to the merger.

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- Novant Health/CHS: In January 2024, the FTC issued a complaint challenging Novant Health's proposed acquisition of two Community Health Systems (CHS) hospitals in an area north of Charlotte, NC. The FTC alleged that the transaction would give Novant a nearly 65% market share of inpatient acute care services in a growing suburban area.
 - On June 5, 2024, a district court judge denied the FTC's request for a preliminary injunction, allowing the acquisition to move forward. In part, the Court relied on evidence that there were no other bidders for the two CHS hospitals.
 - FTC appealed and on June 18 a split panel of the 4th Circuit granted the FTC an emergency injunction blocking Novant's acquisition.
 - On the same day that the injunction issued, Novant abandoned the transaction.
 - In October 2024, Iredell Health System acquired Davis Regional Psychiatric Hospital (formerly Davis Regional Medical Center) from CHS.
 - In April 2025, Duke Health acquired Lake Norman Regional Medical Center from CHS.

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- GTCR BC Holdings, LLC/Surmodics, Inc.: On March 6, 2025, the FTC sued to block private equity firm GTCR BC Holding's acquisition of Surmodics, alleging the acquisition would result in a combined company controlling over half of the market for outsourced hydrophilic coatings, which are used on medical devices like catheters and guidewires. GCTR, a private equity firm, owns a majority stake in Biocoat, Inc., which the FTC alleges competes directly with Surmodics. Illinois and Minnesota joined the lawsuit in April.
- Owens & Minor/Rotech Healthcare: On June 5, 2025, healthcare solutions and surgical care product manufacturer Owens & Minor announced it had mutually agreed to terminate its acquisition of Rotech Healthcare, a manufacturer of home medical equipment products and services provider.
 - The CEO of Owens & Minor noted that although the companies "worked tirelessly in cooperation with the [FTC]... the path to obtain regulatory clearance for this merger proved unviable in terms of time, expense, and opportunity."

- In September 2023, the FTC sued U.S. Anesthesia Partners, Inc. (USAP) and its private equity owner, Welsh, Carson, Anderson & Stowe (Welsh Carson), alleging a multi-year anticompetitive scheme to consolidate anesthesiology practices in Texas, drive up the price of anesthesia services provided to Texas patients, and boost their profits.
- On May 13, 2024, a district court judge granted Welsh Carson's motion to dismiss, while keeping USAP in the case. The FTC's case against USAP is proceeding to trial.
- On January 17, 2025, the FTC announced it settled a potential administrative case against Welsh Carlson through a consent order in which Welsh Carson is required to limit ownership rights in USAP, among other requirements. The Consent Order was finalized on May 19, 2025.

- State-level healthcare transaction notification laws are on the rise. Currently, most states require advanced notice of at least some healthcare mergers, about half of which limit notice to transactions involving a nonprofit entity.
- However, states are increasingly passing legislation to grant their office of attorney general or some other state agency review authority over these transactions.
- As of June 2025, several states have enacted such healthcare merger review laws, including California, Connecticut, Hawaii, Illinois, Indiana, New York, New Mexico, Nevada, Oregon, Rhode Island, Massachusetts, Minnesota, Vermont, and Washington.
- Healthcare companies considering “material transactions” should pay close attention to the changing merger review landscape at the state level.

- Regeneron Pharmaceutical v. Amgen Inc.: On May 15, 2025, a federal jury in Delaware ordered Amgen to pay \$271.2 million in punitive damages for illegal bundling practices. Regeneron filed suit in 2022, alleging that Amgen’s practice of bundling its anti-cholesterol drug Repatha with rebates for two of its blockbuster medications illegally undercut Regeneron’s price for its own anti-cholesterol drug.
- Sutter Health Settles “Tying” Suit: Originally filed in 2012, Sutter Health resolved a lawsuit against a class action of 3 million small business and individuals alleging it used tying arrangements to inflate insurance premiums by preventing health plans to direct patients to non-Sutter hospitals. Sutter Health agreed to the \$228 million settlement in April 2025 before the case was supposed to go to trial for the second time in 13 years.

- On September 20, 2024, the FTC filed an administrative complaint against Caremark Rx, Express Scripts, and Optum Rx– the three largest Pharmacy Benefit Managers (PBMs)– and their affiliated Group Purchasing Organizations (GPOs) alleging they have engaged in anticompetitive rebate practices resulting in artificially inflated prices for insulin drugs.
- On March 31, 2025, the FTC filed a motion for an expedited order to stay the proceeding for at least 105 days after President Trump fired the agency’s two democratic commissioners, leaving no commissioners to preside over the litigation (the two republican commissioners were recused).
- On April 2, 2025, FTC Chair Ferguson stated that he was reversing his recusal. The current timeline for the proceeding is unclear.

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- In January 2025, FTC released its second interim staff report on the prescription drug middleman industry, which focuses on PBMs’ influence over specialty generic drugs.
- The report details that the “Big 3 PBMs”– Caremark Rx, LLC (CVS), Express Scripts, Inc., and OptumRx, Inc. mark up certain generic drugs by “thousands of percents.”
- Commissioner Ferguson issued a concurring statement noting that the “Commission still has more work to do on this Section 6(b) study. I remain committed to bringing it to a conclusion, culminating in a final report.”

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House Judiciary Committee Launches Investigation into CVS Caremark

- In December 2024, the House Judiciary Committee sent a letter to CVS Caremark requesting documents and communications, citing concerns that CVS Caremark may prevent independent pharmacies from participating in hub arrangements, excluding them from PBMs networks.

Members of Senate Request that FTC Investigate Co-Manufacturing Arrangements

- On September 30, 2024, Senator Ron Wyden (D-OR) and former Senator Sherrod Brown (D-OH) wrote a letter to the FTC requesting it investigate CVS Caremark and Cigna Express Script's creation of subsidiary manufacturers that, "purport to co-manufacture certain biosimilars" of popular drugs like Humira and Hyrimoz, citing concerns over vertical integration in the industry.

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On April 23, 2024, the FTC voted 3-2 to approve a rule that, with limited exceptions, prohibits employers from entering into or imposing existing non-compete clauses with employees.

Under the rule, prohibited non-competes are considered an unfair method of competition under Section 5 of the FTC Act.

Two lawsuits have challenged the FTC's authority to promulgate its non-compete ban. A Texas judge ordered that the non-compete rule could not be enforced across the country, and a Florida judge found the FTC did not show it had "clear congressional authorization" to enact the ban. The FTC has appealed in both cases.

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FTC Launches Joint Labor Task Force to “Protect American Workers”

- On February 26, 2025, FTC Chair Ferguson directed the FTC to form a labor taskforce to prioritize rooting out and prosecuting anticompetitive labor-market practices.
- According to the press release, “a healthy labor market is critical to the country’s success. But deceptive, unfair, and anticompetitive labor practices are widespread.”
- This actions indicates that the FTC under the new administration will continue to be interested in labor theories of harm in antitrust conduct and merger cases.

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EMTALA



In 1986, Congress enacted the Emergency Medical Treatment & Labor Act (EMTALA) to ensure public access to emergency services regardless of ability to pay. [Emergency Medical Treatment & Labor Act \(EMTALA\) | CMS](#)

Emergency Abortion Services



2024-2025 OIG Settlements



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EMTALA



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Emergency Medical Treatment & Labor Act (EMTALA)

Pursuant to the preliminary injunction in *Texas v. Becerra*, No. 5:22-CV-185-H (N.D. Tex.), HHS may not enforce the following interpretations contained in the [July 11, 2022](#), CMS guidance (and the corresponding letter sent the same day by HHS Secretary Becerra):

- (1) HHS may not enforce the Guidance and Letter's interpretation that Texas abortion laws are preempted by EMTALA; and
- (2) HHS may not enforce the Guidance and Letter's interpretation of EMTALA—both as to when an abortion is required and EMTALA's effect on state laws governing abortion—within the State of Texas or against the members of the American Association of Pro Life Obstetricians and Gynecologists (AAPLOG) and the Christian Medical and Dental Association (CMDA).

[Emergency Medical Treatment & Labor Act \(EMTALA\) | CMS](#)

2022 Guidance and Letter Rescinded

CMS Statement on Emergency Medical Treatment and Labor Act (EMTALA)

[Administration](#)

Share

The Department of Health and Human Services and Centers for Medicare & Medicaid Services ("CMS") are rescinding July 2022 guidance from CMS with the subject "Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss" ([QSO-22-22-Hospitals](#)) and ([QSO-21-22-Hospitals](#)) and the accompanying [Letter](#) from the former Secretary of Health and Human Services, which do not reflect the policy of this Administration. CMS will continue to enforce EMTALA, which protects all individuals who present to a hospital emergency department seeking examination or treatment, including for identified emergency medical conditions that place the health of a pregnant woman or her unborn child in serious jeopardy. CMS will work to rectify any perceived legal confusion and instability created by the former administration's actions.

11 Nursing Associations Issue Joint Statement on EMTALA Abortion Rule Change

On June 3, 2025, CMS announced it was withdrawing a 2022 directive that instructed hospitals to provide abortions in medical emergencies, even in states where abortion is otherwise banned.

The 2022 guidance, issued after the Supreme Court's Dobbs decision, was intended to clarify that federal law required hospitals to offer emergency abortion care if necessary to stabilize a patient's condition.

Multiple state nurses' associations have issued [a joint statement](#) expressing concern following the Trump administration's recent decision [to rescind federal guidance](#) that required hospitals to provide emergency abortion care under the Emergency Medical Treatment and Labor Act (EMTALA).



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Emergency Abortion Services



The U.S. Supreme Court on June 27, 2024 refused to say whether federal law requires hospitals to provide stabilizing abortion care.

The case involved the State of Idaho's near-total abortion ban, which conflicts with the Emergency Medical Treatment and Labor Act (EMTALA)—a long-time federal law that requires hospital emergency rooms to provide “stabilizing treatment,” including emergency abortion care. The U.S. Department of Justice sued Idaho, arguing that the state's abortion ban conflicts with EMTALA by preventing Idaho hospitals from stabilizing patients in need of emergency care.

In its decision, the Supreme Court dismissed the case and reinstated a lower court ruling blocking Idaho's abortion ban to the extent that it conflicts with EMTALA.

Additional reading: Published online 2024 Jan 4. Pregnancy Complications After *Dobbs*: The Role of EMTALA [Kimberly Chernoby](#), MD, JD, MA* and [Brian Acunto](#), DO, EJD

<https://www.americanhealthlaw.org/publications/health-law-hub-current-topics/reproductive-law>



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State Battles re Emergency Abortions

CMS stated that it will continue to enforce EMTALA, including cases where a pregnant patient or unborn child is in serious jeopardy, and explained that "CMS will work to rectify any perceived legal confusion and instability created by the former administration's actions,"

According to Dr. Oz posted on X: "The Biden Administration created confusion, but EMTALA is clear, and the law has not changed: women will receive care for miscarriage, ectopic pregnancy, and medical emergencies in all fifty states—this has not and will never change in the Trump Administration."

Status of Abortion Litigation in State Courts, as of June 6, 2025

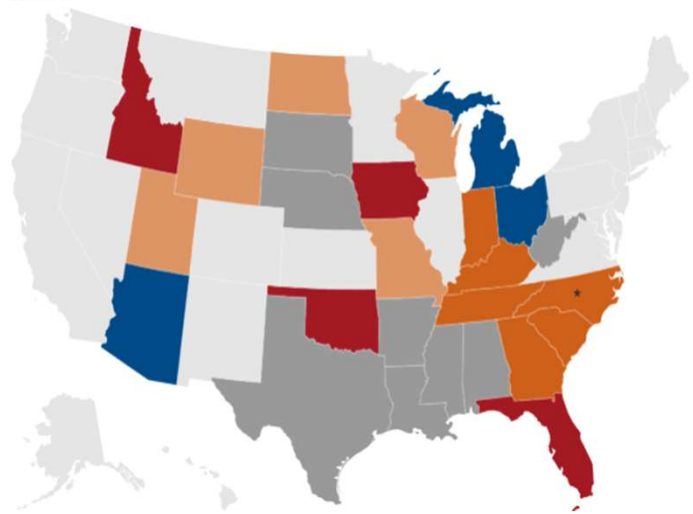
Status of Litigation

- Concluded, ban in effect
- Concluded, ban permanently blocked
- Ongoing, ban in effect
- Ongoing, ban temporarily blocked
- None, abortion banned
- None, abortion legal

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Women's Health Policy



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U.S. Department of Health and Human Services
Office of Inspector General

2024-2025 EMTALA OIG Settlements

*In each EMTALA CMP case resolved through a settlement agreement,
the settling party does not admit to liability*

Failure to Provide Appropriate Medical Screening Examination

Parkwest Medical Center Agreed to Pay \$80,000 for Allegedly Violating Patient Dumping Statute by Failing to Provide an Appropriate Medical Screening Examination May 27, 2025

ECU Health Medical Center Agreed to Pay \$119,000 for Allegedly Violating Patient Dumping Statute by Failing to Provide an Appropriate Medical Screening Examination May 9, 2025

Ascension Resurrection Agreed to Pay \$133,420 for Allegedly Violating Patient Dumping Statute by Failing to Provide Appropriate Medical Screening Examination February 26, 2025

Memorial Health Care System Agreed to Pay \$97,000 for Allegedly Violating Patient Dumping Statute by Failing to Provide Appropriate Medical Screening Examination November 19, 2024

Coliseum Medical Center Agreed to Pay \$100,000 for Allegedly Violating Patient Dumping Statute by Failing to Provide Appropriate Medical Screening Examination October 23, 2024

Big South Fork Medical Center Agreed to Pay \$60,000 for Allegedly Violating Patient Dumping Statute by Failing to Provide Appropriate Medical Screening Examinations September 24, 2024

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2024 - 2025 EMTALA OIG Settlements

Failure to Provide Appropriate Medical Screening Examination and Stabilizing Treatment
Baptist Medical Center South Agreed to Pay \$290,000 for Allegedly Violating Patient Dumping Statute by Failing to Provide Appropriate Medical Screening Examinations and Stabilizing Treatment February 20, 2025

Failure to Provide Stabilizing Treatment

Freeman Health System – Freeman West Agreed to Pay \$250,000 for Allegedly Violating Patient Dumping Statute by Failing to Provide Stabilizing Treatment December 4, 2024

Failure to Accept Appropriate Transfer

Brentwood Behavioral Healthcare of Mississippi Agreed to Pay \$350,000 for Allegedly Violating Patient Dumping Statute by Failing to Accept Appropriate Transfers May 9, 2025

CHI St. Joseph Health - Saint Joseph Hospital Agreed to Pay \$133,000 for Allegedly Violating Patient Dumping Statute by Failing to Accept an Appropriate Transfer April 22, 2025

Dr. Van Stephen Monroe, Jr. Agreed to Pay \$65,000 for Allegedly Violating Patient Dumping Statute by Failing to Accept an Appropriate Transfer October 15, 2024



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Tax and Tax-Exempt Organizations

June 30, 2025
Kim Harvey Looney
K&L Gates LLP



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Thank You to the Efforts of the AHLA Year in Review Tax-Exempt Organizations Review Topic Team

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DOGE's IRS Cuts

- March 2025: DOGE announced massive IRS cuts – reduce workforce by 20% (18,200 employees) by May 15
 - Workforce shrank 11% through voluntary resignation and probationary employee termination
- April 28: Lawsuit filed by American Federation of Government Employees and other labor unions citing Treasury RIF that would reduce IRS by 40%
- May 19: Probationary workers returning to office
- May 22: Unions' motion for preliminary injunction granted
- Some judges have ruled that Trump administration cannot proceed with firings while litigation pending, but others allowed



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IRS and Treasury Tax and Audit Activity

Internal Revenue Service

- On June 7, 2024, Robert Malone, IRS Director of Exempt Organizations and Government Entities, shared news about increased hospital audit activity during a TEGE Exempt Organizations Council panel discussion held in Washington, D.C.
- Mr. Malone shared that hospital audits are part of the IRS's 2025 fiscal year compliance strategy, and that particular focus will be given to compliance with community benefit requirements and section 501(r).
- The IRS Tax-Exempt & Government Entities Division expects to initiate approximately thirty-five (35) audits of tax-exempt hospitals before the fiscal year concludes September 30, 2025.
- The IRS Fiscal Year 2025 Program Letter (issued in October 2024) prioritizes focus on highly complex and/or emerging issues including, but not limited to, examinations of tax-exempt hospitals.



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IRS and Treasury Tax and Audit Activity (cont.)

Department of the Treasury

- Treasury released the initial 2024–2025 Priority Guidance Plan on October 3, 2024. Topics of interest to the health care community include:
 - Guidance revising Rev. Proc. 80-27 regarding group exemption letters;
 - Regulations under sections 119 and 132 concerning employer-provided meals;
 - Regulations under section 512 concerning expense allocations when computing unrelated business taxable income; and
 - Regulations on health insurance reporting under sections 6055.



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Senators Warren and Grassley Letter to the IRS – November 19, 2024

Strengthen and enforce regulations under Sections 501(c)(3) and 501(r) for nonprofit hospitals. The letter acknowledges the IRS' plan to audit 35 hospitals this year but also had additional recommendations:

- Increase oversight of nonprofit hospitals, including increasing the number of hospital audits, reviews for compliance issues, imposing more penalties and partnering with state agencies.
- Establish clear standards for financial assistance policies and practices to provide more protection to patients to be able to access financial assistance and more transparency in the billing and collection process.
- Prohibit nonprofit hospitals from using aggressive collection practices and require hospitals to determine patient eligibility prior to initiating any extraordinary collections actions.
- Issue a new Revenue Ruling reinstating previous IRS guidance requiring nonprofit hospitals provide charity care to the extent of their financial ability and issuing new guidance on when hospitals should assume that patients are unable to pay.



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New State Law Developments Related to Hospital Community Benefit Standards/ Nonprofit Hospitals

- **Illinois:** Starting July 1, 2024, hospitals must screen patients for financial assistance or public health insurance program eligibility at the earliest reasonable moment.
- **Minnesota:** A 2024 omnibus bill requires hospitals to report more details on community health improvement and information on how community needs identified in CHNA are being addressed.
- **North Carolina:** In July 2024, the NC Department of Health and Human Services submitted a request to CMS to approve a set of conditions that hospitals must meet to be eligible for enhanced Medicaid payments, including relieving all unpaid debt back to 2014 for Medicaid patients, providing discounts on medical bills and automatically screening patients for financial assistance that are below 300% of the FPL.



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New State Law Developments Related to Hospital Community Benefit Standards/Nonprofit Hospitals (cont.)

Indiana:

- January 21, 2025: Executive order directing the state Secretary of Health and Family Services to conduct an investigation and prepare a report analyzing amount of charity care rendered by each nonprofit hospital in Indiana and compare it to the “tax-exempt benefits enjoyed.” Also analyze “any practices of nonprofit hospitals that permit such hospitals to avoid providing charity care to the truly need in their community.” Purpose for hospital to verify it provided more charity care than value of tax exemptions received.
- Bill introduced into legislature that would require “nonprofit hospitals” to report annually on aggregate items and services billed and to provide a comparison of those charges with their “respective Medicare reimbursement rates.” If hospital charges an amount for item or service that exceeds 200% of Medicare reimbursement rate, hospital “forfeits its status as a nonprofit hospital.” Bill would also revise definition of “community benefits” so that only services remaining unpaid after 180 days where nonprofit hospital “received less than Medicaid rate for service” are included.



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Tax Litigation to Watch

Varian Medical Systems, Inc. v. Commissioner (163 T.C. No. 4), August 26, 2024

- Varian (and now other companies) are benefitting from one of the first U.S. Tax Court rulings issued following the U.S. Supreme Court’s *Loper Bright* decision, overruling *Chevron* deference
- The Tax Court concluded that Congress intended to create a loophole to 2017’s Tax Cuts and Jobs Act (“TCJA”) to allow an end-run of the Dividends Received Deduction (“DRD”) under I.R.C. § 245A by amendments to I.R.C. § 78
 - TCJA added § 245A to give domestic corporations a deduction for certain dividends received from foreign subsidiaries
 - TCJA also amended § 78 to provide that amounts treated as dividends under § 78 would not qualify for the DRD under § 245A
 - But Congress made an error by delaying the effective date of § 78’s amendment until a tax year starting **after** when § 245A took effect
- Treasury and the IRS attempted to fix this timing snafu via regulations
 - The Tax Court held invalid Treas. Reg. § 1.78-1 as it broke from “unambiguous” statutory text
 - Some view the Tax Court’s willingness in *Varian* to overrule a Treasury regulation as a positive indication for future challenges of Executive Branch overreach



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Tax Litigation to Watch

***Memorial Hermann Accountable Care Org. v. Commissioner* (5th Cir., 10/28/2024)(No. 23-60608)**

- MHACO appealed the IRS denial of its application for tax-exempt status
- IRS concluded that:
 - Non-MSSP activities are MHACO's primary activity based on its assigned population of member-patients and revenue;
 - Non-MSSP activities primarily benefit MHACO's member-patients, commercial payors and providers; and
- The Tax Court agreed with the IRS:
 - It did not consider which ACO activities (e.g., MSSP v. non-MSSP, patient v. non-patient) were "primary." rather, denying section 501(c)(4) status based on the ACO's "substantial nonexempt purpose"



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Memorial Herman (cont.)

The Fifth Circuit

- On September 5, 2024, heard oral arguments.
- On October 28, 2024, affirmed the Tax Court's decision (i.e., held in favor of the IRS):
- Cited *Loper Bright* and refused to give deference to the (c)(4) Treasury Regulations
- Agreed with the Tax Court's application of the *Better Business Bureau's* substantial nonexempt purpose test. 326 U.S. 279 (1945).
- Found there to be too much private benefit - if MHACO's operations generated health care cost savings, then that revenue would flow to insurance companies, private providers and private payors – not to the broader Houston community.



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Pottstown

- 2017 Tower Health predecessor bought several for-profit facilities and formed 4 non-profit LLCs to run each of 4 hospitals and charged management fee
- Commonwealth Court denied all 4 tax exemptions, holding that hospitals did not operate entirely free from private profit motive as required by test set forth in Hospital Utilization Project (HUP)
- Supreme Court granted permission to appeal: Held Pottstown “Purely Public Charity” entitled to Tax-Exempt Status
 - Mere dollar size of Tower Health’s executive compensation and amount of management fees Hospital paid, standing alone, insufficient to show a private profit motive
 - Executive compensation – salary/fringe benefits reasonable

Pottstown: Reasonableness of Executive Compensation

- Levels of compensation paid by similar organizations
- Need of organization for services of individual whose comp is being evaluated
- Individual’s background, education, training, experience, and responsibilities
- Whether comp resulted from arm’s length bargaining (Ind. Board of Directors)
- Size and complexity of organization (assets, income, # of employees)
- Prior comp arrangement
- Relationship of comp to other employees in same organization
- Sharp increase in comp from one year to next
- Amount of time devoted to position

NOTE: Particular weight given to type of charitable services provided, geographic location, and skills, duties, and competencies required of executive to fulfill charitable mission

Treasury Decision 10020 (TD 10020) Reissuance of State or Local Bonds under the Internal Revenue Code

- Clarifies the circumstances under which the reissuance of state or local bonds does not trigger a change in their tax status.
- Addresses the following points:
 - Reissuance and Tax Treatment: TD 10020 addresses when a bond is considered “reissued” for tax purposes and when certain modifications to the terms of a bond may be treated as a reissuance, potentially impacting its tax-exempt status.
 - Clarification of Significant Modifications: TD 10020 provides clearer guidance on what constitutes a significant modification to a bond’s terms under Treas. Reg. 1.1001-3. If changes to a bond are significant, it may result in the bond being treated as a new issuance for tax purposes, which could affect its qualification for tax-exempt status.
 - Practical Impact: TD 10020 aims to prevent unintended tax implications for bondholders, ensuring that the tax-exempt status is preserved when certain changes are made to the bonds without triggering reissuance.



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IRS Finalizes Consolidated Return Regulations

- IRS finalized regulations for affiliated groups of corporations that file consolidated Federal income tax returns.
- The final rules (89 FR 106848) released December 27, 2024, closely follow the August 2023 proposed rules (88 FR 52057).
- The regulations update language to remove antiquated terminology and enhance clarity by:
 - Eliminating obsolete or otherwise outdated provisions, and
 - Modernizing language, updating formatting, and improving clarity.
- In separately proposed rules, Treasury and the IRS sought to clarify that, “for certain transfers between members of a consolidated group, a transferee’s assumption of certain liabilities will not reduce the transferor’s basis in the transferee’s stock received in the transfer.”



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2025 TIGTA Report

Vague and Outdated Guidance Creates Challenges for Tax-Exempt Hospital Oversight

- 4 US Senators requested that the Treasury Inspector General for Tax Administration (TIGTA) evaluate concerns regarding compliance with tax-exempt hospital requirements
- TIGTA Findings and Recommendations:
 - Finding: Rev. Rul. 69-545 does not provide clear criteria for determining community benefit
 - Recommendation: Consider legislation to specifically define community benefit, including the level of services and activities that are sufficient to meet the community benefit standard
 - Finding: Financial Assistance (FAP) policy guidelines are not adequately defined
 - Recommendation: Consider legislation to establish baseline criteria for tax-exempt hospital FAP eligibility
 - Finding: Streamlined IRS community benefit review process has resulted in a 98% decrease in audit examination referrals. IRS did not identify or review all tax-exempt hospitals subject to community benefit requirements (e.g. no community benefit reviews for dual status governmental hospitals or church-affiliated hospitals)
 - Recommendation: Update IRS processes to ensure the proper identification and review of all tax-exempt hospitals
 - Recommendation: Update IRS guidance to include reasons for excluding certain hospitals from community benefit reviews
- The IRS agreed with all recommendations and plans to implement corrective actions.



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Tariffs

Whether tax-exempt hospitals should be subject to tariffs when they purchase international goods to carry out charitable missions

- Harmonized Tariff Schedule (HTS), Section XXII, heading 9810 shows whether importation meets any of specifications for one of provisions
- Exemption Examples (no tariff):
 - Instruments and appliances used in medical, surgical, dental or veterinary sciences
 - Apparatus using any radioactive substance in medical diagnosis or therapeutic treatment
- Hospitals can seek rulings from U.S. Customs and Border Protection if product in gray area or unsure



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Check out Session 24

Life Sciences



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Remote Patient Monitoring News



Modern
Healthcare

[Intelligent Patient Monitoring: Empowering Clinicians, Enhancing Patient Care - Modern Healthcare](#)

[Intelligent patient monitoring](#) is a portfolio of remote monitoring, connectivity and interoperable solutions to help optimize workflow efficiencies, simplify patient management and empower clinicians to prioritize care.

Peterson Center on Healthcare report (April 2025) found that in 2023 only a small portion (approximately 1%) of traditional Medicare beneficiaries received RPM services and fewer than 0.2% of Medicare beneficiaries received RTM services, but that the use of both RPM and RTM have expanded rapidly since Medicare began paying for RPM and for RTM. Medicare RPM expenditures grew due to increases in both the number of beneficiaries receiving RPM (a tenfold increase, from 44,500 to 451,000) and the duration of RPM services (the average duration of RPM increased from 1.7 months to 5.2 months). RPM use for Medicare Advantage and Medicaid also increased.

[Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment - Peterson Center on Healthcare](#)

[Remote Patient Monitoring Market Insights 2024-2029](#)

[Business Wire](#) <https://www.businesswire.com/news/home/Remote-...>
Nov 28, 2024 – The Remote Patient Monitoring Market was valued at USD 39.54 Billion in 2023, and is expected to reach USD 77.90 Billion by 2029, rising at a CAGR of 11.97%.



Health and Human Services, Office of Inspector General (.gov)
<https://oig.hhs.gov> › ... › 2024

[Additional Oversight of Remote Patient Monitoring in Medicare ...](#)

Sep 24, 2024 – Our findings demonstrate the need for additional oversight to ensure that remote patient monitoring is being used and billed appropriately.



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FDA AND HRSA NEWS



January 20, 2025 The FDA issued Final Guidance for firms in the medical products industry titled, "[Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers](#)".

Final Guidance summarizes FDA's enforcement policies related to communications by firms regarding unapproved uses of medical products and aims to balance the need for health care providers to access scientific information with FDA's mandate to protect public health and ensure compliance with regulatory standards.

HRSA Announces New OPTN Board of Directors

June 5, 2025 *Pivotal Governance Reform Sets New Course for U.S. Organ Transplant System*

HRSA announced the new 34-member Board of Directors for the Organ Procurement and Transplantation Network (OPTN). This launch of the OPTN Board of Directors advances HRSA's ongoing efforts to strengthen OPTN governance, mitigate conflicts of interest, and modernize the organ donation, procurement, and transplantation system within the United States.

"Establishing a new, independent Board of Directors was a critical step in our efforts to modernize the OPTN, and today we achieved this incredible milestone," said HRSA Administrator Tom Engels.

HRSA improves access to health care for people who are uninsured, isolated, or medically vulnerable.



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Clinical Labs - CLIA and LDTs

Several provisions of the CMS [Final Rule, establishing new Clinical Laboratory Improvement Amendments \(CLIA\) regulations](#) (published December 23, 2023) became effective **December 28, 2024**. The Final Rule added new education and training requirements [2023-28170.pdf](#)

FDA Regulation of Laboratory-Developed Tests (LDTs)

One year after publication of the final rule (May 6, 2025): Manufacturers of IVDs offered as LDTs must comply with medical device adverse event reporting (MDR, 21 C.F.R. Part 806) and reports of corrections and removals (21 C.F.R. Part 803). This allows FDA to begin monitoring the safety of LDTs as soon as practically possible. In addition, manufacturers must comply with quality system (QS) requirements regarding complaint files (21 C.F.R. §820.198). [FDA Regulation of Laboratory-Developed Tests \(LDTs\) | Congress.gov | Library of Congress](#)



What's New & Important

Act Now: Make the Switch by March 1, 2026

Laboratories must switch to email notifications to start receiving electronic CLIA fee coupons and certificates.

After March 1, 2026, paper fee coupons and CLIA certificates will no longer be available. Don't miss this important transition to paperless. Help us spread the word.

Download this [toolkit](#), which provides ready-to-use messaging for your outreach to laboratories and providers, plus these materials you can share: [Fact Sheet](#) | [Poster](#)



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Medical Devices



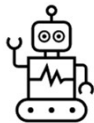
June 15, 2025 – 2 in 3 orgs use outdated tech to manage IoT and medical devices, less than 30% of orgs ready for AI-driven cyberattacks

Medtronic

[Medtronic wins 2025 MedTech Breakthrough Award for 'Best Overall Medical Device Solution' for HealthCast™.](#)



[Tariffs on medical devices will raise costs. Here's what to know](#)



Communications Pilot to Enhance Medical Device Recall Program

The pilot aims to minimize the time between the FDA's initial awareness of and public notification of potentially high-risk medical device removals or corrections.

The tariffs will boost medical device prices, but hospitals may be temporarily shielded by their contracts.



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Newsweek

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1.9M Followers



Nationwide Blood Pressure Drug Recall As FDA Issues Fatal Warning

An injectable blood pressure drug called phenylephrine hydrochloride has been recalled after a customer noticed "a visible black particulate matter" in a vial of the product, raising the risk of stroke or death, according to the FDA.

Provepharm, Inc., of Pennsylvania, announced their nationwide voluntary recall on Friday, January 24, 2025 and the FDA followed suit the same day. The recall affects one lot of phenylephrine hydrochloride injection, 10mg/ml, sold to wholesalers, distributors, compounding companies and hospitals.

The drug is used to treat low blood pressure, also known as hypotension, mainly after anesthesia when the blood vessels dilate.

"This recall was initiated based on a customer complaint from a pharmacy after observing a visible black particulate matter found in a single-sealed vial of the product," said the FDA announcement.

A drug recall is the most effective way to protect the public from a defective or potentially harmful product. A recall is a voluntary action taken by a company to remove a defective drug product from the market or warn patients and consumers about a potential risk.

The list below includes voluntary drug recalls in which public notification has been issued.



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February 4, 2025: CDC's website is being modified to comply with President Trump's Executive Orders.

U.S. Outbreaks

JUN 2025	Pistachio Cream - <i>Salmonella</i>
JUN 2025	Eggs - <i>Salmonella</i>
MAY 2025	Whole Cucumbers - <i>Salmonella</i>
MAY 2025	Ready-to-Eat Foods - <i>Listeria</i>
MAY 2025	Backyard Poultry - <i>Salmonella</i>
MAR 2025	Geckos - <i>Salmonella</i>
JAN 2025	Measles Outbreaks 2025

One in 31

On any given day, about [one in 31](#) hospital patients has at least one healthcare-associated infection.



HAIs: Reports and Data

Public Health
NOVEMBER 25, 2024

KEY POINTS

- Although significant progress has been made in preventing some healthcare-associated infection types, there is much more work to be done.
- CDC publishes data reports to help track progress and target areas that need assistance.
- The data come from two complementary HAI surveillance systems, the National Healthcare Safety Network (NHSN) and the Emerging Infections Program Healthcare-Associated Infections – Community Interface (EIP HAIC).

OIG Reports & Recommendations *PLUS*

Drug Spending (Drug Spending | HHS-OIG) Updated: 12-16-2024

For over 25 years, the HHS Office of Inspector General has conducted work to assess drug spending in HHS programs. This work covers three domains: reimbursement, program compliance, and incentive alignment. The webpage is a compilation of completed reports, unimplemented recommendations, enforcement actions, and industry guidance. OIG work includes examinations of Medicare Part D plan sponsors' insights into the services and information provided by pharmacy benefit managers (PBMs) and of conflicts of interest on pharmacy and therapeutics (P&T)



PharmaVoice: Locked in a federal stalemate, states take PBM reform into their own hands Arkansas is leading the nation in [banning PBMs from owning pharmacies](#), as other states advance new restrictions.



Fierce Health Payer: Governor of Iowa has signed into law [a bill that seeks to rein in pharmacy benefit managers](#), with policy changes looking to even out reimbursement to independent pharmacies.

How FDA Used Its Accelerated Approval Pathway Raised Concerns in 3 of 24 Drugs Reviewed Evaluation OEI-01-21-00400 HHS Agency FDA Issued 01/08/2025

Medicaid Gross Spending on 10 Selected Diabetes and 2 Selected Weight Loss Drugs Totaled More Than \$9 Billion in 2023, an Increase of 540 Percent From 2019 Audit A-05-24-00016 HHS Agency CMS Issued 12/16/2024

Unauthorized Distribution



The screenshot shows a DOJ press release dated Monday, November 4, 2024. The headline reads: "Telehealth Company Cerebral Agrees to Pay Over \$3.6 Million in Connection with Business Practices that Encouraged the Unauthorized Distribution of Controlled Substances". The release is categorized as a "PRESS RELEASE" and is marked as "For Immediate Release". It is issued by the U.S. Attorney's Office, Eastern District of New York. The text mentions a "Non-Prosecution Agreement Resolves Investigation of the Company's Efforts to Increase Prescriptions of Adderall and Other Controlled Substances via Telemedicine".

Cerebral's Prescription Practices

Between February 2021 and October 2022, Cerebral instituted internal measures to increase the prescriptions of medications with the goal of boosting patient retention and, by extension, Cerebral's revenue.

Cerebral monitored the rates at which its providers prescribed medications, including controlled substances, primarily through two metrics which measured: (1) the number of drug prescriptions issued to patients who enrolled in a medication management subscription plan after their first 30-minute telehealth visit (the Initial Visit Rx Rate); and (2) the number of stimulant prescriptions prescribed to patients diagnosed with ADHD who had no comorbidities (the ADHD Stimulant Rx Metric). Cerebral did not consult with any members of its clinical advisory board—which included multiple experts in the fields of psychology and psychiatry—prior to implementing targeted campaigns to improve both metrics.

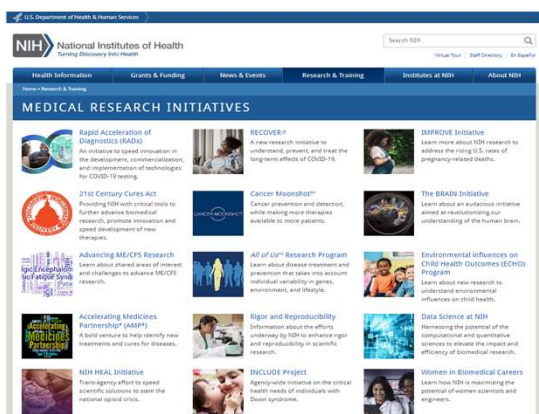
[Eastern District of New York | Telehealth Company Cerebral Agrees to Pay Over \\$3.6 Million in Connection with Business Practices that Encouraged the Unauthorized Distribution of Controlled Substances | United States Department of Justice](#)



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Clinical Research

Check out Session 45



The screenshot shows the NIH Medical Research Initiatives page. It features a grid of various research initiatives, including "Rapid Acceleration of Diagnostics (RADx)", "RECOVER", "IMPROVE Initiative", "21st Century Cures Act", "Cancer Moonshot", "The BRAIN Initiative", "Advancing ME/CFS Research", "All of Us Research Program", "Environmental influences on Child Health Outcomes (ECHO)", "Accelerating Medicines Partnership (AMP)", "Rigor and Reproducibility", "Data Science at NIH", "NIH HDL Initiative", "INCLUDE Project", and "Women in Biomedical Careers". Each initiative is accompanied by a brief description and a small image.



The screenshot shows the NIH Research Matters page, dated December 18, 2024. The headline is "2024 NIH Research Highlights - Promising Medical Findings". The page features a section titled "Results with Potential for Enhancing Human Health" which discusses the impact of NIH research on human health. It also includes a section titled "Insight into mechanisms of ME/CFS" and another titled "Skin test detects evidence of Parkinson's and related disorders".



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FDA concerns re AI listed in JAMA



“Special Communication” in [JAMA](#) (October 15, 2024) described FDA’s concerns with the use of AI in clinical research [FDA Perspective on the Regulation of Artificial Intelligence in Health Care and Biomedicine | Artificial Intelligence | JAMA | JAMA Network](#)

Potential Uses of AI in Clinical Trials

FDA noted that several areas of clinical research could benefit from AI, including participant recruitment; selection and stratification of trial participants and sites; adherence and retention; clinical trial data collection, management, and analysis; and postmarket safety surveillance and evaluation.



China in Research News



[Home](#) / [News & Events](#)

[Takes Action to Address Data Integrity Concerns with Two Chinese Third-Party Testing Firms](#)

FDA NEWS RELEASE

FDA Takes Action to Address Data Integrity Concerns with Two Chinese Third-Party Testing Firms

For Immediate Release: May 22, 2025

The U.S. Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) issued General Correspondence Letters to two third-party testing companies in China after discovering data that was falsified or otherwise found to be invalid.

“Let me be clear. The FDA has no room for bad actors. Once we discover data integrity issues, we will respond accordingly,” said **FDA Commissioner Marty Makary, M.D., M.P.H.** “Such false and shoddy activity jeopardizes access to new devices for patients and healthcare providers, negatively impacts product sponsors, and potentially disrupts the medical device supply chain.”



University of Michigan
<https://publicaffairs.vpcomm.umich.edu/key-issues>
University Statement on Chinese Research Fellow
It is important to note that the university has received no funding from the Chinese government in relation to research conducted by the accused ...

MLive.com
<https://www.mlive.com/news/ann-arbor/2025/06/>
'Pattern emerging' with University of Michigan's Chinese ...
6 days ago — Since October 2024, four federal cases involving University of Michigan students from China have gone public. The two most recent involve a ...

CBS News
<https://www.cbsnews.com/CBS-Detroit-Crime>
Third Chinese national accused of smuggling biological ...
Jun 9, 2025 — A third Chinese national is accused of smuggling biological materials into the U.S. for work at a University of Michigan laboratory.

Family and Medical Leave Act – applied to Participation in Clinical Trials



Work addressing barriers to clinical trial participation by the Foundation for Sarcoidosis Research could bolster participation and diversity in clinical trials. [June 17, 2025](#)

Because the Family and Medical Leave Act policy's language only allowed for time off to receive "treatments" for a medical condition, employees couldn't leverage it for clinical trials, which often administer placebos.

After lobbying the Department of Labor, FSR [got word last year](#) that regulators were on board to switch the language and account for clinical trials.

Foundation surveyed about 400 patients last year and then met with industry leaders to learn more about representation in clinical trials. Ultimately, the efforts pinpointed key issues of doctors not informing patients about trials and getting time off from work to participate in research.

The Foundation sought insights about the clinical trial journey of a rare inflammatory disease, sarcoidosis that disproportionately impacts Black Americans, who are 12 times more likely [to die from the condition](#) than the general population.



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Diversity in Clinical Trials

[Check out Session 11](#)

News | Article | January 31, 2025



FDA Quietly Removes Draft Guidance on Diversity in Clinical Trials Following Executive Order on DEI

[citeline.com](#)
<https://insights.citeline.com/medtech-insight/fda-guid...>

FDA Guidance Docs On Trial Diversity, Sex Differences ...

Feb 13, 2025 — A judge ordered the FDA to restore webpages for draft guidances on clinical trial diversity action plans and sex differences in clinical ...

<https://www.fda.gov/search?s=draft+guidance+trial+diversity> (visited 6-22-25)

2020 meeting info and 2024 symposium info posted

<https://www.fda.gov/search?s=draft+guidance+trial+diversity#:~:text=https%3A/www.fda.gov/drugs/news%2Devents%2Dhuman%2Ddrugs/diversity%2Dclinical%2Dtrials%2Dlearn%2Dabout%2Denrollment%2Dtrends%2Dand%2Dresources%2Dfda%2D12162020%2D12162020>

<https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/benchmarks-diversity-oncology-clinical-trials-fda-ac-s-hybrid-symposium-10162024>

FDA Withdrawn Clinical Trial Guidance Documents

Title	Issue	Withdrawal
	Date	Date
Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22: (Laser Notice No. 50)	06/24/2007	12/31/2024



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Orange Book Listing – Warning Letters



FTC Revives Orange Book Listing Challenges

What Happened:

On May 21, 2025, the Federal Trade Commission (FTC) issued its third round of warning letters – and its first under the Trump administration – against pharmaceutical manufacturers challenging their allegedly improper patent listings in the Food and Drug Administration’s Orange Book.

Why It Matters:

The FTC’s action aims to ensure fair competition and lower healthcare costs by preventing brand-name manufacturers from delaying generic competition.



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FDA’s Heavy Workload



KalVista Pharmaceuticals faces delays to the FDA’s decision-making, FDA is pushing back a PDUFA date.

Cambridge, Mass.-based biotech KalVista had been expecting the FDA to make a decision June 17 about whether to approve the oral plasma kallikrein inhibitor sebetralstat for hereditary angioedema (HAE).

KalVista [announced Friday](#) that it had been informed by the FDA earlier in the day that it could have to wait up to four weeks for the agency to make the call.

The FDA blamed “heavy workload and limited resources” for the delay, according to KalVista.

FDA NEWS RELEASE

FDA to Issue New Commissioner’s National Priority Vouchers to Companies Supporting U.S. National Interests

“Commissioner’s National Priority Voucher” (CNPV) program will include a “limited number of vouchers” for “companies aligned with U.S. national priorities,” according to a [June 17 press release](#). Novel priority program by the FDA that shortens its review time from approximately 10-12 months to 1-2 months following a sponsor’s final drug application submission



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New Developments in Right to Try Legislation

January 24, 2025

Health Law Weekly

Almost exactly a decade after the first Right to Try laws (RTTs) were passed in state legislatures and over six years after the enactment of the federal Right to Try law, a new iteration of RTT is gaining momentum in state chambers. This legislation, known as the “Right to Try For Individualized Treatments” (RTT 2.0), is grounded in the same principles as the original law but focuses more narrowly on individualized therapies.

While 41 states enacted RTT 1.0 prior to the passage of the federal Right To Try Act, it has rarely been utilized as an alternative pathway to access investigational products.

Nevertheless, RTT 2.0 laws have been passed in six states and appear to be advancing in a number of additional states. This article discusses the federal RTT law in comparison to the U.S. Food and Drug Administration (FDA) expanded access pathway, compares RTT with RTT 2.0, and explores the challenges of each.



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HOPE Act updates

OPTN Organ Procurement & Transplantation Network

U.S. Department of Health & Human Services

HRSA Health Resources & Services Administration

A Rule by the [Health and Human Services Department](#) on [11/27/2024](#)

Published on: Wednesday, May 14, 2025

In response to a [recent HRSA directive](#), the Organ Procurement and Transplantation Network (OPTN) will soon consider adoption of [revised policies and requirements](#) for transplantation under the HIV Organ Policy Equity (HOPE) Act for liver, kidney and combined liver-kidney candidates.

While these revisions are expected to be approved and implemented soon, the current HOPE Act provisions in OPTN policy continue to apply to transplant programs wishing to use organs from donors with HIV to treat candidates living with HIV. These provisions are specifically addressed in [OPTN Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors](#).



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NIH RFI and ORI Final Rule

- On September 12, 2024, ORI published the [final rule](#) updating 42 CFR Section 93, Public Health Service Policies (“PHS”) on Research Misconduct
- The Final Rule applies to institutions starting on January 1, 2026.
 - ORI advised that it “will not require institutions to implement and submit revised policies and procedures that comply with the final rule until the submission of their annual report covering 2025, which is due on or before April 30, 2026.”



Defining, Identifying and Reporting Protocol Deviations

A Notice by the [Food and Drug Administration](#) on [12/30/2024](#)

Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices; Draft Guidance for Industry; Availability
Created by the Food and Drug Administration

 Closed for Comments

 Docket Details

 Docket Documents 2

 All Comments on Docket 53

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.



Research Involving Artificial Intelligence—Considerations for Academic Medical Centers

November 20, 2024 This Briefing is brought to you by AHLA's Academic Medical Centers and Teaching Hospitals Practice Group

GUIDANCE DOCUMENT

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers

OCTOBER 2024

[Download the Final Guidance Document](#)

[Read the Federal Register Notice](#)

Final

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Docket Number: [FDA-2017-D-1105](#)

Issued by: Center for Drug Evaluation and Research
Office of the Commissioner, Office of Clinical Policy and Programs

This guidance provides information for sponsors, clinical investigators, institutional review boards, contract research organizations, and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of foods, medical products, tobacco products, and new animal drugs. The guidance provides recommendations regarding the requirements in our regulations, pursuant to which FDA considers electronic systems, electronic records, and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

[Clinical Trials Guidance Documents | FDA](#)



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ORI Research Misconduct Administrative Actions – finding of research misconduct

Case Summaries

This page contains cases in which administrative actions were imposed due to findings of research misconduct. The list only includes those who CURRENTLY have an imposed administrative actions against them. It does NOT include the names of individuals whose administrative actions periods have expired. Each case is categorized according to the year in which ORI closed the case.

2025

[Case Summary: Zhang, Liping](#)

2024

[Case Summary: Bhan, Arunoday K.](#)
[Case Summary: Brigidi, Gian-Stefano](#)
[Case Summary: Eckert, Richard L](#)
[Case Summary: Mousa, Shaker](#)
[Case Summary: Nguyen, Darrion](#)
[Case Summary: Rutherford, Bret](#)



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Drug Shortages

June 9, 2025

BECKER'S
HOSPITAL REVIEW

New shortages and discontinuations from FDA and American Society of Health-System Pharmacists.

1. Atazanavir sulfate capsules: Bristol Myers Squibb has permanently discontinued its Reyataz 200 mg and 300 mg capsules, used as part of antiviral therapy for **HIV**

2. Atazanavir sulfate oral powder: Bristol Myers Squibb has permanently discontinued Reyataz 50 mg oral powder used in pediatric and adult patients for **HIV** treatment

3. Bosentan tablet: Actelion Pharmaceuticals has discontinued both 62.5 mg and 125 mg presentations of Tracleer, a treatment used for **pulmonary arterial hypertension**

4. Metoprolol tartrate tablet: Aurobindo Pharma USA has permanently discontinued all 25 mg, 50 mg and 100 mg strengths of its cardiovascular drug used to manage **high blood pressure and chest pain**

5. Octreotide intramuscular injection kits: Teva Pharmaceuticals has all 10 mg, 20 mg and 30 mg octreotide kits on back order; the drug is used to manage symptoms of **certain hormone-secreting tumors**. The company estimates resupply date in mid- to late June. Novartis' Sandostatin LAR Depot remains available as an alternative

6. Scopolamine transdermal system: Baxter and Teva report shortages of scopolamine patches used to prevent **nausea and vomiting**. Baxter cannot estimate a resupply date, while Teva expects resupply of several presentations between July and October. Alternatives from Ingenus, Padagis, Rhodes, Viatris and Zydus remain available

7. Triamcinolone acetonide injectable suspension: Multiple manufacturers, including Teva, Eugia, Hikma, Long Grove and Viatris, report shortages of 40 mg/mL injectable formulations commonly used to treat **inflammation and allergies**. Amneal and Bristol Myers Squibb have several presentations available and resupply estimates vary from early June to late July, depending on the manufacturer

HL AMERICAN
HEALTH LAW
ASSOCIATION

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спасибо 谢谢
GRACIAS 谢谢
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