

Health Privacy + Security Law Workshop: New Developments

2021 Privacy+Security Forum Fall Academy

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Agenda

- Status of HIPAA Rulemaking
- Update on Information Blocking
- FTC Developments with Respect to Health and Wellness Apps
- State Privacy Laws
- Health Information Enforcement Actions and Litigation
- Status of Changes to 42 C.F.R. Part 2



Status of HIPAA Rulemaking

Right of Access

- 30 days + 30 days becomes “as soon as practicable” + 15 days + 15 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

- End requirement to obtain acknowledgment of receipt
- Substantially increase required language
- Add right to discuss the notice with designated contact person

Other Proposals

- Clarify definition of “health care operations”
- Add 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
- Revise “professional judgment” to “good faith belief”
- “Serious and imminent threat” → “serious and reasonably foreseeable threat”

OCR Issues Proposed Rule (Jan. 21, 2021)



6446

Federal Register / Vol. 86, No. 12 / Thursday, January 21, 2021 / Proposed Rules

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)

2/17/22, 1:11 PM

Extension of the Public Comment Period for Proposed Modifications to the HIPAA Privacy Rule | HHS.gov

HHS.gov

U.S. Department of Health & Human Services

[Home](#) > [About](#) > [News](#) > Extension of the Public Comment Period for Proposed Modifications to the HIPAA Privacy Rule

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

An official website of the United States government



OFFICE of INFORMATION and REGULATORY AFFAIRS
OFFICE of MANAGEMENT and BUDGET
 EXECUTIVE OFFICE OF THE PRESIDENT

Reginfo.gov

U.S. General Services Administration 

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NPRM Comment Period Extended End

05/06/2021

Final Action

10/00/2022

Title: HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement

Abstract:

This rule will modify provisions of the HIPAA Privacy Rule to strengthen individuals' rights to access their own protected health information, including electronic information; improve information sharing for care coordination and case management for individuals; facilitate greater family and caregiver involvement in the care of individuals experiencing emergencies or health crises; enhance flexibilities for disclosures in emergency or threatening circumstances; and reduce administrative burdens on HIPAA covered health care providers and health plans, while continuing to protect individuals' health information privacy interests.

Agency: Department of Health and Human Services(HHS)

Priority: Economically Significant

RIN Status: Previously published in the Unified Agenda

Agenda Stage of Rulemaking: Final Rule Stage

Major: Yes

Unfunded Mandates: Private Sector

CFR Citation: [45 CFR 160](#) [45 CFR 164](#)

Legal Authority: [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\), sec. 264 \(42 U.S.C. 1320d-2 note\)](#) [Health Information Technology for Economic and Clinical Health \(HITECH\) Act, sec. 13405 \(42 U.S.C. 201 note\)](#)

Legal Deadline: None

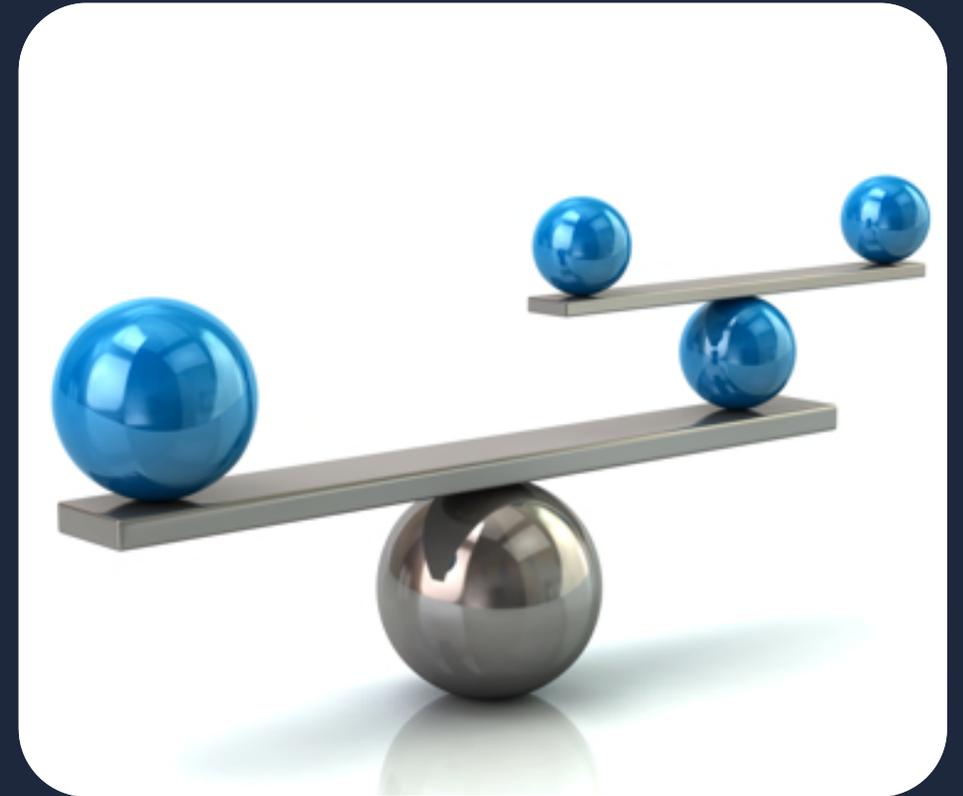
Timetable:



21st Century Cures Act Information Blocking Rule

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)

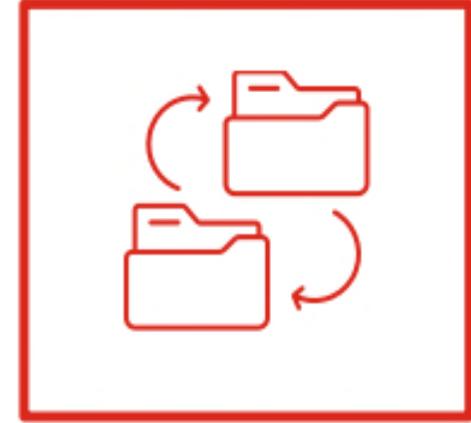
Information Blocking - Actors



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 w/r/t 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

Status of Enforcement

- Enforcement w/r/t 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



FTC Policy & Enforcement

FTC & Health Apps

- Section 5 of the FTC Act prohibiting 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)

The screenshot shows the FTC website's navigation and content for the Health Breach Notification Rule. At the top left is the FTC logo and the text "FEDERAL TRADE COMMISSION PROTECTING AMERICA'S CONSUMERS". To the right are links for "Contact", "Stay Connected", "Privacy Policy", and "FTC en español", along with a search bar. A horizontal menu below contains "ABOUT THE FTC", "NEWS & EVENTS", "ENFORCEMENT", "POLICY", "TIPS & ADVICE", and "I WOULD LIKE TO...". The main content area features a breadcrumb trail: "Home » Tips & Advice » Business Center » Guidance » Complying with FTC's Health Breach Notification Rule". Below this is a dark blue banner with the title "COMPLYING WITH FTC'S HEALTH BREACH NOTIFICATION RULE". Underneath the banner are "TAGS: Privacy and Security | Health Privacy | Consumer Privacy | Data Security" and "RELATED RULE: Health Breach Notification Rule". A light blue box at the bottom contains the introductory text: "Guidance for business on complying with the FTC's Health Breach Notification Rule. Who's covered by the Rule and what companies must do if they experience a breach of personal health records."

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COMPLYING WITH FTC'S HEALTH BREACH NOTIFICATION RULE

TAGS: [Privacy and Security](#) | [Health Privacy](#) | [Consumer Privacy](#) | [Data Security](#)

RELATED RULE: [Health Breach Notification Rule](#)

Guidance for business on complying with the FTC's Health Breach Notification Rule. Who's covered by the Rule and what companies must do if they experience a breach of personal health records.



30-Minute Break



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

California Consumer Privacy Act

- Privacy notice must identify sale or disclosure of HIPAA de-identified information (including which method of de-identification) (“businesses” only)
- Sale or licensing of HIPAA de-identified information must include contractual provisions (any “person”):
 - 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

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

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

- Awaiting governor's signature
- Excludes HIPAA PHI (not limited to HIPAA covered entities or business associates)
- Excludes HIPAA covered entities and business associates (not limited to PHI)

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 and Litigation

\$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 \(dc.gov\)](#)

Iowa Criminal HIPAA Case (June 2021)

The screenshot shows the website for the Northern District of Iowa U.S. Attorney's Office. At the top left is the United States Department of Justice logo and name. At the top right is the text "Offices of the United States Attorneys". Below this is the office name "THE UNITED STATES ATTORNEY'S OFFICE NORTHERN DISTRICT of IOWA" and a search bar with a "SEARCH" button. A navigation menu includes links for HOME, ABOUT, NEWS, MEET THE U.S. ATTORNEY, DIVISIONS, PROGRAMS, JOBS, and CONTACT. The main content area shows a breadcrumb trail "U.S. Attorneys » Northern District of Iowa » News" and a "Department of Justice" header with a "SHARE" button. The article title is "Former Cedar Rapids Hospital Employee Sentenced for Accessing Ex-Boyfriend's Medical Records" with a sub-headline "Gave Picture of Medical Record to Friend, Who Uploaded it to Facebook". The text describes the sentencing of Jennifer Lynne Bacor on June 14, 2021. On the right side, there are three promotional banners: a Twitter icon, a "FIND YOUR LOCAL VOTING RESOURCES" banner with a map of Iowa, and a "JUSTICE 101" banner. At the bottom right is a "REPORT COVID-19 CRIME" banner with contact information for the National Center for Disaster Fraud Hotline.

United States Department of Justice

Offices of the United States Attorneys

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Northern District of Iowa

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FOR IMMEDIATE RELEASE 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.

FIND YOUR LOCAL VOTING RESOURCES

JUSTICE 101

REPORT COVID-19 CRIME
Contact the National Center for Disaster Fraud Hotline:
866-720-5721 or

Massachusetts Criminal HIPAA Case (Sept. 2021)

United States Department of Justice Offices of the United States Attorneys

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FOR IMMEDIATE RELEASE 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.

FIND YOUR LOCAL VOTING RESOURCES

JUSTICE 101

REPORT COVID-19 CRIME
Contact the National Center for Disaster Fraud Hotline:
866-720-5721 or

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.

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

Acting AG Bruck Announces Settlement with Fertility Clinic over Cybersecurity Lapses and Data Breach

Millburn-based Clinic Will Pay \$495,000 and Implement Additional Data Security Measures

For Immediate Release: October 12, 2021

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*

For Further Information:

Media Inquiries-

Gema de las Heras

DCApress@dca.njoag.gov

Consent Order

NEWARK – Acting Attorney General Andrew J. Bruck and the Division of Consumer Affairs today announced that a healthcare provider focused on the diagnosis and treatment of infertility will pay \$495,000 and implement new data security measures following a data breach that compromised the personal information of 14,663 patients, including 11,071 New Jersey residents.

25th OCR Right of Access Case (Nov. 2021)

FOR IMMEDIATE RELEASE

November 30, 2021

Contact: HHS Press Office

202-690-6343

media@hhs.gov

Five enforcement actions hold healthcare providers accountable for HIPAA Right of Access

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announced the resolution of five investigations in its Health Insurance Portability and Accountability Act (HIPAA) Right of Access Initiative, bringing the total number of these enforcement actions to twenty-five 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.

Florida HIPAA Criminal Prosecution

United States Department of Justice Offices of the United States Attorneys

THE UNITED STATES ATTORNEY'S OFFICE
MIDDLE DISTRICT *of* FLORIDA

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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.

FIND YOUR LOCAL VOTING RESOURCES

Update on Investigations
Regarding Violence at the
Capitol

Healthcare Provider Website Settlement (Jan. 2022)

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

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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/>



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.



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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

For more information ...



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