Successfully Resolving a Multi-Year OCR Investigation

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Agenda

- Anatomy of a Breach
- Responding to the Office for Civil Rights
- A Focus on Corrective Action
CenterLight at a Glance

- Not-for-profit leader in managed long term care since 1985
- Integrated provider-payer
- Largest Program of All-inclusive Care for the Elderly (PACE) in the nation — 3,400+ members
- 5,800+ Partial Capitation MLTC Plan members (2016)
- Over 1000 I-SNP managed care members residing in skilled nursing facilities

Embedded in a Long-Term Care Continuum

- **Nursing homes**
  Skilled nursing, short-term rehabilitation and long-term residential care.

- **Skilled nursing at home**
  Our Certified Home Health Agency (CHHA) to help regain function following injury or surgery.

- **Assistance at home**
  Our Licensed Home Care Services Agency (LHCSA) provides assistance with activities of daily living.

- **Independent housing**
  Four housing facilities in the Bronx, staffed by CenterLight professionals and subsidized by New York City and New York State funding programs.

- **Music therapy**
  Groundbreaking techniques that harness the power of music to heal and recover physical and cognitive function.
Setting the Scene…

- Temp hired to process new member enrollments
- Temp downloads and emails files containing PHI to his personal email account
- Email with PHI was not identified by security controls
- Compliance Office receives a report of potentially suspicious activity
- Investigation initiated and incident identified

What Happened Next?

1. Conducted breach risk assessment to assess situation and to stem further disclosure
2. Complete an Incident Report
3. Determine if incident is a breach
4. Gather documentation
5. Mobilize incident response team
Who Did We Involve?

- Department Involved and Temp agency
- Customer Service/Finance/IT/Human Resources
- Healthcare IT Consultant
- HIPAA Counsel
- Credit Monitoring Services
- Corporate Communications / PR Team
- Board of Directors

Notification Process

1. Drafted and notified impacted members
2. Placed ad in local paper
3. Notified OCR, CMS, if applicable and State Attorney General (depending on State law requirements)
4. Trained customer service, develop FAQ
5. Contacted Business Associate (Temp vendor) involved
Be Prepared to Wait…

- Gather documentation to support your case
  - Training materials
  - Privacy & Security policies and procedures
  - Disciplinary action policies
- Further assess risks - consider whether you have adequate resources to do risk assessment or hire consultant with expertise in HIPAA Privacy & Security
- Consult with HIPAA counsel

Enforcement Highlights (as of 12/31/16)

- Corrective Action, 24,774, 18%
- Technical Assistance, 17,905, 11%
- No Violation, 11,133, 8%
- Settlement/CMP, 41, 0%
### Potential Violations

<table>
<thead>
<tr>
<th>Potential Violation</th>
<th>Description</th>
<th># of Years</th>
<th>Potential CMP</th>
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<td>§ 164.502(a)</td>
<td>Disclosure</td>
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<td>Minimum Necessary</td>
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<td>§ 164.530(c)</td>
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<td>§ 164.308(a)(1)(ii)(A)</td>
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<td>Risk Management</td>
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<tr>
<td>§ 164.308(a)(1)(ii)(D)</td>
<td>Information System Activity Review</td>
<td>6</td>
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<td>§ 164.308(a)(6)(ii)</td>
<td>Security Incident</td>
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<td>§ 164.310(a)(1)</td>
<td>Facility Access Controls</td>
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<tr>
<td>§ 164.312(a)(2)(iv)</td>
<td>Encryption (at rest)</td>
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<tr>
<td>§ 164.312(b)</td>
<td>Audit Controls</td>
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<td>§ 164.312(d)</td>
<td>Authentication</td>
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<td>§ 164.312(e)(1)</td>
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<td><strong>Total</strong></td>
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<td><strong>$94.5M</strong></td>
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### What OCR Is Focused On

- Corrective Action
- Risk Analysis
- Risk Management
- Policies and Procedures
- Training
- Sanctions
How to Respond to OCR

- Collaborative rather than adversarial
- Transparent rather than obscuring
- Recognize gaps and explain future corrective action

Drafting a Response

- Don’t merely respond to specific requests; provide a complete picture
- Highlight a culture of compliance
- Professional and gracious tone
- Include relevant supporting documentation as attachments
- Consider Bates stamping attachments
Corrective Action Plan

If you don’t provide a solution a solution will be provided for you that you may not like

- Corrective Action Plan Characteristics
  - Identified Risk
  - Risk level (e.g., High, Med, Low)
  - Remediation Steps
  - Owner
  - Timeframe
  - Status and progress

Corrective Action Plan - Governance

- Executive accountability
- Project management
- Roles and responsibilities
- Regular status updates and progress reporting
Corrective Action Plan - Scope

- Policy updates
- Process documentation
- People
  - Skillsets
  - Contract resources
  - Consulting
- Technology Solutions
  - Patch management
  - Two factor authentication
  - Monitoring solution

Corrective Action Plan – Key Considerations

- Don’t set yourself up to fail:
  - Timing (i.e., start and end dates)
  - Level of effort (i.e., FTE effort to get the work done)
  - Investment (i.e., budget)
  - Skillsets
  - Dependencies
  - At first focus on quick wins
Corrective Action – Challenges

- Accommodating for all exceptions
- Fixes that have dependencies on various teams
  - Secure configuration
  - Patch management
- Fixes that require technical components
  - Strong authentication
  - Logging and monitoring
- Fixes that require significant process improvements
  - Access reviews
  - Vendor assessments

"Better a diamond with a flaw than a pebble without."
— Confucius

Final thoughts

- The corrective action plan should not become the security strategy
- The security strategy should encompass the corrective action plan
- Continue to update risk assessments and adjust priorities accordingly
- Fully leverage the moment to increase management’s attention and support
Questions?

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