

Health Law Year-in-Review

Michael W. Chase
Baird Holm LLP





Politics

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Facts First

2024 Elections

How the Supreme Court's blockbuster 'Chevron' ruling puts countless regulations in jeopardy



By Tierney Sneed, Jeanne Sahadi, Tami Luhby, Brian Fung, Ella Nilsen, Jen Christensen and Katie Lobosco, CNN

🕒 10 minute read · Published 1:29 PM EDT, Sun June 30, 2024



<https://www.cnn.com/2024/06/30/politics/chevron-ruling-explained-supreme-court-meaning/index.html>

HHS, FBI warn healthcare sector of social engineering scheme

Threat actors have been using phishing schemes to steal login credentials and divert automated clearinghouse payments, HHS and the FBI warned in a joint cybersecurity advisory.



<https://www.ic3.gov/Media/News/2024/240624.pdf>



World

Africa

Americas

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Australia

China

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India

Middle East

United Kingdom

World / Asia

Finance worker pays out \$25 million after video call with deepfake 'chief financial officer'



By Heather Chen and [Kathleen Magramo](#), CNN

🕒 2 minute read · Published 2:31 AM EST, Sun February 4, 2024



<https://www.cnn.com/2024/02/04/asia/deepfake-cfo-scam-hong-kong-intl-hnk/index.html>



HEALTH TECH

CMS: Providers may now text patient info, orders to care teams

By **Dave Muoio** · Feb 12, 2024 3:40pm

Centers for Medicare & Medicaid Services (CMS)

HIPAA

Privacy and Security

Text messaging



<https://www.cms.gov/files/document/qso-24-05-hospital-cah.pdf>

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REGULATORY

HHS pushes forward with new requirements for AI transparency, interoperability

By Heather Landi · Dec 13, 2023 1:28pm

Office of the National Coordinator for Health IT (ONC)

Interoperability

Artificial Intelligence

Clinical Decision Support



<https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program>

COVID-19

U.S. Department of Justice
Washington, DC 20530

COVID-19 FRAUD ENFORCEMENT TASK FORCE 2024 REPORT

APRIL 2024



<https://www.justice.gov/coronavirus/media/1347161/dl?inline>

Ad Tracking



U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates

On March 18, 2024, OCR updated this guidance to increase clarity for regulated entities and the public.

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) is issuing this Bulletin to highlight the obligations of Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities¹ and business associates² (“regulated entities”) under the HIPAA Privacy, Security, and Breach Notification Rules (“HIPAA Rules”) when using online tracking technologies (“tracking technologies”).³ OCR administers and enforces the HIPAA Rules, including by investigating breach reports and complaints about regulated entities’ noncompliance with the HIPAA Rules. A regulated entity’s failure to comply with the HIPAA Rules may result in a civil money penalty.⁴

<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html>

AHA v. Becerra

OCR Online Tracking Technology Guidance Set Aside by Texas Federal Court



On Thursday, June 20, a Texas federal court judge **ruled** that HHS' Online Tracking Technology Guidance, first released in December of 2022 and **later modified in March 2024** is unlawful. This article covers that guidance and why the court found that HHS issued the online tracking technology guidance beyond the scope of its authority.

<https://compliance-group.com/hipaa-online-tracking-update/>

HHS Drops Appeal

HHS reverses course, will no longer appeal federal court's hospital web tracker decision

By Dave Muoio · Aug 29, 2024 3:30pm

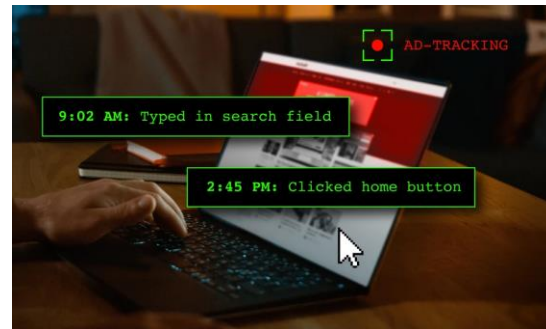
Lawsuits

HIPAA

Department of Health and Human Services (HHS)

HHS Office for Civil Rights

<https://www.fiercehealthcare.com/regulatory/hhs-reverses-course-will-no-longer-appeal-federal-courts-hospital-web-tracker-decision>



HIPAA Updates Anytime Soon?



The HIPAA Journal is the leading provider of news, updates, and independent advice for HIPAA compliance

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Sen. Cassidy Proposes Legislative Updates to Improve Health Data Privacy

Posted By Steve Alder on Mar 7, 2024

Senator Bill Cassidy (R-LA), Ranking Member of the U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee, has published a white paper that proposes updates to the Health Insurance Portability and Accountability Act (HIPAA) to improve privacy protections for health information and urges Congress to take action to expand privacy protections for all health data.



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https://www.help.senate.gov/imo/media/doc/privacy_report.pdf

Information Blocking

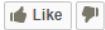


Healthcare providers face Medicare payment-rate penalties for information blocking under new rule

In an accommodation, the HHS Office of Inspector General says it will not investigate any act of information blocking alleged to have occurred before July 31 of this year.



Nick Hut



July 3, 2024 10:11 am



<https://www.hhs.gov/about/news/2024/06/24/hhs-finalizes-rule-establishing-disincentives-health-care-providers-that-have-committed-information-blocking.html>

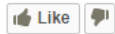
Information Blocking

Healthcare providers face Medicare payment-rate penalties for information blocking under new rule

In an accommodation, the HHS Office of Inspector General says it will not investigate any act of information blocking alleged to have occurred before July 31 of this year.



Nick Hut



July 3, 2024 10:11 am



Print

HIPAA & Reproductive Health



U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

Final Rule HIPAA Privacy Rule to Support Reproductive Health Care Privacy

On April 22, 2024, OCR issued a Final Rule, entitled *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*. The Final Rule strengthens the Health Insurance Portability Act of 1996 (HIPAA) Privacy Rule by prohibiting the disclosure of protected health information related to lawful reproductive health care in certain circumstances. HHS issued this Final Rule after hearing from communities that changes were needed to better protect patient confidentiality and prevent medical records from being used against people for providing or obtaining lawful reproductive health care. This Final Rule bolsters patient-provider confidentiality and helps promote trust and open communication between individuals and their health care providers or health plans, which is essential for high-quality health care.

[Press Release](#)

[To read the Fact Sheet](#)

<https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html>

HIPAA Enforcement

FOR IMMEDIATE RELEASE

February 6, 2024

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS' Office for Civil Rights Settles Malicious Insider Cybersecurity Investigation for \$4.75 Million

*The OCR Settlement with Montefiore Medical Center resolves multiple potential
HIPAA Security Rule Violations*

Today, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), announced a settlement with Montefiore Medical Center, a non-profit hospital system based in New York City for several potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Security Rule. OCR is responsible for

<https://www.hhs.gov/about/news/2024/02/06/hhs-office-civil-rights-settles-malicious-insider-cybersecurity-investigation.html>

HIPAA Enforcement

FOR IMMEDIATE RELEASE

December 7, 2023

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS' Office for Civil Rights Settles First Ever Phishing Cyber-Attack Investigation

Louisiana Medical Group settles after investigation reveals large cybersecurity breach affecting nearly 35,000 patients

Today, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), announced a settlement with Lafourche Medical Group, a Louisiana medical group specializing in emergency medicine, occupational medicine, and laboratory testing. The settlement resolves an investigation following a phishing attack that affected the electronic protected health information of approximately 34,862 individuals. Phishing is a type of

<https://www.hhs.gov/about/news/2023/12/07/hhs-office-for-civil-rights-settles-first-ever-phishing-cyber-attack-investigation.html>

Trends



**Annual Report to Congress on
Breaches of Unsecured Protected Health Information
For Calendar Year 2022**

<https://www.hhs.gov/hipaa/for-professionals/breach-notification/reports-congress/index.html>

Cyber Attacks Continue



healthcare financial
management association

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Cyberattack on Change Healthcare brings turmoil to healthcare operations nationwide

Optum, which combined with Change Healthcare after a 2022 merger, has been providing regular updates but hasn't offered new information in the days since the attack.



Nick Hut



February 25, 2024 3:47 pm



https://www.hfma.org/technology/cybersecurity/cyberattack-on-change-healthcare-brings-turmoil-to-healthcare-operations-nationwide/?utm_medium=email&utm_source=rasa_io&utm_campaign=newsletter

It's Not If ...

The New York Times

Cyberattack Paralyzes the Largest U.S. Health Care Payment System

The hacking shut down the nation's biggest health care payment system, causing financial chaos that affected a broad spectrum ranging from large hospitals to single-doctor practices.

The Impact...

 healthcare financial
management association

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Cybersecurity

Cyberattack on Change Healthcare brings turmoil to healthcare operations nationwide

April 17 update: UnitedHealth Group says it expects to incur at least \$1 billion in costs this year as a result of the attack.

 Nick Hut

https://www.hfma.org/technology/cybersecurity/cyberattack-on-change-healthcare-brings-turmoil-to-healthcare-operations-nationwide/?utm_medium=email&utm_source=rasa_io&utm_campaign=newsletter

A Swift Response



Never Ending ...

MAY 17 | MORE ON COMPLIANCE & LEGAL

Ascension faces class action lawsuits for Black Basta ransomware attack

The cyberattack that brought down the Ascension IT Systems was "foreseeable and preventable," complaints say.

 Susan Morse, *Executive Editor*



<https://www.healthcarefinancenews.com/news/ascension-faces-class-action-lawsuits-black-basta-ransomware-attack>

Cybersecurity Trends



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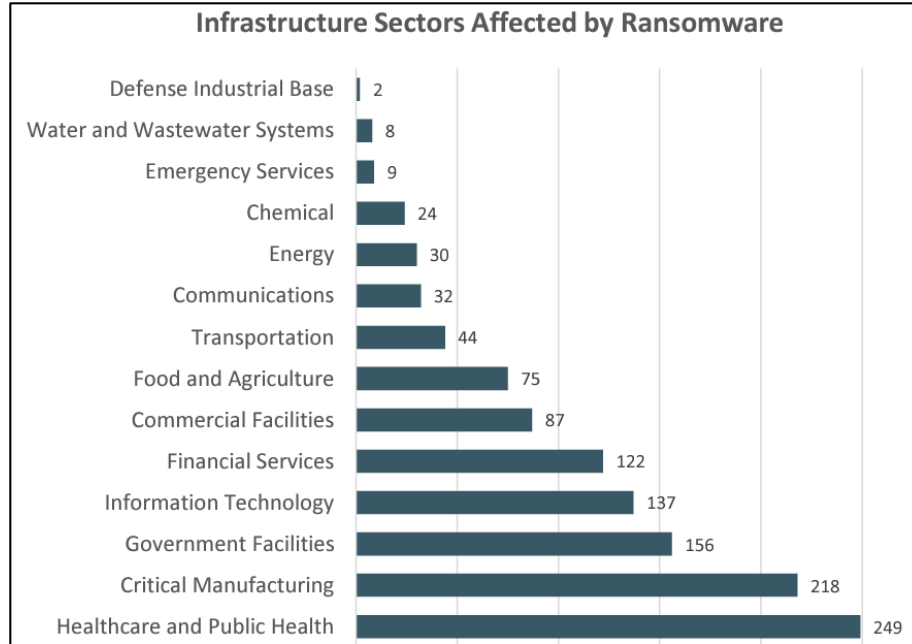
[HIPAA and Compliance](#) [Cybersecurity](#) [Cloud](#) [Mobile](#) [Patient Privacy](#) [Data Breaches](#)

Healthcare hit hardest by ransomware last year, FBI IC3 report shows

LockBit and ALPHV/BlackCat were the top ransomware variants to impact critical infrastructure sectors last year, according to the FBI's 2023 Internet Crime Report.

<https://healthitsecurity.com/news/healthcare-hit-hardest-by-ransomware-last-year-fbi-ic3-report-shows>

Cybersecurity Trends



https://www.ic3.gov/Media/PDF/AnnualReport/2023_IC3Report.pdf

Some Good News?

US indicts North Korean hacker accused of helping extort US hospitals

By Sean Lyngaas, CNN

🕒 2 minute read · Published 2:27 PM EDT, Thu July 25, 2024



CISA Breach Reporting

 **HEALTHCARE DIVE**

Deep Dive Opinion Library Events Press Releases

Hospitals Payer Health IT Government Finances Medical Groups

CISA issues notice for long-awaited critical infrastructure reporting requirements

The proposed rule will require covered entities — including major healthcare companies — to promptly disclose major cyber incidents and ransomware payments.

Published March 27, 2024

<https://www.healthcaredive.com/news/cisa-notice-critical-infrastructure/711788/>

But...

DIVE BRIEF

Healthcare groups say cyber rule should explicitly name insurers, vendors

The proposed rule would require critical infrastructure industries to report cyber incidents.

Published July 8, 2024



[Emily Olsen](#)
Reporter



HIPAA Enforcement



<https://www.hhs.gov/about/news/2024/02/21/hhs-office-civil-rights-settles-second-ever-ransomware-cyber-attack.html>

HIPAA Enforcement

Attorney General Todd Rokita continues fight for patient privacy, files suit against Apria Healthcare

📅 Thursday, February 29, 2024

😊 I'm Interested



**OFFICE OF THE INDIANA
ATTORNEY GENERAL**

https://events.in.gov/event/attorney_general_todd_rokita_continues_fight_for_patient_privacy_files_suit_against_apria_healthcare

Not Just in the U.S.

UK data watchdog 'assessing' report hospital staffer tried to access Princess of Wales' medical records



By Max Foster, Pauline Lockwood, Niamh Kennedy and Lauren Said-Moorhouse, CNN

🕒 4 minute read · Updated 10:14 AM EDT, Wed March 20, 2024



OIG Advisory Opinion 23-15



U.S. Department of Health and Human Services
Office of Inspector General

Posted: January 3, 2024

Favorable opinion regarding a physician consulting company's proposal to offer physician practices that are current customers of the company certain gift cards for referring potential new physician practice customers.

<https://oig.hhs.gov/compliance/advisory-opinions/23-15/>

Fraud & Abuse



The screenshot shows the official website of the U.S. Department of Justice Office of Public Affairs. The header includes the department's seal, name, and navigation links. The main content area features a breadcrumb trail, a news sidebar, a press release title, date, and a 'Share' button. A 'For Immediate Release' banner is also present.

Office of Public Affairs
U.S. Department of Justice

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Justice.gov > Office of Public Affairs > News > Press Releases > False Claims Act Settlements and Judgments Exceed \$2.68 Billion In Fiscal Year 2023

News

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PRESS RELEASE

False Claims Act Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023

Thursday, February 22, 2024

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Office of Public Affairs

<https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023>

Fraud & Abuse



The screenshot displays the official website of the U.S. Department of Justice Office of Public Affairs. The header features the department's seal, the text "Office of Public Affairs U.S. Department of Justice", and navigation links for "Our Offices", "Find Help", and "Contact Us". A search bar is also present. Below the header is a dark navigation bar with links for "About", "News", "Documents", "Internships", "FOIA", "Contact", and "Information for Journalists". The main content area shows a breadcrumb trail: "Justice.gov > Office of Public Affairs > Principal Deputy Assistant Attorney General Brian M. Boynton Delivers Remarks at the 2024 Federal Bar Association's Qui Tam Conference". On the left, a "News" sidebar lists "All News", "Blogs", "Photo Galleries", "Podcasts", and "Press Releases". The main headline, categorized under "SPEECH", reads "Principal Deputy Assistant Attorney General Brian M. Boynton Delivers Remarks at the 2024 Federal Bar Association's Qui Tam Conference". The date "Thursday, February 22, 2024" is displayed below the headline.

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U.S. Department of Justice

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SPEECH

Principal Deputy Assistant Attorney General Brian M. Boynton Delivers Remarks at the 2024 Federal Bar Association's Qui Tam Conference

Thursday, February 22, 2024

<https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-brian-m-boynton-delivers-remarks-2024>

HEALTH

U.S. investigates alleged Medicare fraud scheme estimated at \$2 billion

By [Dan Diamond](#), [Lauren Weber](#) and [Dan Keating](#)
February 9, 2024 at 4:31 p.m. EST



IBM

Put AI to work
for customer
service

<https://www.washingtonpost.com/national-security/2024/02/09/medicare-alleged-fraud-catheters/>

Whistleblowers Wanted

**Criminal Division**
U.S. Department of Justice

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Justice.gov > Criminal Division > Report Crime > Criminal Division Corporate Whistleblower Awards Pilot Program

Criminal Division Corporate Whistleblower Awards Pilot Program

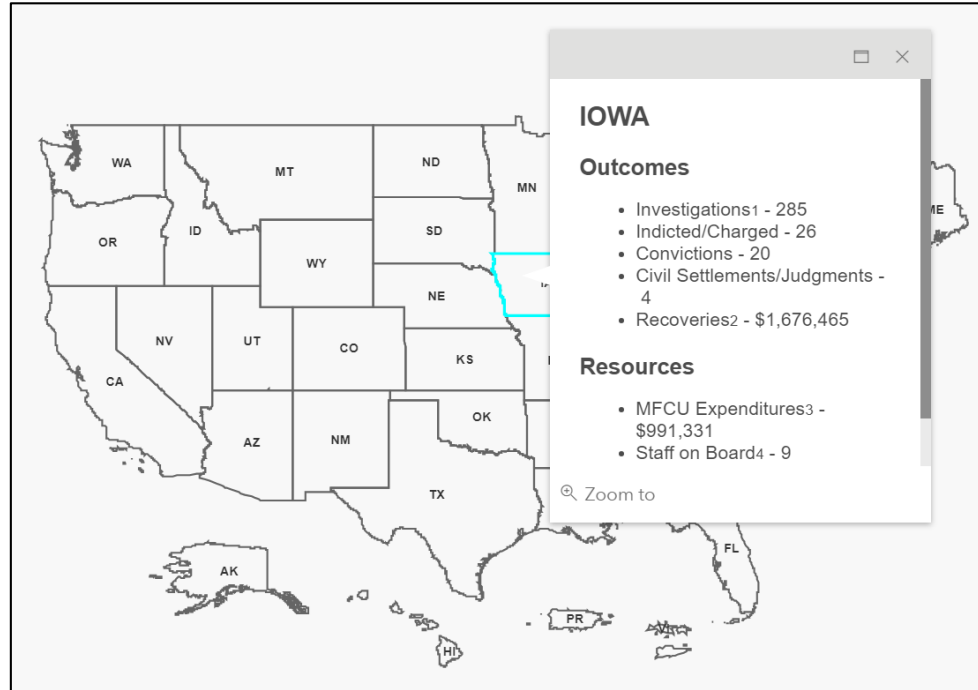
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The Department of Justice's Criminal Division has launched a Corporate Whistleblower Awards Pilot Program to uncover and prosecute corporate crime. Under this pilot program, a whistleblower who provides the Criminal Division with original and truthful information about corporate misconduct that results in a successful forfeiture may be eligible for an award.

As described in more detail in the program [guidance](#), the information must relate to one of the following areas: (1) certain crimes involving financial institutions, from traditional banks to cryptocurrency businesses; (2) foreign corruption involving misconduct by companies; (3) domestic corruption involving misconduct by companies; or (4) health care fraud schemes involving private insurance plans.



Medicaid Fraud Control Unit



Overpayments/Repayments

ICD10monitor

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Coders Beware: Newly Updated Overpayment Refund Rule

By Rose T. Dunn, MBA, RHIA, CPA, FACHE, FHFMA, CHPS, AHIMA-approved ICD-10-CM/PCS Trainer | January 27, 2025



Cannabis



January 17, 2024

US DHHS Publishes Full Report Detailing Recommendation to Move Cannabis from Schedule I to III

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Artificial Intelligence (AI)

HTI-1 final rule now in effect, with an eye on AI – and there's more to come, says ONC

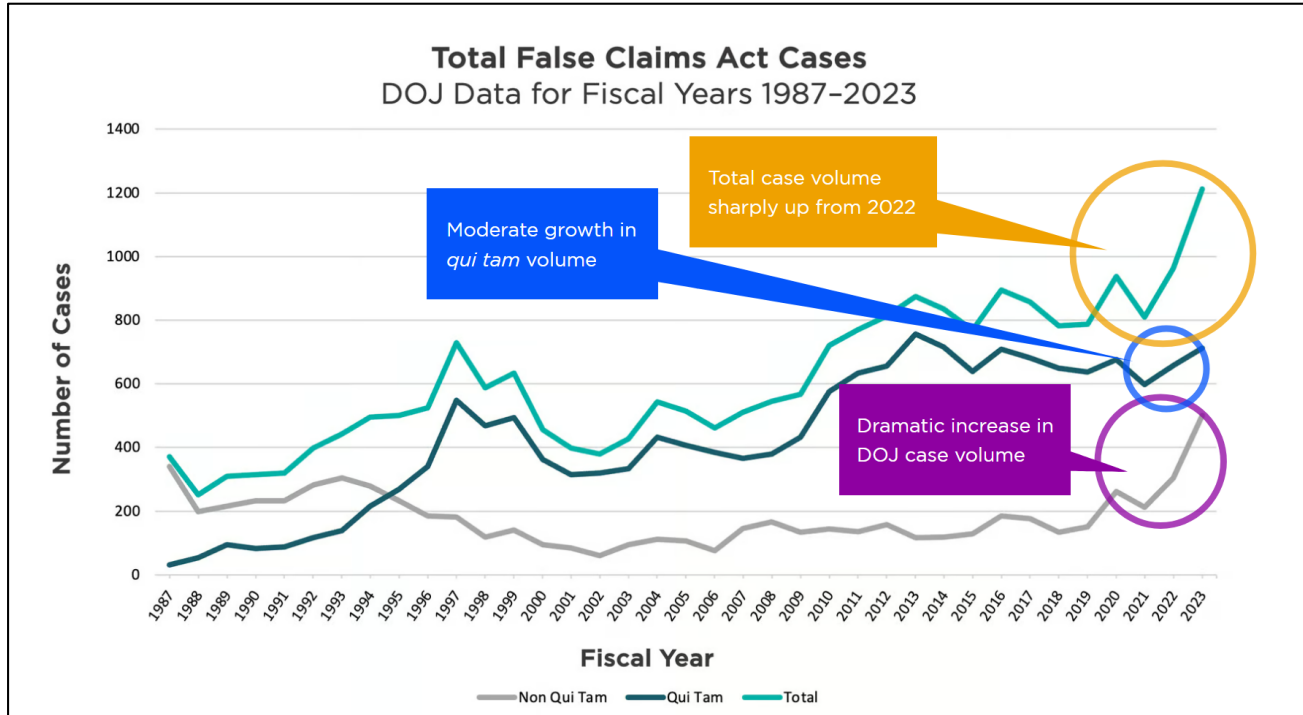
"We thought if we could bring more transparency to decision support intervention, we can instill more trust and we can help optimize the use of these algorithms."

By [Mike Miliard](#) | March 15, 2024 | 09:00 AM



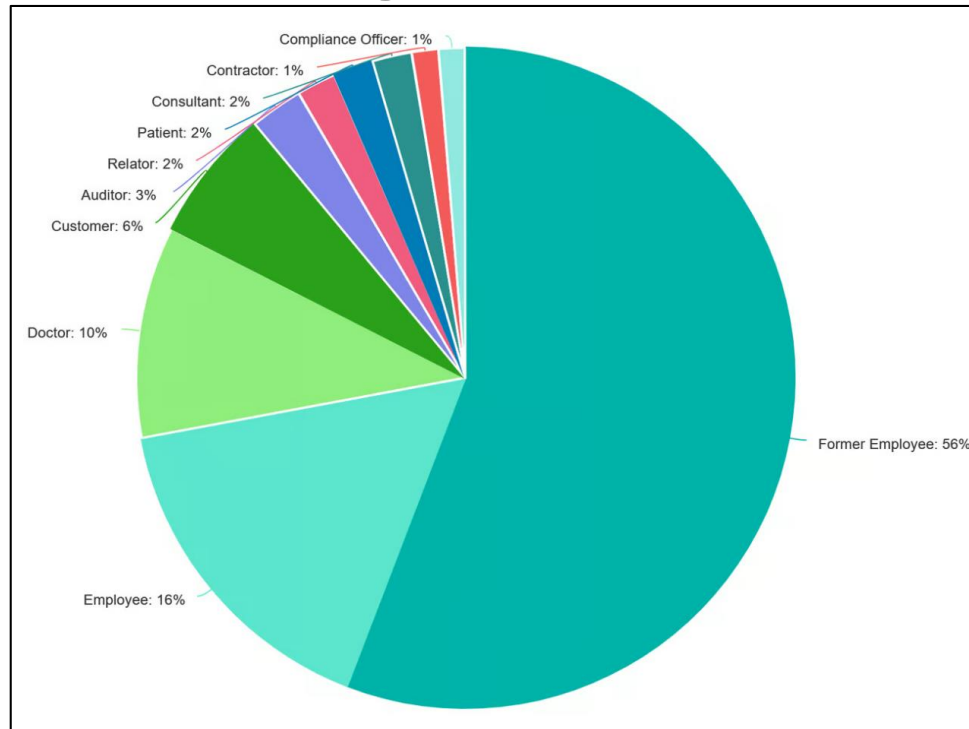
<https://www.healthcareitnews.com/news/hti-1-final-rule-now-effect-eye-ai-and-theres-more-come-says-onc>

False Claims Act Stats



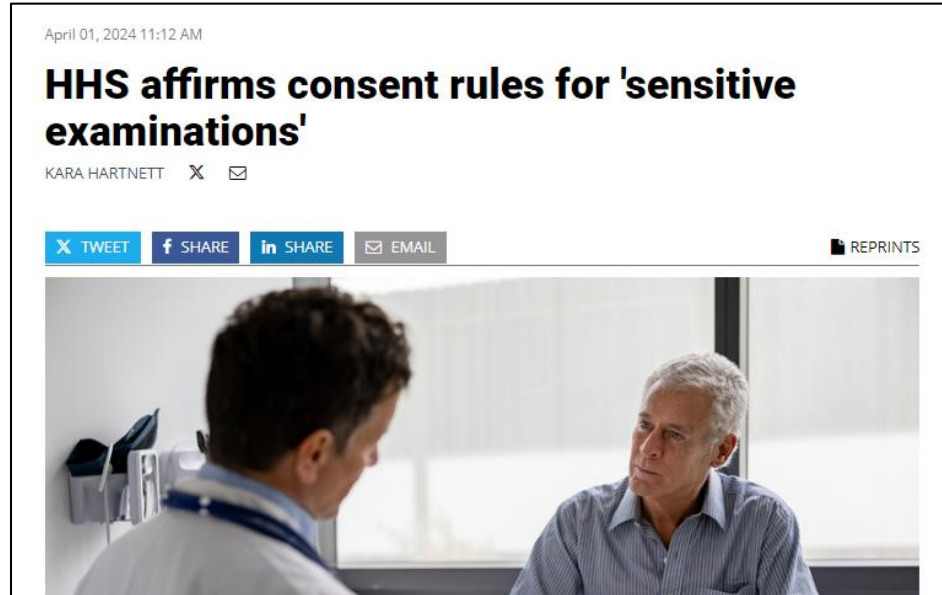
<https://www.mintz.com/insights-center/viewpoints/2406/2024-03-20-health-care-enforcement-false-claims-act-2024-statistical>

Who Brings These Cases?



<https://www.mintz.com/insights-center/viewpoints/2406/2024-03-20-health-care-enforcement-false-claims-act-2024-statistical>

Informed Consent



<https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos-states/revisions-and-clarifications-hospital-interpretive-guidelines-informed-consent>

Remember § 1557?



U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

FOR IMMEDIATE RELEASE

April 26, 2024

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Issues New Rule to Strengthen Nondiscrimination Protections and Advance Civil Rights in Health Care

[Download the News Release - PDF](#)

[Download the News Release - Word](#)

Today, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and the Centers for Medicare & Medicaid Services (CMS) issued a final rule under Section 1557 of the Affordable Care Act (ACA) advancing protections against discrimination in health care. By taking bold action to strengthen protections against discrimination on the basis of race, color, national origin, sex, age, and disability, this rule reduces language access barriers, expands physical and digital accessibility, tackles bias in health technology, and much more.

<https://www.hhs.gov/about/news/2024/04/26/hhs-issues-new-rule-strengthen-nondiscrimination-protections-advance-civil-rights-health-care.html>

Non-Competes



FEDERAL TRADE COMMISSION
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For Release

FTC Announces Rule Banning Noncompetes

FTC's final rule will generate over 8,500 new businesses each year, raise worker wages, lower health care costs, and boost innovation

April 23, 2024 | [f](#) [t](#) [i](#)

<https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-noncompetes>

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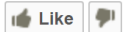
Medicaid Payment and Reimbursement

Hospital revenue is enhanced by state-directed Medicaid payments, health systems report

Providers were encouraged that 2024 regulations set a comparatively high limit for the supplemental payment rate.



Nick Hut



21 hours ago



https://www.hfma.org/payment-reimbursement-and-managed-care/medicaid-payment-and-reimbursement/hospital-revenue-is-enhanced-by-state-directed-medicaid-payments-health-systems-report/?utm_medium=email&utm_source=rasa_io&utm_campaign=newsletter

Medicare Advantage



healthcare financial
management association

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Medicare Payment and Reimbursement

CMS's 2024 MA rule brings some improvements but falls short of addressing all providers' concerns

After CMS's issuance of its 2024 final rule for Medicare Advantage (MA) organizations, providers face many questions about next steps in their strategies in working with these organizations.

An eventful period for healthcare policy looms as Trump and GOP members of Congress prepare to govern

Depending on how bold Republicans want to be, big changes could be in store for the Affordable Care Act, Medicaid and more.



Nick Hut



November 15, 2024 11:18 am



Can You Hear Me Now?

Apple AirPods Pro granted FDA approval to serve as hearing aids

Brian Heater / 8:51 AM PDT • September 12, 2024

 Comment



Duh???

Ultra-processed food linked to 32 poor health outcomes in largest study to date

By Flora Southey

05-Mar-2024 - Last updated on 05-Mar-2024 at 10:26 GMT

SHARE



<https://www.foodnavigator.com/Article/2024/03/05/Ultra-processed-food-linked-to-mortality-in-largest-UPF-study-to-date#>

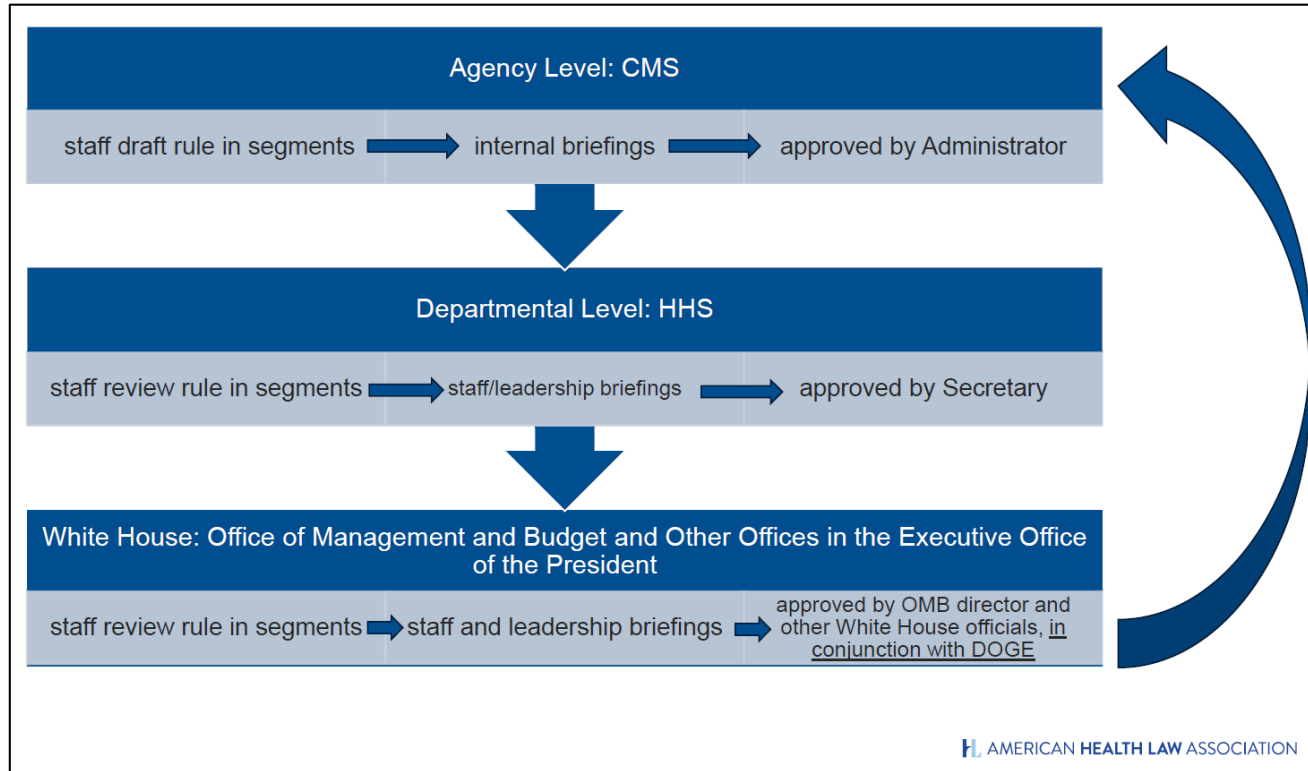
What happens to your data if 23andMe collapses?



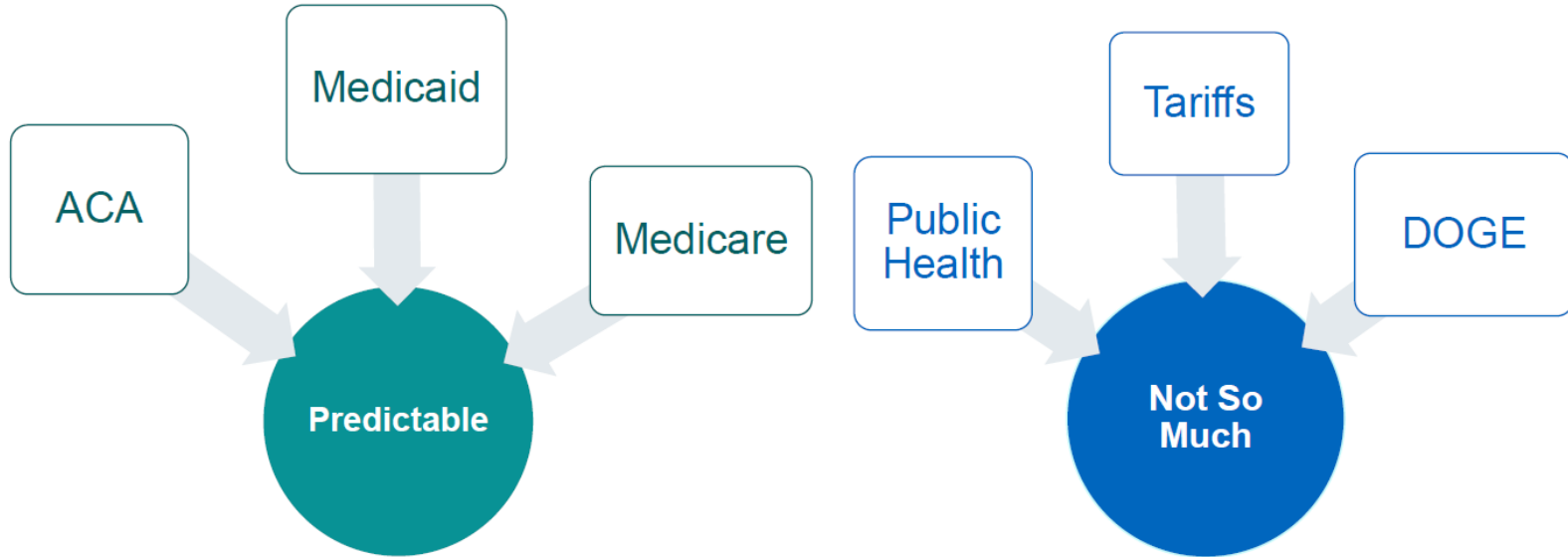
Predictions for 2025



2025?!



Unpredictable in 2025



The road to \$880B

Policy	10 Yr Savings
Nursing facility staffing rule	\$22B
Medicaid work requirements	\$100B
FMAP for ACA expansion group: 90% to rate used for other enrollees	\$561B
Medicaid provider taxes lowering allowed patient revenue percent, 2.5%	\$241B
Reduce OPPS payments for drugs at 340B entities, ASP-22.5%	\$74B
Medicare site neutral payments (MedPAC proposal)	\$157B
Health Risk Payments to MAOs; increase reduction from 5.9% to 8%	\$159B
Total	\$1,314B

Questions?

Michael W. Chase

Baird Holm LLP

402-636-8326

mchase@bairdholm.com