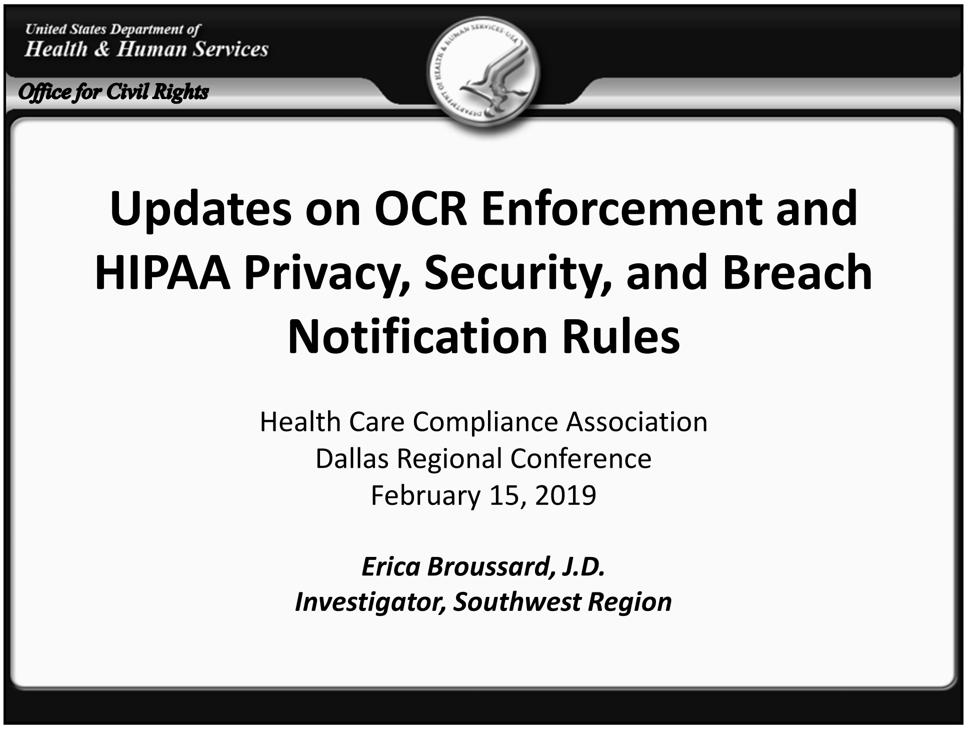
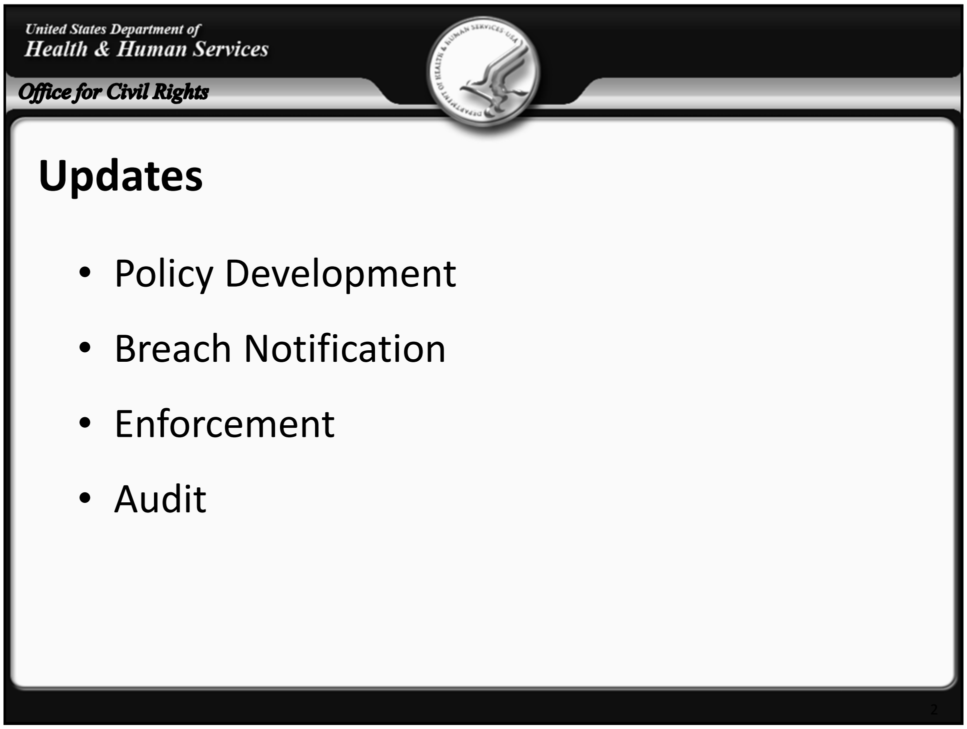


Updates on OCR Enforcement and HIPAA Privacy, Security, and Breach Notification Rules

Health Care Compliance Association
Dallas Regional Conference
February 15, 2019

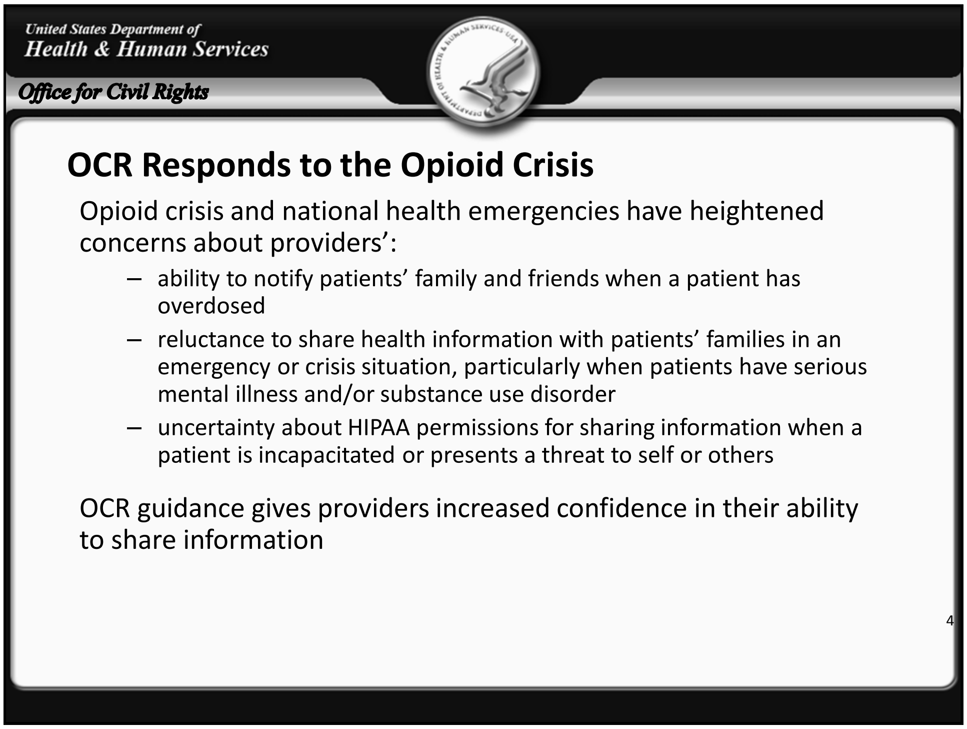
Erica Broussard, J.D.
Investigator, Southwest Region



Updates

- Policy Development
- Breach Notification
- Enforcement
- Audit

POLICY DEVELOPMENT

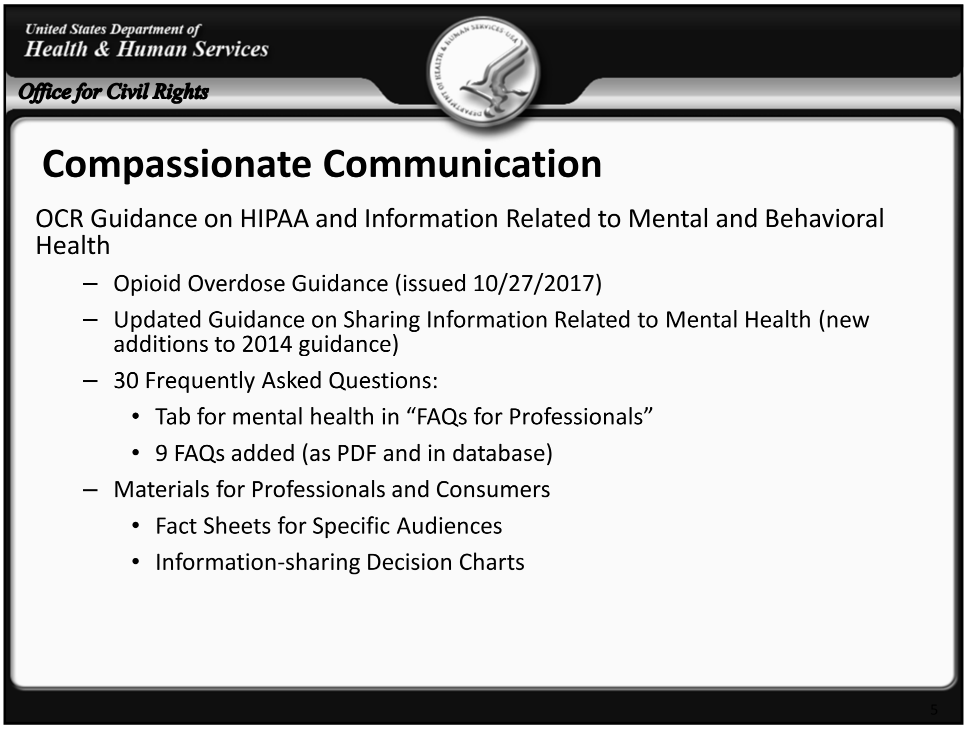


OCR Responds to the Opioid Crisis

Opioid crisis and national health emergencies have heightened concerns about providers':

- ability to notify patients' family and friends when a patient has overdosed
- reluctance to share health information with patients' families in an emergency or crisis situation, particularly when patients have serious mental illness and/or substance use disorder
- uncertainty about HIPAA permissions for sharing information when a patient is incapacitated or presents a threat to self or others

OCR guidance gives providers increased confidence in their ability to share information



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Compassionate Communication

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:
  - Tab for mental health in “FAQs for Professionals”
  - 9 FAQs added (as PDF and in database)
- Materials for Professionals and Consumers
  - Fact Sheets for Specific Audiences
  - Information-sharing Decision Charts

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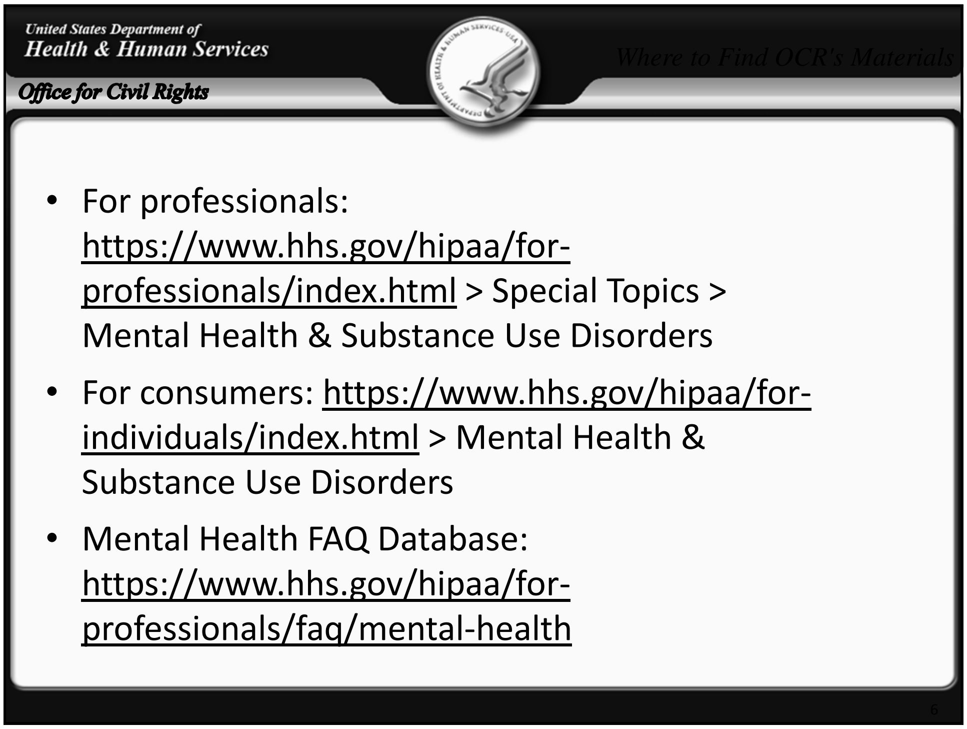

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Where to Find OCR's Materials

- 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

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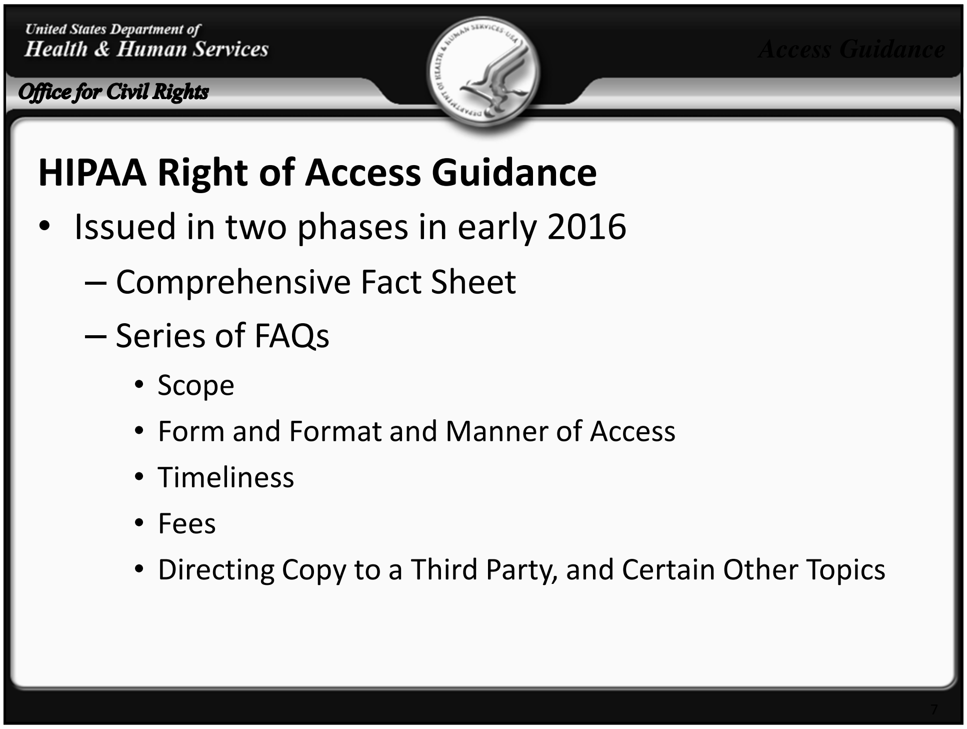
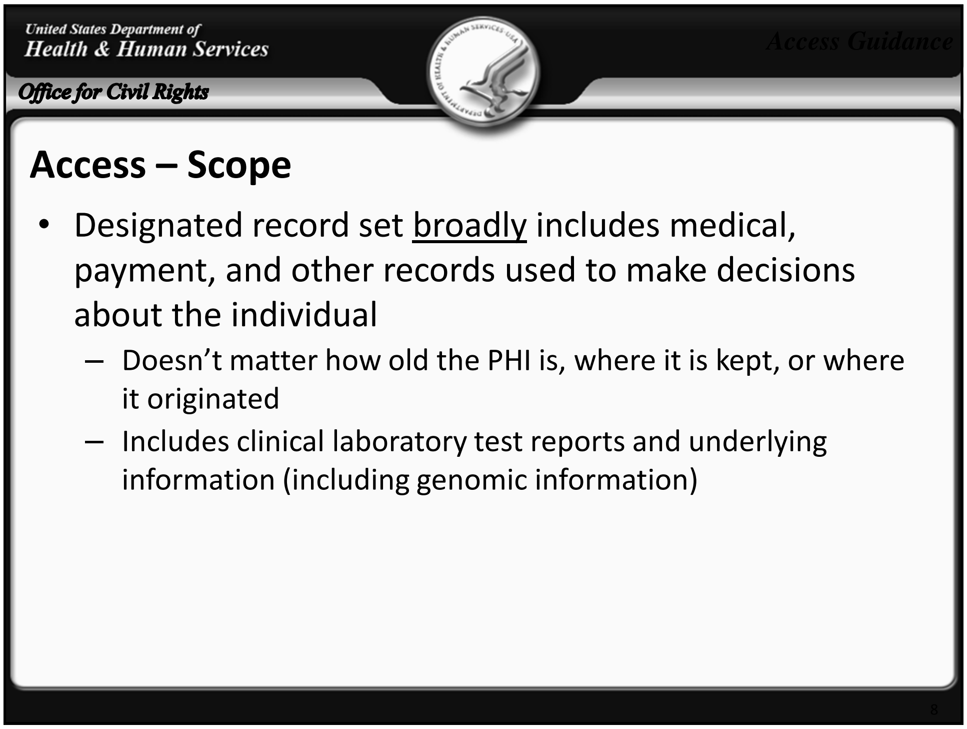


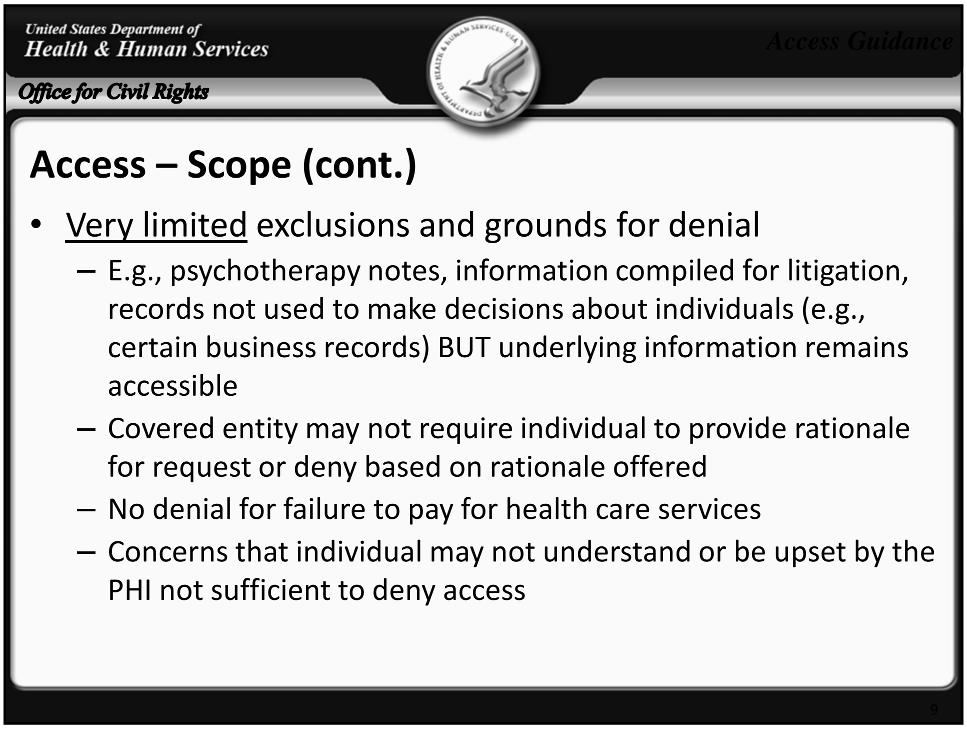
HIPAA Right of Access Guidance

- 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



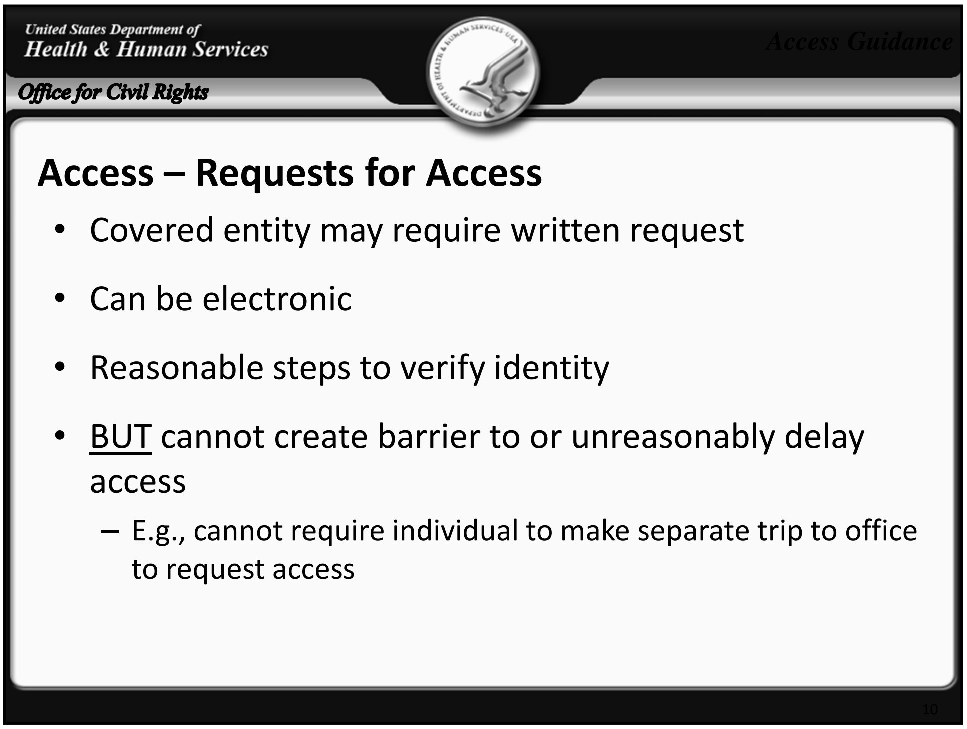
Access – Scope

- 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)



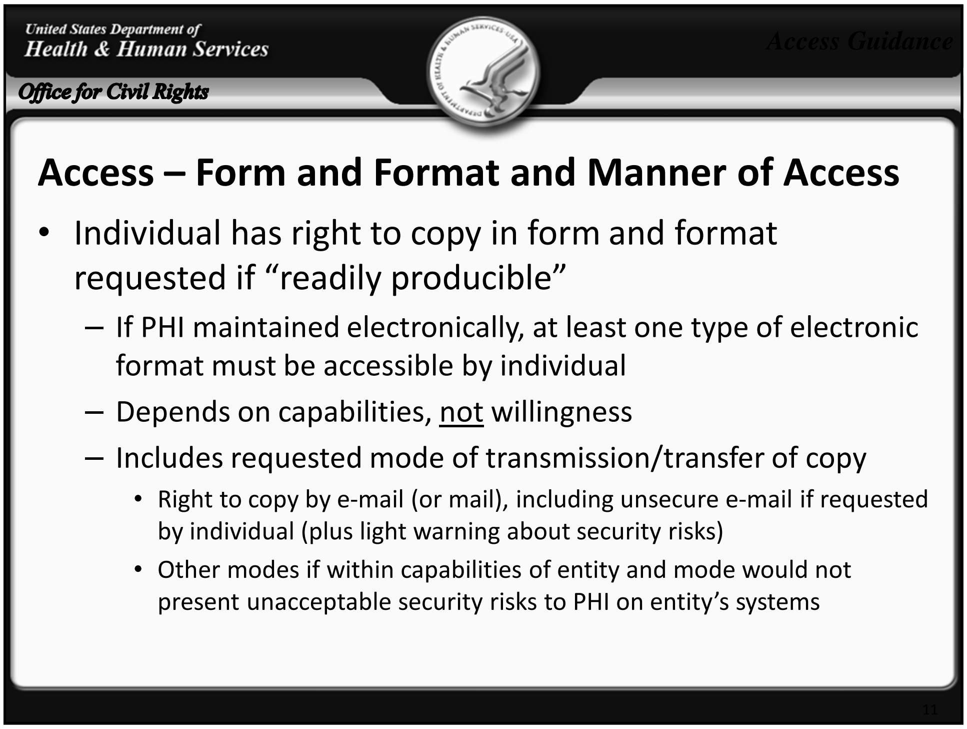
Access – Scope (cont.)

- 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



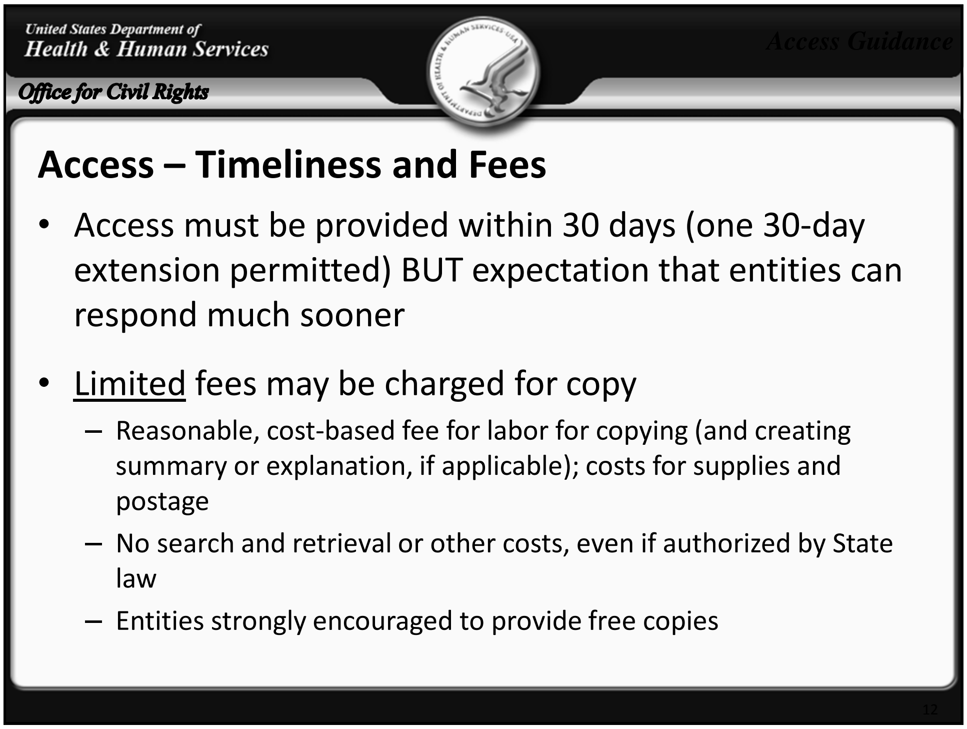
Access – Requests for Access

- 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



Access – Form and Format and Manner of Access

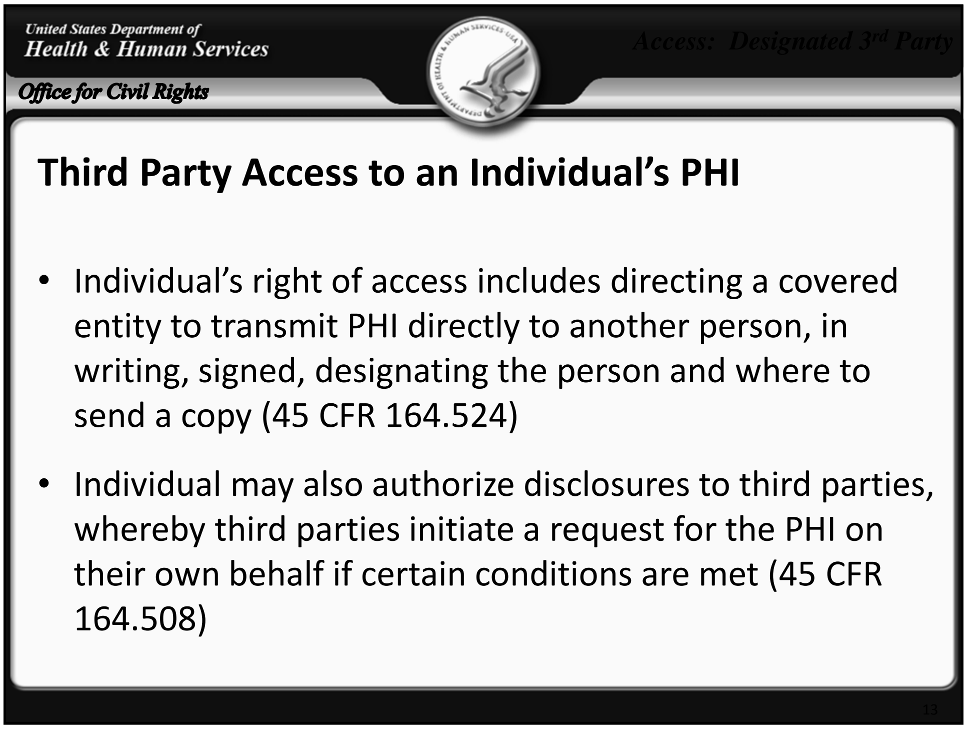
- Individual has right to copy in form and format requested if "readily producible"
  - If PHI maintained electronically, at least one type of electronic format must be accessible by individual
  - Depends on capabilities, not willingness
  - Includes requested mode of transmission/transfer of copy
    - 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



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



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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)

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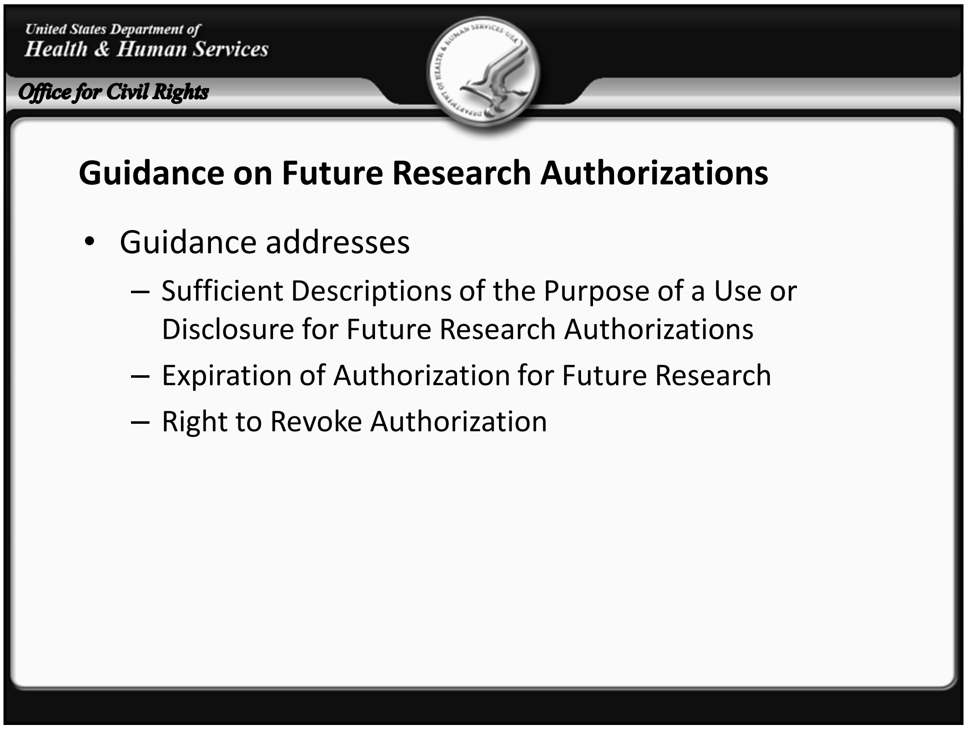

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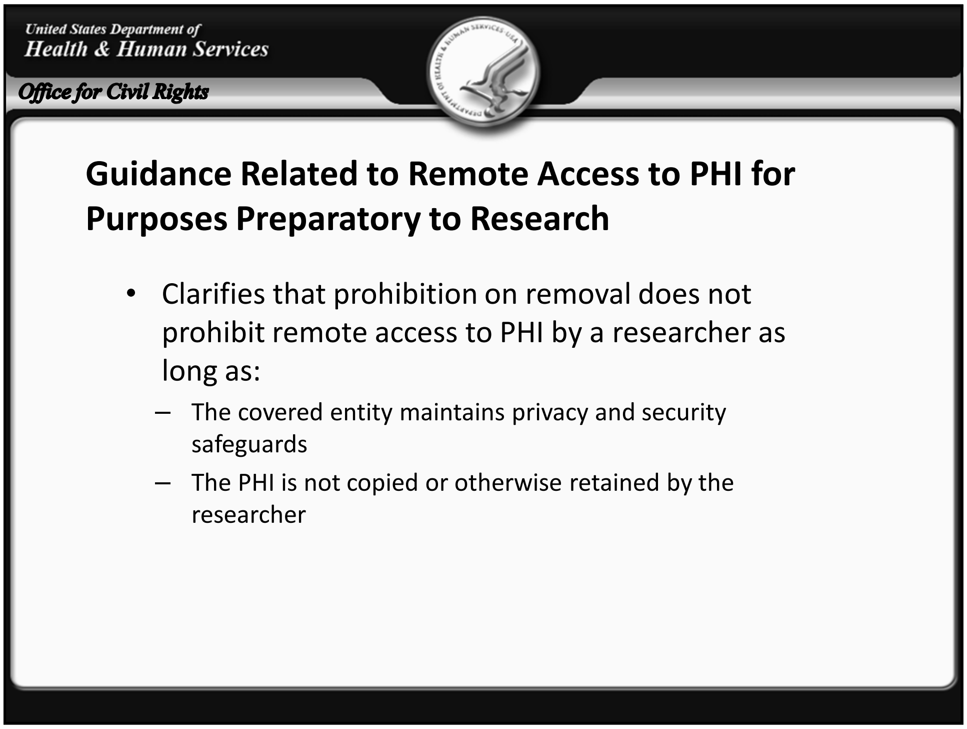
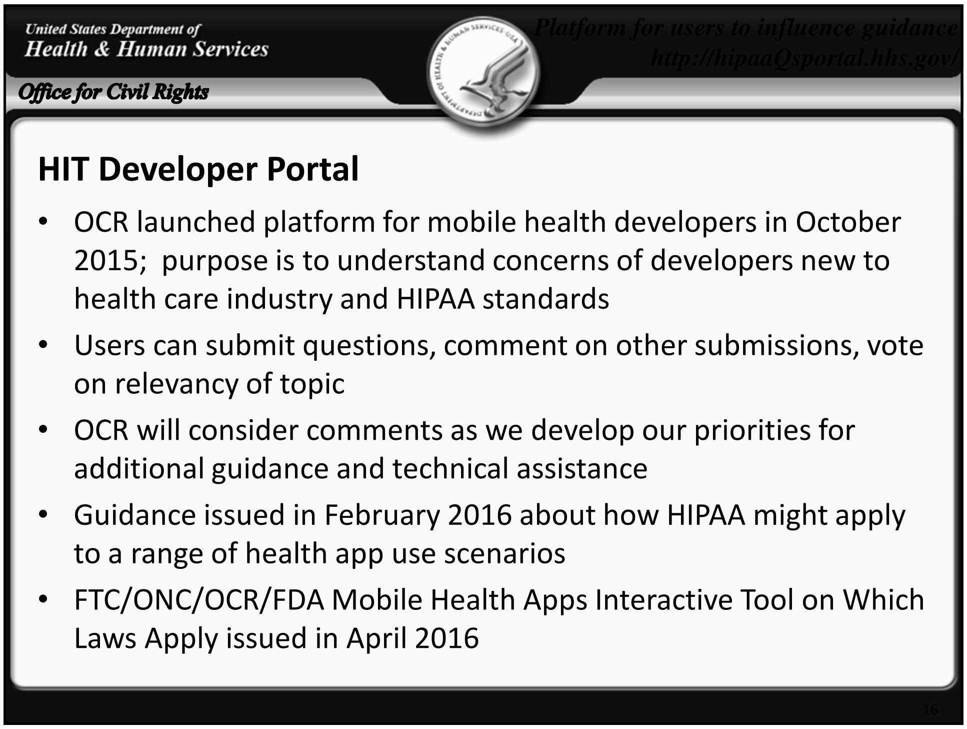
Guidance on Future Research Authorizations

- Guidance addresses
  - Sufficient Descriptions of the Purpose of a Use or Disclosure for Future Research Authorizations
  - Expiration of Authorization for Future Research
  - Right to Revoke Authorization



Guidance Related to Remote Access to PHI for Purposes Preparatory to Research

- Clarifies that prohibition on removal does not prohibit remote access to PHI by a researcher as long as:
  - The covered entity maintains privacy and security safeguards
  - The PHI is not copied or otherwise retained by the researcher

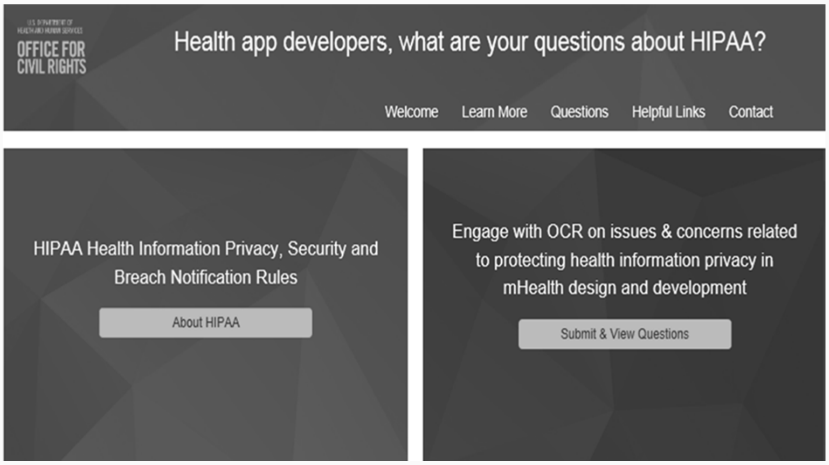


Platform for users to influence guidance
http://hipaaQsportal.hhs.gov/

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

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



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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

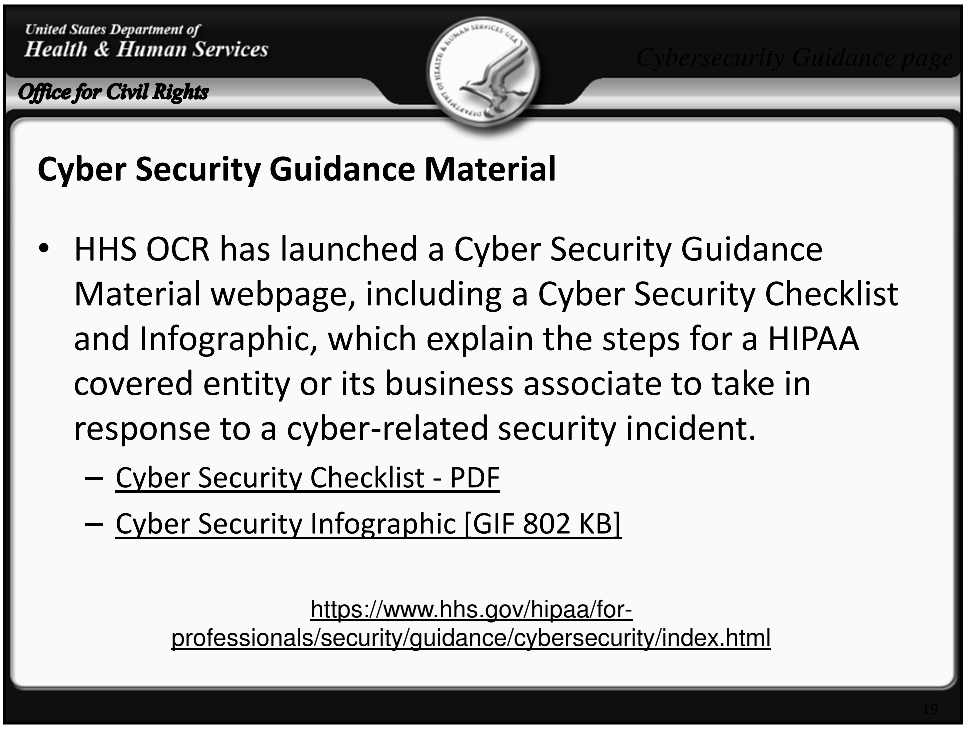
Cloud Guidance

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



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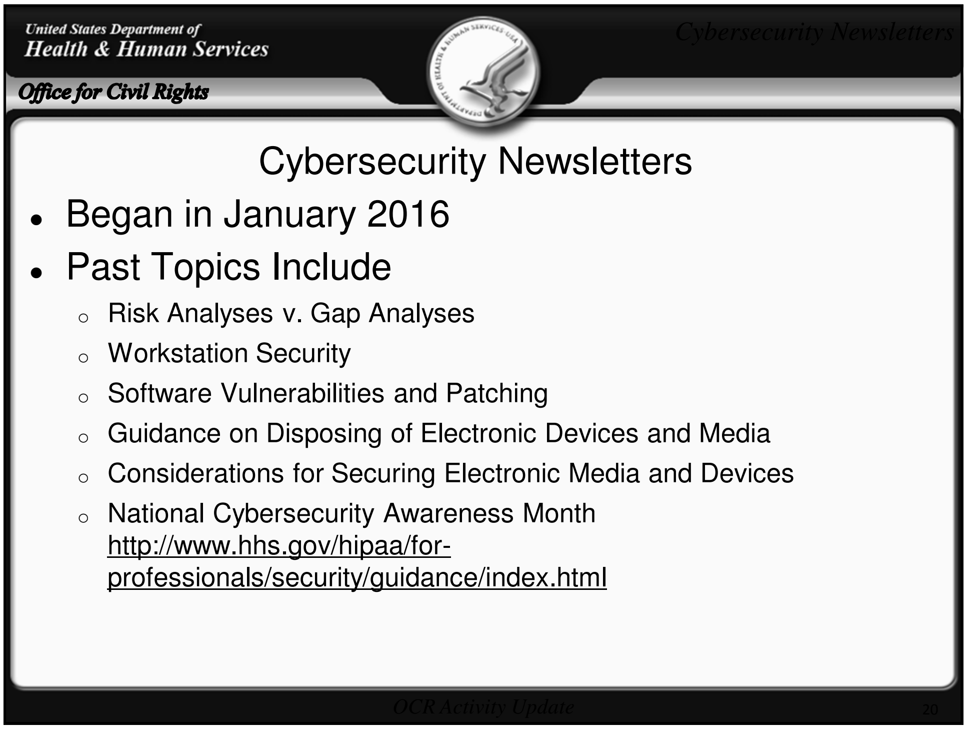
Cybersecurity Guidance page

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



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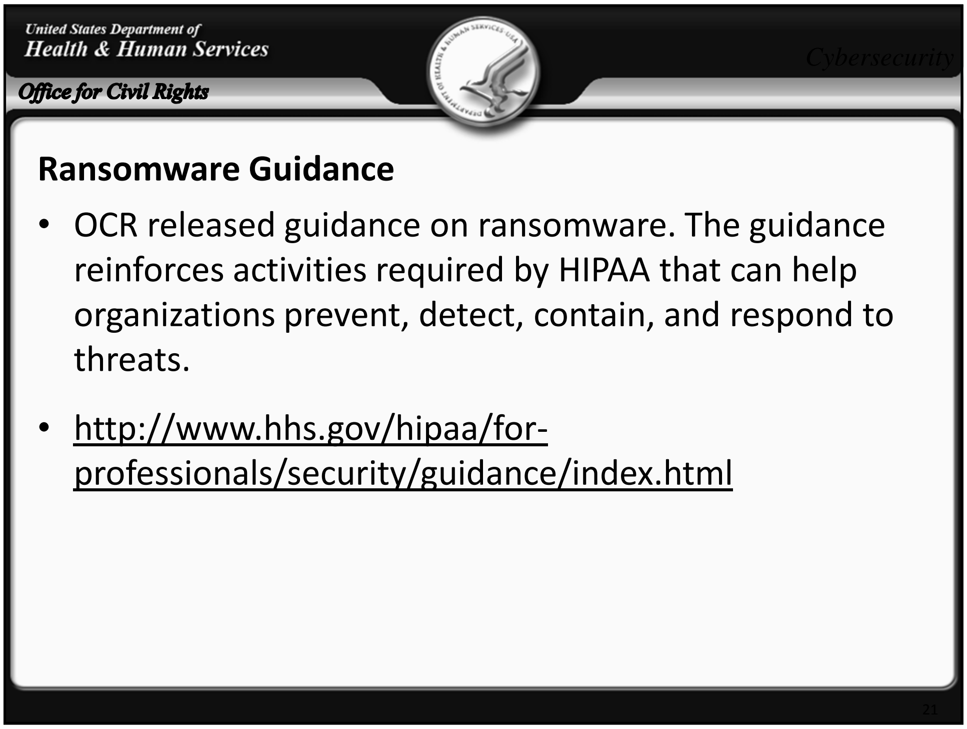
Cybersecurity Newsletters

Cybersecurity Newsletters

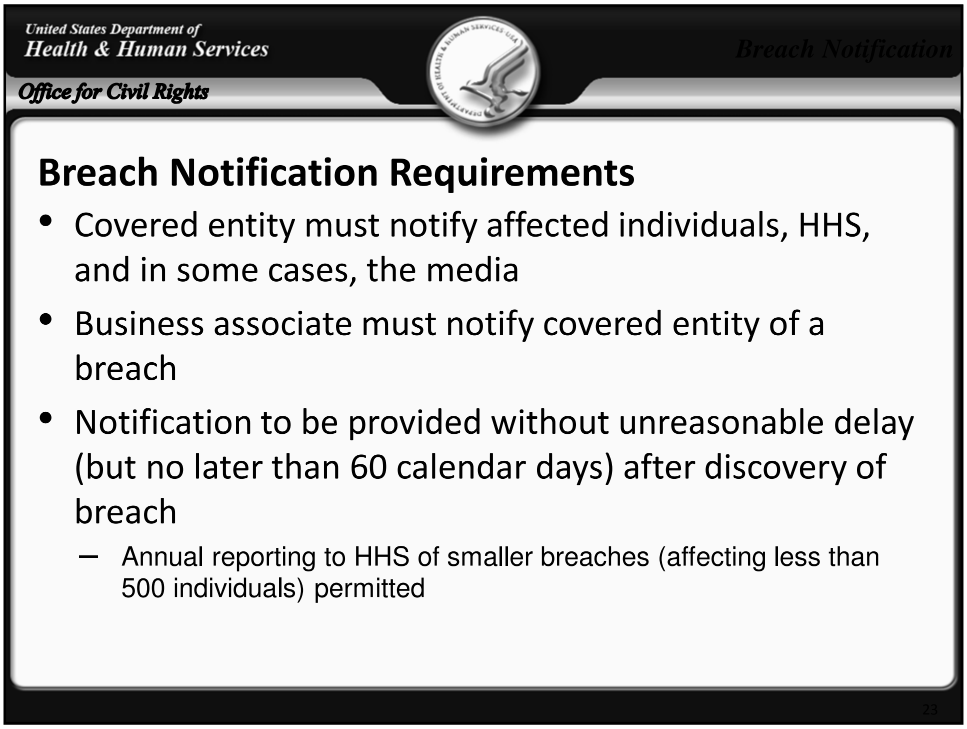
- Began in January 2016
- Past Topics Include
  - Risk Analyses v. Gap Analyses
  - Workstation Security
  - Software Vulnerabilities and Patching
  - Guidance on Disposing of Electronic Devices and Media
  - Considerations for Securing Electronic Media and Devices
  - National Cybersecurity Awareness Month http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html



Ransomware Guidance

- OCR released guidance on ransomware. The 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

BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY



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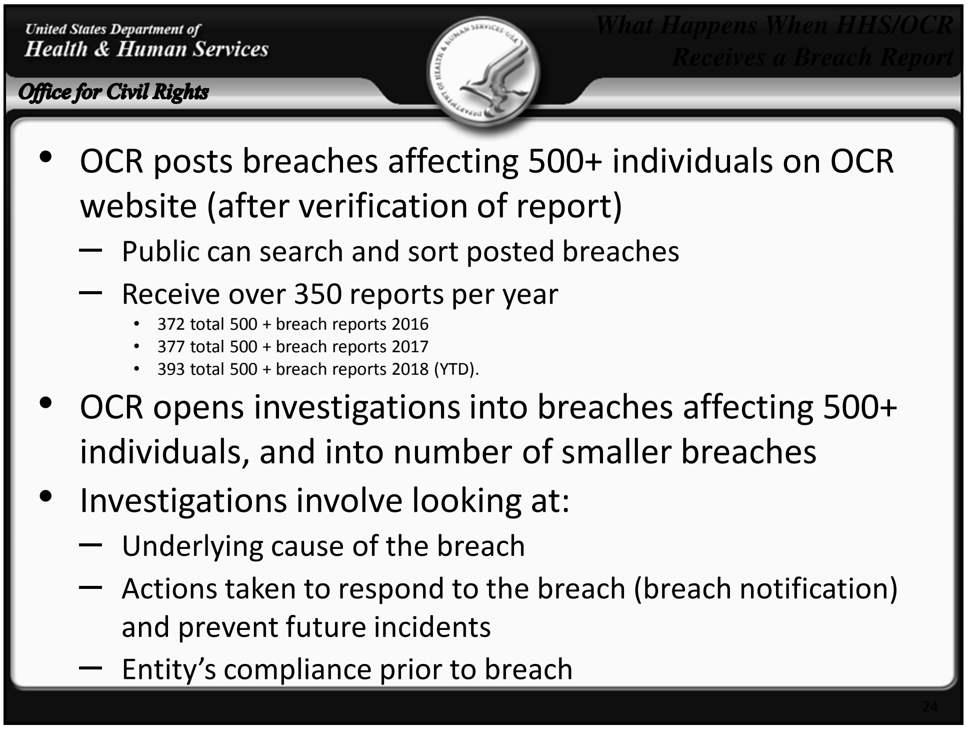
Breach Notification

Breach Notification Requirements

- Covered entity must notify affected individuals, HHS, and in some cases, the media
- Business associate must notify covered entity of a 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



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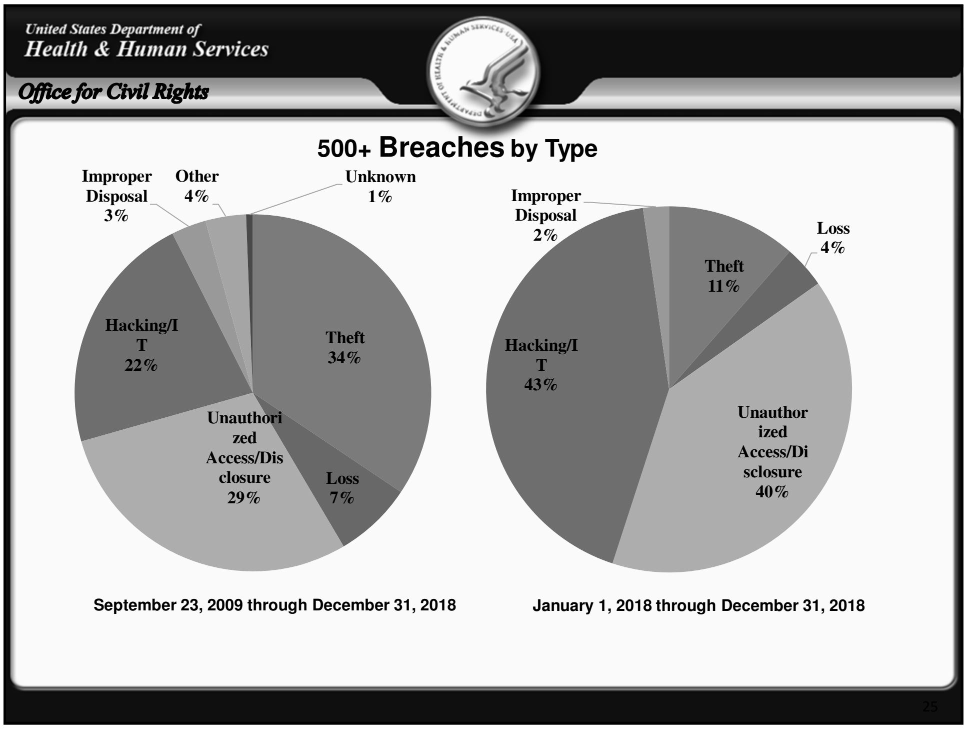
What Happens When HHS/OCR Receives a Breach Report

- OCR posts breaches affecting 500+ individuals on OCR website (after verification of report)
  - Public can search and sort posted breaches
  - Receive over 350 reports per year
    - 372 total 500 + breach reports 2016
    - 377 total 500 + breach reports 2017
    - 393 total 500 + breach reports 2018 (YTD).
- 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 (breach notification) and prevent future incidents
  - Entity’s compliance prior to breach



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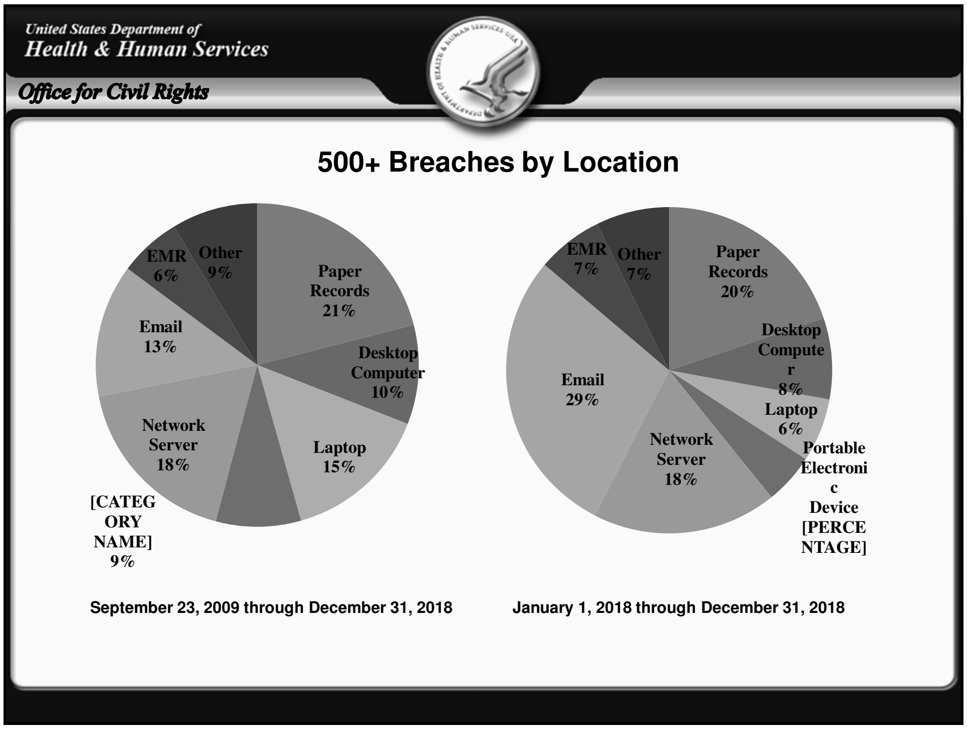
500+ Breaches by Type

September 23, 2009 through December 31, 2018

January 1, 2018 through December 31, 2018



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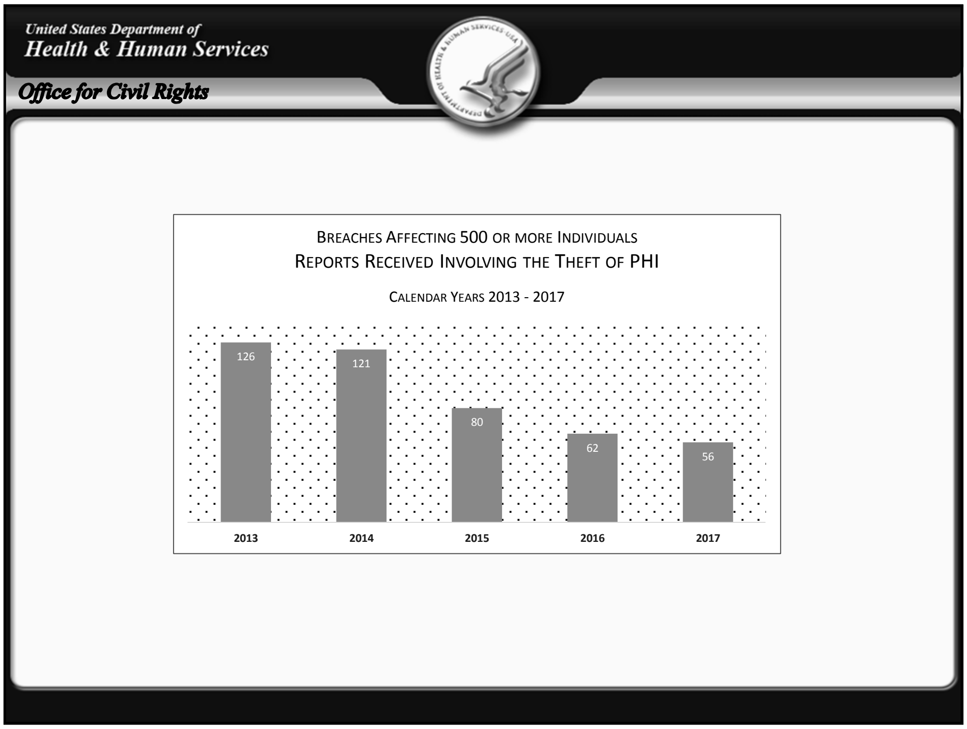
500+ Breaches by Location

September 23, 2009 through December 31, 2018

January 1, 2018 through December 31, 2018



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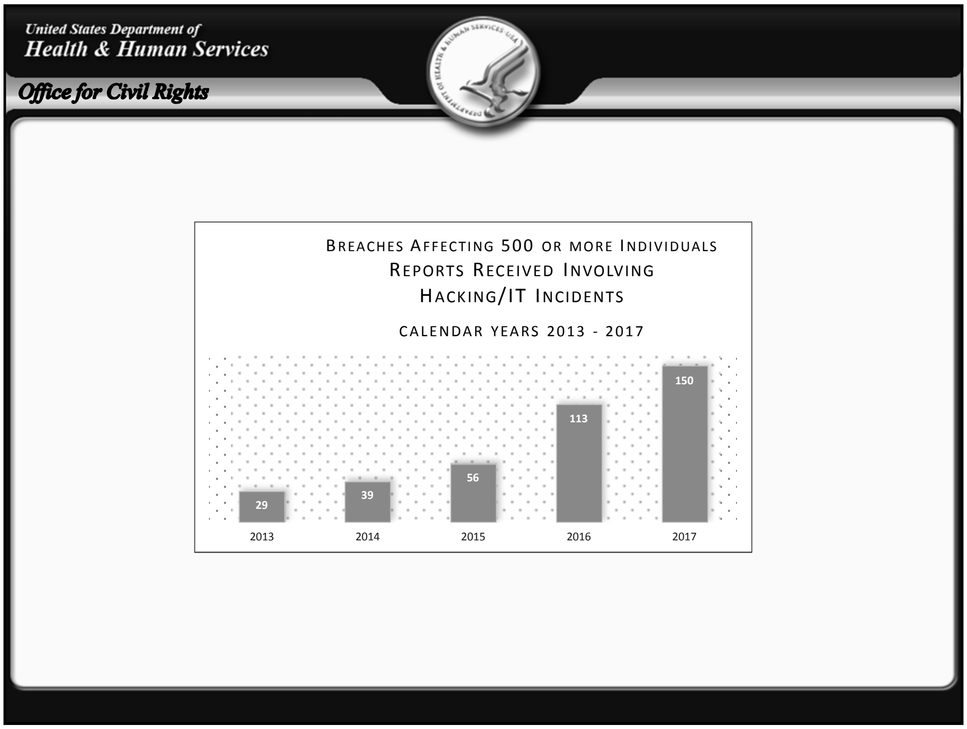
Breaches Affecting 500 or more Individuals
Reports Received Involving the Theft of PHI

Calendar Years 2013 - 2017



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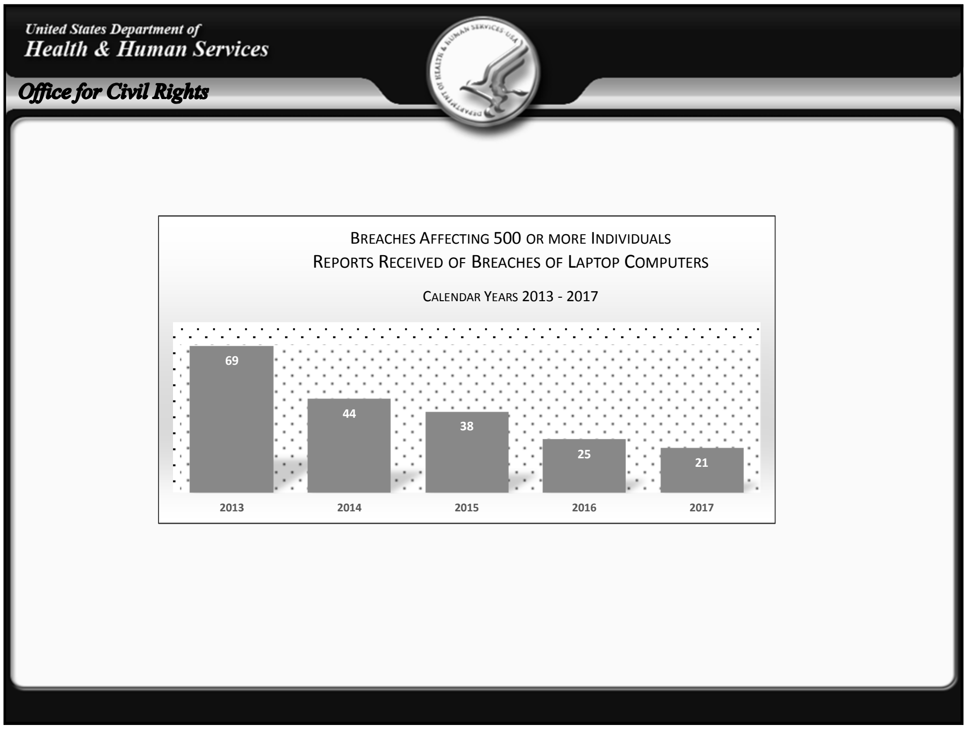
Breaches Affecting 500 or more Individuals
Reports Received Involving
Hacking/IT Incidents

Calendar Years 2013 - 2017



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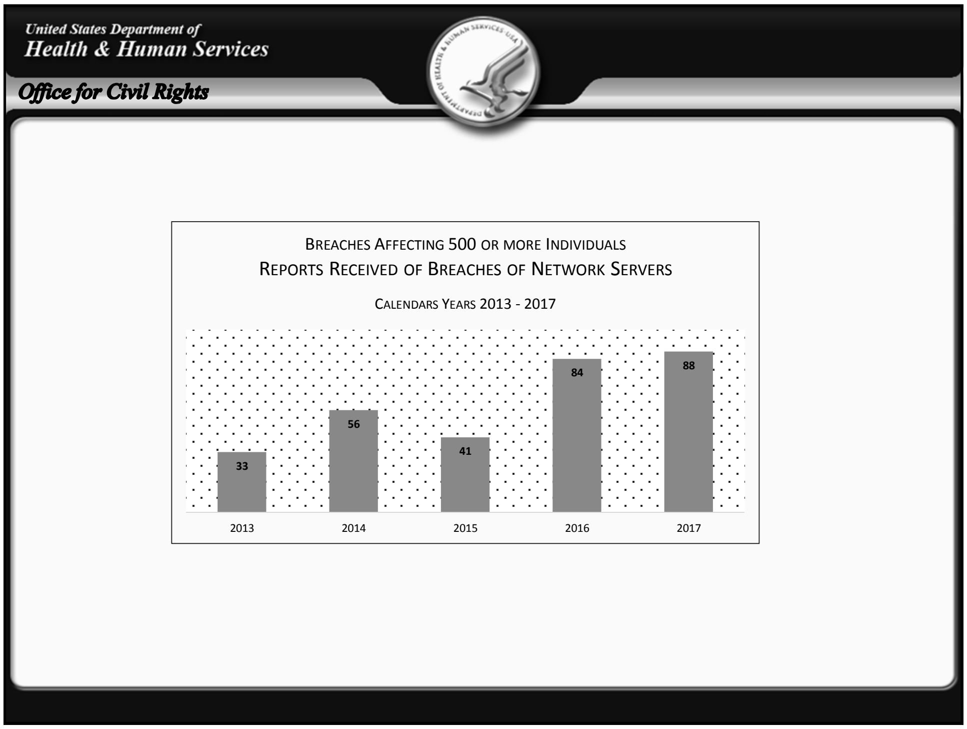
BREACHES AFFECTING 500 OR MORE INDIVIDUALS
REPORTS RECEIVED OF BREACHES OF LAPTOP COMPUTERS

CALENDAR YEARS 2013 - 2017



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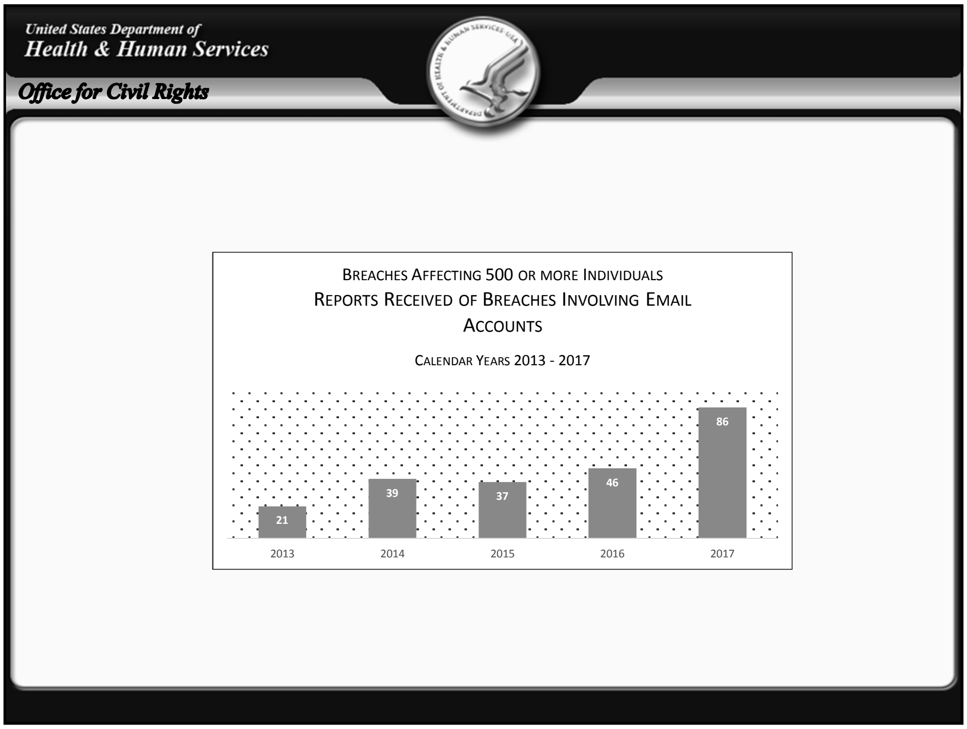
BREACHES AFFECTING 500 OR MORE INDIVIDUALS
REPORTS RECEIVED OF BREACHES OF NETWORK SERVERS

CALENDARS YEARS 2013 - 2017



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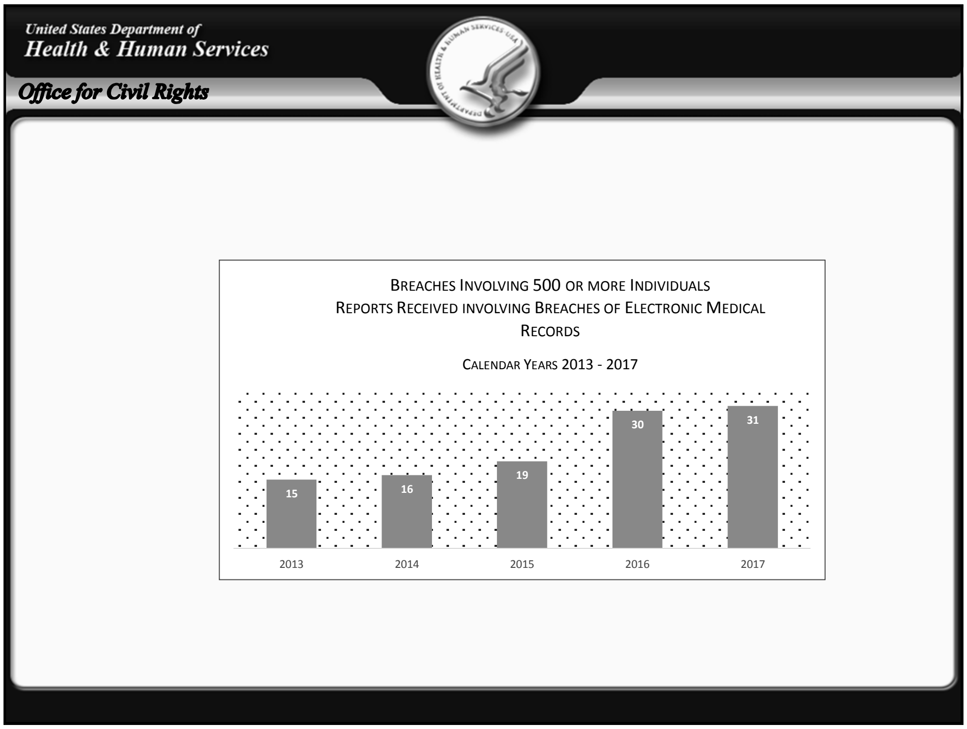
BREACHES AFFECTING 500 OR MORE INDIVIDUALS
REPORTS RECEIVED OF BREACHES INVOLVING EMAIL ACCOUNTS

CALENDAR YEARS 2013 - 2017



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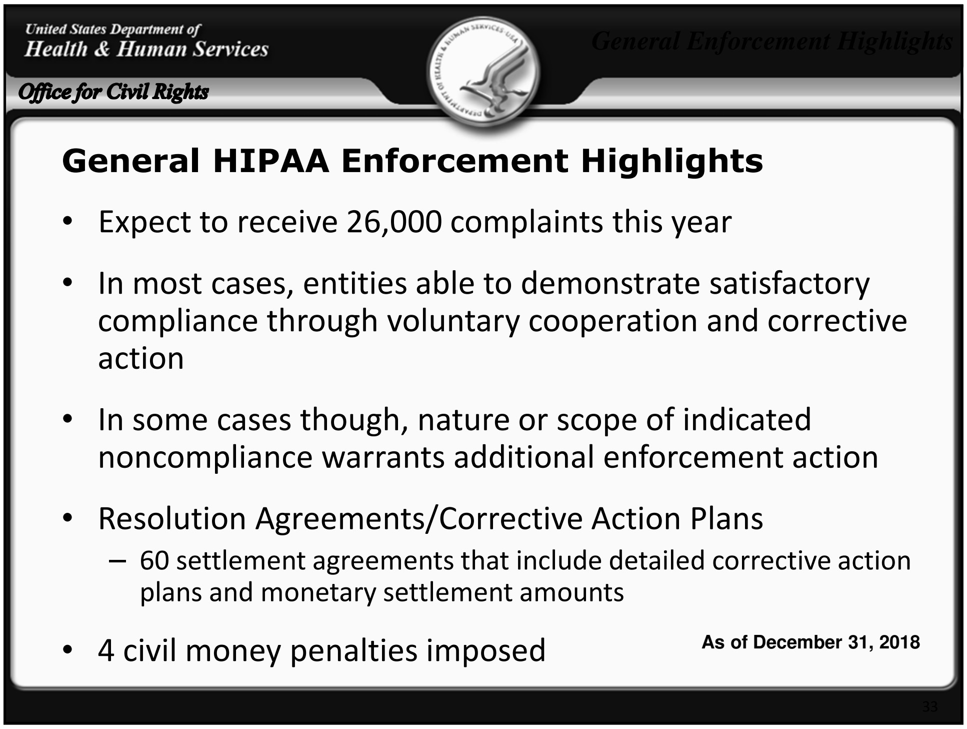
BREACHES INVOLVING 500 OR MORE INDIVIDUALS
REPORTS RECEIVED INVOLVING BREACHES OF ELECTRONIC MEDICAL RECORDS

CALENDAR YEARS 2013 - 2017



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General Enforcement Highlights

General HIPAA Enforcement Highlights

- Expect to receive 26,000 complaints this year
- 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
  - 60 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 4 civil money penalties imposed

As of December 31, 2018

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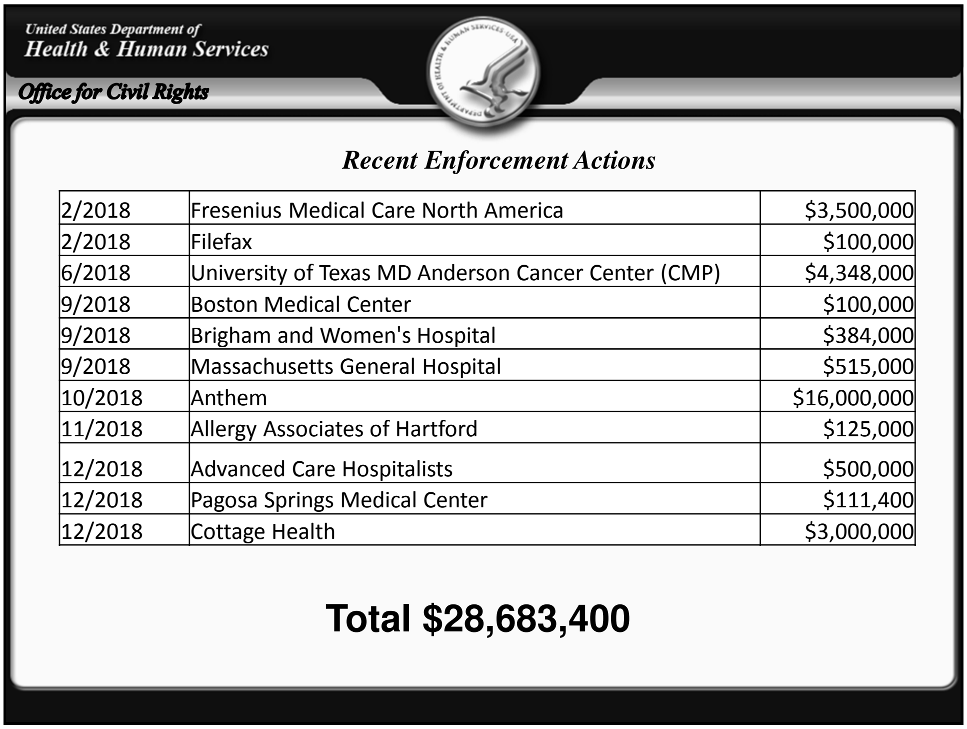

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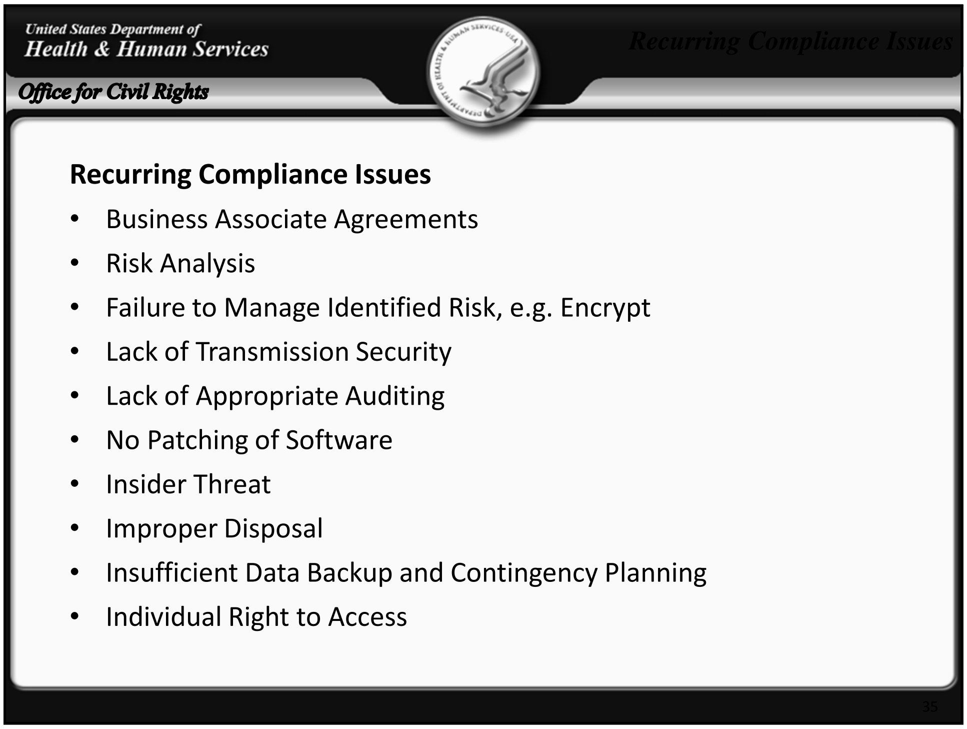
Recent Enforcement Actions

2/2018	Fresenius Medical Care North America	$3,500,000
2/2018	Filefax	$100,000
6/2018	University of Texas MD Anderson Cancer Center (CMP)	$4,348,000
9/2018	Boston Medical Center	$100,000
9/2018	Brigham and Women's Hospital	$384,000
9/2018	Massachusetts General Hospital	$515,000
10/2018	Anthem	$16,000,000
11/2018	Allergy Associates of Hartford	$125,000
12/2018	Advanced Care Hospitalists	$500,000
12/2018	Pagosa Springs Medical Center	$111,400
12/2018	Cottage Health	$3,000,000

Total $28,683,400



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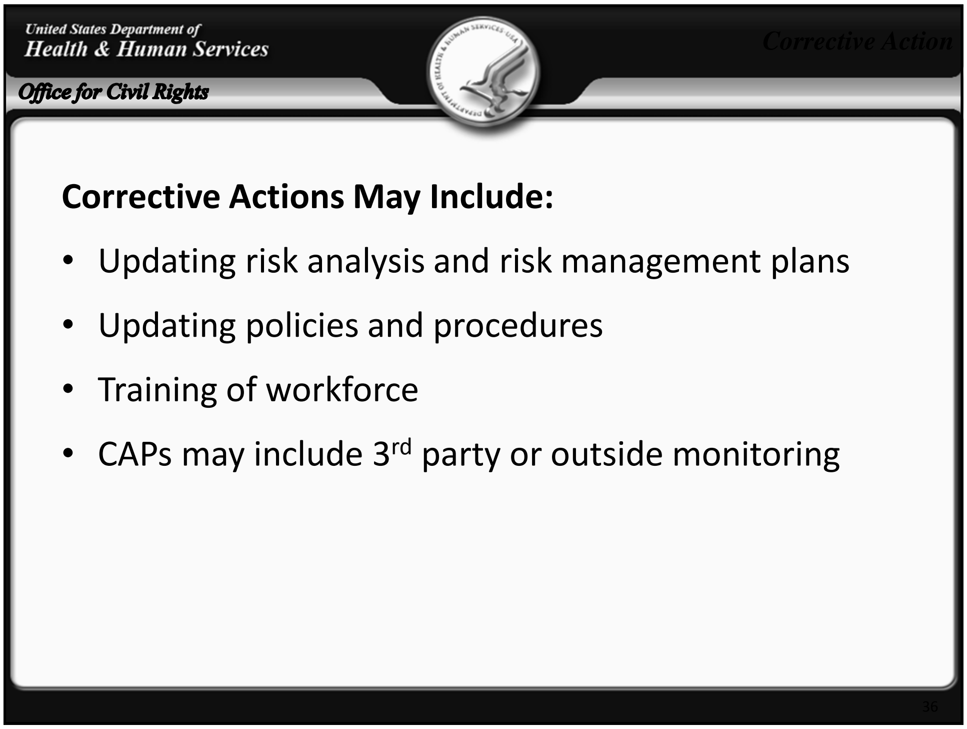
Recurring Compliance Issues

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
- Individual Right to Access



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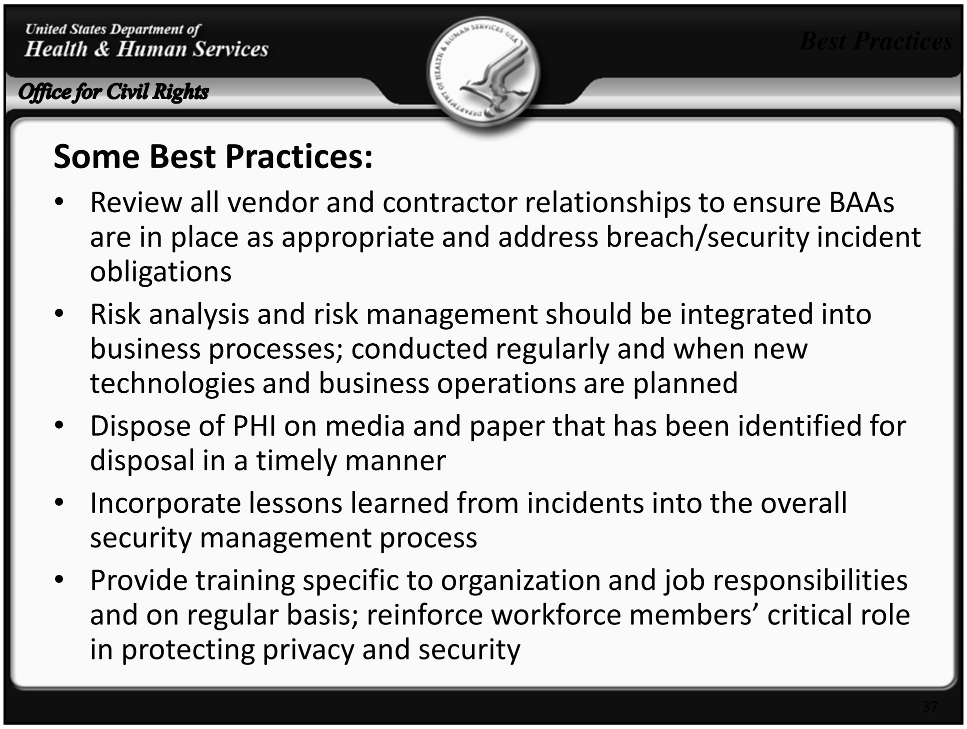
Corrective Action

Corrective Actions May Include:

- Updating risk analysis and risk management plans
- Updating policies and procedures
- Training of workforce
- CAPs may include 3rd party or outside monitoring



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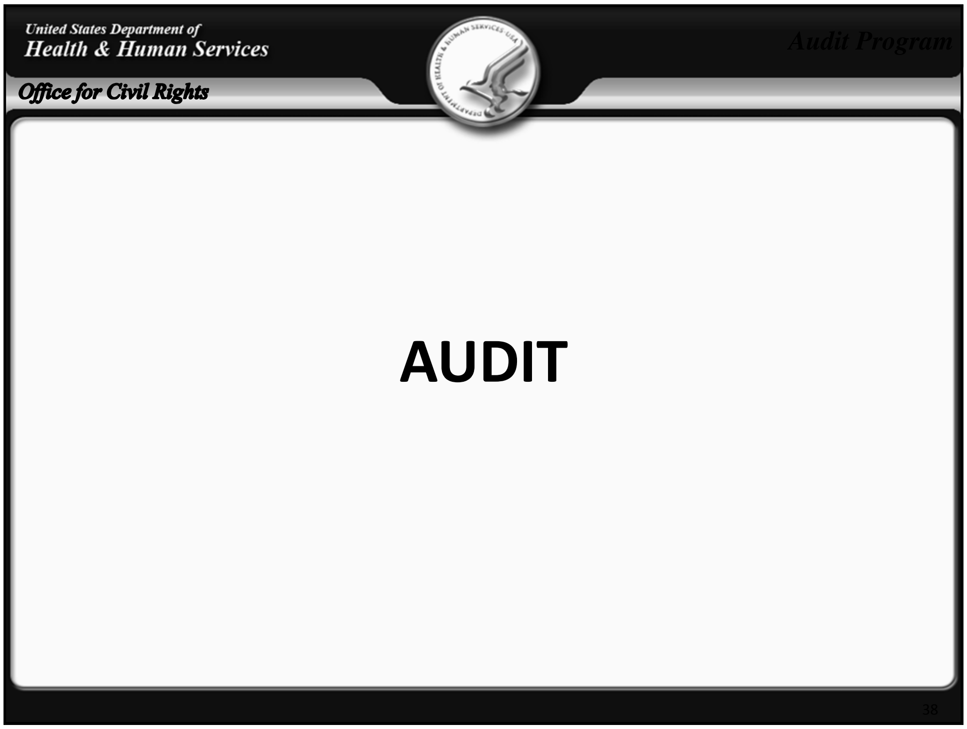
Best Practices

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



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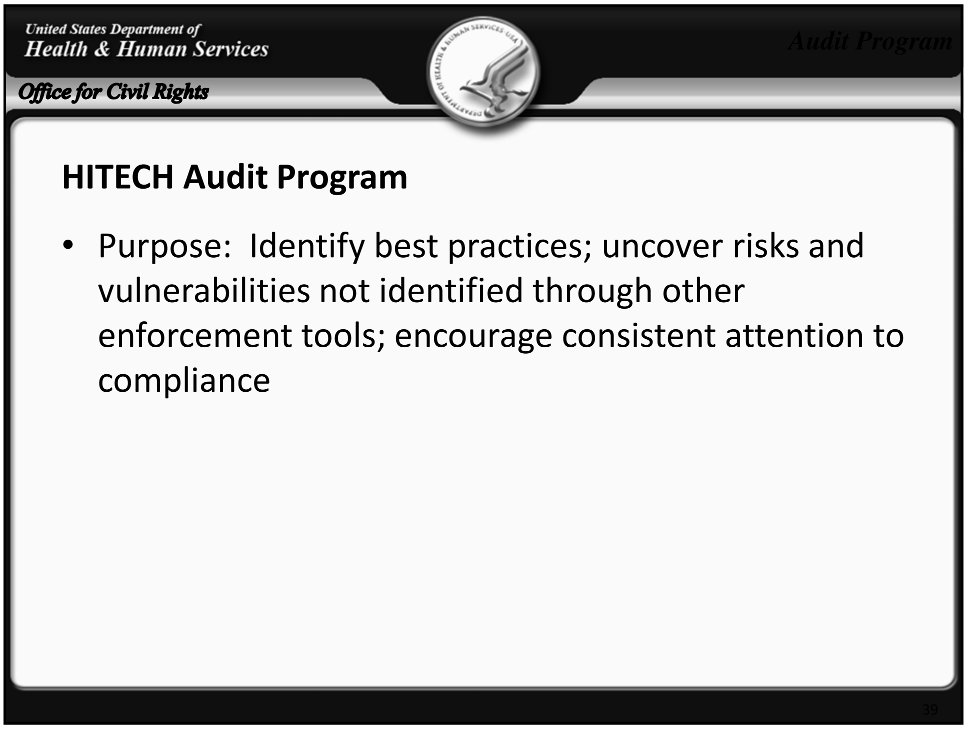
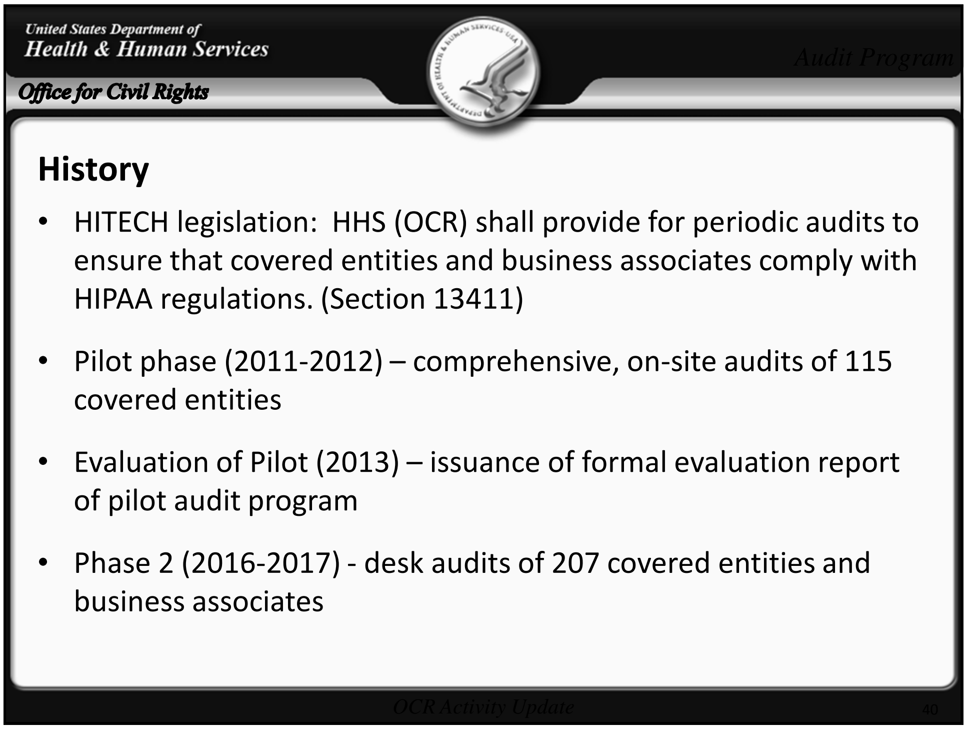
Audit Program

AUDIT



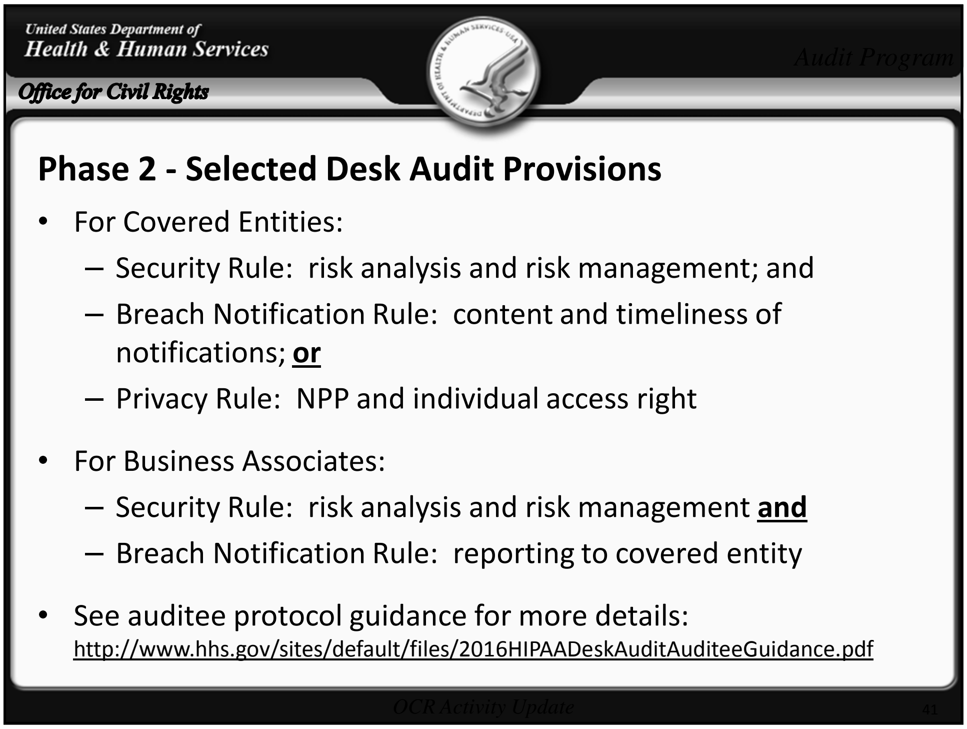
HITECH Audit Program

- Purpose: Identify best practices; uncover risks and vulnerabilities not identified through other enforcement tools; encourage consistent attention to compliance



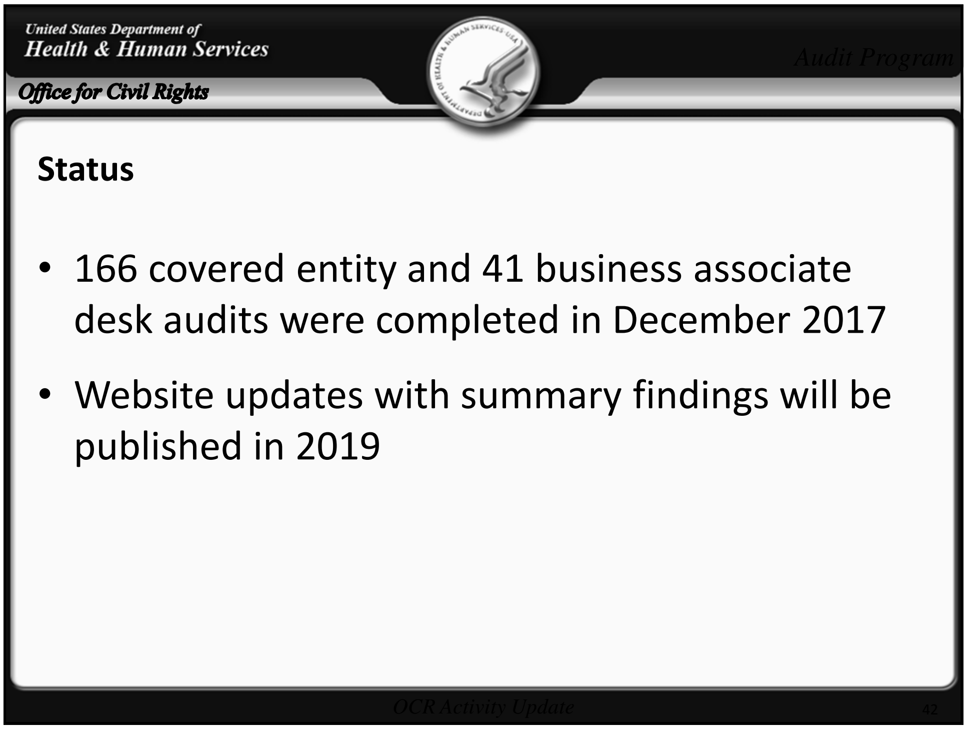
History

- 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



Phase 2 - Selected Desk Audit Provisions

- For Covered Entities:
  - Security Rule: risk analysis and risk management; and
  - 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



Status

- 166 covered entity and 41 business associate desk audits were completed in December 2017
- Website updates with summary findings will be published in 2019

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

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

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

Right to Access Your Health Information Under HIPAA

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

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.

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.

Includes:
Links to Fact Sheets and FAQs, Videos, Poster, Brochure
Digital Ads and Banners, Mobile Platform
Also – a link to join All of Us Research Initiative

INFORMATION IS POWERFUL MEDICINE
Access to your health information is your right
Get it. Check it. Use it.

HHS.gov/GetItCheckItUseIt

United States Department of
Health & Human Services

Office for Civil Rights

More Information

http://www.hhs.gov/hipaa

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