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Health Law Year-in-Review

Michael Chase

Iowa HFMA

April 17, 2024

Legal advice is highly dependent on the facts unique to each situation. The content of this presentation is not legal advice and is provided for general information purposes only. No attorney-client relationship is created by the use of this content.

Agenda

- Overview of last year's headlines
- Regulatory updates
- Agency guidance
- Recommendations/strategies for implementation



HEALTH AND SCIENCE

Biden administration plans to end Covid public health emergency in May

PUBLISHED MON, JAN 30 2023-6:24 PM EST | UPDATED 3 HOURS AGO



Spencer Kimball
@SPENCEKIMBALL

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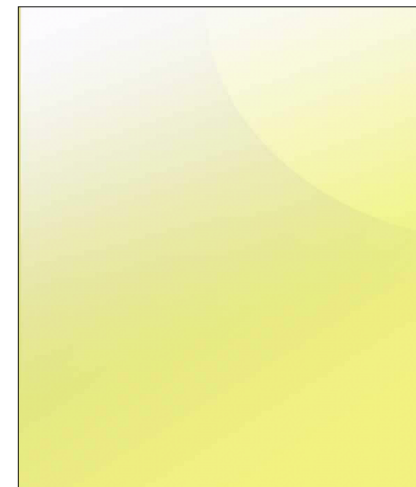
KEY POINTS

- The White House, in a statement Monday, said it would terminate on May 11 both the public health and national emergencies declared in response to Covid.
- The Trump administration first issued the emergency declarations in early 2020.



Squawk on the Street [WATCH LIVE](#)


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January 31, 2023 02:11 PM | 21 HOURS AGO

What the end of the federal COVID-19 emergency means for healthcare

MAYA GOLDMAN    MARI DEVEREAUX   

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<https://www.modernhealthcare.com/policy/end-covid-public-health-emergency-healthcare-medicare-telehealth-medicaid>

Aug 18, 2022

Creating a Roadmap for the End of the COVID-19 Public Health Emergency

By: Jonathan Blum, Chief Operating Officer and Principal Deputy Administrator; Carol Blackford, Director Hospital and Ambulatory Policy Group; and Jean Moody-Williams, Deputy Director of the Center for Clinical Standards and Quality

Safety

Share



The Centers for Medicare & Medicaid Services (CMS) plays an important role in protecting the health and safety of all Americans as they journey through the health care system. This is especially true during a pandemic, natural disaster, or other emergencies. Throughout the COVID-19 public health emergency (PHE), CMS has used a combination of emergency authority waivers, regulations, enforcement discretion, and sub-regulatory guidance to ensure access to care and give health care providers the flexibilities needed to respond to COVID-19 and help keep people safer. Many of these waivers and broad flexibilities will terminate at the eventual end of the PHE, as they were intended to address the acute and extraordinary circumstances of a rapidly evolving pandemic and not replace existing requirements.

<https://www.cms.gov/blog/creating-roadmap-end-covid-19-public-health-emergency>

COVID-19 \$\$\$



The screenshot shows the top portion of a press release from the Department of Justice. At the top left is the Department of Justice seal. To its right, the text reads "THE UNITED STATES DEPARTMENT of JUSTICE". Below this is a navigation menu with links for "ABOUT", "OUR AGENCY", "OUR WORK", "NEWS", "RESOURCES", and "CAREERS". The breadcrumb trail indicates the page is in the "News" section. A black banner with the text "JUSTICE NEWS" is present. Below the banner, the text "Department of Justice" and "Office of Public Affairs" is centered. The release is dated "Tuesday, January 17, 2023" and is marked "FOR IMMEDIATE RELEASE". The headline is "Physician Convicted for Misappropriating Approximately \$250,000 from COVID-19 Relief Programs". The first sentence of the body text reads: "A federal jury convicted a Colorado physician on Friday for misappropriating approximately \$250,000 from two separate COVID-19 relief programs."

THE UNITED STATES
DEPARTMENT of JUSTICE

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Home » Office of Public Affairs » News

JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, January 17, 2023

Physician Convicted for Misappropriating Approximately \$250,000 from COVID-19 Relief Programs

A federal jury convicted a Colorado physician on Friday for misappropriating approximately \$250,000 from two separate COVID-19 relief programs.

<https://www.justice.gov/opa/pr/physician-convicted-misappropriating-approximately-250000-covid-19-relief-programs>

COVID-19 \$\$\$

hfma healthcare financial management association

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Audit and Internal Controls

Money received through the Provider Relief Fund could be at risk as audits ramp up

Payments made through the COVID-19 Uninsured Program also are coming under close inspection.

 Nick Hut

 Like 

September 1, 2023 11:27 am

      Print

https://www.hfma.org/accounting-and-financial-reporting/audit-and-internal-controls/money-received-through-covid-19-relief-programs-could-be-at-risk/?utm_medium=email&utm_source=rasa_io&utm_campaign=newsletter

Telehealth Update

2024 Medicare Physician Fee Schedule

- Implemented several provisions of the Consolidated Appropriations Act of 2023
 - Originating sites (including patient's home)
 - Expansion of practitioners
 - RHC/FQHC payments
 - Direct supervision requirements

Telehealth Update

The screenshot shows the top portion of the DEA website. The header is dark blue with the DEA logo (50th anniversary) and the text "United States Drug Enforcement Administration". On the right, there are links for "Get Updates", "Scam Alert", "English", and "Español", along with a search bar labeled "Search DEA.gov". Below the header is a white navigation bar with links for "Who We Are", "What We Do", "Careers", and "Resources", and a blue "Submit A Tip" button. The main content area features a large blue headline: "DEA and HHS Extend Telemedicine Flexibilities through 2024". Below the headline, the date "October 06, 2023" and the word "Announcement" are displayed.

50 **DEA** United States Drug Enforcement Administration

Get Updates | Scam Alert | [English](#) | [Español](#)

Search DEA.gov

Who We Are | What We Do | Careers | Resources | [Submit A Tip](#)

DEA and HHS Extend Telemedicine Flexibilities through 2024


October 06, 2023
Announcement


<https://www.dea.gov/documents/2023/2023-10/2023-10-06/dea-and-hhs-extend-telemedicine-flexibilities-through-2024>

Overpayments

January 4, 2023


No More Reasonable Diligence? CMS Proposes to Change Standard for Identifying Medicare Overpayments to Align with False Claims Act

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<https://www.jdsupra.com/legalnews/no-more-reasonable-diligence-cms-9130986/>

<https://www.govinfo.gov/content/pkg/FR-2022-12-27/pdf/2022-26956.pdf>

OIG Advisory Opinion 22-20



Compliance

OIG describes how hospitals can use NPs to treat patients without violating the Anti-Kickback Statute

A recent advisory opinion issued by the federal watchdog is favorable to hospitals but may apply only in limited scenarios.

https://oig.hhs.gov/documents/advisory-opinions/1062/AO-22-20_Ot53Mmd.pdf

HIPAA Enforcement



FOR IMMEDIATE RELEASE

December 14, 2022

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Civil Rights Office Enters Settlement with Dental Practice Over Disclosures of Patients' Protected Health Information

The dental practice responded to reviews on social media by disclosing patient health information in violation of the law; OCR warns others against this practice

<https://www.hhs.gov/about/news/2022/12/14/hhs-civil-rights-office-enters-settlement-with-dental-practice-over-disclosures-of-patients-protected-health-information.html>

So The Story Goes...

FOR IMMEDIATE RELEASE

June 5, 2023

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Office for Civil Rights Reaches Agreement with Health Care Provider in New Jersey That Disclosed Patient Information in Response to Negative Online Reviews

New Jersey psychiatry practice pays \$30,000 to settle complaint about impermissible disclosure of protected health information by disclosing this information in online review

<https://www.hhs.gov/about/news/2023/06/05/hhs-office-civil-rights-reaches-agreement-health-care-provider-new-jersey-disclosed-phi-response-negative-online-reviews.html>

HIPAA Enforcement



FOR IMMEDIATE RELEASE

January 3, 2023

Contact: HHS Press Office

202-690-6343

media@hhs.gov

Lab Pays \$16,500 Settlement to HHS, Resolving Potential HIPAA Violation over Medical Records Request

<https://www.hhs.gov/about/news/2023/01/03/lab-pays-16-thousand-5-hundred-dollar-settlement-to-hhs-resolving-potential-hipaa-violation.html>

HIPAA Enforcement

Snooping in Medical Records by Hospital Security Guards Leads to \$240,000 HIPAA Settlement

OCR has announced a settlement with Yakima Valley Memorial Hospital, a not-for-profit community hospital located in Yakima, Washington resolving an investigation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. OCR investigated allegations of several security guards from Yakima Valley Memorial Hospital, who impermissibly accessed the medical records of 419 individuals. To voluntarily resolve this matter, Yakima Valley Memorial Hospital agreed to pay \$240,000 and implement a plan to update its policies and procedures to safeguard protected health information and train its employees to prevent this type of snooping behavior in the future.

<https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/yakima/index.html>

HIPAA & Reproductive Health Care

The screenshot shows the American Hospital Association (AHA) website. The header includes the AHA logo with the tagline "Advancing Health in America", navigation links for "AHA Member Center", "About", "Press Center", and "Contact Us", a "Register / Log In" button, and a search bar. A secondary navigation bar lists "Advocacy", "Career Resources", "Data & Insights", "Education & Events", "News", and "Individuals & Communities". The main content area features a breadcrumb trail "Home / News / Headline" and a news article titled "HIPAA proposed rule would prohibit certain reproductive health care disclosures" dated "Apr 12, 2023 - 02:35 PM". Below the title is a social media sharing bar with icons for email, Facebook, Twitter, LinkedIn, and a plus sign. The article's image shows an orange pill bottle tipped over with white pills spilling out.

<https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/index.html>

December 2022 OCR Guidance

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

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>

Online Tracking Technology

AHA Sues Federal Government Over OCR Tracking Technology Guidance

The AHA's lawsuit suggests that OCR's tracking technology bulletin disturbs the balance between privacy and information sharing under HIPAA.



<https://healthitsecurity.com/news/aha-sues-federal-government-over-ocr-tracking-technology-guidance>

HIPAA Updates Anytime?

Senator Seeks Stakeholder Feedback on Improving Health Data Privacy

US Senator Bill Cassidy, ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, is seeking feedback on how to modernize HIPAA and safeguard health data privacy.



<https://healthitsecurity.com/news/senator-seeks-stakeholder-feedback-on-improving-health-data-privacy>

FBI has seized website used by notorious ransomware gang

By Sean Lyngaas, CNN

Updated 10:28 AM EST, Thu January 26, 2023



Antitrust

REGULATORY

in
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DOJ withdraws 'outdated' and 'overly permissive' healthcare antitrust enforcement guidance

By **Dave Muoio** • Feb 3, 2023 04:00pm

DOJ antitrust mergers and acquisitions Competition



<https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements>

Iowa House File 161

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Des Moines Register

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POLITICS

Iowa Legislature passes \$2M cap on medical malpractice damages. Here's the likely impact:

6 minute read

 **Stephen Gruber-Miller**
Des Moines Register

Published 5:37 p.m. CT Feb. 8, 2023 | Updated 4:36 p.m. CT Feb. 9, 2023

[View Comments](#)    



<https://www.legis.iowa.gov/legislation/BillBook?ga=90&ba=hf%20161>

Fraud & Abuse



THE UNITED STATES
DEPARTMENT *of* JUSTICE

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JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, February 7, 2023

False Claims Act Settlements and Judgments Exceed \$2 Billion in Fiscal Year 2022

Second-Highest Number of Settlements in History

Annual Report of the Departments of Health and Human Services and Justice



Health Care Fraud and Abuse Control Program FY 2022

<https://oig.hhs.gov/publications/docs/hcfac/FY2022-hcfac.pdf>

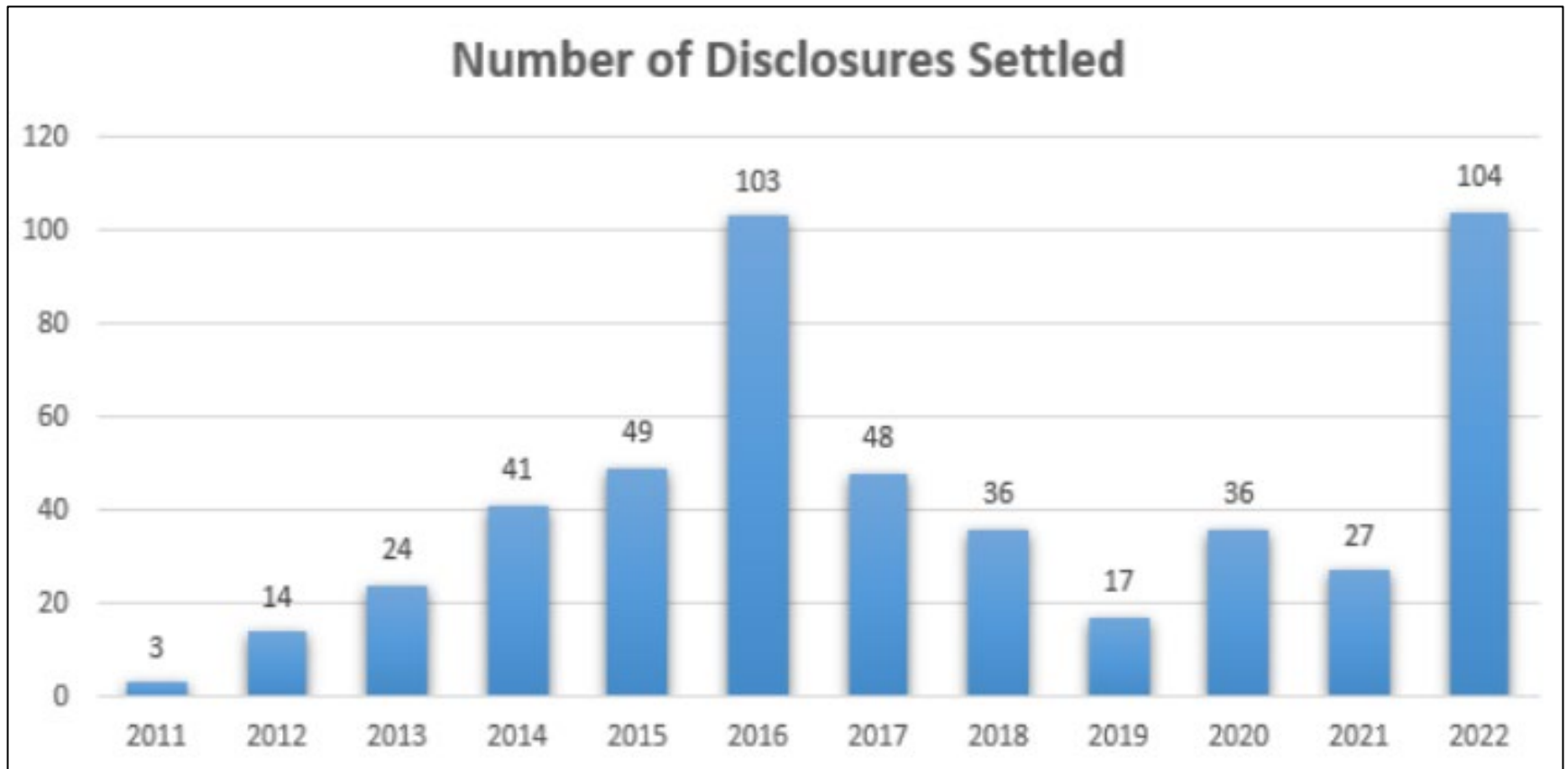
Feds promise to trim backlog of health care investigations

By AMANDA SEITZ yesterday



<https://apnews.com/article/politics-health-civil-rights-privacy-89e31a9518728327889b426671ef2a46>

Stark Self-Disclosures



Security Risk Assessments



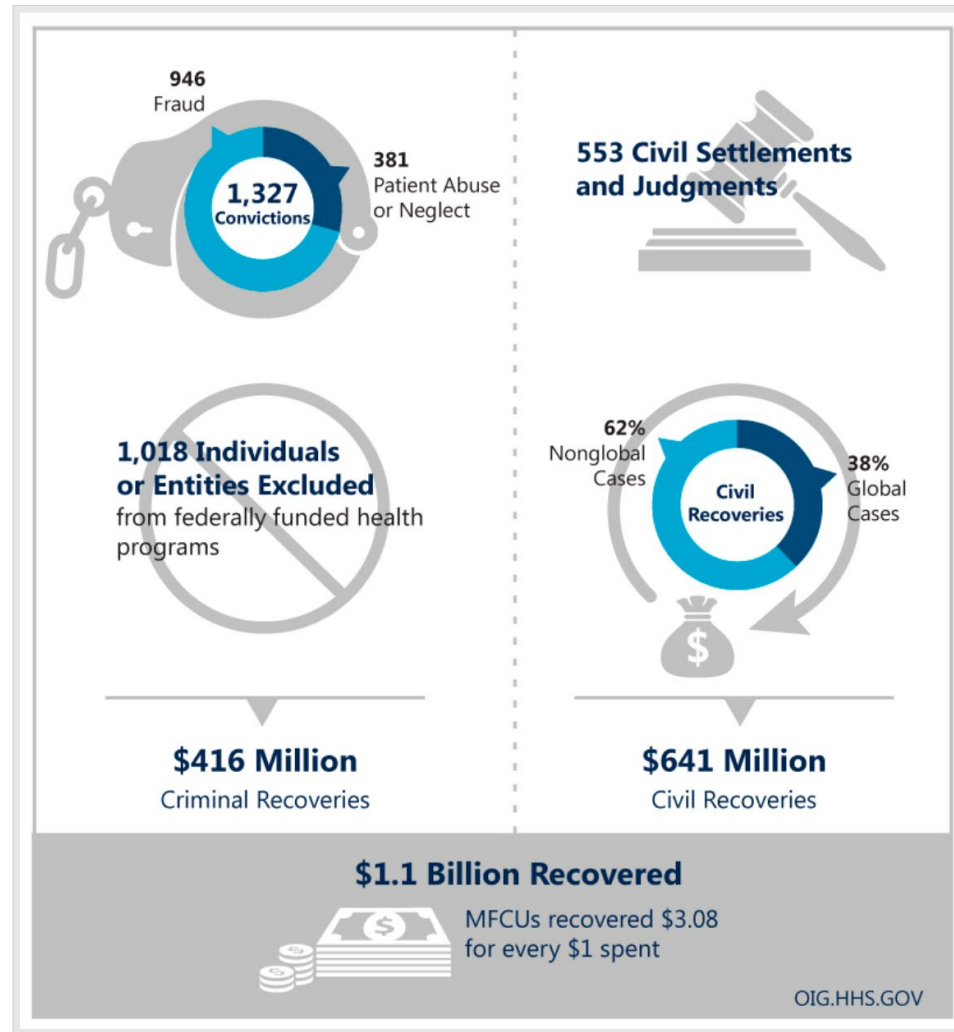
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE FOR CIVIL RIGHTS

Security Risk Assessment Tool

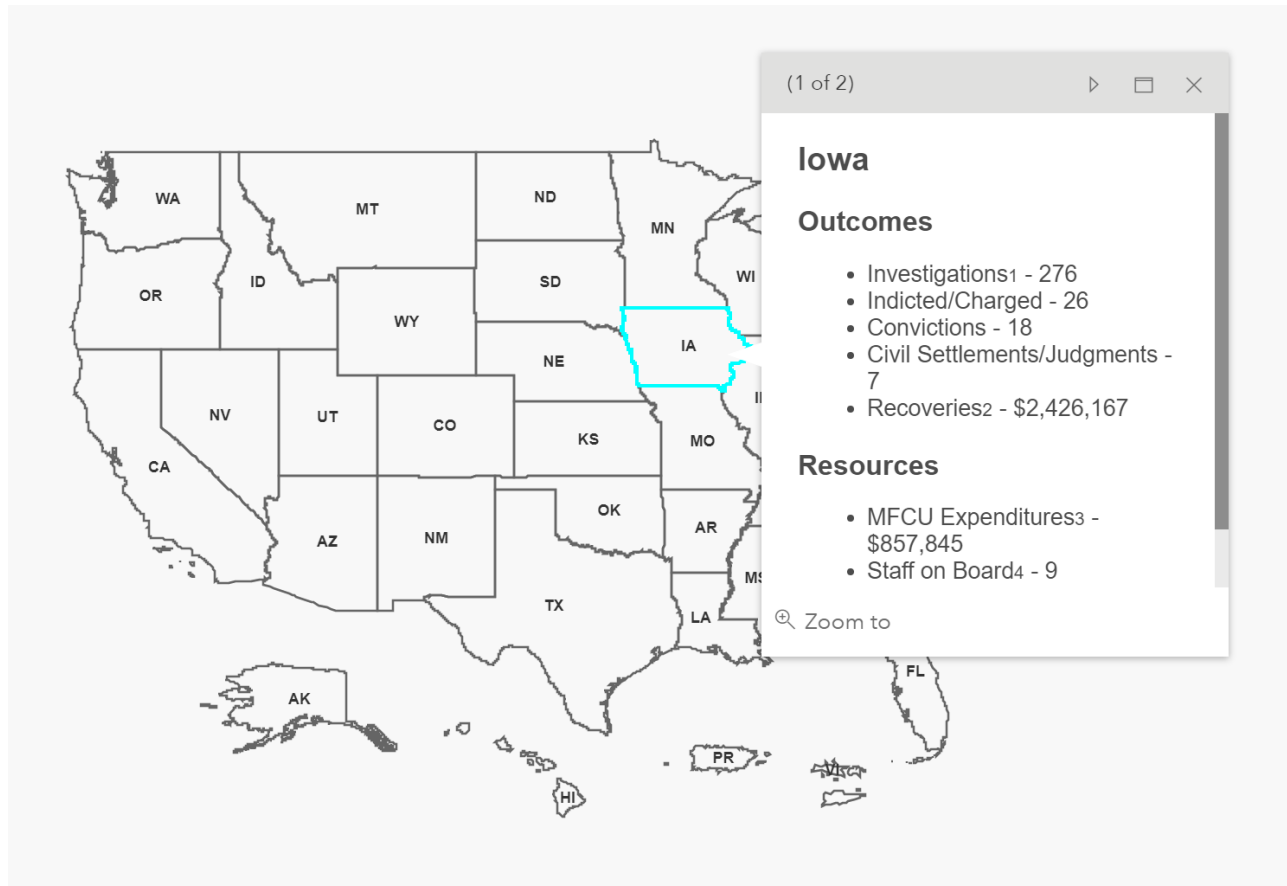
The Health Insurance Portability and Accountability Act (HIPAA) Security Rule requires that covered entities and its business associates conduct a risk assessment of their healthcare organization. A risk assessment helps your organization ensure it is compliant with HIPAA's administrative, physical, and technical safeguards. A risk assessment also helps reveal areas where your organization's protected health information (PHI) could be at risk. To learn more about the assessment process and how it benefits your organization, visit the Office for Civil Rights' official guidance.

<https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>

Medicaid Fraud Control Units



Medicaid Fraud Control Units



Iowa Data Privacy Law



Senate File 262

AN ACT
RELATING TO CONSUMER DATA PROTECTION, PROVIDING CIVIL
PENALTIES, AND INCLUDING EFFECTIVE DATE PROVISIONS.

OIG Stakeholder Guidance

The screenshot shows the website for the U.S. Department of Health and Human Services Office of Inspector General. The header includes the department's name and logo, a search bar, and a navigation menu with items like 'About OIG', 'Reports', 'Fraud', 'Compliance', 'Exclusions', 'Newsroom', and 'Careers'. The main content area is titled 'Frequently Asked Questions' and lists several links: 'General Questions Regarding Certain Fraud and Abuse Authorities', 'Application of Certain Fraud and Abuse Authorities to Certain Types of Arrangements', 'Compliance Considerations', 'Corporate Integrity Agreement FAQs', and 'Exclusions FAQs'. A brief description of a Corporate Integrity Agreement (CIA) is provided under the 'Corporate Integrity Agreement FAQs' link.

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

About OIG ▾ Reports ▾ Fraud ▾ Compliance ▾ Exclusions ▾ Newsroom ▾ Careers ▾ CO

[Home](#) > Frequently Asked Questions

Frequently Asked Questions

[General Questions Regarding Certain Fraud and Abuse Authorities](#)

[Application of Certain Fraud and Abuse Authorities to Certain Types of Arrangements](#)

[Compliance Considerations](#)

[Corporate Integrity Agreement FAQs](#)

A Corporate Integrity Agreement (CIA) is a document that outlines the obligations a provider or entity agrees to as part of a civil settlement.

[Exclusions FAQs](#)

<https://oig.hhs.gov/faqs/>

Iowa PA Supervision House File 424

Governor Reynolds signs bill changing rules for physician assistants, expanding rural healthcare access

Daniel Perreault **May 11, 2023** Updated **May 11, 2023**  3

<https://www.legis.iowa.gov/docs/publications/LGE/90/HF424.pdf>

Look Good in Orange?

MICHIGAN

Michigan surgeon sentenced to 80 months in prison for health care fraud



Jakkar Aimery

The Detroit News

Published 7:05 p.m. ET May 25, 2023

[View Comments](#)



A Bay City vascular surgeon was sentenced to 80 months in prison for orchestrating a multimillion-dollar scheme to defraud health care programs, the U.S. Department of Justice announced on Thursday.

Vasso Godiali was ordered to pay \$19.5 million in restitution to Medicare, Medicaid and Blue Cross Blue Shield of Michigan. He was sentenced on May 3, according to the release Thursday.

<https://www.justice.gov/opa/pr/michigan-vascular-surgeon-sentenced-80-months-prison-health-care-fraud-conviction-and-agrees>

Artificial Intelligence

OCTOBER 30, 2023

FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence



▶ BRIEFING ROOM



▶ STATEMENTS AND RELEASES

Today, President Biden is issuing a landmark Executive Order to ensure that America leads the way in seizing the promise and managing the risks of artificial intelligence (AI). The Executive Order establishes new standards for AI safety and security, protects Americans' privacy, advances equity and civil rights, stands up for consumers and workers, promotes innovation and competition, advances American leadership around the world, and more.

<https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/>

340B Remedy?


hfma healthcare financial management association


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Medicare Payment and Reimbursement







Medicare's final \$9 billion remedy plan for 340B providers doesn't address hospitals' key concerns

The only notable change from the proposed rule issued several months ago was a one-year delay in the start of the budget neutrality reduction to outpatient payments.

 Nick Hut

 Like 

November 3, 2023 4:53 pm

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Information Blocking

healthleaders TOPICS EVENTS RESOURCES SUBSCRIBE f t in v o

HHS PROPOSES INFORMATION BLOCKING PENALTIES FOR HEALTH SYSTEMS

ANALYSIS | BY [ERIC WICKLUND](#) | OCTOBER 30, 2023

<https://www.govinfo.gov/content/pkg/FR-2023-11-01/pdf/2023-24068.pdf>

OIG Advisory Opinion 23-07

Physician Bonuses

OIG Issues Favorable Opinion Regarding Physician Group's Proposal to Pay Bonuses to its Employed Physicians Based on Net Profits

by: Nathaniel T. Arden , Michael G. Lisitano of Robinson & Cole LLP - *Health Law Diagnosis*

© Posted On Thursday, October 19, 2023



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<https://oig.hhs.gov/documents/advisory-opinions/1132/AO-23-07.pdf>

Corporate Transparency Act



Starting January 1, 2024, many companies will be required to report information to the U.S. government about who ultimately owns and controls them.

OIG Compliance Program Guidance

The screenshot shows the official website of the U.S. Department of Health and Human Services Office of Inspector General. The header includes the department's name, the Office of Inspector General logo, a search bar, and a "Submit a Complaint" button. The navigation menu features links for "About OIG", "Reports", "Fraud", "Compliance", "Exclusions", "Newsroom", "Careers", and "COVID-19 Portal". The main content area is titled "General Compliance Program Guidance" and contains two paragraphs of text. The first paragraph states that the General Compliance Program Guidance (GCPG) is a reference guide for the health care compliance community and other health care stakeholders, providing information about relevant Federal laws, compliance program infrastructure, and other useful information. The second paragraph notes that the GCPG is voluntary guidance that discusses general compliance risks and programs, and is not binding on any individual or entity. Below the text is a red button labeled "Download Complete Guidance". To the right of the text is a graphic for the "General Compliance Program Guidance" document, dated "November 2023", featuring the OIG logo and a blue geometric pattern.

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

Search [Submit a Complaint](#)

[About OIG](#) [Reports](#) [Fraud](#) [Compliance](#) [Exclusions](#) [Newsroom](#) [Careers](#) [COVID-19 Portal](#)

General Compliance Program Guidance

The General Compliance Program Guidance (GCPG) is a reference guide for the health care compliance community and other health care stakeholders. The GCPG provides information about relevant Federal laws, compliance program infrastructure, OIG resources, and other information useful to understanding health care compliance.

The GCPG is voluntary guidance that discusses general compliance risks and compliance programs. The GCPG is not binding on any individual or entity. Of note, OIG uses the word “should” in the GCPG to present voluntary, nonbinding guidance.

You may download the guidance in whole, or access individual sections below.

[Download Complete Guidance](#)

General Compliance Program Guidance
November 2023

<https://oig.hhs.gov/compliance/general-compliance-program-guidance/>

Last Year...



A shopping cart outside a Costco store in San Francisco, on March 3, 2021.

David Paul Morris/Bloomberg

Costco Raspberry Seltzer Ingredients Suit Fizzles Out in Court

Sept. 30, 2022, 11:44 AM



A Costco consumer's contention that red coloring, a picture of two black raspberries, and the words "Black Raspberry Flavor" meant actual black raspberry juice in sparkling water was rejected by a federal judge.



Julie Steinberg
Reporter



This Year...

Fireball is getting sued for selling mini bottles that don't actually contain whiskey

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Updated: 2:15 PM CST Jan 25, 2023

Infinite Scroll Enabled



Danielle Harling

Weekend Editor/Contributing Writer





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