

Health Law Year-in-Review

Iowa HFMA
January 11, 2023

Michael W. Chase

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

Ok...What The....?

MORNING MIX

A transplant surgeon used an electric beam to burn his initials into patients' organs. He just lost his medical license.



By [Jonathan Edwards](#)

January 13, 2022 at 7:42 a.m. EST





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



HEALTH CARE

Biden declared the pandemic 'over.' His Covid team says it's more complicated.

Biden's "60 Minutes" remarks surprised his own health advisers, and came as the administration seeks more Covid response funding.





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United States



1 minute read · October 13, 2022 6:48 PM CDT · Last Updated 4 days ago



U.S. extends COVID-19 public health emergency declaration

By Kanishka Singh


- ~~January 27, 2020~~
- ~~April 21, 2020~~
- ~~July 23, 2020~~
- ~~October 2, 2020~~
- ~~January 7, 2021~~
- ~~April 15, 2021~~
- ~~July 19, 2021~~
- ~~October 15, 2021~~
- ~~January 14, 2022~~
- ~~April 12, 2022~~
- ~~July 15, 2022~~
- ~~October 13, 2022~~
- January 11, 2023

Is There An End in Sight?



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

Provider-Specific Guidance

 Centers for Medicare & Medicaid Services

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[Home](#) > [Coronavirus Waivers](#)

Coronavirus waivers & flexibilities

In certain circumstances, the Secretary of the Department of Health and Human Services (HHS) using section 1135 of the Social Security Act (SSA) can temporarily modify or waive certain Medicare, Medicaid, CHIP, or HIPAA requirements, called 1135 waivers. There are different kinds of 1135 waivers, including Medicare blanket waivers. When there's an emergency, sections 1135 or 1812(f) of the SSA allow us to issue blanket waivers to help beneficiaries access care. When a blanket waiver is issued, providers don't have to apply for an individual 1135 waiver. When there's an emergency, we can also offer health care providers other flexibilities to make sure Americans continue to have access to the health care they need.

Waivers & flexibilities for health care providers

<https://www.cms.gov/coronavirus-waivers>

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

**DOBBS, STATE HEALTH OFFICER OF THE
MISSISSIPPI DEPARTMENT OF HEALTH, ET AL. *v.*
JACKSON WOMEN'S HEALTH ORGANIZATION ET AL.**

**CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR
THE FIFTH CIRCUIT**

No. 19–1392. Argued December 1, 2021—Decided June 24, 2022

Roe v. Wade Overturned



By Allen Smith, J.D.
June 24, 2022



REUSE PERMISSIONS ?



<https://www.shrm.org/resourcesandtools/legal-and-compliance/employment-law/pages/supreme-court-dobbs.aspx>



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

July 11, 2022

VIA ELECTRONIC MAIL

Dear Health Care Providers:

In light of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, I am writing regarding the Department of Health and Human Services (HHS) enforcement of the Emergency Medical Treatment and Active Labor Act (EMTALA). As frontline health care providers, the federal EMTALA statute protects your clinical judgment and the action that you take to provide stabilizing medical treatment to your pregnant patients, regardless of the restrictions in the state where you practice.

The EMTALA statute requires that all patients receive an appropriate medical screening examination, stabilizing treatment, and transfer, if necessary, irrespective of any state laws or mandates that apply to specific procedures. It is critical that providers know that a physician or other qualified medical personnel's professional and legal duty to provide stabilizing medical treatment to a patient who presents to the emergency department and is found to have an emergency medical condition preempts any directly conflicting state law or mandate that might otherwise prohibit such treatment.

<https://www.hhs.gov/sites/default/files/emergency-medical-care-letter-to-health-care-providers.pdf>

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality

Ref: QSO-22-22-Hospitals

DATE: July 11, 2022
TO: State Survey Agency Directors
FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)
SUBJECT: Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss (QSO-21-22-Hospitals-UPDATED JULY 2022)

NOTE: This memorandum is being issued to remind hospitals of their existing obligation to comply with EMTALA and does not contain new policy.

Memorandum Summary

- **The Emergency Medical Treatment and Labor Act (EMTALA)** provides rights to any individual who comes to a hospital emergency department and requests examination or treatment. In particular, if such a request is made, hospitals must provide an appropriate medical screening examination to determine whether an emergency medical condition exists or whether the person is in labor. If an emergency medical condition is found to exist, the hospital must provide available stabilizing treatment or an appropriate transfer to another hospital that has the capabilities to provide stabilizing treatment. The EMTALA statute requires that all patients receive an appropriate medical screening examination, stabilizing treatment, and transfer, if necessary, **irrespective of any state laws or mandates that apply to specific procedures.**
- **The determination of an emergency medical condition** is the responsibility of the examining physician or other qualified medical personnel. An emergency medical condition may include a condition that is likely or certain to become emergent without stabilizing treatment. Emergency medical conditions involving pregnant patients may include, but are not limited to, ectopic pregnancy, complications of pregnancy loss, or emergent hypertensive disorders, such as preeclampsia with severe features.

<https://www.cms.gov/files/document/qso-22-22-hospitals.pdf>

Workforce Shortage

- **Iowa Code 135Q.2** (Iowa health care employment agencies)
- Prohibits certain contract provisions
- Shifts compliance and record-keeping requirements
 - Health care entities → health care employment agency
- IDIA Final Rules and Guidance

— <https://www.legis.iowa.gov/docs/iac/chapter/12-14->

CMS issues CY 2023 physician fee schedule final rule

🕒 Nov 01, 2022 - 06:00 PM



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PRESS RELEASES

AMA: Fee schedule reminds Congress that cuts threaten patient access

 Bookmark

NOV 1, 2022

<https://www.ama-assn.org/press-center/press-releases/ama-fee-schedule-reminds-congress-cuts-threaten-patient-access>

The Markup

Pixel Hunt

Facebook Is Receiving Sensitive Medical Information from Hospital Websites

Experts say some hospitals' use of an ad tracking tool may violate a federal law protecting health information

By [Todd Feathers](#), [Simon Fondrie-Teitler](#), [Angie Waller](#), and [Surya Mattu](#)

A tracking tool installed on many hospitals' websites has been collecting patients' sensitive health information—including details about their medical conditions, prescriptions, and doctor's appointments—and sending it to Facebook.

The Markup tested the websites of [Newsweek's](#) top 100 hospitals in America. On 33 of them we found the tracker, called the Meta Pixel, sending Facebook a packet of data whenever a person clicked a button to schedule a doctor's appointment. The data is connected to an IP address—an identifier that's like a computer's mailing address and can generally be linked to a specific individual or household—creating an intimate receipt of the appointment request for Facebook.

A Third of Top Hospitals' Websites Sent Patient Data to Facebook

The Markup found 33 of Newsweek's top 100 hospitals in the country sending sensitive data to Facebook via the pixel. Data accurate as of June 15, 2022.

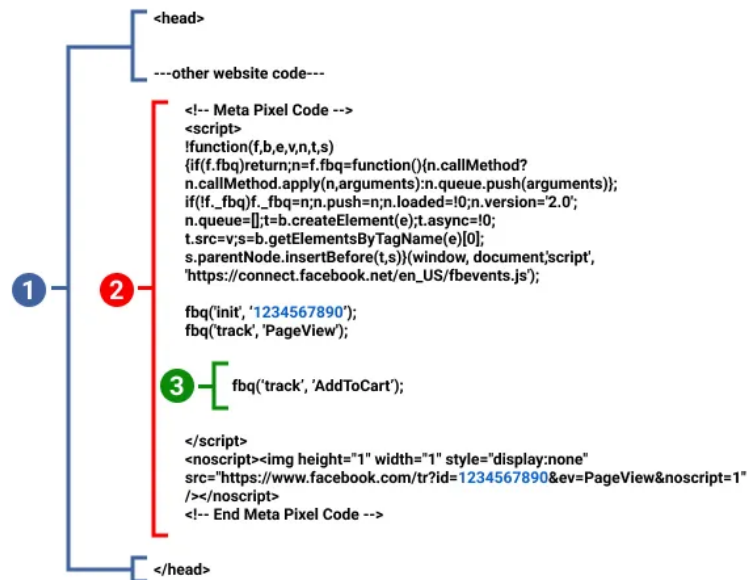
<https://themarkup.org/pixel-hunt/2022/06/16/facebook-is-receiving-sensitive-medical-information-from-hospital-websites>

Remove Meta Pixel Code From Your Website

1,697 views

If you installed a Meta Pixel on your website using code and decide you no longer want to send Pixel events from web browsers to Meta, you can remove the Pixel code from your website.

You should be familiar with these parts of your website code before you begin:



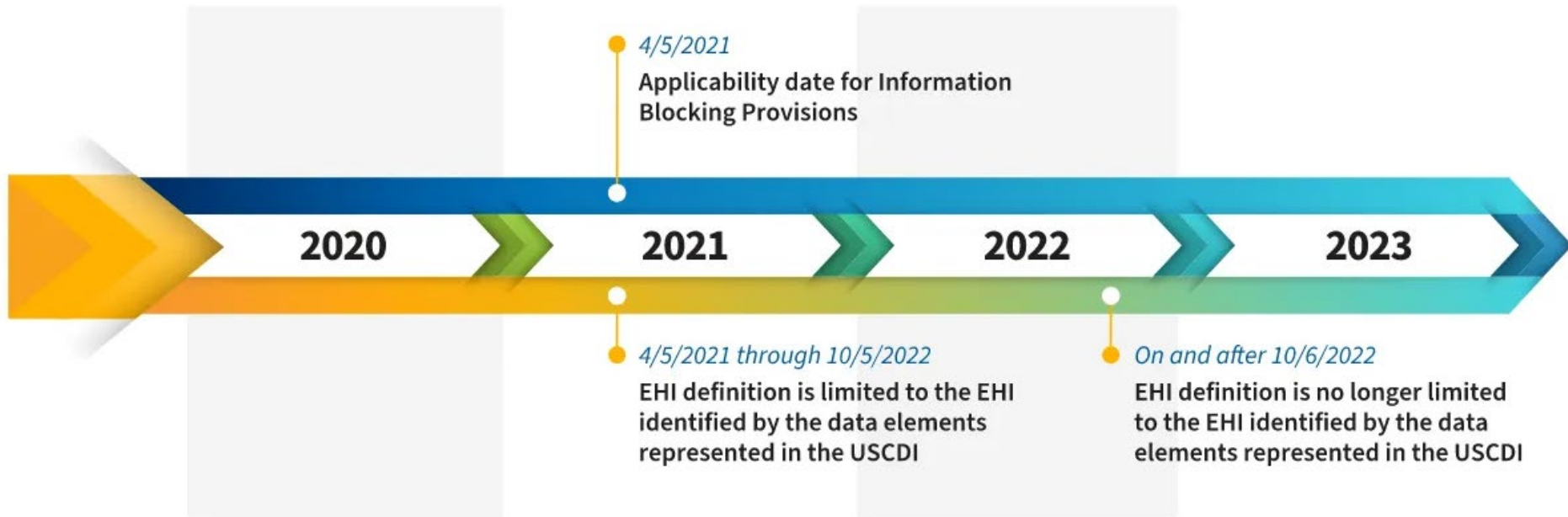
<https://www.facebook.com/business/help/4224030857607474>

Office for Civil Rights (OCR) Guidance

The screenshot shows the HHS.gov website with the "Health Information Privacy" section. The breadcrumb trail is: HHS > HIPAA Home > For Professionals > Privacy > Guidance Materials > Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates. The main content area features the title "Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates" and a paragraph explaining that the 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>

Information Blocking



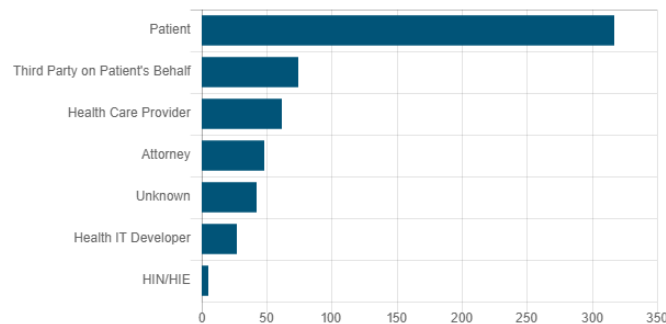
<https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule>

Information Blocking

Information on submissions received through the Report Information Blocking Portal²

| | |
|--|-----|
| Total number of information blocking portal submissions received | 560 |
| Total number of possible claims of information blocking | 517 |
| Total number of submissions received that did not appear to be claims of potential information blocking ³ | 43 |

Claims Counts by Types of Claimant



<https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>

Overview

What It Means for Me

Final Rule Policy

Resources

Fact Sheets

Webinars

Media/Press

Blog Posts

View Final Rules

**Information Blocking
FAQs**

Information Blocking FAQs

Filter by Tags:

Electronic Health Information

Filter

Reset

Electronic Health Information

Q: When information blocking is no longer limited to the subset that is represented by data elements in the United States Core Data for Interoperability (USCDI), what information will be covered by information blocking regulations as “electronic health information (EHI)”? (IB.FAQ39.1.2021NOV)

<https://www.healthit.gov/curesrule/resources/information-blocking-faqs?options=2450b60a-e96a-4f4c-ab17-40aac81e40be>

HIPAA Enforcement

| |
|---|
| HHS Civil Rights Office Resolves HIPAA Right of Access Investigation with \$20,000 Settlement - December 15, 2022 |
| HHS Civil Rights Office Enters Settlement with Dental Practice Over Disclosures of Patients' Protected Health Information - December 14, 2022 |
| OCR Settles Three Cases with Dental Practices for Patient Right of Access under HIPAA - September 20, 2022 |
| OCR Settles Case Concerning Improper Disposal of Protected Health Information - August 23, 2022 |
| Eleven Enforcement Actions Uphold Patients' Rights Under HIPAA - July 15, 2022 |
| Oklahoma State University - Center for Health Services Pays \$875,000 to Settle Hacking Breach - July 14, 2022 |
| Four HIPAA enforcement actions hold healthcare providers accountable with compliance - March 28, 2022 |
| Five enforcement actions hold healthcare providers accountable for HIPAA Right of Access - November 30, 2021 |
| OCR Resolves Twentieth Investigation in HIPAA Right of Access Initiative with \$80,000 Settlement - September 10, 2021 |
| OCR Settles Nineteenth Investigation in HIPAA Right of Access Initiative - June 2, 2021 |
| Clinical Laboratory Pays \$25,000 to Settle Potential HIPAA Security Rule Violations - May 25, 2021 |
| OCR Settles Eighteenth Investigation in HIPAA Right of Access Initiative - March 26, 2021 |
| OCR Settles Seventeenth Investigation in HIPAA Right of Access Initiative - March 24, 2021 |
| OCR Settles Sixteenth Investigation in HIPAA Right of Access Initiative - February 12, 2021 |
| OCR Settles Fifteenth Investigation in HIPAA Right of Access Initiative - February 10, 2021 |
| Health Insurer Pays \$5.1 Million to Settle Data Breach Affecting Over 9.3 Million People - January 15, 2021 |
| OCR Settles Fourteenth Investigation in HIPAA Right of Access Initiative - January 12, 2021 |

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

HIPAA Enforcement

(the theme continues)

Eleven Enforcement Actions Uphold Patients' Rights Under HIPAA

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announced the resolution of eleven investigations in its Health Insurance Portability and Accountability Act (HIPAA) Right of Access Initiative, bringing the total number of these enforcement actions to thirty-eight since the initiative began. OCR created this initiative to support individuals' right to timely access their health records at a reasonable cost under the HIPAA Privacy Rule.

- Read the [HHS Press Release](#)
- Read the [ACPM Podiatry](#) Notice of Proposed Determination, and Notice of Final Determination
- Read the [Associated Retina Specialists](#)
- Read the [Lawrence Bell, Jr., D.D.S.](#) Resolution Agreement and Corrective Action Plan
- Read the [Coastal Ear, Nose, and Throat \(ENT\)](#) Resolution Agreement and Corrective Action Plan
- Read the [Danbury Psychiatric Consultants \(DPC\)](#)
- Read the [Erie County Medical Center Corporation](#) Resolution Agreement and Corrective Action Plan
- Read the [Fallbrook Family Health Center](#) Resolution Agreement and Corrective Action Plan
- Read the [Hillcrest Nursing and Rehabilitation](#) Resolution Agreement and Corrective Action Plan
- Read the [MelroseWakefield Healthcare \(MWH\)](#) Resolution Agreement and Corrective Action Plan
- Read the [Memorial Hermann Health System](#) Resolution Agreement and Corrective Action Plan
- Read the [Southwest Surgical Associates \(SWSA\)](#) Resolution Agreement and Corrective Action Plan

<https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/july-2022-hipaa-enforcement/index.html>

HIPAA Enforcement

(yes, it applies to dentists)

Northcutt Dental-Fairhope, LLC (Northcutt Dental) HIPAA Enforcement Action

Northcutt Dental-Fairhope, LLC (Northcutt Dental), a dental practice in Fairhope, Alabama, who impermissibly disclosed its patients' PHI to a campaign manager and a third-party marketing company hired to help with a state senate election campaign, agreed to take corrective action and pay \$62,500 to settle potential violations of the HIPAA Privacy Rule.

Dr. U. Phillip Igbinadolor, D.M.D. & Associates, P.A. (UPI) HIPAA Enforcement Action

Dr. U. Phillip Igbinadolor, D.M.D. & Associates, P.A. (UPI), a dental practice with offices in Charlotte and Monroe, North Carolina, impermissibly disclosed a patient's PHI on a webpage in response to a negative online review. UPI did not respond to OCR's data request, did not respond or object to an administrative subpoena, and waived its rights to a hearing by not contesting the findings in OCR's Notice of Proposed Determination. OCR imposed a \$50,000 civil money penalty.

Dr. Donald Brockley, D.D.M. HIPAA Enforcement Action

Dr. Donald Brockley, D.D.M., a solo dental practitioner in Butler, Pennsylvania, failed to provide a patient with a copy of their medical record. After being issued a Notice of Proposed Determination, Dr. Donald Brockley, D.D.M requested a hearing before an Administrative Law Judge. The litigation was resolved before the court made a determination by a settlement agreement in which Dr. Donald Brockley, D.D.M agreed to pay \$30,000 and take corrective actions to comply with the HIPAA Privacy Rule's right of access standard.

<https://www.hhs.gov/about/news/2022/03/28/four-hipaa-enforcement-actions-hold-healthcare-providers-accountable-with-compliance.html>

HIPAA Enforcement

Resolution Agreements

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.

- [OCR Settles Case Concerning Improper Disposal of Protected Health Information](#) - August 23, 2022
- [Eleven Enforcement Actions Uphold Patients' Rights Under HIPAA](#) - July 15, 2022
- [Oklahoma State University - Center for Health Services Pays \\$875,000 to Settle Hacking Breach](#) - July 14, 2022

HIPAA Updates

Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication Technologies for Audio-Only Telehealth

Covered health care providers and health plans (covered entities)¹ can use remote communication technologies² to provide audio-only telehealth³ services when such communications are conducted in a manner that is consistent with the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules (HIPAA Rules).⁴ The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) developed this guidance to help covered entities understand how they can use remote communication technologies for audio-only telehealth⁵ in compliance with the HIPAA Rules, including when OCR's Notification of Enforcement Discretion for Telehealth Remote Communications (Telehealth Notification)⁶ is no longer in effect.⁷

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

HIPAA Updates

HHS Issues Guidance to Protect Patient Privacy in Wake of Supreme Court Decision on Roe

Guidance includes information about what's protected – and what's not – when using period trackers and other health information apps on smartphones.

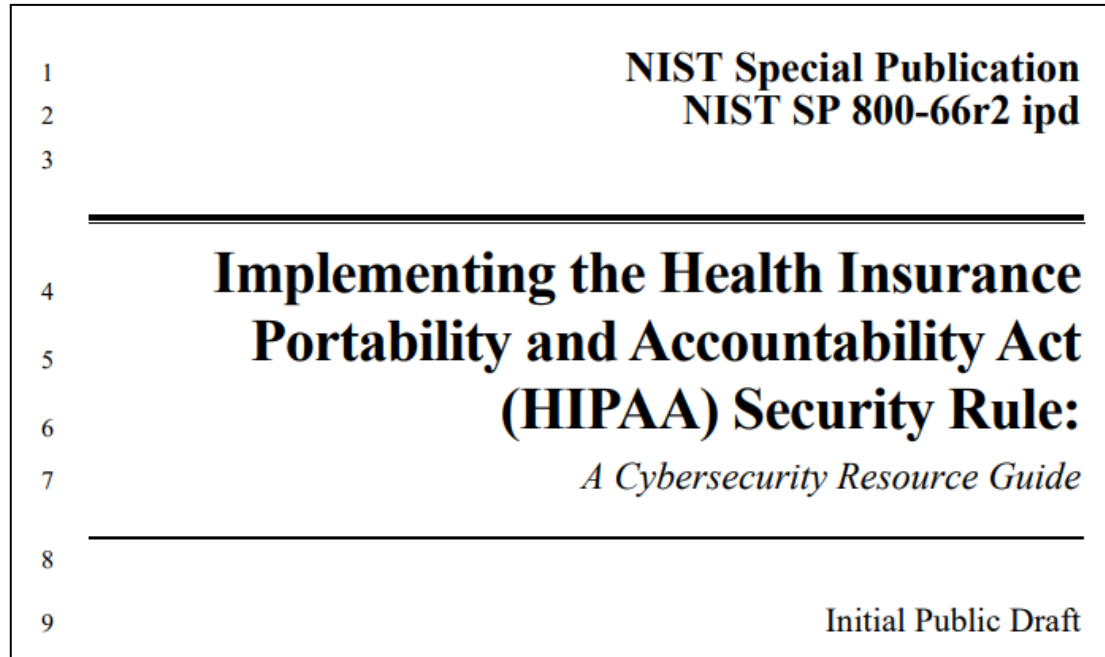
On the heels of the Supreme Court ruling in *Dobbs vs. Jackson Women's Health Organization*, where the right to safe and legal abortion was taken away, President Biden and U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra [called on HHS agencies](#) to take action to protect access to sexual and reproductive health care, including abortion, pregnancy complications, and other related care. Today, in direct response, the HHS Office for Civil Rights (OCR) issued new guidance to help protect patients seeking reproductive health care, as well as their providers.

In general, the guidance does two things:

1. addresses how federal law and regulations protect individuals' private medical information (known as protected health information or PHI) relating to abortion and other sexual and reproductive health care – making it clear that providers are not required to disclose private medical information to third parties; and
2. addresses the extent to which private medical information is protected on personal cell phones and tablets, and provides tips for protecting individuals' privacy when using period trackers and other health information apps.

<https://www.hhs.gov/about/news/2022/06/29/hhs-issues-guidance-to-protect-patient-privacy-in-wake-of-supreme-court-decision-on-roe.html>

NIST Healthcare Guidance



<https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-66r2.ipd.pdf>

“Recognized Security Practices”



<https://www.youtube.com/watch?v=e2wG7jUiRjE>

Telehealth

The screenshot shows the CONGRESS.GOV website. At the top, there is a navigation bar with "CONGRESS.GOV" in blue and red, "Advanced Searches" in blue, and "Browse" in blue. On the right, there is a "Legislation" link. Below the navigation bar, there is a search bar with "Legislation" selected and a dropdown arrow. To the right of the search bar, there are examples: "Examples: hr5, sres9, 'health care'". Below the search bar, there is a "MORE OPTIONS" button. The main content area shows the breadcrumb "Home > Legislation > 117th Congress > H.R. 4040" and a "Citation" link. The title of the bill is "H.R. 4040 - Advancing Telehealth Beyond COVID-19 Act of 2021". Below the title, it says "117th Congress (2021-2022) | Get alerts". There is a red button labeled "BILL" and a "Hide Overview" button with a close icon. The bill details are as follows:

- Sponsor:** [Rep. Cheney, Liz \[R-WY-At Large\]](#) (Introduced 06/22/2021)
- Committees:** House - Energy and Commerce; Ways and Means | Senate - Finance
- Committee Prints:** [H.Prt. 117-59](#)
- Latest Action:** Senate - 07/28/2022 Received in the Senate and Read twice and referred to the Committee on Finance. ([All Actions](#))
- Roll Call Votes:** There have been [2 roll call votes](#)
- Tracker:** Introduced Passed House Passed Senate To President Became Law

<https://www.congress.gov/bill/117th-congress/house-bill/4040>

Telehealth

RemotelCU sues over HHS telehealth restrictions

The agency currently does not allow payment for critical-care telemedicine if the physician is located outside the United States.

By **Kat Jercich** | September 13, 2021 | 01:35 PM



<https://www.healthcareitnews.com/news/remotelcu-sues-over-hhs-telehealth-restrictions>

Fraud & Abuse



THE UNITED STATES
DEPARTMENT OF JUSTICE

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JUSTICE NEWS

Department of Justice
Office of Public Affairs

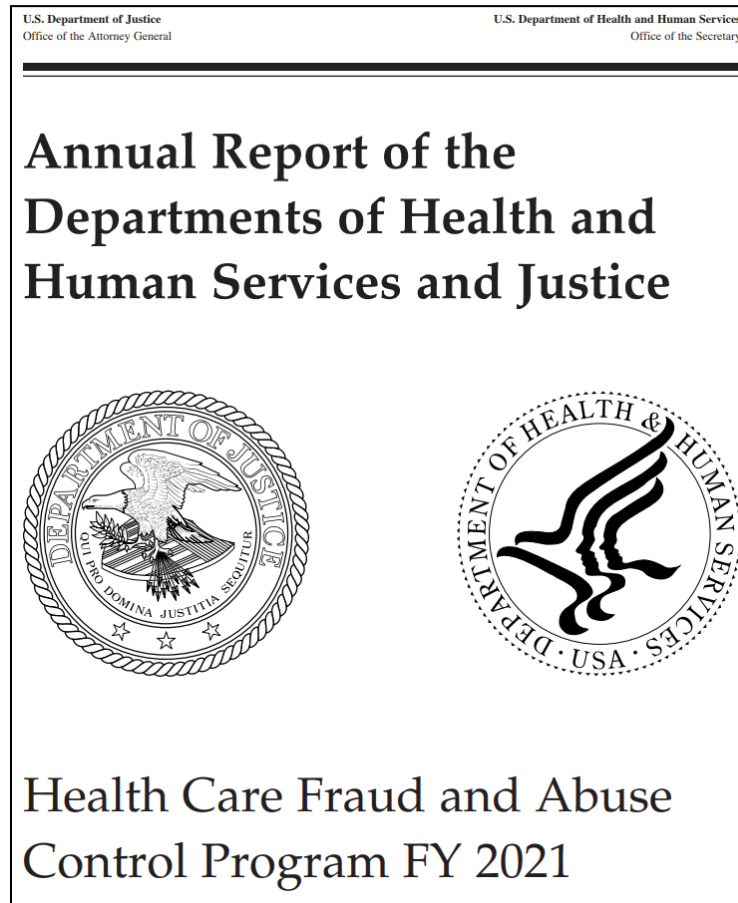
FOR IMMEDIATE RELEASETuesday, February 1, 2022

Justice Department's False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021
Second Largest Amount Recorded, Largest Since 2014

The Justice Department obtained more than \$5.6 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2021, Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division announced today. This is the second largest annual total in False Claims Act history, and the largest since 2014. Settlement and judgments since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than \$70 billion.

<https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year>

Fraud & Abuse



<https://oig.hhs.gov/publications/docs/hcfac/FY2021-hcfac.pdf>

Fraud & Abuse

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

Semiannual Report to Congress

October 1, 2021–March 31, 2022



<https://oig.hhs.gov/reports-and-publications/archives/semiannual/2022/2022-spring-sar.pdf>

Fraud & Abuse Stats

| Statistic | Semiannual Reporting Period (10/1/2021—3/31/2022) |
|--|--|
| Audit Reports Issued | 47 |
| Evaluations Issued | 14 |
| Expected Audit Recoveries | \$1.14 billion |
| Questioned Costs | \$1.6 billion |
| Potential Savings | \$162.1 million |
| New Audit and Evaluation Recommendations | 130 |
| Recommendations Implemented by HHS OpDivs | 265 |
| Expected Investigative Recoveries | \$1.44 billion |
| Criminal Actions | 320 |
| Civil Actions | 320 |
| Exclusions | 1043 |

Fraud & Abuse

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, July 2, 2021

Northern Ohio Health System Agrees to Pay Over \$21 Million to Resolve False Claims Act Allegations for Improper Payments to Referring Physicians

Department of Justice

U.S. Attorney's Office

District of Massachusetts

SHARE 

FOR IMMEDIATE RELEASE

Thursday, January 28, 2021

Athenahealth Agrees to Pay \$18.25 Million to Resolve Allegations that It Paid Illegal Kickbacks

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, July 19, 2021

Prime Healthcare Services and Two Doctors Agree to Pay \$37.5 Million to Settle Allegations of Kickbacks, Billing for a Suspended Doctor, and False Claims for Implantable Medical Hardware

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, December 18, 2020

Texas Heart Hospital and Wholly-Owned Subsidiary THHBP Management Company LLC to Pay \$48 Million to Settle False Claims Act Allegations Related to Alleged Kickbacks

Recoveries in Whistleblower Suits

Of the \$5.6 billion in settlements and judgments reported by the government in fiscal year 2021, over \$1.6 billion arose from lawsuits filed under the *qui tam* provisions of the False Claims Act. During the same period, the government paid out \$237 million to the individuals who exposed fraud and false claims by filing these actions.

The number of lawsuits filed under the *qui tam* provisions of the Act has grown significantly since 1986, with 598 *qui tam* suits filed this past year – an average of over 11 new cases every week.

Fraud & Abuse

HHS-OIG Investigates

**PANDEMIC-RELATED
SCHEME**



Scammers leveraged pandemic-related circumstances to prey on Medicare beneficiaries. Then they used the beneficiaries' Medicare information to fraudulently bill for medically unnecessary testing and medical equipment.*

* This graphic represents tactics used in some, but not all, schemes investigated as part of the 2021 National Health Care Fraud Enforcement Action.

<https://oig.hhs.gov/documents/root/987/pandemic-scheme-static.pdf>

Fraud & Abuse



THE UNITED STATES
DEPARTMENT *of* JUSTICE

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JUSTICE NEWS

Department of Justice
Office of Public Affairs


FOR IMMEDIATE RELEASE Wednesday, July 20, 2022

Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

<https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud>

OIG Work Plan



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

Search

Submit a Complaint

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Active Work Plan Items

[Work Plan Home](#) | [Recently Added](#) | [Work Plan Archive](#)

Active Work Plan Items reflect OIG audits, evaluations, and inspections that are underway or planned. Search the Work Plan using any words or numbers or download the Active Work Plan Items into a spreadsheet.

Download the Work Plan

Show

10

▾

entries

Search:

COVID

| Announced or Revised | Agency | Title | Component | Report Number(s) |
|----------------------|--|---|--------------------------|----------------------------|
| October 2022 | Centers for Disease Control and Prevention | CDC Oversight of the President's Emergency Plan for AIDS Relief Funds | Office of Audit Services | W-00-23-57301 |
| August 2022 | Centers for Medicare and Medicaid Services | CMS's Emergency Preparedness Related to Clinical Laboratories During the COVID-19 Public Health Emergency | Office of Audit Services | WA-22-0010 (W-00-22-35889) |

Improper Billing



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[Justice.gov](#) > [U.S. Attorneys](#) > [Northern District of California](#) > [Press Releases](#) > [Sutter Health Agrees To Pay \\$13 Million To Settle False Claims Act Allegations Of Improper Billing For Lab Tests](#)

PRESS RELEASE

Sutter Health Agrees To Pay \$13 Million To Settle False Claims Act Allegations Of Improper Billing For Lab Tests



Monday, October 17, 2022

Share >

For Immediate Release
U.S. Attorney's Office, Northern District of California

<https://www.justice.gov/usao-ndca/pr/sutter-health-agrees-pay-13-million-settle-false-claims-act-allegations-improper>

Medical Necessity

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

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

[Home](#) > [Fraud](#) > [Enforcement Actions](#) > Carter Healthcare Affiliates And Two Senior Managers To Pay \$7.175 Million To Resolve False...

Carter Healthcare Affiliates And Two Senior Managers To Pay \$7.175 Million To Resolve False Claims Act Allegations For False Florida Home Health Billings

Carter Healthcare LLC, an Oklahoma-based for-profit home health provider, its affiliates CHC Holdings and Carter-Florida (collectively Carter Healthcare), and their President Stanley Carter and Chief Operations Officer Bradley Carter have agreed to pay \$7.175 million to resolve allegations that they violated the False Claims Act by billing the Medicare program for medically unnecessary therapy provided to patients in Florida.

<https://oig.hhs.gov/fraud/enforcement/carter-healthcare-affiliates-and-two-senior-managers-to-pay-7175-million-to-resolve-false-claims-act-allegations-for-false-florida-home-health-billings/>

Anti-Kickback Statute

“False or Fraudulent”

- *U.S. ex rel. Cairns v. D.S. Medical LLC* (8th Circuit)
- Win for False Claims Act defendants
- Stricter “but-for” causation standard
 - Gov’t must prove that the defendant would not have submitted claims absent illegal kickbacks

Telehealth Oversight

U.S. Government Accountability Office

FOR CONGRESS PRESS CENTER CAREERS

GAO REPORTS & TESTIMONIES VIEW TOPICS VIEW AGENCIES BID PROTESTS & APPROPRIATIONS LAW ABOUT

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Medicare Telehealth: Actions Needed to Strengthen Oversight and Help Providers Educate Patients on Privacy and Security Risks

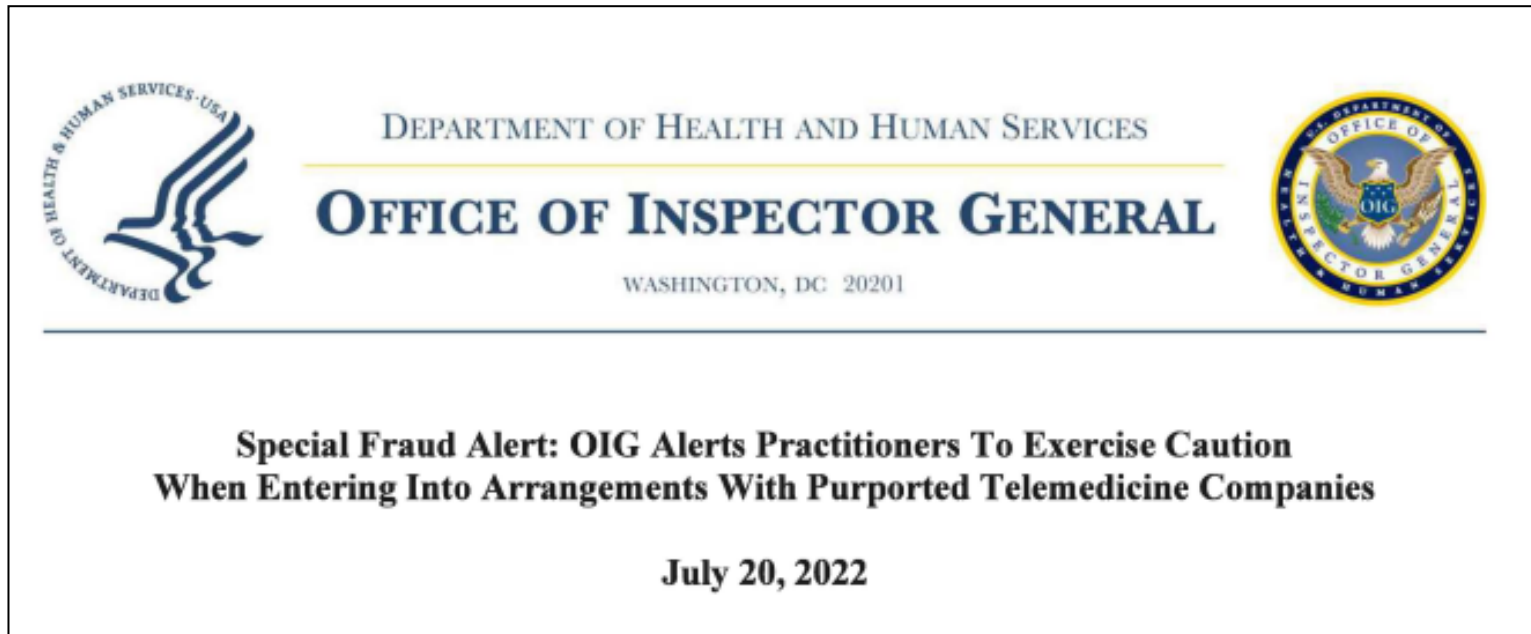
GAO-22-104454

Published: Sep 26, 2022. Publicly Released: Sep 26, 2022.

[f](#) [t](#) [in](#) [e](#)

<https://www.gao.gov/products/gao-22-104454>

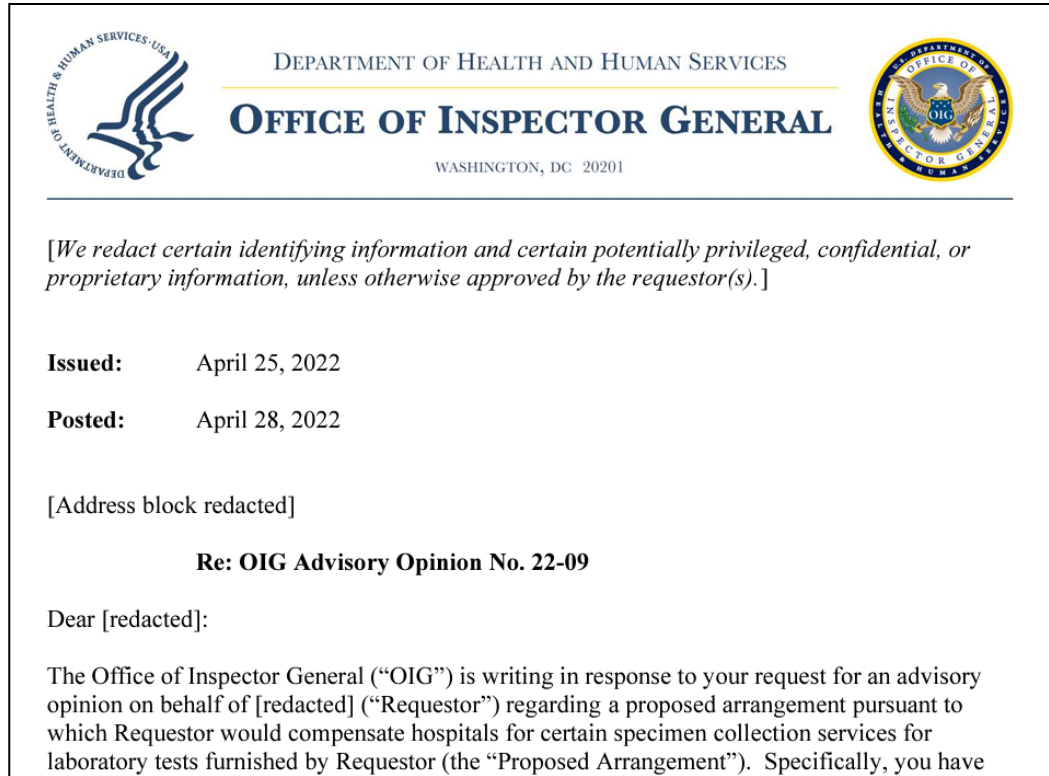
OIG Special Fraud Alert Telemedicine



<https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf>

OIG Advisory Opinion 22-09

Lab/Specimen Collection



<https://oig.hhs.gov/documents/advisory-opinions/1031/AO-22-09.pdf>

No Surprises Act

Agencies release a final rule for No Surprises Act

The update includes guidance on how entities conducting independent reviews of disputes about charges can resolve differences.

Aug 25 22 | 4 min read

Fred Bazzoli Editor-in-Chief, HDM

SHARE:



Three federal agencies have released a final rule updating several key provisions of the No Surprises Act.

<https://www.healthdatamanagement.com/articles/agencies-release-a-final-rule-for-no-surprises-act?id=130939>

Good Faith Estimate Co-Providers

Q1: Will CMS enforce the requirement that GFEs for uninsured (or self-pay) individuals include cost estimates from co-providers and co-facilities beginning on January 1, 2023?

A1: No. HHS is extending enforcement discretion, pending future rulemaking, for situations where GFEs for uninsured (or self-pay) individuals do not include expected charges from co-providers or co-facilities.

<https://www.cms.gov/files/document/good-faith-estimate-uninsured-self-pay-part-3.pdf>

CMS finalizes requirements for rural emergency hospital designation

Published Nov. 2, 2022



[Shannon Muchmore](#)
Senior Editor



Rural Emergency Hospitals



The screenshot shows the CMS.gov website header with the logo and the text "Centers for Medicare & Medicaid Services". Below this is a blue navigation bar with the word "Newsroom" in large white letters, and links for "Press Kit", "Data", "Contact", "Blog", and "Podcast". The main content area features a yellow "Fact sheet" tag. The title of the fact sheet is "CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS 1772-FC) Rural Emergency Hospitals – New Medicare Provider Type". At the bottom of the fact sheet, it says "Nov 01, 2022 | Rural health, Hospitals".

CMS.gov Centers for Medicare & Medicaid Services

Newsroom Press Kit Data Contact Blog Podcast

Fact sheet

CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS 1772-FC) Rural Emergency Hospitals – New Medicare Provider Type

Nov 01, 2022 | Rural health, Hospitals

<https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-1>

Rural Emergency Hospitals

- New provider type effective 1/1/23
- Allows for the provision of emergency services, observation care, and additional medical and health outpatient services
- Do not exceed annual patient average of 24 hours

Cyber Fraud



The screenshot shows the official website of the U.S. Department of Justice. At the top left is the Department of Justice seal. To its right, the text "THE UNITED STATES DEPARTMENT of JUSTICE" is displayed. Below this is a navigation bar with links: "ABOUT", "OUR AGENCY", "TOPICS", "NEWS", "RESOURCES", and "CAREERS". The main content area shows a breadcrumb trail: "Home » Office of Public Affairs » News". Below this is a black banner with the text "JUSTICE NEWS" in white. Underneath the banner, the text "Department of Justice" and "Office of Public Affairs" is centered. A horizontal line separates the header from the main content. Below the line, on the left, it says "FOR IMMEDIATE RELEASE" and on the right, "Wednesday, October 6, 2021". The main headline is "Deputy Attorney General Lisa O. Monaco Announces New Civil Cyber-Fraud Initiative". Below the headline is a paragraph: "Deputy Attorney General Lisa O. Monaco announced today the launch of the department's Civil Cyber-Fraud Initiative, which will combine the department's expertise in civil fraud enforcement, government procurement and cybersecurity to combat new and emerging cyber threats to the security of sensitive information and critical systems."

THE UNITED STATES
DEPARTMENT of JUSTICE

ABOUT OUR AGENCY TOPICS NEWS RESOURCES CAREERS

Home » Office of Public Affairs » News

JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, October 6, 2021

Deputy Attorney General Lisa O. Monaco Announces New Civil Cyber-Fraud Initiative

Deputy Attorney General Lisa O. Monaco announced today the launch of the department's Civil Cyber-Fraud Initiative, which will combine the department's expertise in civil fraud enforcement, government procurement and cybersecurity to combat new and emerging cyber threats to the security of sensitive information and critical systems.

<https://www.justice.gov/opa/pr/deputy-attorney-general-lisa-o-monaco-announces-new-civil-cyber-fraud-initiative>

Cyber Fraud



<https://www.justice.gov/opa/pr/medical-services-contractor-pays-930000-settle-false-claims-act-allegations-relating-medical>



<https://www.justice.gov/opa/pr/aerojet-rocketdyne-agrees-pay-9-million-resolve-false-claims-act-allegations-cybersecurity>



NEWS

Biden signs law on reporting critical infrastructure cyber attacks

- Applies to critical infrastructure, which potentially consists of up to 16 different, broadly defined industries.
- Requires breach reporting to CISA within 72 hours of a substantial cyber incident and within 24 hours of paying a ransom.
- Gives CISA up to two years to issue proposed rules and an additional 18 months to issue final rules, although it could move much faster in response to recent cyber threats from Russia.
- Substantially increases CISA's budget to address cyber crime.

Article | Risk Management



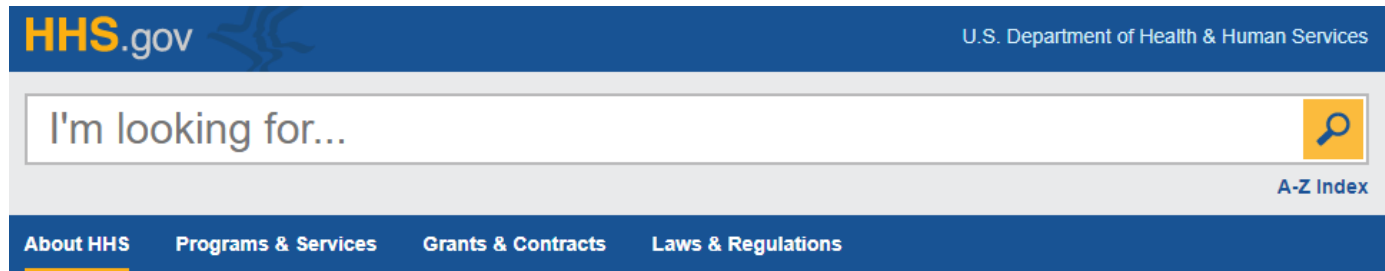
Healthcare's cybersecurity stakes reach alarming levels

Oct 26, 2022

By Eric C. Reese, PhD

https://www.hfma.org/topics/hfm/2022/november/healthcare-s-cybersecurity-stakes-reach-alarming-levels.html?utm_medium=email&utm_source=rasa_io&utm_campaign=newsletter

Data Breaches



[Home](#) > [About](#) > [News](#) > Oklahoma State University – Center for Health Services Pays \$875,000 to Settle Hacking Breach

Text Resize **A A A** | Print | Share

FOR IMMEDIATE RELEASE
July 14, 2022

Contact: HHS Press Office
202-690-6343
media@hhs.gov

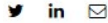
Oklahoma State University – Center for Health Services Pays \$875,000 to Settle Hacking Breach

Oklahoma State University – Center for Health Sciences (OSU-CHS) has paid \$875,000 to the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) and agreed to implement a corrective action plan to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules. OSU-CHS is a public land-grant research university which provides preventive, rehabilitative, and diagnostic care in Oklahoma.

<https://www.hhs.gov/about/news/2022/07/14/oklahoma-state-university-center-health-services-pays-875000-settle-hacking-breach.html>

Healthcare leaders facing dozens of cyberattacks annually: survey

JESSICA KIM COHEN

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MH Illustration/Getty Images

Healthcare leaders say it can cost more than \$4 million for an organization to recover from a single cyberattack, according to a new survey.

What Happens to the Bad Guys?



The screenshot shows the official website of the U.S. Department of Justice. At the top is the Department of Justice seal and the text "THE UNITED STATES DEPARTMENT OF JUSTICE". Below this is a navigation bar with links: ABOUT, OUR AGENCY, TOPICS, NEWS, RESOURCES, and CAREERS. The main content area has a breadcrumb trail: "Home » Office of Public Affairs » News". A black banner with the text "JUSTICE NEWS" is displayed. Below the banner, the text "Department of Justice" and "Office of Public Affairs" is shown. The release date "Friday, November 18, 2022" is on the right. The headline reads: "10 Charged in Business Email Compromise and Money Laundering Schemes Targeting Medicare, Medicaid, and Other Victims". A sub-headline states: "Justice Department's first coordinated action against individuals using BEC and money laundering schemes to target public and private health insurers". The body text begins: "The U.S. Department of Justice announced charges today against 10 defendants in multiple states in connection with multiple business email compromise (BEC), money laundering, and wire fraud schemes that targeted Medicare, state Medicaid programs, private health insurers, and numerous other victims and resulted in more than \$11.1 million in total losses."

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 Friday, November 18, 2022

10 Charged in Business Email Compromise and Money Laundering Schemes Targeting Medicare, Medicaid, and Other Victims

Justice Department's first coordinated action against individuals using BEC and money laundering schemes to target public and private health insurers

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<https://www.justice.gov/opa/pr/10-charged-business-email-compromise-and-money-laundering-schemes-targeting-medicare-medicaid>

Data Breaches



Photo Illustration: Jonathan Hurtarte/Bloomberg Law

Sincera Reproductive Medicine Loses Bid to Toss Breach Claims

May 25, 2022, 1:07 PM



- Breach allegedly compromised personal data of 37,000 patients
- Most of plaintiffs' claims were adequately pleaded



**Samantha
Hawkins**
Legal Reporter



Sincera Reproductive Medicine must face claims alleging that it was negligent in securing patient data, resulting in a data breach that compromised sensitive health information of 37,000 people, after a Pennsylvania federal judge declined to dismiss most of a lawsuit.

<https://news.bloomberglaw.com/privacy-and-data-security/sincera-reproductive-medicine-loses-bid-to-toss-breach-claims>

Price Transparency

CMS Takes First Enforcement Actions Under Hospital Price Transparency Rule

June 10, 2022



<https://www.cms.gov/hospital-price-transparency/enforcement-actions>

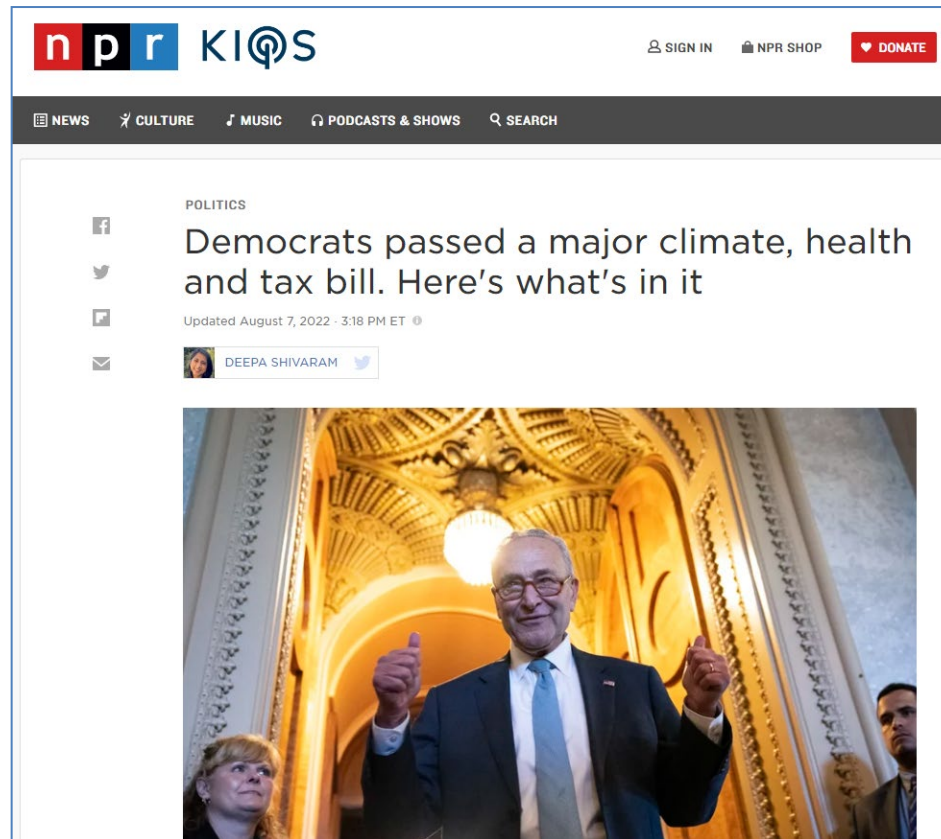
Price Transparency

OIG Work Plan

To evaluate CMS's monitoring and enforcement of the hospital price transparency rule, we will review the controls in place at CMS and statistically sample hospitals to determine whether CMS's controls are sufficient to ensure that hospital pricing information is readily available to patients as required by Federal law. Additionally, if hospitals are not in compliance with CMS's rule for listing their charges, we will contact the hospitals to determine the reason for noncompliance and determine whether CMS identified the noncompliance and imposed consequences on the hospitals.

| Announced or Revised | Agency | Title | Component | Report Number(s) | Expected Issue Date (FY) |
|----------------------|--|-----------------------------|--------------------------|----------------------------|--------------------------|
| September 2022 | Centers for Medicare and Medicaid Services | Hospital Price Transparency | Office of Audit Services | WA-22-0013 (W-00-22-35890) | 2023 |

Inflation Reduction Act



<https://www.npr.org/2022/08/07/1116190180/democrats-are-set-to-pass-a-major-climate-health-and-tax-bill-heres-whats-in-it>

Controlled Substances Act

OCTOBER 06, 2022

Statement from President Biden on Marijuana Reform



► BRIEFING ROOM ► STATEMENTS AND RELEASES

Third, I am asking the Secretary of Health and Human Services and the Attorney General to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law. Federal law currently classifies marijuana in Schedule I of the Controlled Substances Act, the classification meant for the most dangerous substances. This is the same schedule as for heroin and LSD, and even higher than the classification of fentanyl and methamphetamine – the drugs that are driving our overdose epidemic.

<https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/>

Medical Marijuana & Cannabidiol Research Expansion Act

One Hundred Seventeenth Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday,
the third day of January, two thousand and twenty-two*

An Act

To expand research on cannabidiol and marijuana, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Medical Marijuana and Cannabidiol Research Expansion Act”.

<https://www.congress.gov/bill/117th-congress/house-bill/8454/text>

42 CFR Part 2

FOR IMMEDIATE RELEASE

November 28, 2022

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Proposes New Protections to Increase Care Coordination and Confidentiality for Patients With Substance Use Challenges

New Proposed Rule to Implement the Bipartisan CARES Act Legislation

<https://www.hhs.gov/about/news/2022/11/28/hhs-proposes-new-protections-increase-care-coordination-confidentiality-patients-substance-use-challenges.html>



Press release

Amazon and One Medical Sign an Agreement for Amazon to Acquire One Medical

July 21, 2022 at 8:30 AM EDT

<https://press.aboutamazon.com/news-releases/news-release-details/amazon-and-one-medical-sign-agreement-amazon-acquire-one-medical/>

CHECK OUT HEALTH IT WHITEPAPERS FROM **BECKER'S
HEALTHCARE**

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Cybersecurity EHRs Telehealth Innovation Digital Health Disruptors

Walgreens CEO calls Summit Health deal 'transformational': 5 key moves behind it

Naomi Diaz - 5 hours ago

Save Post Tweet Share Listen Text Size Print Email

VillageMD, the primary care disruptor controlled by Walgreens Boots Alliance, is set to acquire physician practice group Summit Health in a \$8.9 billion transaction, which in turn will give Walgreens one of the biggest stakes in the combined company.

<https://www.beckershospitalreview.com/disruptors/walgreens-ceo-calls-summit-health-deal-transformational-5-key-moves-behind-it.html>

Remember § 1557 of the ACA?



The screenshot shows the Federal Register website. At the top, it says "FEDERAL REGISTER" and "The Daily Journal of the United States Government". There is a "Proposed Rule" label. The title of the rule is "Nondiscrimination in Health Programs and Activities". Below the title, it says "A Proposed Rule by the Centers for Medicare & Medicaid Services on 08/04/2022". There is a comment period notice: "This document has a comment period that ends in 55 days. (10/03/2022)". A green button says "SUBMIT A FORMAL COMMENT". Below that, it says "Read the 155 public comments". The main content area is titled "PUBLISHED DOCUMENT" and shows the "AGENCY:" as "Centers for Medicare and Medicaid Services; Office for Civil Rights (OCR), Office of the Secretary, HHS." and the "ACTION:" as "Notice of proposed rulemaking; notice of Tribal consultation." On the right, "DOCUMENT DETAILS" are listed: "Printed version: PDF", "Publication Date: 08/04/2022", "Agencies: Centers for Medicare & Medicaid Services, Office of the Secretary", and "Dates:".

FEDERAL REGISTER
The Daily Journal of the United States Government

Proposed Rule

Nondiscrimination in Health Programs and Activities

A Proposed Rule by the Centers for Medicare & Medicaid Services on 08/04/2022

This document has a comment period that ends in 55 days. (10/03/2022)

SUBMIT A FORMAL COMMENT

Read the **155** public comments

PUBLISHED DOCUMENT

Start Printed Page 47824

AGENCY:
Centers for Medicare and Medicaid Services; Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION:
Notice of proposed rulemaking; notice of Tribal consultation.

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
08/04/2022

Agencies:
Centers for Medicare & Medicaid Services
Office of the Secretary

Dates:

<https://www.federalregister.gov/documents/2022/08/04/2022-16217/nondiscrimination-in-health-programs-and-activities>

Top 10 Healthcare Industry Predictions For 2023

Sachin H. Jain Contributor @

I cover transformation and innovation across the health care industry.

Follow

Nov 7, 2022, 07:00am EST

0



Listen to article 21 minutes



<https://www.forbes.com/sites/sachinjain/2022/11/07/top-10-healthcare-industry-predictions-for-2023/?sh=4ecea7fb664d>

San Diego Zoo penguin fitted with orthopedic footwear

August 29, 2022



SAN DIEGO (AP) — A member of the San Diego Zoo's African penguin colony has been fitted with orthopedic footwear to help it deal with a degenerative foot condition.

Questions?

Michael W. Chase
mchase@bairdholm.com
402-636-8326