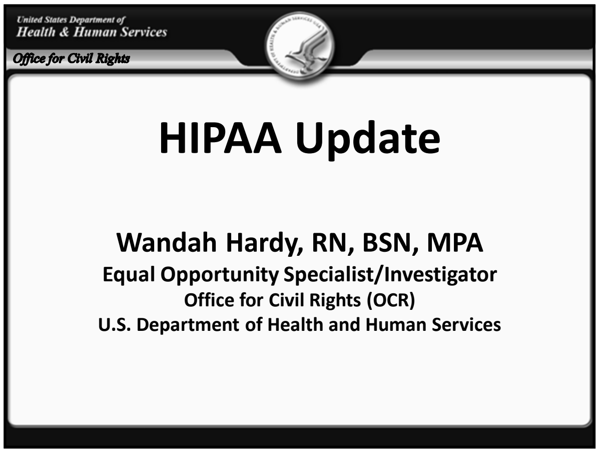
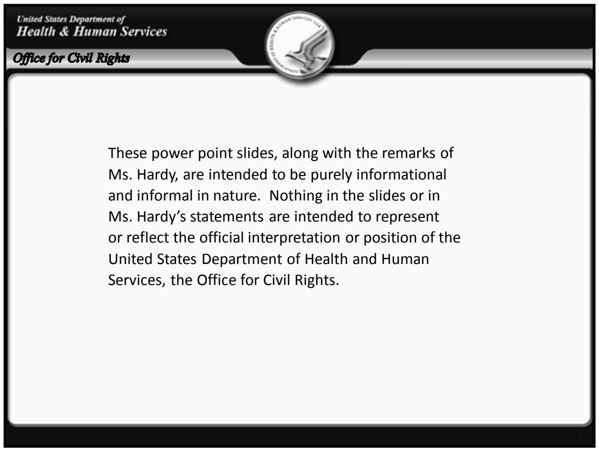


United States Department of
Health & Human Services

Office for Civil Rights

HIPAA Update

Wandah Hardy, RN, BSN, MPA
Equal Opportunity Specialist/Investigator
Office for Civil Rights (OCR)
U.S. Department of Health and Human Services

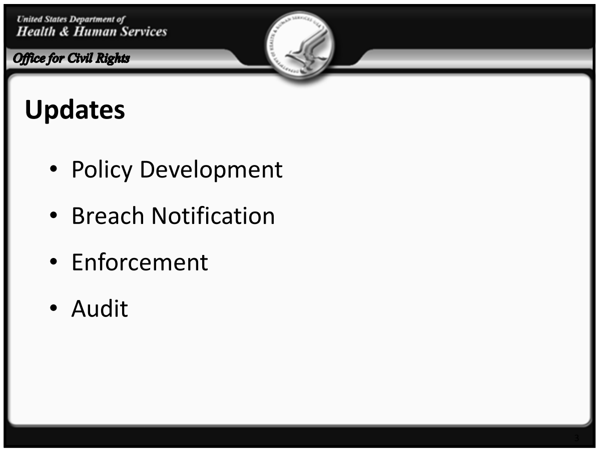


United States Department of
Health & Human Services

Office for Civil Rights

These power point slides, along with the remarks of Ms. Hardy, are intended to be purely informational and informal in nature. Nothing in the slides or in Ms. Hardy's statements are intended to represent or reflect the official interpretation or position of the United States Department of Health and Human Services, the Office for Civil Rights.

2



United States Department of
Health & Human Services

Office for Civil Rights

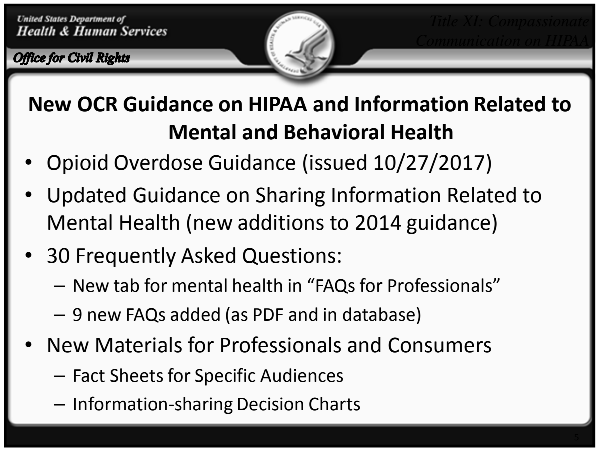
Updates

- Policy Development
- Breach Notification
- Enforcement
- Audit

3

United States Department of
Health & Human Services
Office for Civil Rights

POLICY DEVELOPMENT



United States Department of
Health & Human Services
Office for Civil Rights

Title XI: Compassionate Communication on HIPAA

New OCR Guidance on HIPAA and Information Related to Mental and Behavioral Health

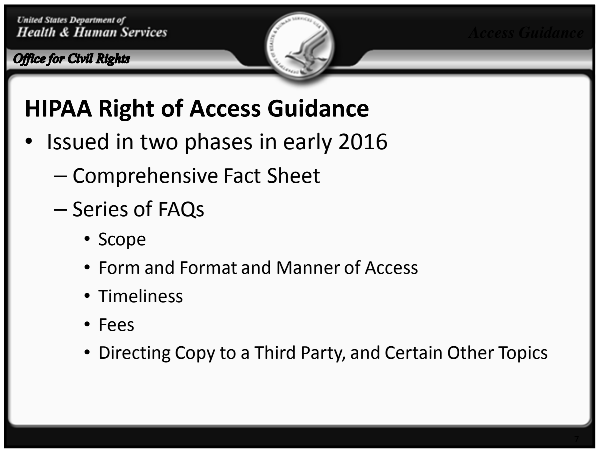
- Opioid Overdose Guidance (issued 10/27/2017)
- Updated Guidance on Sharing Information Related to Mental Health (new additions to 2014 guidance)
- 30 Frequently Asked Questions:
  - New tab for mental health in "FAQs for Professionals"
  - 9 new FAQs added (as PDF and in database)
- New Materials for Professionals and Consumers
  - Fact Sheets for Specific Audiences
  - Information-sharing Decision Charts

United States Department of
Health & Human Services
Office for Civil Rights

Where to Find OCR's New Materials

OCR Website Navigation

- For professionals: https://www.hhs.gov/hipaa/for-professionals/index.html > Special Topics > Mental Health & Substance Use Disorders
- For consumers: https://www.hhs.gov/hipaa/for-individuals/index.html > Mental Health & Substance Use Disorders
- Mental Health FAQ Database: https://www.hhs.gov/hipaa/for-professionals/faq/mental-health



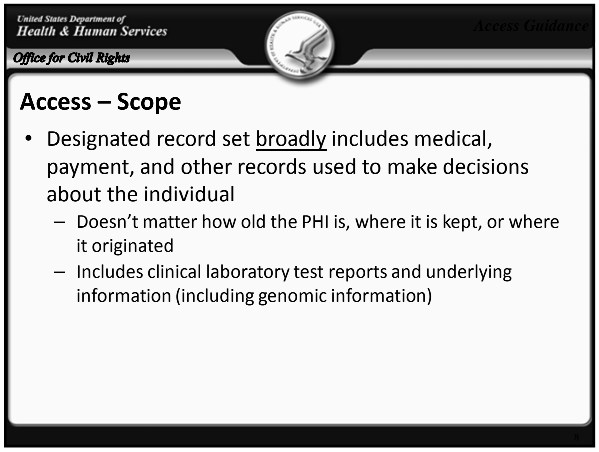
United States Department of
Health & Human Services
Office for Civil Rights

Access Guidance

HIPAA Right of Access Guidance

- Issued in two phases in early 2016
  - Comprehensive Fact Sheet
  - Series of FAQs
    - Scope
    - Form and Format and Manner of Access
    - Timeliness
    - Fees
    - Directing Copy to a Third Party, and Certain Other Topics

7



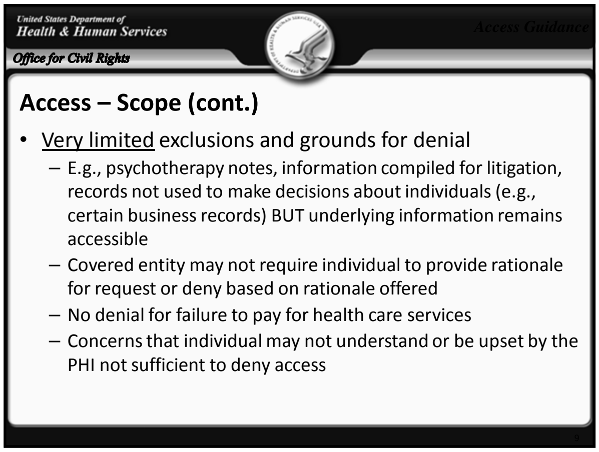
United States Department of
Health & Human Services
Office for Civil Rights

Access Guidance

Access – Scope

- Designated record set broadly includes medical, payment, and other records used to make decisions about the individual
  - Doesn’t matter how old the PHI is, where it is kept, or where it originated
  - Includes clinical laboratory test reports and underlying information (including genomic information)

8



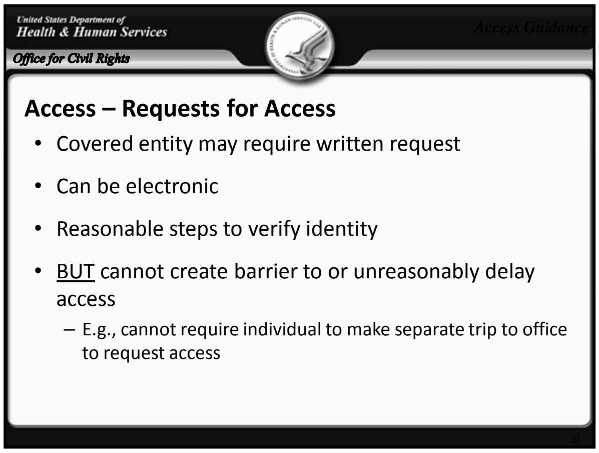
United States Department of
Health & Human Services
Office for Civil Rights

Access Guidance

Access – Scope (cont.)

- Very limited exclusions and grounds for denial
  - E.g., psychotherapy notes, information compiled for litigation, records not used to make decisions about individuals (e.g., certain business records) BUT underlying information remains accessible
  - Covered entity may not require individual to provide rationale for request or deny based on rationale offered
  - No denial for failure to pay for health care services
  - Concerns that individual may not understand or be upset by the PHI not sufficient to deny access

9

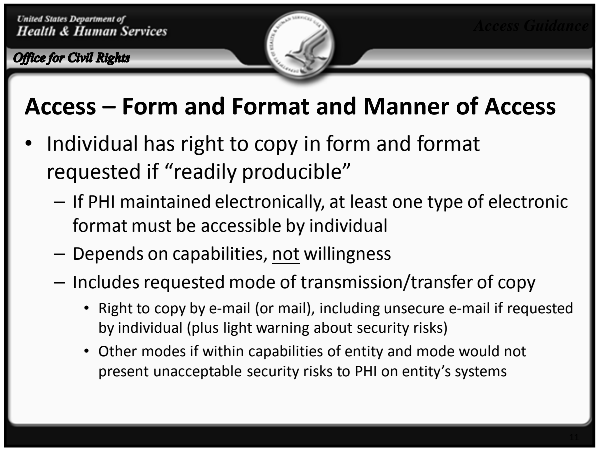


United States Department of
Health & Human Services
Office for Civil Rights

Access Guidance

Access – Requests for Access

- Covered entity may require written request
- Can be electronic
- Reasonable steps to verify identity
- BUT cannot create barrier to or unreasonably delay access
  - E.g., cannot require individual to make separate trip to office to request access

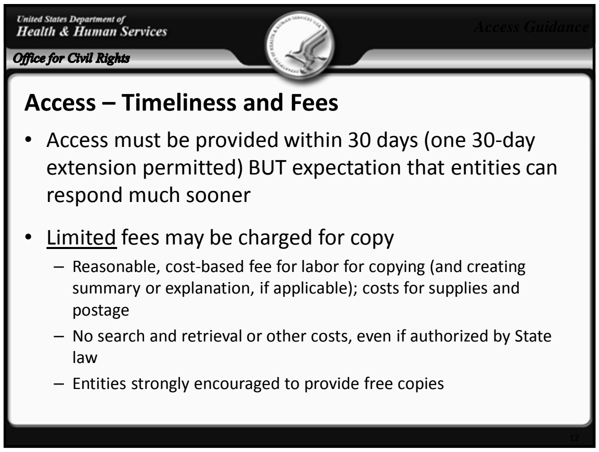


United States Department of
Health & Human Services
Office for Civil Rights

Access Guidance

Access – Form and Format and Manner of Access

- Individual has right to copy in form and format requested if "readily producible"
  - If PHI maintained electronically, at least one type of electronic format must be accessible by individual
  - Depends on capabilities, not willingness
  - Includes requested mode of transmission/transfer of copy
    - Right to copy by e-mail (or mail), including unsecure e-mail if requested by individual (plus light warning about security risks)
    - Other modes if within capabilities of entity and mode would not present unacceptable security risks to PHI on entity's systems



United States Department of
Health & Human Services
Office for Civil Rights

Access Guidance

Access – Timeliness and Fees

- Access must be provided within 30 days (one 30-day extension permitted) BUT expectation that entities can respond much sooner
- Limited fees may be charged for copy
  - Reasonable, cost-based fee for labor for copying (and creating summary or explanation, if applicable); costs for supplies and postage
  - No search and retrieval or other costs, even if authorized by State law
  - Entities strongly encouraged to provide free copies

United States Department of
Health & Human Services
Office for Civil Rights

Access: Designated 3rd Party

Third Party Access to an Individual's PHI

- Individual's right of access includes directing a covered entity to transmit PHI directly to another person, in writing, signed, designating the person and where to send a copy (45 CFR 164.524)
- Individual may also authorize disclosures to third parties, whereby third parties initiate a request for the PHI on their own behalf if certain conditions are met (45 CFR 164.508)

13

United States Department of
Health & Human Services
Office for Civil Rights

Platform for users to influence guidance
http://hipaaQsportal.hhs.gov/

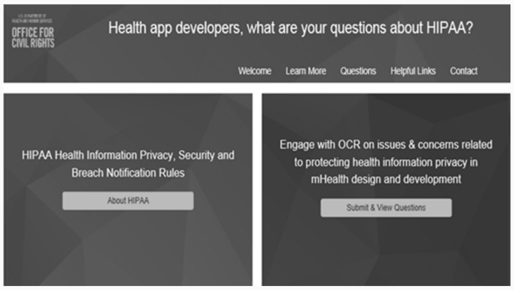
HIT Developer Portal

- OCR launched platform for mobile health developers in October 2015; purpose is to understand concerns of developers new to health care industry and HIPAA standards
- Users can submit questions, comment on other submissions, vote on relevancy of topic
- OCR will consider comments as we develop our priorities for additional guidance and technical assistance
- Guidance issued in February 2016 about how HIPAA might apply to a range of health app use scenarios
- FTC/ONC/OCR/FDA Mobile Health Apps Interactive Tool on Which Laws Apply issued in April 2016

14

United States Department of
Health & Human Services
Office for Civil Rights

Platform for users to influence guidance
http://hipaaQsportal.hhs.gov/

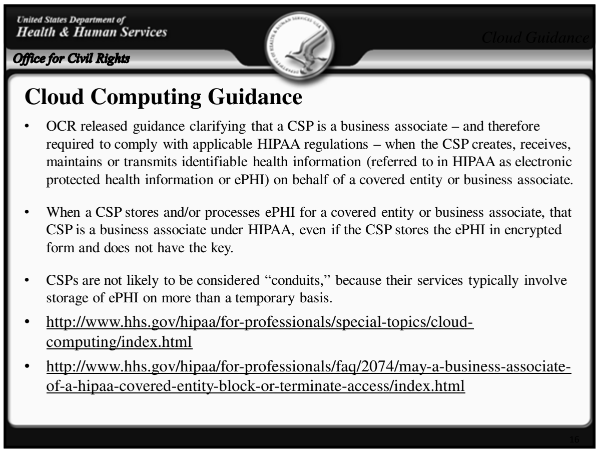


Health app developers, what are your questions about HIPAA?

HIPAA Health Information Privacy, Security and Breach Notification Rules

Engage with OCR on issues & concerns related to protecting health information privacy in mHealth design and development

October 2015



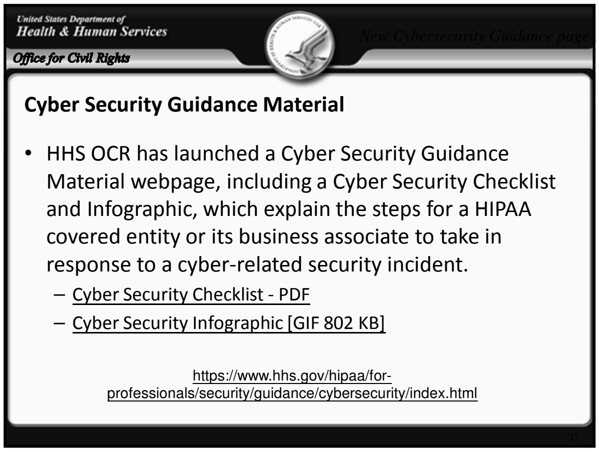
United States Department of
Health & Human Services
Office for Civil Rights

Cloud Guidance

Cloud Computing Guidance

- OCR released guidance clarifying that a CSP is a business associate – and therefore required to comply with applicable HIPAA regulations – when the CSP creates, receives, maintains or transmits identifiable health information (referred to in HIPAA as electronic protected health information or ePHI) on behalf of a covered entity or business associate.
- When a CSP stores and/or processes ePHI for a covered entity or business associate, that CSP is a business associate under HIPAA, even if the CSP stores the ePHI in encrypted form and does not have the key.
- CSPs are not likely to be considered "conduits," because their services typically involve storage of ePHI on more than a temporary basis.
- http://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html
- http://www.hhs.gov/hipaa/for-professionals/faq/2074/may-a-business-associate-of-a-hipaa-covered-entity-block-or-terminate-access/index.html

16



United States Department of
Health & Human Services
Office for Civil Rights

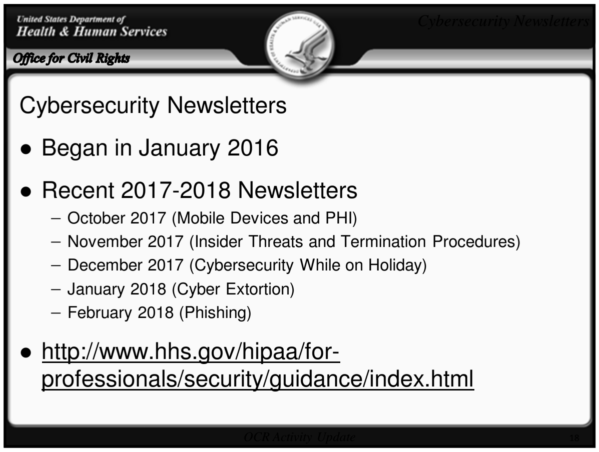
New Cybersecurity Guidance page

Cyber Security Guidance Material

- HHS OCR has launched a Cyber Security Guidance Material webpage, including a Cyber Security Checklist and Infographic, which explain the steps for a HIPAA covered entity or its business associate to take in response to a cyber-related security incident.
  - Cyber Security Checklist - PDF
  - Cyber Security Infographic [GIF 802 KB]

https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html

17



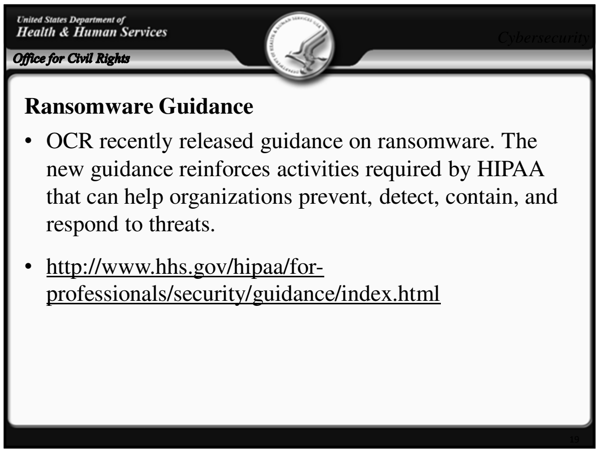
United States Department of
Health & Human Services
Office for Civil Rights

Cybersecurity Newsletters

Cybersecurity Newsletters

- Began in January 2016
- Recent 2017-2018 Newsletters
  - October 2017 (Mobile Devices and PHI)
  - November 2017 (Insider Threats and Termination Procedures)
  - December 2017 (Cybersecurity While on Holiday)
  - January 2018 (Cyber Extortion)
  - February 2018 (Phishing)
- http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html

OCR Activity Update 18



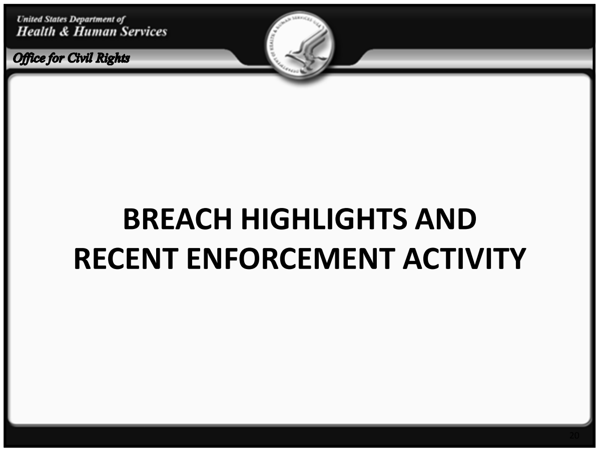
United States Department of Health & Human Services

Office for Civil Rights

Cybersecurity

Ransomware Guidance

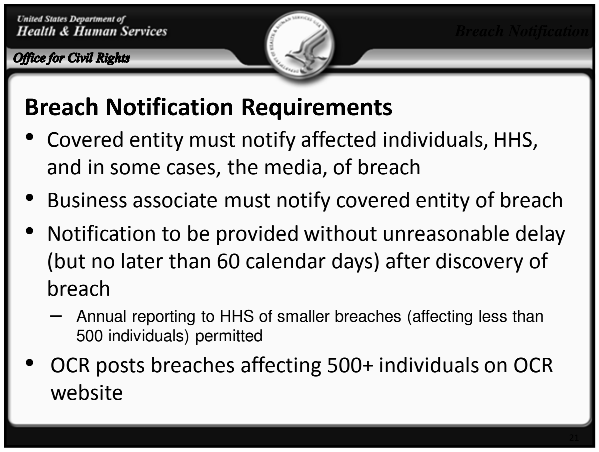
- OCR recently released guidance on ransomware. The new guidance reinforces activities required by HIPAA that can help organizations prevent, detect, contain, and respond to threats.
- http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html



United States Department of Health & Human Services

Office for Civil Rights

BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY



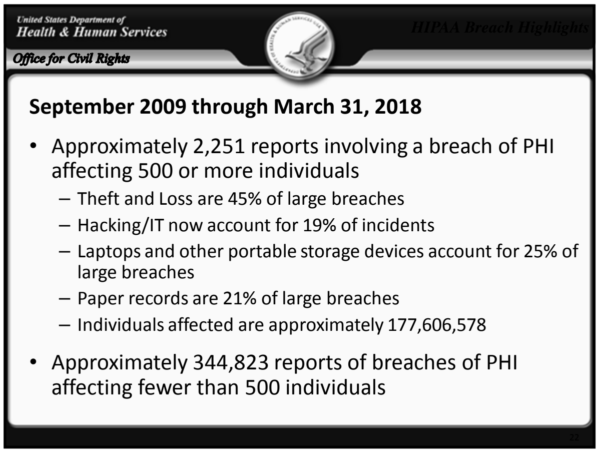
United States Department of Health & Human Services

Office for Civil Rights

Breach Notification

Breach Notification Requirements

- Covered entity must notify affected individuals, HHS, and in some cases, the media, of breach
- Business associate must notify covered entity of breach
- Notification to be provided without unreasonable delay (but no later than 60 calendar days) after discovery of breach
  - Annual reporting to HHS of smaller breaches (affecting less than 500 individuals) permitted
- OCR posts breaches affecting 500+ individuals on OCR website

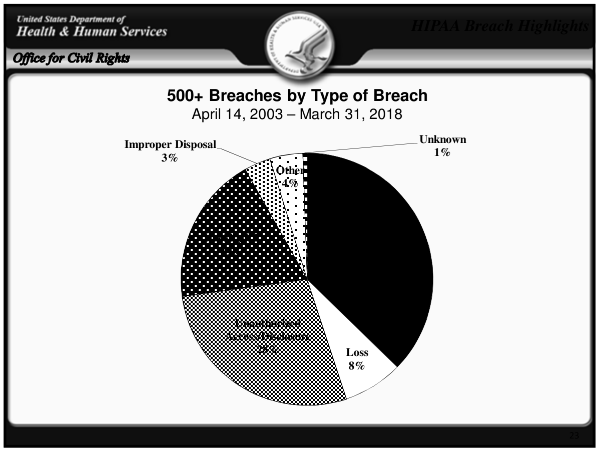


United States Department of
Health & Human Services
Office for Civil Rights
HIPAA Breach Highlights

September 2009 through March 31, 2018

- Approximately 2,251 reports involving a breach of PHI affecting 500 or more individuals
  - Theft and Loss are 45% of large breaches
  - Hacking/IT now account for 19% of incidents
  - Laptops and other portable storage devices account for 25% of large breaches
  - Paper records are 21% of large breaches
  - Individuals affected are approximately 177,606,578
- Approximately 344,823 reports of breaches of PHI affecting fewer than 500 individuals

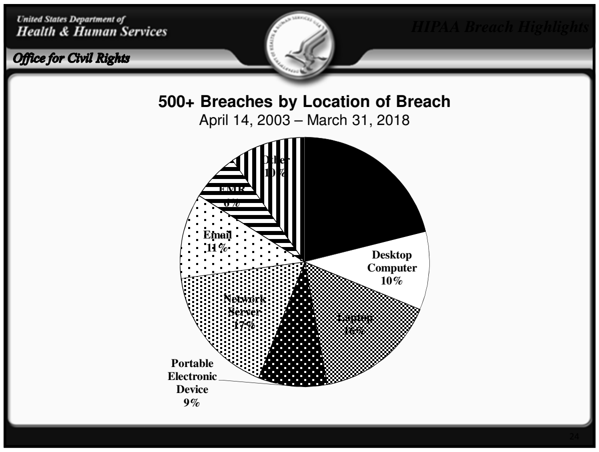
22



500+ Breaches by Type of Breach

April 14, 2003 – March 31, 2018

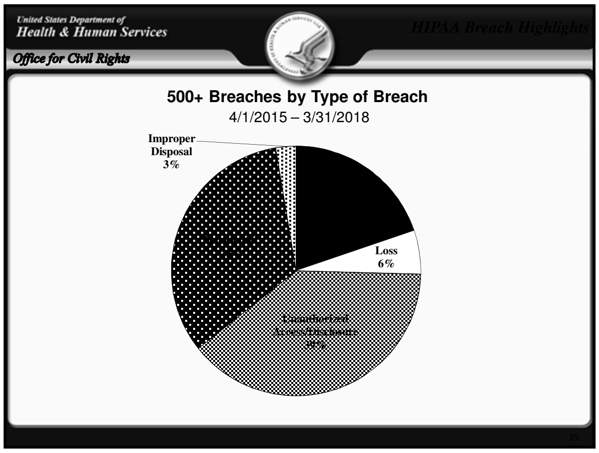
23



500+ Breaches by Location of Breach

April 14, 2003 – March 31, 2018

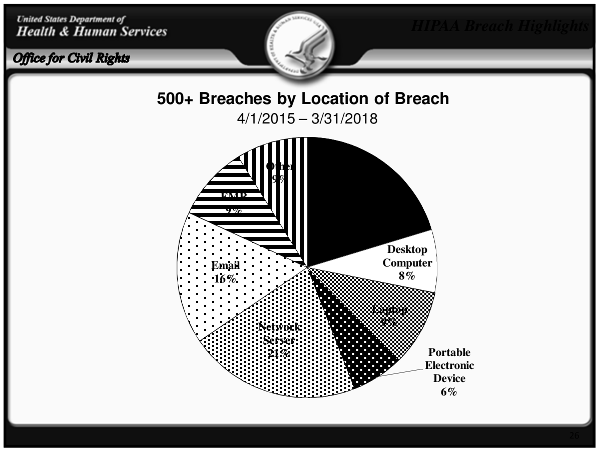
24



United States Department of
Health & Human Services
Office for Civil Rights

HIPAA Breach Highlights

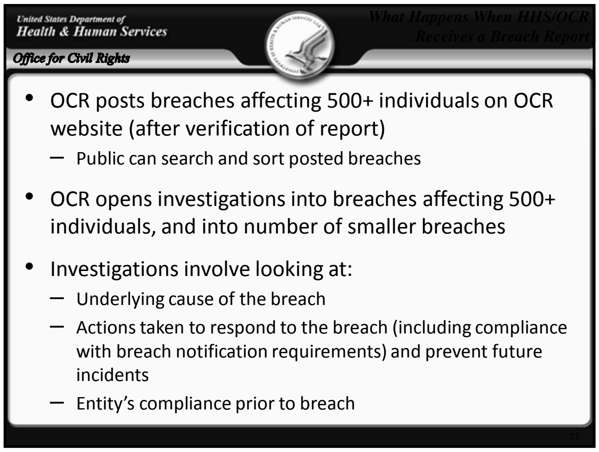
25



United States Department of
Health & Human Services
Office for Civil Rights

HIPAA Breach Highlights

26

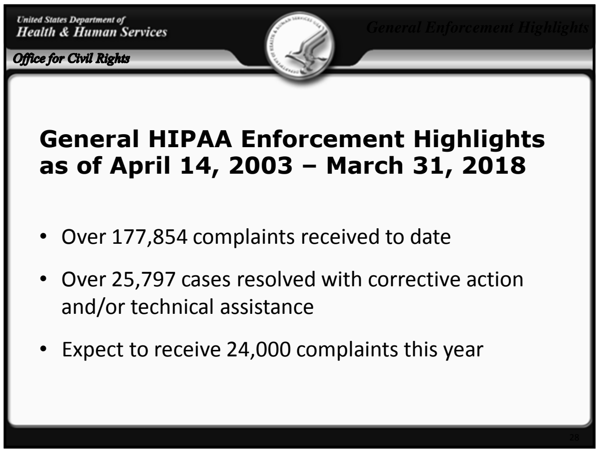


United States Department of
Health & Human Services
Office for Civil Rights

What Happens When HHS/OCR Receives a Breach Report

- OCR posts breaches affecting 500+ individuals on OCR website (after verification of report)
  - Public can search and sort posted breaches
- OCR opens investigations into breaches affecting 500+ individuals, and into number of smaller breaches
- Investigations involve looking at:
  - Underlying cause of the breach
  - Actions taken to respond to the breach (including compliance with breach notification requirements) and prevent future incidents
  - Entity's compliance prior to breach

27



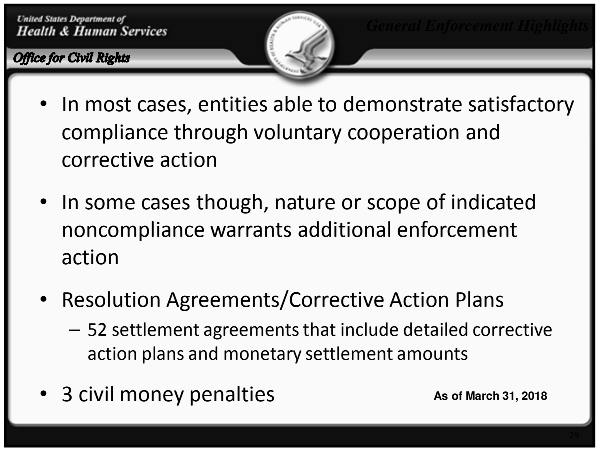
United States Department of
Health & Human Services

Office for Civil Rights

General Enforcement Highlights

General HIPAA Enforcement Highlights as of April 14, 2003 – March 31, 2018

- Over 177,854 complaints received to date
- Over 25,797 cases resolved with corrective action and/or technical assistance
- Expect to receive 24,000 complaints this year



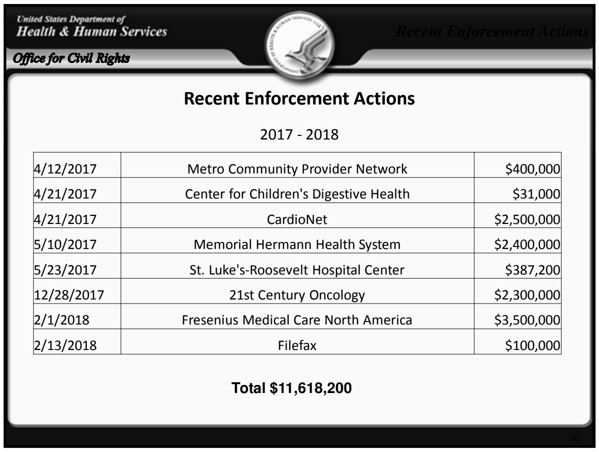
United States Department of
Health & Human Services

Office for Civil Rights

General Enforcement Highlights

- In most cases, entities able to demonstrate satisfactory compliance through voluntary cooperation and corrective action
- In some cases though, nature or scope of indicated noncompliance warrants additional enforcement action
- Resolution Agreements/Corrective Action Plans
  - 52 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 3 civil money penalties

As of March 31, 2018



United States Department of
Health & Human Services

Office for Civil Rights

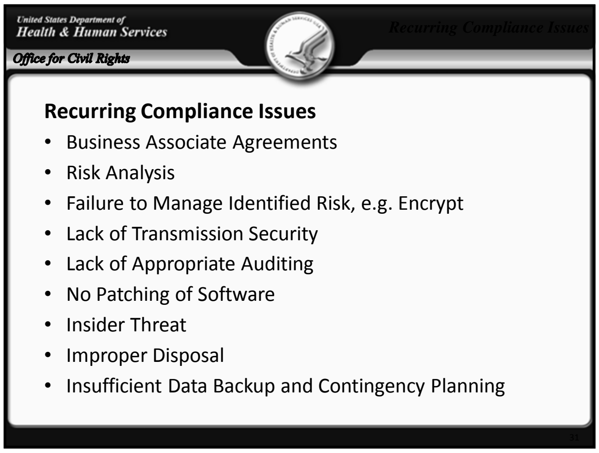
Recent Enforcement Actions

Recent Enforcement Actions

2017 - 2018

4/12/2017	Metro Community Provider Network	$400,000
4/21/2017	Center for Children's Digestive Health	$31,000
4/21/2017	CardioNet	$2,500,000
5/10/2017	Memorial Hermann Health System	$2,400,000
5/23/2017	St. Luke's-Roosevelt Hospital Center	$387,200
12/28/2017	21st Century Oncology	$2,300,000
2/1/2018	Fresenius Medical Care North America	$3,500,000
2/13/2018	Filefax	$100,000

Total $11,618,200



United States Department of Health & Human Services

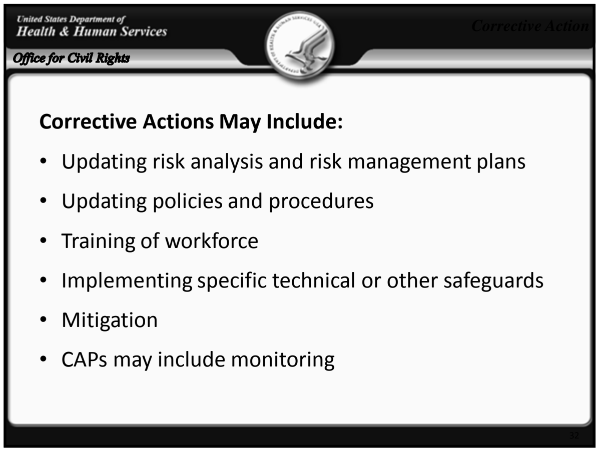
Office for Civil Rights

Recurring Compliance Issues

Recurring Compliance Issues

- Business Associate Agreements
- Risk Analysis
- Failure to Manage Identified Risk, e.g. Encrypt
- Lack of Transmission Security
- Lack of Appropriate Auditing
- No Patching of Software
- Insider Threat
- Improper Disposal
- Insufficient Data Backup and Contingency Planning

31



United States Department of Health & Human Services

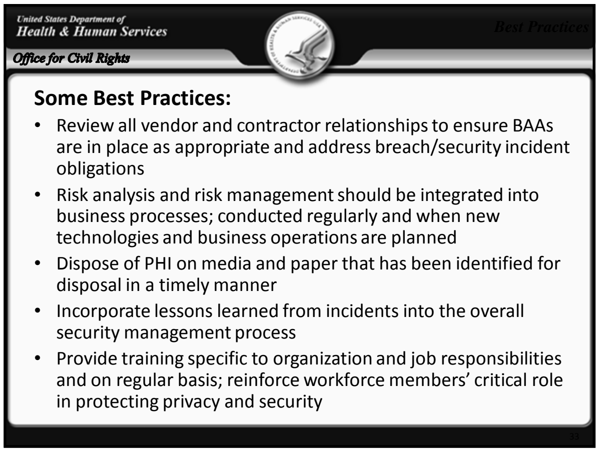
Office for Civil Rights

Corrective Action

Corrective Actions May Include:

- Updating risk analysis and risk management plans
- Updating policies and procedures
- Training of workforce
- Implementing specific technical or other safeguards
- Mitigation
- CAPs may include monitoring

32



United States Department of Health & Human Services

Office for Civil Rights

Best Practices

Some Best Practices:

- Review all vendor and contractor relationships to ensure BAAs are in place as appropriate and address breach/security incident obligations
- Risk analysis and risk management should be integrated into business processes; conducted regularly and when new technologies and business operations are planned
- Dispose of PHI on media and paper that has been identified for disposal in a timely manner
- Incorporate lessons learned from incidents into the overall security management process
- Provide training specific to organization and job responsibilities and on regular basis; reinforce workforce members' critical role in protecting privacy and security

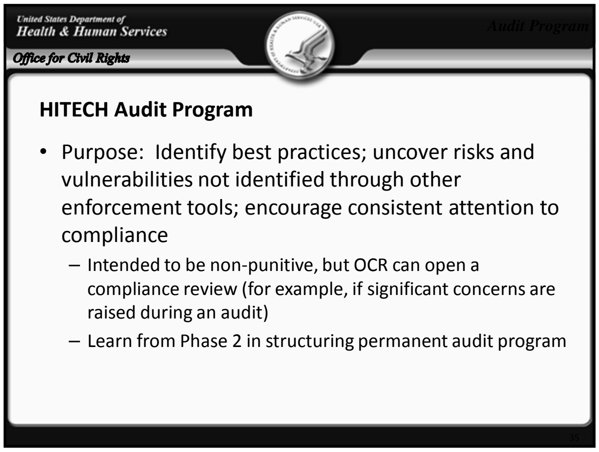
33

United States Department of
Health & Human Services
Office for Civil Rights

Audit Program

AUDIT

34



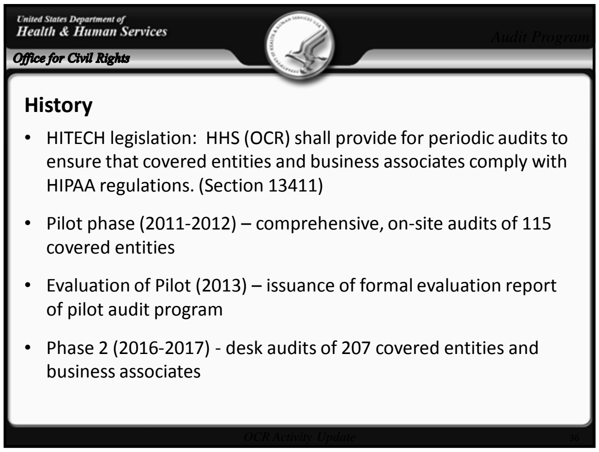
United States Department of
Health & Human Services
Office for Civil Rights

Audit Program

HITECH Audit Program

- Purpose: Identify best practices; uncover risks and vulnerabilities not identified through other enforcement tools; encourage consistent attention to compliance
  - Intended to be non-punitive, but OCR can open a compliance review (for example, if significant concerns are raised during an audit)
  - Learn from Phase 2 in structuring permanent audit program

35



United States Department of
Health & Human Services
Office for Civil Rights

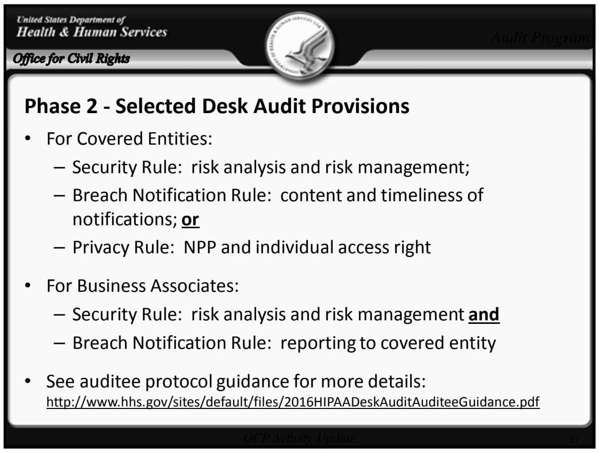
Audit Program

History

- HITECH legislation: HHS (OCR) shall provide for periodic audits to ensure that covered entities and business associates comply with HIPAA regulations. (Section 13411)
- Pilot phase (2011-2012) – comprehensive, on-site audits of 115 covered entities
- Evaluation of Pilot (2013) – issuance of formal evaluation report of pilot audit program
- Phase 2 (2016-2017) - desk audits of 207 covered entities and business associates

OCR Activity Update

36

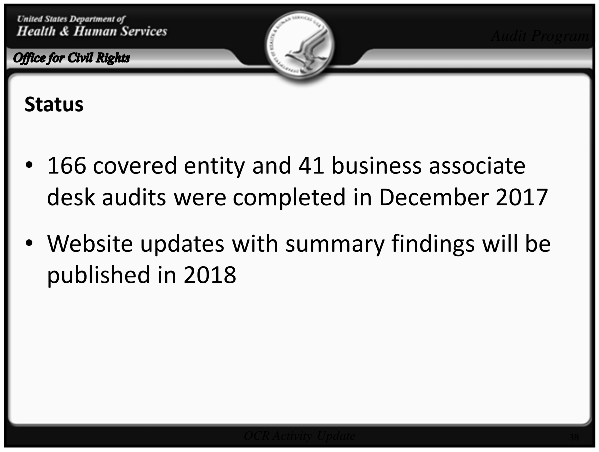


United States Department of
Health & Human Services
Office for Civil Rights

Audit Program

Phase 2 - Selected Desk Audit Provisions

- For Covered Entities:
  - Security Rule: risk analysis and risk management;
  - Breach Notification Rule: content and timeliness of notifications; **or**
  - Privacy Rule: NPP and individual access right
- For Business Associates:
  - Security Rule: risk analysis and risk management **and**
  - Breach Notification Rule: reporting to covered entity
- See auditee protocol guidance for more details: http://www.hhs.gov/sites/default/files/2016HIPAADeskAuditAuditeeGuidance.pdf

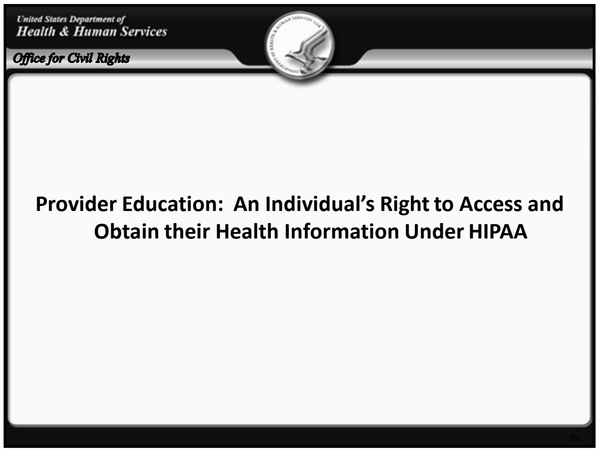


United States Department of
Health & Human Services
Office for Civil Rights

Audit Program

Status

- 166 covered entity and 41 business associate desk audits were completed in December 2017
- Website updates with summary findings will be published in 2018



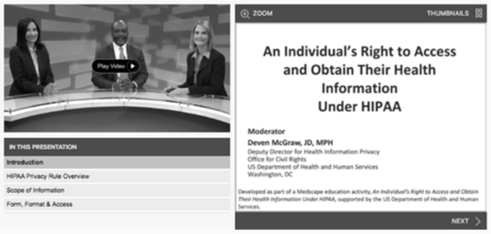
United States Department of
Health & Human Services
Office for Civil Rights

Provider Education: An Individual's Right to Access and Obtain their Health Information Under HIPAA

United States Department of
Health & Human Services
Office for Civil Rights

Provider Education

Web-based Video Training for Free Continuing Medical Education and Continuing Education Credit for Health Care Professionals via Medscape



ZOOM THUMBNAILS

An Individual's Right to Access and Obtain Their Health Information Under HIPAA

Moderator
Deven McGraw, JD, MPH
Deputy Director for Health Information Privacy
Office for Civil Rights
US Department of Health and Human Services
Washington, DC

Developed as part of a Medscape education activity, *An Individual's Right to Access and Obtain Their Health Information Under HIPAA*, supported by the US Department of Health and Human Services.

NEXT

IN THIS PRESENTATION
- Introduction
- HIPAA Privacy Rule Overview
- Scope of Information
- Form, Format & Access

http://www.medscape.org/viewarticle/876110

United States Department of
Health & Human Services
Office for Civil Rights

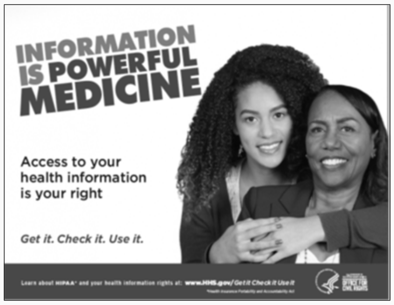
Consumer Facing Resources:

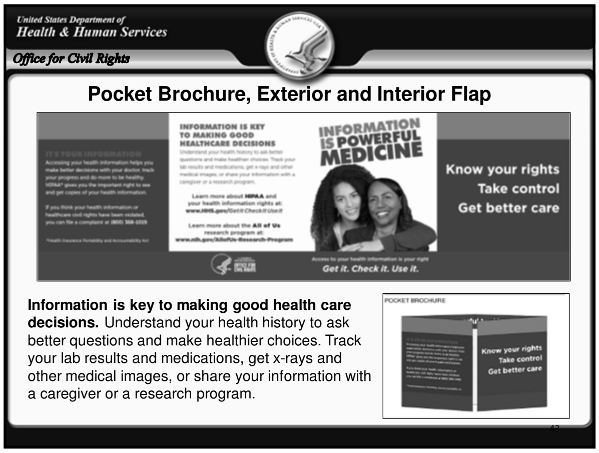
Right to Access Your Health Information Under HIPAA

United States Department of
Health & Human Services
Office for Civil Rights

New Consumer Facing Tools

Phase 2 of OCR's *Information is Powerful Medicine* Campaign


INFORMATION IS POWERFUL MEDICINE
Access to your health information is your right
Get it. Check it. Use it.
Learn about HIPAA* and your health information rights at: www.HHS.gov/Get it Check it Use it
*Health Insurance Portability and Accountability Act
OFFICE FOR CIVIL RIGHTS



United States Department of
Health & Human Services
Office for Civil Rights

Pocket Brochure, Exterior and Interior Flap

IT'S YOUR INFORMATION

Accessing your health information helps you make better decisions with your doctor, track your progress and do more to be healthy. HIPAA* gives you the important right to see and get copies of your health information.

If you think your health information or healthcare civil rights have been violated, you can file a complaint at (800) 368-1019.

*Health Insurance Portability and Accountability Act

INFORMATION IS KEY TO MAKING GOOD HEALTHCARE DECISIONS

Understand your health history to ask better questions and make healthier choices. Track your lab results and medications, get x-rays and other medical images, or share your information with a caregiver or a research program.

Learn more about **HIPAA** and your health information rights at: **www.HHS.gov/*GetItCheckItUseIt***

Learn more about the **All of Us** research program at: **www.nih.gov/AllofUs-Research-Program**

INFORMATION IS POWERFUL MEDICINE

Know your rights
Take control
Get better care

OFFICE FOR CIVIL RIGHTS

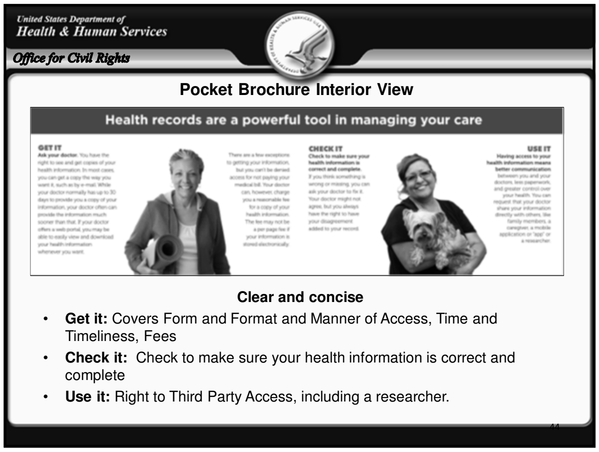
Access to your health information is your right

Get it. Check it. Use it.

Information is key to making good health care decisions. Understand your health history to ask better questions and make healthier choices. Track your lab results and medications, get x-rays and other medical images, or share your information with a caregiver or a research program.

POCKET BROCHURE

Know your rights
Take control
Get better care



United States Department of
Health & Human Services
Office for Civil Rights

Pocket Brochure Interior View

Health records are a powerful tool in managing your care

GET IT

Ask your doctor. You have the right to see and get copies of your health information. In most cases, you can get a copy the way you want it, such as by e-mail. While your doctor normally has up to 30 days to provide you a copy of your information, your doctor often can provide the information much sooner than that. If your doctor offers a web portal, you may be able to easily view and download your health information whenever you want.

There are a few exceptions to getting your information, but you can't be denied access for not paying your medical bill. Your doctor can, however, charge you a reasonable fee for a copy of your health information. The fee may not be a per page fee if your information is stored electronically.

CHECK IT

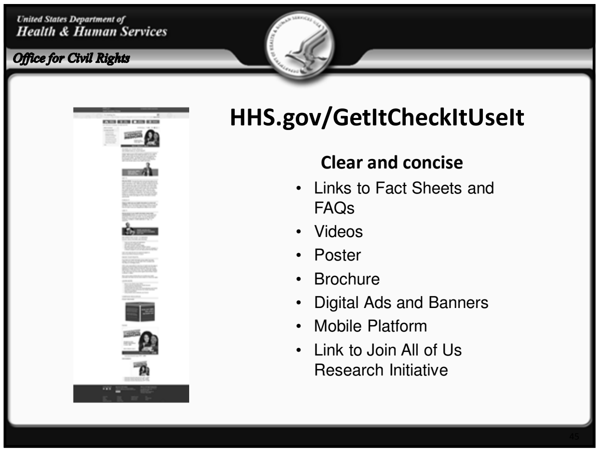
Check to make sure your health information is correct and complete. If you think something is wrong or missing, you can ask your doctor to fix it. Your doctor might not agree, but you always have the right to have your disagreement added to your record.

USE IT

Having access to your health information means better communication between you and your doctors, less paperwork, and greater control over your health. You can request that your doctor share your information directly with others, like family members, a caregiver, a mobile application or "app" or a researcher.

Clear and concise

- **Get it:** Covers Form and Format and Manner of Access, Time and Timeliness, Fees
- **Check it:** Check to make sure your health information is correct and complete
- **Use it:** Right to Third Party Access, including a researcher.

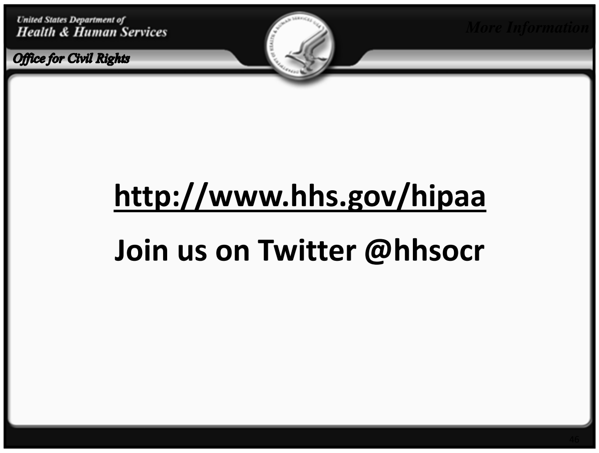


United States Department of
Health & Human Services
Office for Civil Rights

HHS.gov/GetItCheckItUseIt

Clear and concise

- Links to Fact Sheets and FAQs
- Videos
- Poster
- Brochure
- Digital Ads and Banners
- Mobile Platform
- Link to Join All of Us Research Initiative



United States Department of
Health & Human Services

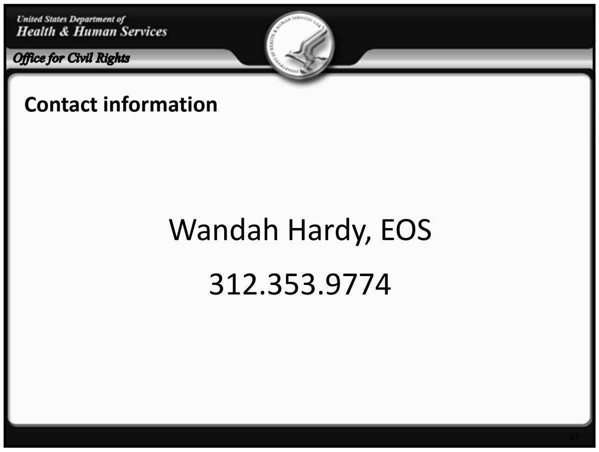
Office for Civil Rights

More Information

http://www.hhs.gov/hipaa

Join us on Twitter @hhsocr

46



United States Department of
Health & Human Services

Office for Civil Rights

Contact information

Wandah Hardy, EOS

312.353.9774

47