Operationalizing Government Corrective Action Plans: Aftermath of an OCR Investigation

Presented By:

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Audience Ice Breaker & Polling

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A Quick Recap

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Learning Objectives

1. Discuss key components of carrying out a Corrective Action Plan (CAP): People, Planning and Process
2. Consider unanticipated government challenges, external resources and cost
3. Discover what complex organizations should consider in their training programs

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Discuss key components of carrying out a Corrective Action Plan (CAP): People, Planning and Process

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Elements of an Office for Civil Rights (OCR) CAP

Security Management Process
- Risk analysis

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Elements of an Office for Civil Rights (OCR) CAP

Implementation of Process for Evaluating Environmental and Operational Changes
- Standard Operating Procedure (SOPs)

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Elements of a CAP (continued)

Policies and Procedures (P&Ps)
- Distribution and Updating P&Ps
- Minimum Content
- Certifications

Minimum content:
- Uses and Disclosures of PHI [45CFR§164.502(a)]
- Security Management Process [45CFR§164.308(a)(1)(i)]
- Information Access Management [45CFR§164.308(a)(4)]
- Workstation Security [45CFR§164.310(c)]
- Device and Media Controls [45CFR§164.310(d)]
- Encryption and Decryption [45CFR§164.312(a)(2)(iv) & 164.312(e)(2)(ii)]

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Elements of a CAP (continued)

Health Information Portability and Accountability Act (HIPAA) Training for Workforce

- Certifications
- Tracking existing and new hires

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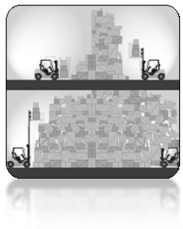
Reporting & Other Requirements

1. Reportable Events
2. Implementation Report
3. Annual Reports
4. Document Retention
5. Breach Provisions



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People

Our workgroup included senior representatives with ***decision making authority*** from:

- Organizational Leadership
- Administration/Operations
- Compliance
- Legal
- IT Security/Risk Management
- Public Relations
- Human Resources
- Policy and Training

The workgroup may include others and will evolve over time

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Planning

- Developing a timeline for the CAP
- Regularly occurring touch points/meetings
- Setting expectations
- Communications

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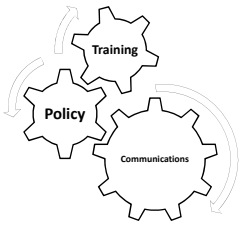
Processes

- Establish smaller working groups to evaluate and develop processes
- Connection to larger organizational Committees



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Consider unanticipated government challenges, external resources and cost

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Things to Think About

Compliance

- Contact, reporting progress & issues
- Tracking and reporting to OCR
- Reporting upwards

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Things to Think About

Legal:

- Dedicated internal legal counsel
- Outside counsel with OCR experience
- Response strategy and time frames

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Things to Think About

Operational:

- Administration
- Developing processes

→ *Think about hiring a Project Manager*

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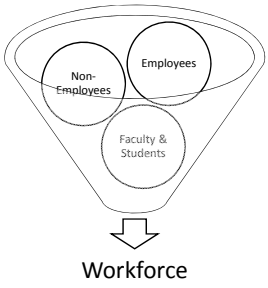
Who is Your Workforce?

Operational:

- Tracking workforce
- Communications
- Reporting to Compliance



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Things to Think About

IT Security

- Risk Assessments & timeframes
- Vendors
- Costs

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Things to Think About

Education and Training:

- Electronic vs. in-person
- Pilot testing
- Tracking and reporting
- HR and escalation procedures

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When you thought you got it all covered…

Changes:

- People (transition planning)
- Process (ensuring stakeholders & leadership are aware of ongoing CAP)

Timing:

- Expectations
- The unknown

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Timelines are complicated

Post Resolution Obligations

HHS/OCR Agreement signed <Date>	Submit Risk Analysis to OCR (180 days)	OCR approval of Risk Analysis	Submit Risk Management Plan (RMP) to OCR by (90 days)	OCR approval of RMP	1) *Implement RMP* (90 days) 2) Submit Policies and Procedures to OCR (60 days)	OCR approval of Policies and Procedures	1) Distribute P&Ps to: • Current workforce *(60 days)* • New workforce (30 days) *Signed compliance certification* 2) Submit training materials to OCR (60 days) 3) Implementation Report (120 days)	OCR approval of training	1) Provide training to: • Current workforce *(90 days & annually)* • New workforce (30 days & annually) • LOA workforce (30 days from return & annually) *Signed compliance certification*
	Submit process to evaluate environmental and operational changes in the environment to OCR (120 days)	HHS approval of Process *Date>*	Implement process & submit to workforce members responsible for implementing process by (90 days)						

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Timelines are complicated

Annual Obligations

	Term I	Term II	Term III
HHS/OCR agreement signed <Date> **3 years**	Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI & document security measure taken • *Assessment date:*	Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI & document security measure taken • *Assessment date:*	Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI & document security measure taken • *Assessment date:*
	Review and revise Policies and Procedures as needed, submit to HHS for approval and distribute to workforce	Review and revise Policies and Procedures as needed, submit to HHS for approval and distribute to workforce	Review and revise Policies and Procedures as needed, submit to HHS for approval and distribute to workforce • Annual review of P&Ps:
	Review and revise training as needed	Review and revise training as needed	Review and revise training as needed • Annual review of training:
	Annual Report (60 days) • *Submission date:*	Annual Report (60 days) • *Submission date:*	Annual Report (60 days) • *Submission date:*
	Submit Reportable events (Ongoing within 30 days) • *Reportable Event Submission date:* • *Reportable Event Submission date:* • *Reportable Event Submission date:*	Submit Reportable events (Ongoing within 30 days) • *Reportable Event Submission date:* • *Reportable Event Submission date:* • *Reportable Event Submission date:*	Submit Reportable events (Ongoing within 30 days) • *Reportable Event Submission date:* • *Reportable Event Submission date:* • *Reportable Event Submission date:*

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Guess how far we are…

Post Resolution Obligations

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Discover what complex organizations should consider in their training programs

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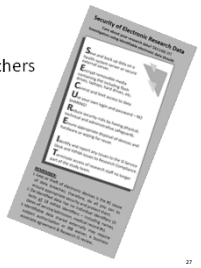
Focus on Implementing Controls

Communication & Dissemination of Policies

Education & Training Programs for Researchers

- Research orientation/onboarding for researchers
- Ongoing HIPAA training
- Development of tools & guidance

→ *Increasing awareness is key*



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Focus on Implementing Controls (Continued)

Institutional HIPAA Privacy & Security Review Process for Research

- Human Research Protection Program (HRPP)
- Pre-reviews/consultations by Research IT
- Use information from process to inform education and training & guidance documents

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Monitoring & Detection

Office of Research Compliance

- Routine reviews and for-cause investigations
- Monitoring PHI
- HIPAA Rounding Audits

Working collaboratively with:

- Research IT Security/Information Systems
- Corporate Compliance
  - Software detection systems
- Researchers

→ *Information used to inform education and training*

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Evaluating Risks

Larger System Level Committees:

- Research Information Security and Compliance (RISC) Committee
- Protected Health Information (PHI) Committee
- IT Risk Governance Committee

Other Sources:

- Internal & external compliance reviews
- Risk Assessments with key stakeholders
- Evaluating regulatory environment and market trends

→ *Information used to inform education and training for broader group*

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Month Day, Year

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Month Day, Year

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