Health Privacy + Security Law Workshop: New Developments

2022 Privacy+Security Forum Fall Academy

Adam Greene, Davis Wright Tremaine LLP

Agenda

- Health Information Privacy in the Wake of *Dobbs*
- Status of HIPAA Rulemaking
- Status of Changes to 42 C.F.R. Part 2
- Update on Information Blocking
- 30-Minute Break
- FTC Developments with Respect to Health and Wellness Apps
- State Privacy Laws
- Health Information Enforcement Actions
- Impactful Court Decisions

Health Information Privacy in the Wake of *Dobbs*

Texas H.B. 1280

This Act may be cited as the Human Life Protection Act of 2021.

* * * * *

Sec. 170A.002. PROHIBITED ABORTION; EXCEPTIONS. (a) A person may not knowingly perform, induce, or attempt an abortion.

* * * * *

Sec. 170A.004. CRIMINAL OFFENSE. (a) A person who violates Section 170A.002 commits an offense.

(b) An offense under this section is a felony of the second degree, except that the offense is a felony of the first degree if an unborn child dies as a result of the offense.

Tex. Pen. Code Sec. 12.32. FIRST DEGREE FELONY PUNISHMENT. (a) An individual adjudged guilty of a felony of the first degree shall be punished by imprisonment in the Texas Department of Criminal Justice for life or for any term of not more than 99 years or less than 5 years.

NATIONAL

A Nebraska woman is charged with helping her daughter have an abortion

August 10, 2022 · 10:23 AM ET

THE ASSOCIATED PRESS

“When your medical record can be used as evidence of illegal behavior, there is an issue. … As long as drug use is illegal, then the medical record can serve to incriminate the user. Furthermore, because those who use illegal substances and who are dependent on alcohol may disclose while in treatment for substance use disorders illegal acts that disclosure has the potential to be used for self-incrimination. … It is illegal to use heroin; it is not illegal to have diabetes. It is illegal to use marijuana; it is not illegal to be depressed. It is illegal to use street methamphetamine; it is not illegal to have hypertension. It is illegal to use PCP; it is not illegal to be obese. … It may be inconvenient for the health care delivery system to ask a patient for permission to codify information that could incriminate them in a legal forum, but it is disingenuous for health care providers to ignore the risk of disclosure of such information to the medical record. Respect for the autonomy of our patients requires that we seek permission from them prior to opening a gate that we cannot control, but which has clear implications.”

- Comment by H. Westley Clark, former Director of Center for Substance Abuse Treatment in the Substance Abuse and Mental Health Administration, commenting on S. Wakeman & P. Friedman, *Outdated Privacy Law Limits Effective Substance Use Disorder Treatment: The Case Against 42 CFR Part 2*, Health Affairs, March 1, 2017, https://www.healthaffairs.org/do/10.1377/forefront.20170301.058969/.

Potential HIPAA Permissions for Disclosures of Reproductive Health Information

- When required by law. [45 C.F.R. § 164.512(a)]
- In response to a court order. [45 C.F.R. § 164.512(e)]
- To law enforcement pursuant to a court order, court-ordered warrant, subpoena issued by a judicial officer, grand jury subpoena, or administrative request that includes three elements. [45 C.F.R. § 164.512(f)(1)]
- To report a crime on the premises. [45 C.F.R. § 164.512(f)(6)]
- To avert a serious and imminent threat to the health or safety of a person. [45 C.F.R. § 164.512(j)]
- Workforce member believes in good faith that the covered entity has engaged in unlawful conduct. [45 C.F.R. § 164.502(j)]

FOR IMMEDIATE RELEASE
June 29, 2022

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

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.

OCR Guidance

- “The Privacy Rule permits but **does not require** covered entities to disclose PHI about an individual, without the individual’s authorization, when such disclosure is required by another law and the disclosure complies with the requirements of the other law.”
- “In the absence of a mandate enforceable in a court of law, the Privacy Rule’s permission to disclose PHI for law enforcement purposes does not permit a disclosure to law enforcement where a hospital or other health care provider’s workforce member chose to report an individual’s abortion or other reproductive health care.”
- “A statement indicating an individual’s intent to get a legal abortion, or any other care tied to pregnancy loss, ectopic pregnancy, or other complications related to or involving a pregnancy does not qualify as a ‘serious and imminent threat to the health or safety of a person or the public’.”

Senators Seek HIPAA Changes to Protect Reproductive Info

Letter Sent to HHS Secretary Urges 'Immediate Action' for HIPAA Rule-Making

Marianne Kolbasuk McGee (HealthInfoSec) • September 15, 2022

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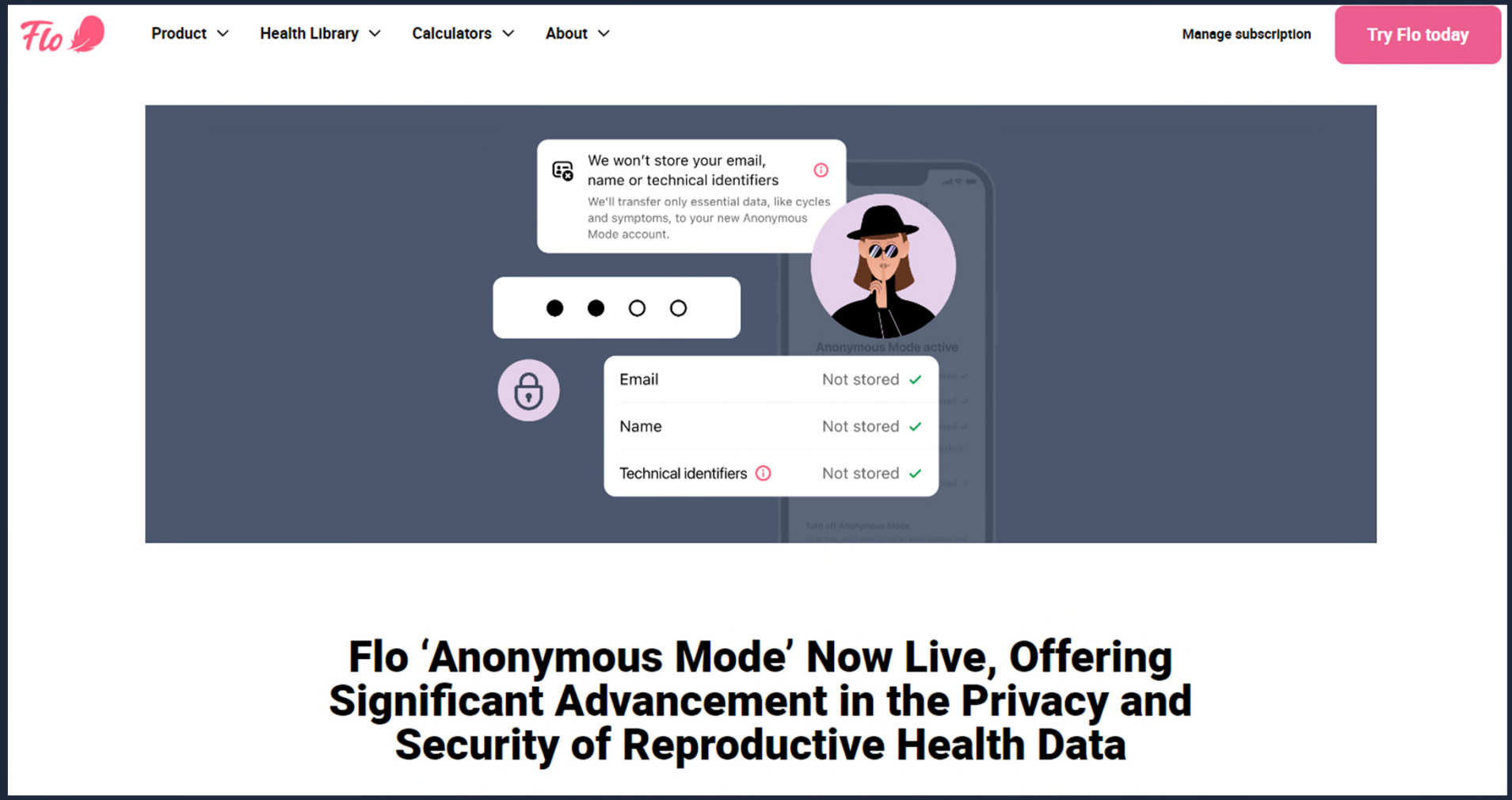
https://www.healthcareinfosecurity.com/senators-seek-hipaa-changes-to-protect-reproductive-info-a-20086

Google Changes Location History Practices

Location History is a Google account setting that is off by default, and for those that turn it on, we provide simple controls like auto-delete so users can easily delete parts, or all, of their data at any time. Some of the places people visit — including medical facilities like counseling centers, domestic violence shelters, abortion clinics, fertility centers, addiction treatment facilities, weight loss clinics, cosmetic surgery clinics, and others — can be particularly personal. Today, we're announcing that if our systems identify that someone has visited one of these places, we will delete these entries from Location History soon after they visit. This change will take effect in the coming weeks.

- Jen Fitzpatrick, Senior Vice President, Google, https://blog.google/technology/safety-security/protecting-peoples-privacy-on-health-topics/ (July 1, 2022)

Flo Health Enables Anonymous Mode



New State Protections

Cal. Civ. Code § 56.108 (.

- “[A] provider of health care … shall not release medical information related to an individual seeking or obtaining an abortion in response to a subpoena or request if that subpoena or request is based on either another state’s laws that interfere with a person’s rights under the Reproductive Privacy Act (Article 2.5 (commencing with Section 123460) of Chapter 2 of Part 2 of Division 106 of the Health and Safety Code) or a foreign penal civil action, as defined in Section 2029.200 of the Code of Civil Procedure.”
- “A provider of health care … shall not release medical information that would identify an individual or that is related to an individual seeking or obtaining an abortion to law enforcement for either of the following purposes, unless that release is pursuant to a subpoena not otherwise prohibited by subdivision (a):
    1. Enforcement of another state’s law that would interfere with a person’s rights under the Reproductive Privacy Act (Article 2.5 (commencing with Section 123460) of Chapter 2 of Part 2 of Division 106 of the Health and Safety Code).
    2. Enforcement of a foreign penal civil action, as defined in Section 2029.200 of the Code of Civil Procedure.”

Status of HIPAA Rulemaking

Right of Access

- 30 days + 30 days becomes “as soon as practicable” + 15 calendar days + 15 calendar days
- Policy must prioritize “urgent or otherwise high priority requests”
- Third-party directives: (1) limited to e-copy of EHR; and (2) can be based on verbal request
- Clarifies right of inspection and “unreasonable measures”

Right of Access

- Right to receive copy through a “personal health application”
- Must post fees and provide individualized estimate upon request
- Right to have a covered entity submit an access request to a health care provider on individual’s behalf

Notice of Privacy Practices

- Ends requirement to obtain acknowledgment of receipt
- Substantially increases required language
- Adds right to discuss the notice with designated contact person

Other Proposals

- Clarifies definition of “health care operations”
- Adds exception to minimum necessary standard for case management and care coordination
- Permits disclosure for treatment to social services agencies, community-based organizations, home and community-based providers, and similar third parties
- Revises “professional judgment” to “good faith belief”
- “Serious and imminent threat” → “serious and reasonably foreseeable threat”

OCR Issues Proposed Rule (Jan. 21, 2021)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 160 and 164

[Docket No.: HHS–OCR–0945–AA00]

RIN 0945–AA00

Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement

AGENCY: Office for Civil Rights, Office of the Secretary, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Department of Health and Human Services (HHS or ''the Department'') is issuing this Notice of Proposed Rulemaking (NPRM) to modify the Standards for the Privacy of Individually Identifiable Health Information (Privacy Rule) under the Health Insurance Portability and

any personal information provided about the commenter, and such posting may occur before or after the closing of the comment period.

The Department will consider all comments received by the date and time specified in the **DATES** section above, but, because of the large number of public comments normally received on **Federal Register** documents, the Department is not able to provide individual acknowledgments of receipt.

Please allow sufficient time for mailed comments to be timely received in the event of delivery or security delays. Electronic comments with attachments should be in Microsoft Word or Portable Document Format (PDF).

Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For complete access to background documents or posted

1. Adding Definitions for ''Electronic Health Record'' or EHR and ''Personal Health Application'' (45 CFR 164.501)
2. Strengthening the Access Right To Inspect and Obtain Copies of PHI
3. Modifying the Implementation Requirements for Requests for Access and Timely Action in Response to Requests for Access
4. Addressing the Form of Access
5. Addressing the Individual Access Right To Direct Copies of PHI to Third Parties
6. Adjusting Permitted Fees for Access to PHI and ePHI
7. Notice of Access and Authorization Fees
8. Technical Change to General Rules for Required Business Associate Disclosures of PHI
9. Request for Comments

B. Reducing Identity Verification Burden for Individuals Exercising the Right of Access (45 CFR 164.514(h))
1. Current Provision and Issues To Address
2. Proposal
3. Request for Comments

C. Amending the Definition of Health Care Operations To Clarify the Scope of Care

OCR Extends Comment Period (Mar. 9, 2021)

HHS.gov

U.S. Department of Health & Human Services

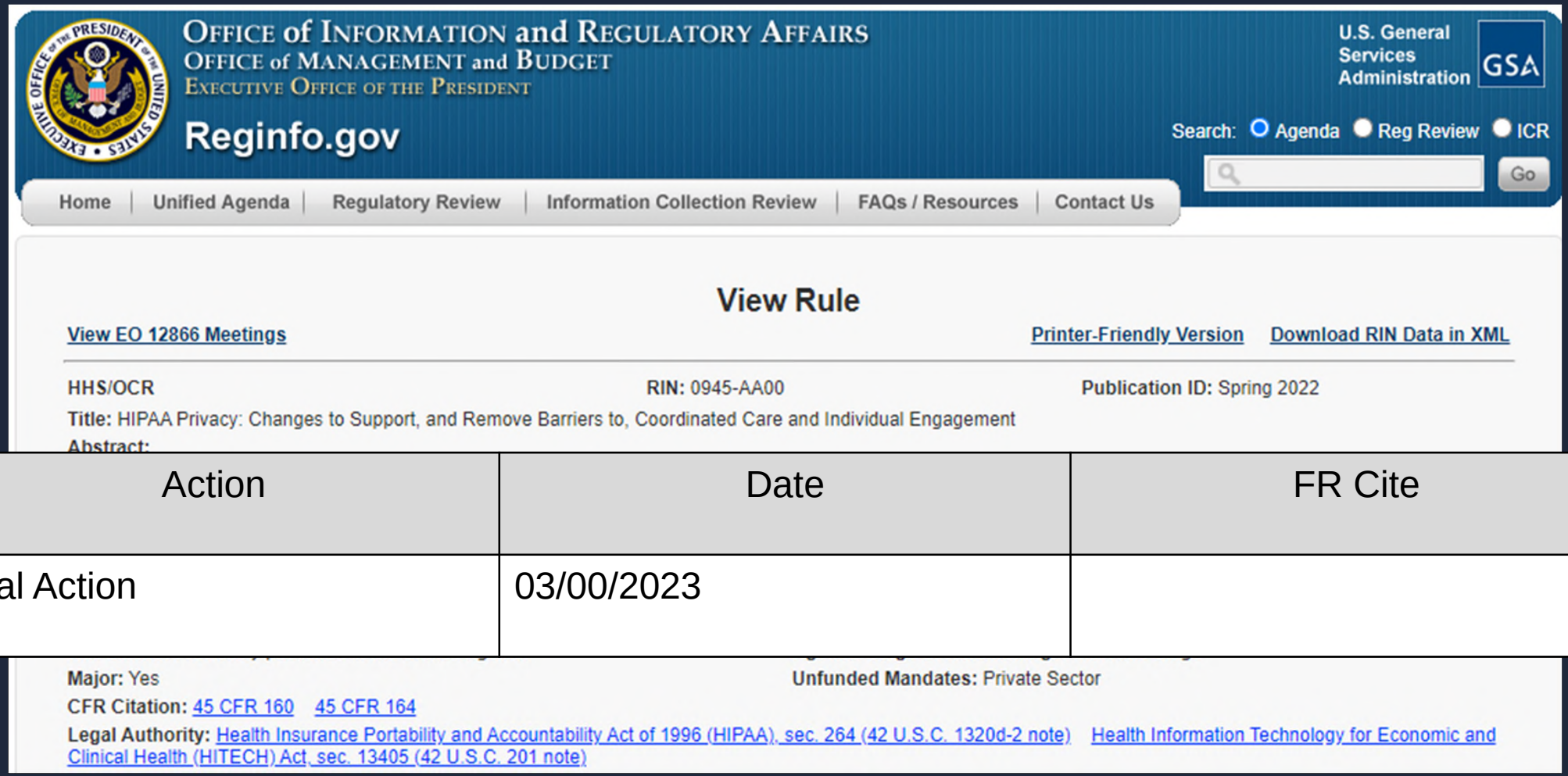
FOR IMMEDIATE RELEASE
March 9, 2021

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

Extension of the Public Comment Period for Proposed Modifications to the HIPAA Privacy Rule

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announces a 45-day extension of the public comment period for the Notice of Proposed Rulemaking (NPRM) to modify the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Current Status of Final Rule



Action	Date	FR Cite
Final Action	03/00/2023	

April 2022 Request for Information

- With respect to penalties and audits, “the Secretary shall consider whether the covered entity or business associate has adequately demonstrated that it had, for not less than the previous 12 months, recognized security practices in place ….”
  - Questions about “recognized security practices” that organizations have implemented.
  - What steps do organizations take to ensure that recognized security practices are in place and consistently in use?

April 2022 Request for Information

- Distribution of penalties/settlements to harmed individuals
  - What constitutes compensable harm?
  - Should harm be presumed in certain cases? If not, what evidence of harm is needed?
  - Should there be a minimum or maximum percentage distributed to harmed individuals?
  - How should harmed individuals be identified and notified?
- Deadline for comments: June 6, 2022

Changes to 42 C.F.R. Part 2

CARES Act

- Patient can provide general treatment, payment, health care operations (“TPO”) consent.
- Once disclosed for TPO, then Part 2 record may be redisclosed consistent with HIPAA.
- HIPAA penalties apply to the Part 2 Rule.
- New breach notification requirement consistent with HIPAA.
- Waiting on regulations.

SAMHSA
Substance Abuse and Mental Health Services Administration

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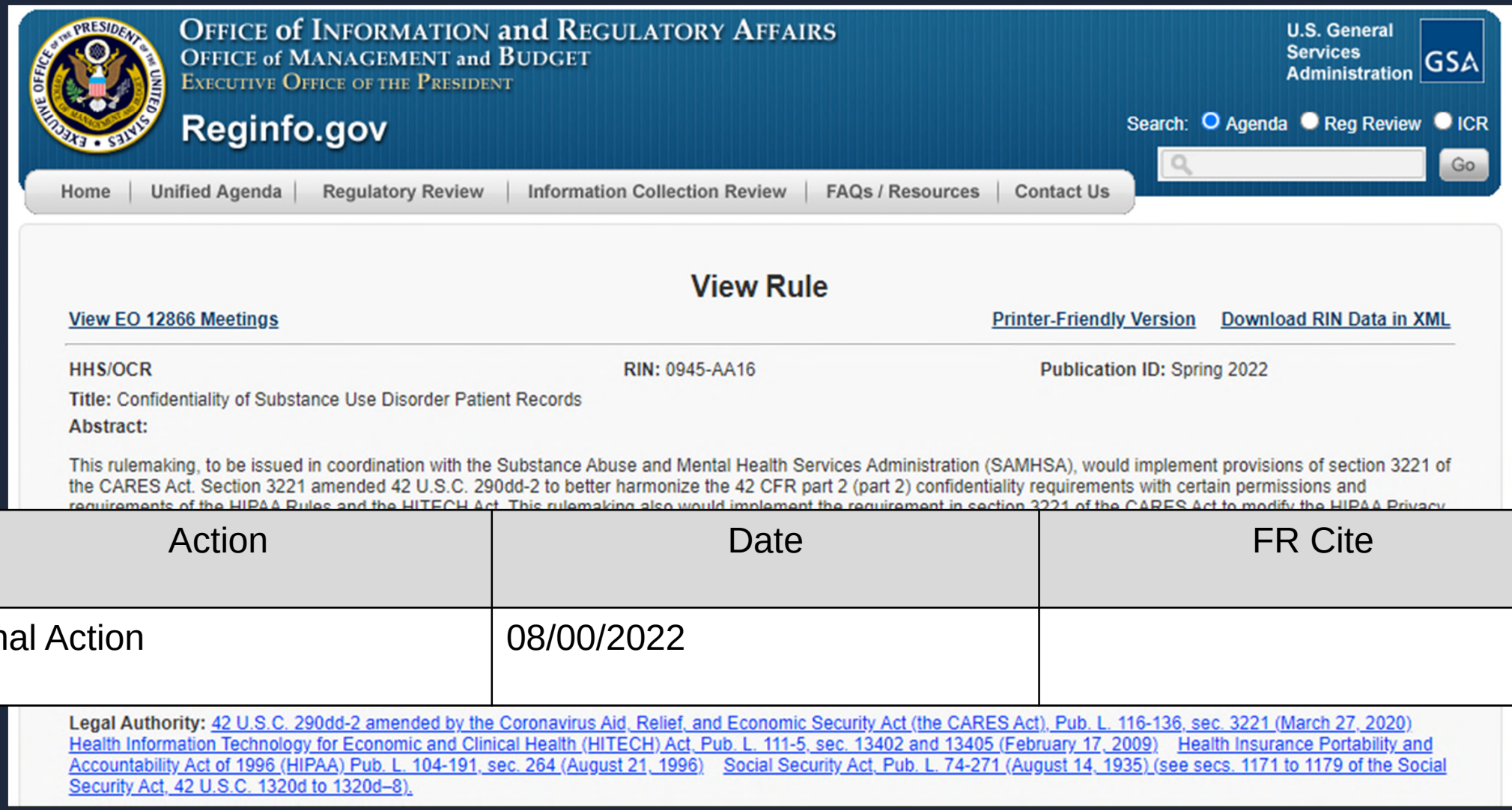
- Media Guidelines for Bullying Prevention
- Press Announcements
- Statements
- Logo Use Guidelines

Statement on 42 CFR Part 2 Amendments Process

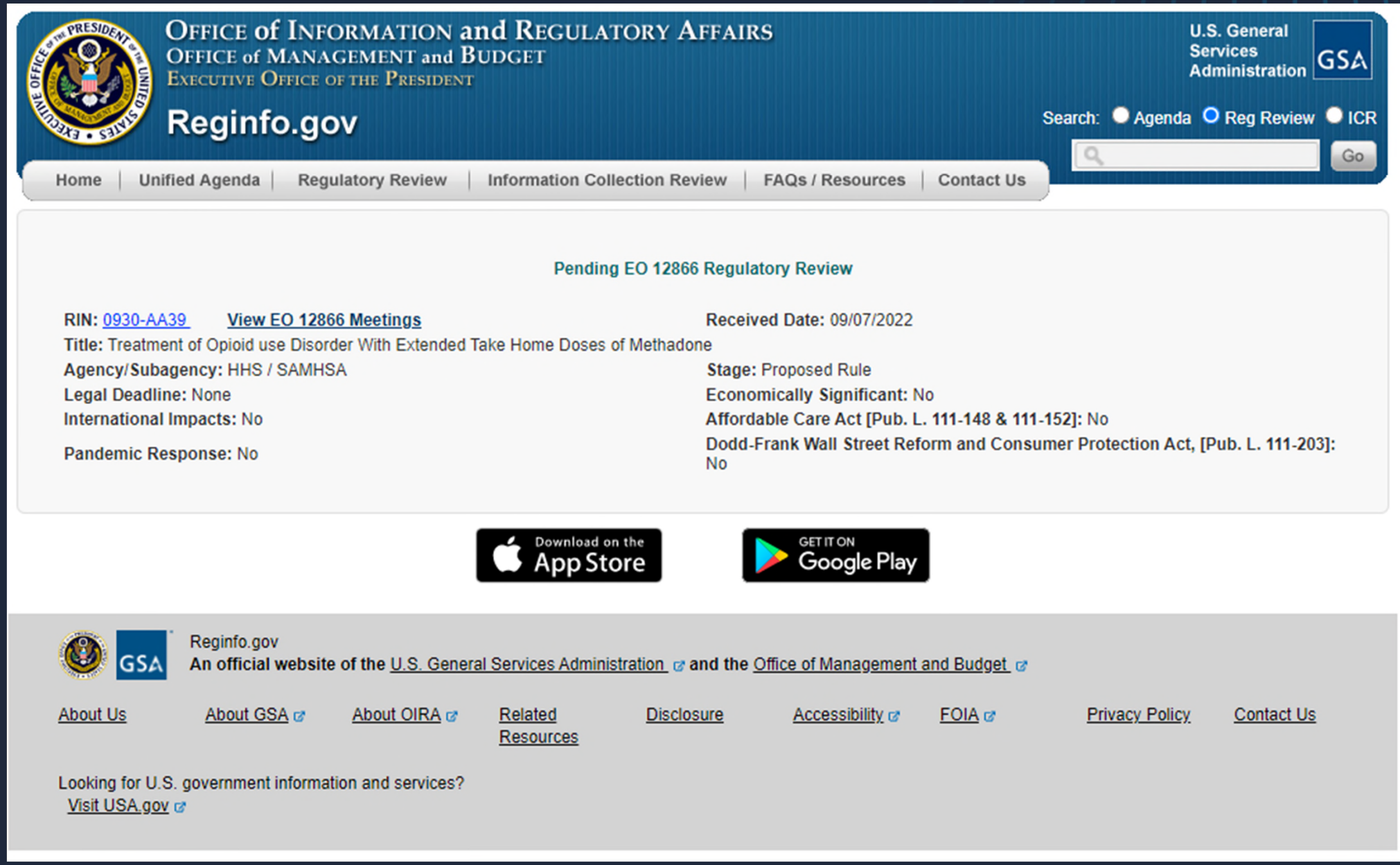
Friday, April 9, 2021

SAMHSA is working with the HHS Office for Civil Rights on a Notice of Proposed Rulemaking to address the changes required by the CARES Act, to the 42 CFR part 2 regulations governing the confidentiality of substance use disorder patient records. We intend to publish these amendments later this year in the Federal Register, and we will be seeking comments from the public. Until new regulations are promulgated, the current 42 CFR part 2 regulations remain in effect. We know that many stakeholders are eagerly awaiting these revisions and appreciate your patience as we work to provide a thoughtful and thorough review of these provisions and amendments.

Last Updated: 04/09/2021



Action	Date	FR Cite
Final Action	08/00/2022	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Pending EO 12866 Regulatory Review
RIN: 0930-AA39 View EO 12866 Meetings
Received Date: 09/07/2022
Title: Treatment of Opioid use Disorder With Extended Take Home Doses of Methadone
Agency/Subagency: HHS / SAMHSA
Stage: Proposed Rule
Legal Deadline: None
Economically Significant: No
International Impacts: No
Affordable Care Act [Pub. L. 111-148 & 111-152]: No
Pandemic Response: No
Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]: No
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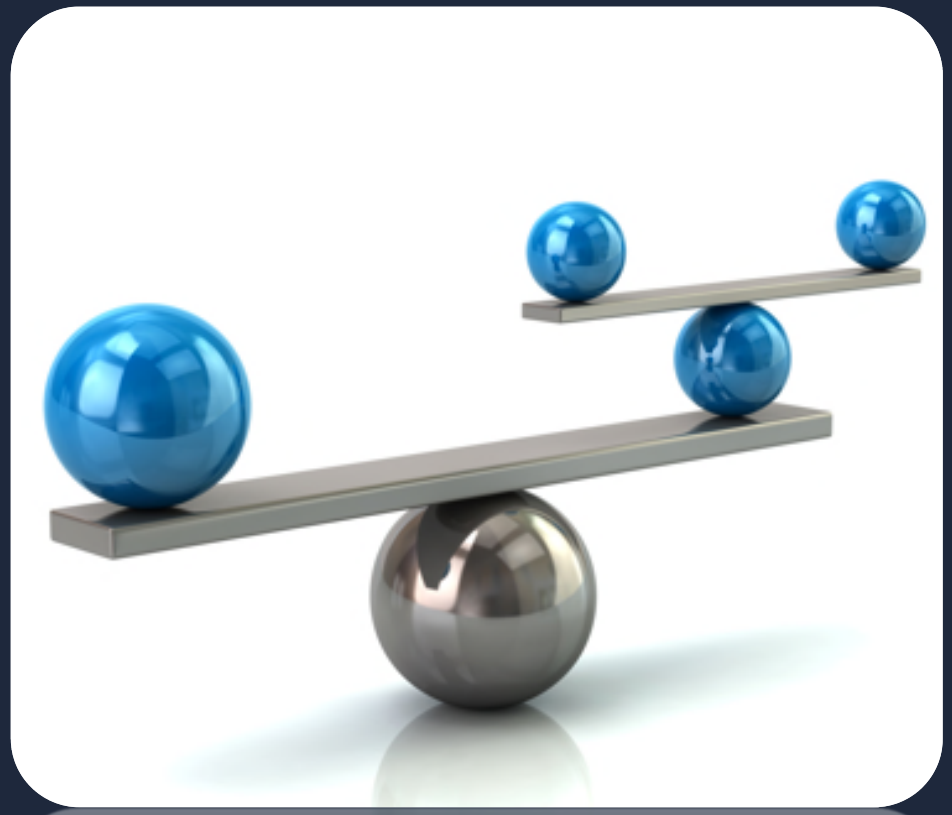
Update on Information Blocking

Cures Act – Information Blocking Definition

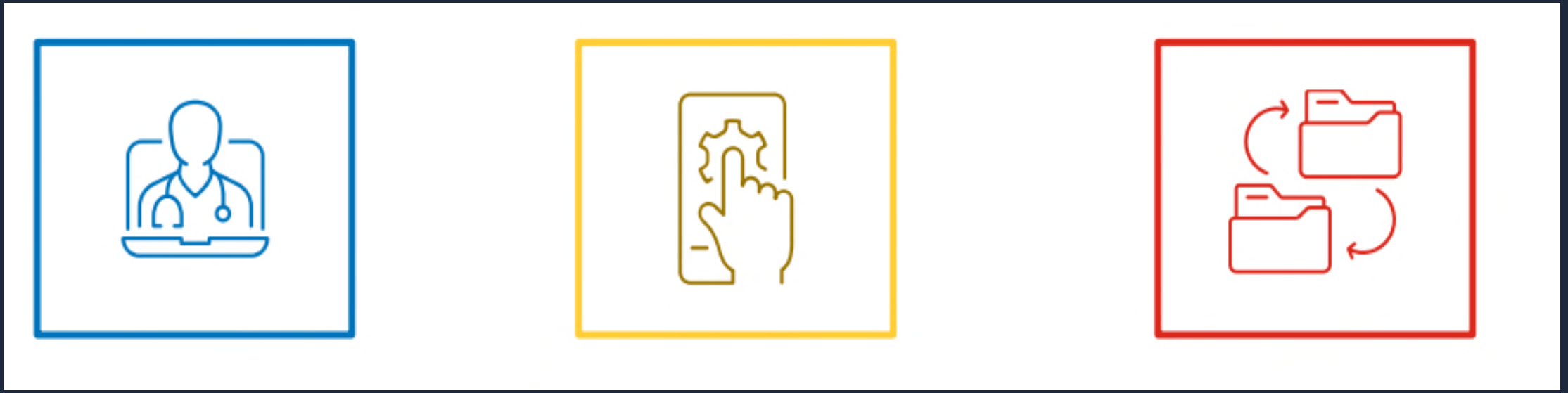
- Except if:
  - Practice is required by law
  - Falls under HHS rulemaking exception
- Practice is likely to …
- Interfere with, prevent, or materially discourage …



Cures Act – Information Blocking Definition (Cont'd)

- Access, exchange, or use …
- Electronic Health Information
- Knowledge
  - Knows or Should Know (health information technology developer, exchange, or network); or
  - Knows practice is unreasonable (health care provider)

Information Blocking - Actors



Health Care Providers

Health IT Developers of Certified Health IT

Health Information Networks/Health Information Exchanges

Eight Exceptions

HHS Office of the National Coordinator of Health IT, https://www.healthit.gov/topic/information-blocking

Can I Block EHI from Going to the Patient Portal?

Old Guidance:

“There is no requirement under the information blocking regulations to proactively make available any EHI to patients or others who have not requested the EHI. We note, however, that a delay in the release or availability of EHI in response to a request for legally permissible access, exchange, or use of EHI may be an interference under the information blocking regulations (85 FR 25813, 25878).”

https://www.healthit.gov/curesrule/resources/information-blocking-faqs

Can I Block EHI from Going to the Patient Portal?

New Guidance:

"'Proactively' or 'proactive' is not a regulatory concept included within the information blocking regulations. Rather, the information blocking regulations focus on whether a practice (an act or omission) constitutes information blocking. Further, an important consideration is whether the practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of EHI. In this regard, we direct readers to the following FAQ, which explains when a delay in making EHI available through a "patient portal" or an API for patients could constitute an interference and thus implicate the information blocking regulations:

Q: When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the information blocking regulation? (IB.FAQ22.1.2021MAR)"

https://www.healthit.gov/curesrule/resources/information-blocking-faqs

Can I Block EHI from Going to the Patient Portal?

“To further illustrate, it also would likely be considered an interference:

- where a delay in providing access, exchange, or use occurs after a patient logs in to a patient portal to access EHI that a health care provider has (including, for example, lab results) and such EHI is not available—for any period of time—through the portal.”

https://www.healthit.gov/curesrule/resources/information-blocking-faqs

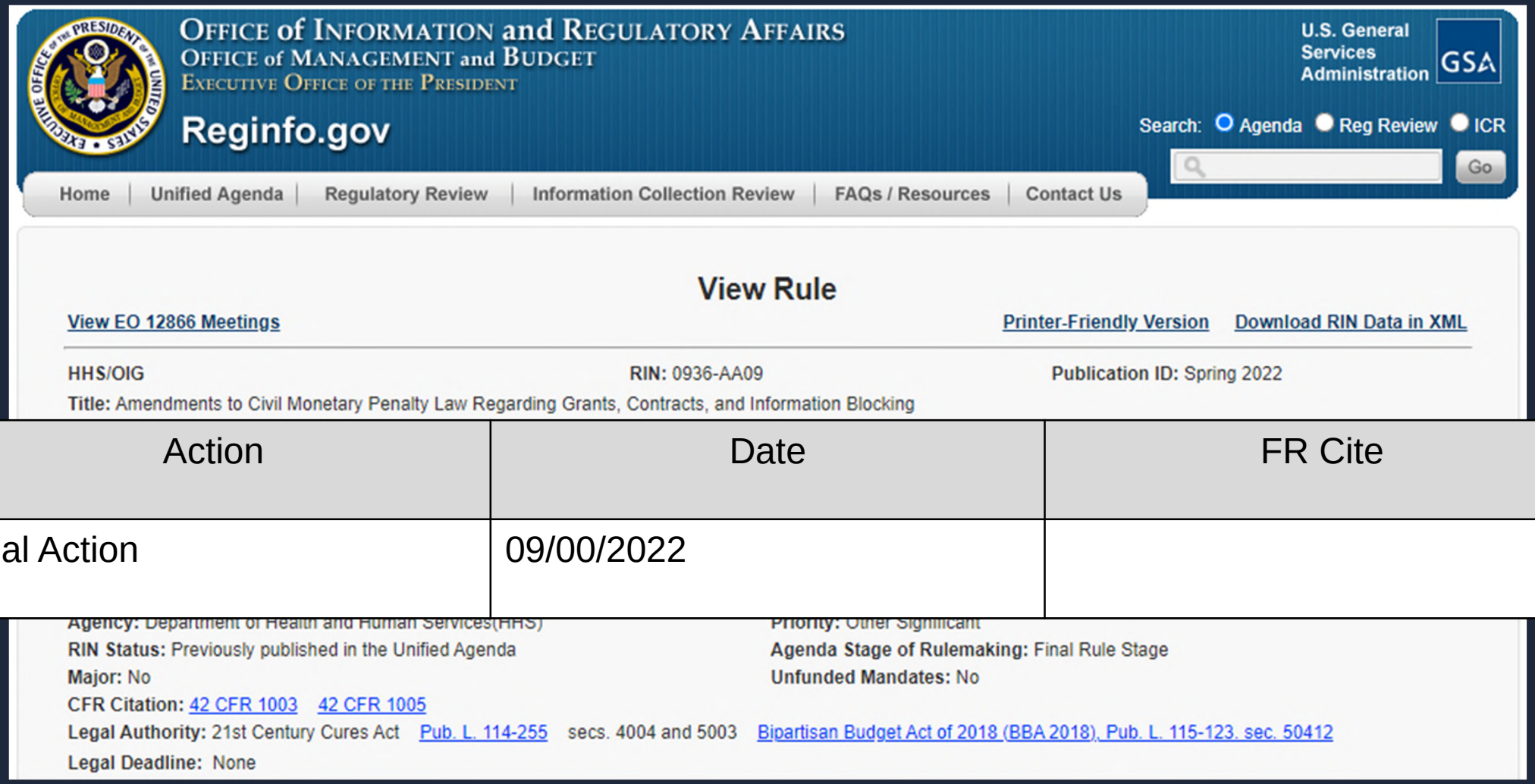
Can I Block EHI from Going to the Patient Portal If I Believe Doing So Is Reasonable?

- Statute:
  - “In this section, the term ‘information blocking’ means a practice that … if conducted by a health care provider, such provider knows that such practice is unreasonable ….”
- Regulation:
  - “Information blocking means a practice that … If conducted by a health care provider, such provider knows that such practice is unreasonable …”
- Risk – HHS may take the position that anything that does not fall within a regulatory exception is inherently unreasonable.

Status of Enforcement

- Applicability date was April 5, 2021
- OIG enforcement with respect to health IT developers and HIEs/HINs:
  - $1 million per violation
  - Proposed enforcement rule on 4/24/20
  - Final rule expected shortly
  - Enforcement will begin for conduct occurring 60 days after final rule

Current Status of Final OIG Rule



Action	Date	FR Cite
Final Action	09/00/2022	

Status of Enforcement

- Enforcement with respect to health care providers:
  - No proposed enforcement rule yet
  - No information on what “appropriate disincentives will be”
  - No information on which agency will enforce the rule
  - No information on whether conduct prior to final enforcement rule is subject to enforcement

30-Minute Break

FTC Developments with Respect to Health and Wellness Apps

FTC & Health Apps

- Section 5 of the FTC Act prohibits unfair and deceptive trade practices
- FTC Health Breach Notification Rule governing personal health records

FTC & Health Apps

- FTC Health Breach Notification Rule Request for Public Comment (5/22/20)
- Three members of Congress urge FTC to take action against menstruation-tracking mobile apps that violate the Health Breach Notification Rule (3/4/21).
- FTC enters into consent order with Flo Health over disclosures from menstruation app to Facebook, Flurry, Fabric, and Google (6/22/21).
- FTC issues Policy Statement “clarifying” the Health Breach Notification Rule’s application to health and fitness apps (9/15/21).

FTC & Health Apps

- PHR Identifiable Health Information:
  - Individually Identifiable Health Information
    - Definition limited to information created or received by a health care provider, health plan, employer, or health care clearinghouse
  - That is provided by or on behalf of the individual
  - That identifies the individual

FTC & Health Apps

- Personal Health Record:
  - Electronic record
  - PHR identifiable health information
  - Can be drawn from multiple sources
  - Managed, shared, and controlled by or primarily for the individual

FTC & Health Apps

“Under the definitions cross-referenced by the Rule, the developer of a health app or connected device is a ‘health care provider’ because it ‘furnish[es] health care services or supplies.’”

FTC Statement on Breaches by Health Apps and Other Connected Devices

FTC & Health Apps

“The statute directing the FTC to promulgate the Rule requires that a “personal health record” be an electronic record that can be drawn from multiple sources. The Commission considers apps covered by the Rule if they are capable of drawing information from multiple sources, such as through a combination of consumer inputs and application programming interfaces (‘APIs’).”

FTC Statement on Breaches by Health Apps and Other Connected Devices

FTC & Health Apps

“For example, an app is covered if it collects information directly from consumers and has the technical capacity to draw information through an API that enables syncing with a consumer’s fitness tracker.”

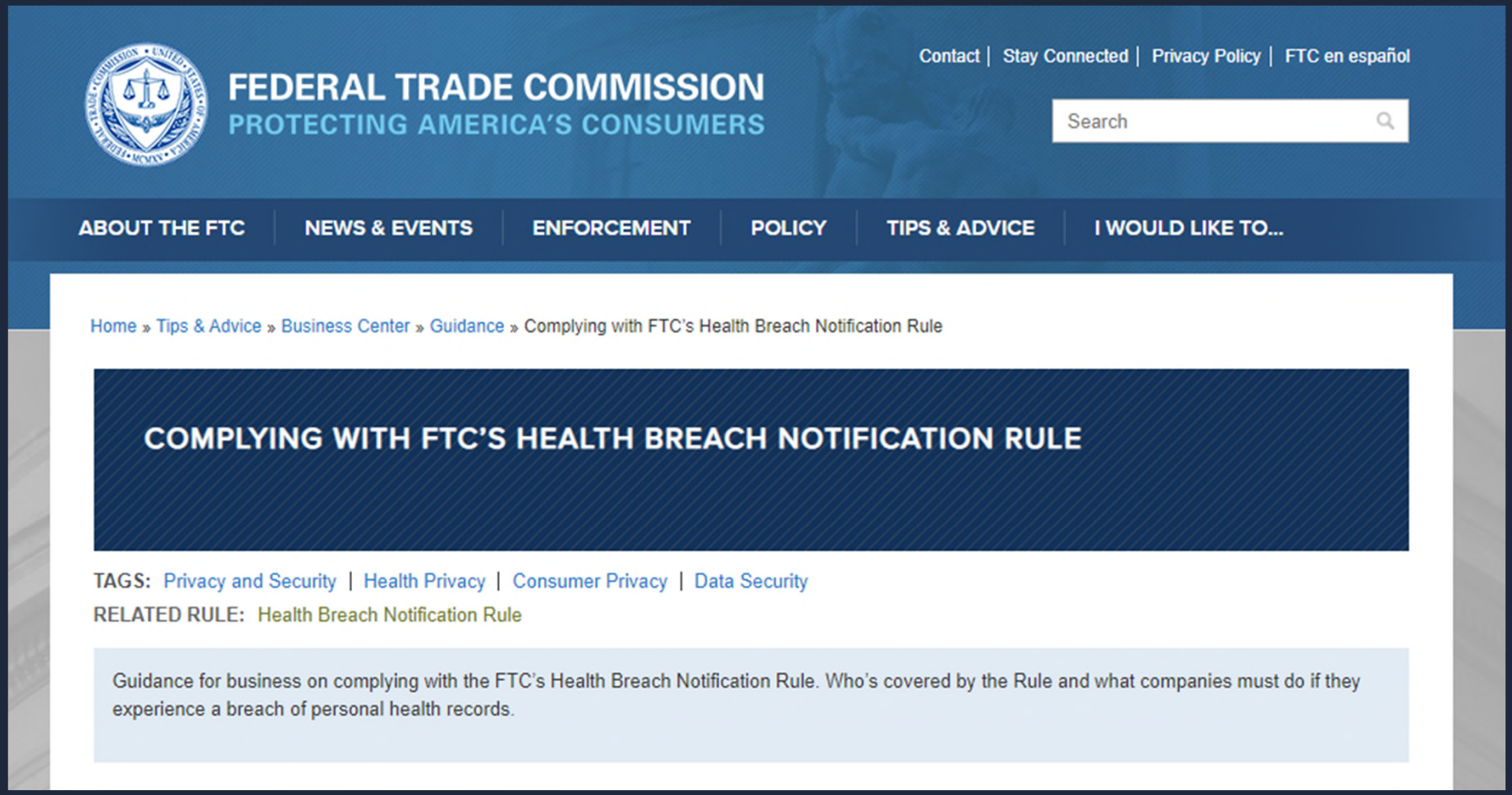
FTC Statement on Breaches by Health Apps and Other Connected Devices

FTC & Health Apps

“For example, if a blood sugar monitoring app draws health information only from one source (e.g., a consumer’s inputted blood sugar levels), but also takes non-health information from another source (e.g., dates from your phone’s calendar), it is covered under the Rule.”

FTC Statement on Breaches by Health Apps and Other Connected Devices

FTC Health Breach Notification Rule Resources (Jan. 2022)



State Privacy Laws

California Consumer Privacy Act

- Excludes:
  - Medical information governed by California Confidentiality of Medical Information Act
  - PHI governed by HIPAA
  - Provider of health care or covered entity to the extent that patient information is maintained in the same manner as CMIA/HIPAA information
  - Clinical trial information subject to Common Rule
  - HIPAA de-identified information
  - Most non-profits

California Consumer Privacy Act

- Privacy notice must identify sale or disclosure of HIPAA de-identified information (including which method of de-identification) (“businesses” only) (ends 1/23)
- Sale or licensing of HIPAA de-identified information must include contractual provisions (any “person,” including non-profits):
  - A statement that the deidentified information being sold or licensed includes deidentified patient information.
  - A statement that reidentification, and attempted reidentification, of the deidentified information by the purchaser or licensee of the information is prohibited pursuant to this section.
  - A requirement that, unless otherwise required by law, the purchaser or licensee of the deidentified information may not further disclose the deidentified information to any third party unless the third party is contractually bound by the same or stricter restrictions and conditions.

Virginia Consumer Data Protection Act

- Excludes:
  - PHI under HIPAA
  - Health records of health entities subject to Va. health records privacy statute
  - Substance use disorder information subject to 42 C.F.R. part 2
  - Identifiable private information subject to the Common Rule for research
  - HIPAA de-identified information
  - Non-profits
- Becomes effective January 1, 2023

Colorado Privacy Act

- Excludes:
  - PHI collected, stored, and processed by a covered entity or business associate
  - Health care information subject to Colorado patient record privacy law "solely for the purpose of access to medical records"
  - Substance use disorder information subject to 42 C.F.R. part 2
  - Identifiable private information subject to the Common Rule for research
  - HIPAA de-identified information
- Becomes effective July 1, 2023

California Genetic Information Privacy Act

- Signed into law on October 6, 2021, became effective January 1, 2022
- Governs direct-to-consumer genetic testing companies
- Requires:
  - Summary of privacy practices
  - Privacy notice
  - Notice about sharing de-identified genetic information for research
  - Consumer consent for collection, use, and disclosure of the consumer's genetic data
  - "Separate and express" consents for certain uses and disclosures
  - Reasonable security measures
  - Access and deletion rights
  - Special limits on disclosures to insurers and employers

Utah Consumer Privacy Act

- Excludes
  - HIPAA PHI (not limited to HIPAA covered entities or business associates)
  - HIPAA covered entities and business associates (not limited to PHI)
  - Substance use disorder information subject to 42 C.F.R. part 2
  - Identifiable private information subject to the Common Rule for research
  - HIPAA de-identified information
  - Non-profits
- Becomes effective December 31, 2023

Connecticut Data Privacy Act

- Excludes:
  - HIPAA PHI (not limited to HIPAA covered entities or business associates)
  - Substance use disorder information subject to 42 C.F.R. part 2
  - Identifiable private information subject to the Common Rule for research
  - HIPAA de-identified information
  - Non-profits
- Becomes effective July 1, 2023

State Law Issues

- Is website visitor information subject to HIPAA, state law, or both?
- Does the state’s breach notification law apply to health information? Is there special treatment of HIPAA entities?
- Don’t forget about employee privacy issues under new state laws.

Health Information Enforcement Actions

OCR Aggregate Enforcement Data (Sept. 2022)

- Voluntary corrective action - 29,779 cases
- Technical assistance – 52,133 cases
- No violation – 14,117 cases
- Not eligible (e.g., no covered entity) – 204,398 complaints
- Financial enforcement – 126 cases
  - Highest action - $16 million (Anthem)
  - Average settlement/penalty - $1,059,676

41st OCR Right of Access Case (Sept. 2022)

FOR IMMEDIATE RELEASE
September 20, 2022

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

OCR Settles Three Cases with Dental Practices for Patient Right of Access under HIPAA

Enforcement Actions Ensure Patients Receive Timely Access to their Records, at a Reasonable Cost

Today, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) announced the resolution of three investigations concerning potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's patient right of access provision. These cases are part of a collective effort, bringing the total 41 cases, to drive compliance on right of access under the law.

HHS Announces New OCR Director (Sept. 2021)

FOR IMMEDIATE RELEASE
September 27, 2021

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

U.S. Department of Health and Human Services Announces Lisa J. Pino as Director for Office for Civil Rights

The U.S. Department of Health & Human Services today announced the appointment of Lisa J. Pino as Director of the Office for Civil Rights (OCR). OCR enforces federal civil rights, conscience and religious freedom laws; the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules; and the Patient Safety and Quality Improvement Act and Patient Safety Rule - which together protect individuals' fundamental civil rights and medical privacy.

HHS Announces New OCR Director (Sept. 2022)

FOR IMMEDIATE RELEASE
September 14, 2022

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

HHS Announces Melanie Fontes Rainer as Director of the Office for Civil Rights

On Wednesday, September 14, 2022, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra formally swore in Melanie Fontes Rainer as Director of the Office for Civil Rights (OCR). Director Fontes Rainer previously served as the Acting Director and was officially appointed to the role last month. OCR is responsible for enforcing federal civil rights; conscience protections; the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules; and the Patient Safety and Quality Improvement Act and Patient Safety Rule – which together protect individuals' fundamental civil rights and medical privacy.

$21M, 41-State Attorneys General Settlement (Mar. 2021)

AG Racine Announces Settlement with American Medical Collection Agency Over 2019 Data Breach Affecting 12,530 District Residents

March 11, 2021

Company Will Safeguard Personal Consumer Information as Part of Agreement with 41 Attorneys General

WASHINGTON, D.C. – Attorney General Karl A. Racine today announced a settlement with American Medical Collection Agency ("AMCA") resolving a multistate investigation into a 2019 data breach that exposed the personal information of up to 21 million individuals, including 12,530 District residents. A coalition of 41 attorneys general negotiated the settlement, under which AMCA and its principals have agreed to implement and maintain a series of data security practices designed to strengthen its information security program and safeguard the personal information of consumers. If AMCA violates certain terms of the agreement, it will be required to pay $21 million to the states.

AG Racine Announces Settlement with American Medical Collection Agency Over 2019 Data Breach Affecting 12,530 District Residents (dc.gov)

Three New Jersey AG Settlements (Oct. to Dec. 2021)

Press Release

For Immediate Release:
December 15, 2021

For Further Information Contact:
Gema de las Heras, DCApress@dca.njoag.gov

Office of The Attorney General
Andrew J. Bruck, *Acting Attorney General*

Division of Consumer Affairs
Sean P. Neafsey, *Acting Director*

Division of Law
Michelle Miller, *Director*

New Jersey Health Care Providers Will Adopt New Security Measures and Pay $425,000 to Settle Investigation into Two Data Breaches

More Than 105,200 Consumers Affected, Including 80,333 New Jersey Residents

Consent Order

NEWARK – Acting Attorney General Andrew J. Bruck today announced that the Division of Consumer Affairs has reached a settlement with three New Jersey-based providers of cancer care that the State alleges failed to adequately safeguard patient data, exposing the personal and protected health information of 105,200 consumers, including 80,333 New Jersey residents.

Under the terms of the settlement, Regional Cancer Care Associates LLC, RCCA MSO LLC, and RCCA MD LLC (collectively, "RCCA")—all headquartered in Hackensack, but with 30 locations throughout New Jersey, Connecticut and Maryland—have agreed to pay $425,000 and adopt additional privacy and security measures to safeguard individuals' protected health information and personal information to resolve the State's investigation into alleged violations of the New Jersey Consumer Fraud Act and the federal Health Insurance Portability and Accountability Act ("HIPAA").

Iowa Criminal HIPAA Case (June 2021)

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Monday, June 21, 2021

Former Cedar Rapids Hospital Employee Sentenced for Accessing Ex-Boyfriend's Medical Records

Gave Picture of Medical Record to Friend, Who Uploaded it to Facebook

A former Cedar Rapids hospital employee, who wrongfully accessed and distributed her ex-boyfriend's medical records, was sentenced on June 14, 2021. Jennifer Lynne Bacor, age 41, from Las Vegas, Nevada, received probation after pleading guilty to one count of wrongfully obtaining individually identifiable health information under false pretenses.

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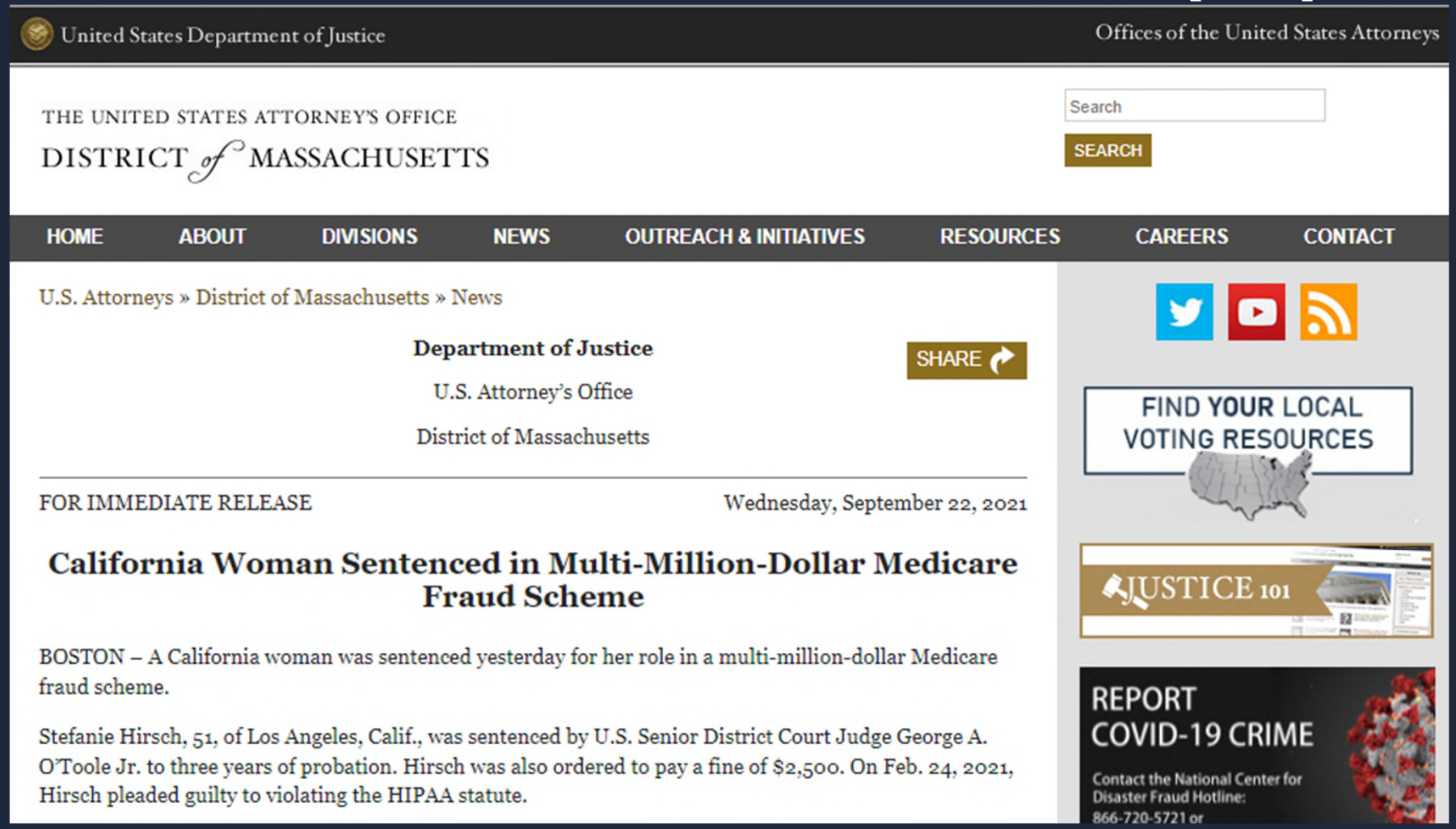
JUSTICE 101

REPORT COVID-19 CRIME

Contact the National Center for Disaster Fraud Hotline: 866-720-5721 or

Massachusetts Criminal HIPAA Case (Sept. 2021)



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Wednesday, September 22, 2021

California Woman Sentenced in Multi-Million-Dollar Medicare Fraud Scheme

BOSTON – A California woman was sentenced yesterday for her role in a multi-million-dollar Medicare fraud scheme.

Stefanie Hirsch, 51, of Los Angeles, Calif., was sentenced by U.S. Senior District Court Judge George A. O'Toole Jr. to three years of probation. Hirsch was also ordered to pay a fine of $2,500. On Feb. 24, 2021, Hirsch pleaded guilty to violating the HIPAA statute.

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JUSTICE 101

REPORT COVID-19 CRIME

Contact the National Center for Disaster Fraud Hotline: 866-720-5721 or

Florida HIPAA Criminal Case (Dec. 2021)

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FOR IMMEDIATE RELEASE

Friday, December 3, 2021

Tampa Bay Area Medical Biller Pleads Guilty To Healthcare Fraud, Aggravated Identity Theft, And Tax Offenses

Tampa, Florida – Joshua Maywalt (40, Tampa) has pleaded guilty to four counts of healthcare fraud, four counts of aggravated identity theft, one count of filing a false federal income tax return, and two counts of failing to file federal income tax returns. He faces a maximum penalty of 10 years in federal prison for each healthcare fraud count, a 2-year mandatory consecutive sentence on the aggravated identity theft counts, a maximum penalty of 3 years for filing a false income tax return, and a up to 2 years for each failure to file an income tax return offense. Through the superseding information, the United States also notified Maywalt that it intends to forfeit $2.2 million in funds and real property located at 5346 Northdale Boulevard, in Tampa, all of which are traceable to proceeds of his offenses.

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Update on Investigations Regarding Violence at the Capitol

New Jersey HIPAA Criminal Case (Oct. 2022)

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FOR IMMEDIATE RELEASE

Friday, October 7, 2022

Doctor Admits Criminal HIPAA Scheme for Wrongful Disclosure of Protected Patient Health Information to Pharmaceutical Sales Representative

CAMDEN, N.J. – A former physician with medical practices in New Jersey, New York, and Florida admitted wrongfully disclosing patients' protected personal health information, Attorney for the United States Vikas Khanna announced today.

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Contact the National Center for Disaster Fraud Hotline: 866-720-5721 or Justice.gov/DisasterComplaintForm

REPORT

Impactful Court Decisions

Healthcare Provider Website Settlement (Jan. 2022)

Mass General Brigham Settles 'Cookies Without Consent' Lawsuit for $18.4 Million

Home | Legal News | Mass General Brigham Settles 'Cookies Without Consent' Lawsuit for $18.4 Million

Posted By HIPAA Journal on Jan 20, 2022

https://www.hipaajournal.com/mass-general-brigham-settles-cookies-without-consent-lawsuit-for-18-4-million/

MD Anderson

[O]ne of the most remarkable aspects of the ALJ's order is its insistence that the Government can arbitrarily and capriciously enforce the CMP rules against some covered entities and not others. The ALJ insisted that "I do not evaluate penalties based on a comparative standard.

***U. of Tex. M.D. Anderson Cancer Ctr. v. U.S. Dep't of Health and Human Srvcs.*, No. 19-60226 (5th Cir. Jan. 14, 2021)**

MD Anderson

[A]n administrative agency cannot hide behind the fact-intensive nature of penalty adjudications to ignore irrational distinctions between like cases.

***U. of Tex. M.D. Anderson Cancer Ctr. v. U.S. Dep't of Health and Human Srvcs.*, No. 19-60226 (5th Cir. Jan. 14, 2021)**

MD Anderson

Other findings:

- MD Anderson satisfied Security Rule because it implemented a mechanism to encrypt PHI. “M.D. Anderson undisputedly had ‘a mechanism,’ even if it could’ve or should’ve had a better one. So M.D. Anderson satisfied HHS’s regulatory requirement, even if the Government now wishes it had written a different one.”
- Sided with M.D. Anderson (and the Trump administration) on the lower annual penalty caps.
- “Disclosure” requires an affirmative action, not a passive loss of information.

Dinerstein v. Google

- A violation of HIPAA can support a breach of contract claim
  - The notice of privacy practices created contractual obligations beyond the regulation because it did not include certain exceptions.
- “A nonexclusive, perpetual license to use the [] Trained Models and Predictions” created by Google “for internal non-commercial research purposes” was potentially a form of remuneration for disclosure of PHI (i.e., a “sale of protected health information”

Dinerstein v. Google, No. 19-04311 (E.D. Ill. 2020)

Ciox Health v. Azar

- HITECH Act created right of “third-party directive” limited to e-copy of EHR information.
  - HHS could not rely on more general HIPAA authority to expand to paper and non-EHR information. Regulation is invalid to the extent it does so.
- HHS failed to go through notice-and-comment rulemaking to apply the “HIPAA rate” to third-party directives.

Ciox Health v. Azar, 435 F. Supp.3d 30 (D.D.C. 2020)

For more information …

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