

Keeping you "in the know" in the ASC industry



THE HITECH ACT

- 2009 HEALTH INFORMATION AND TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH (HITECH) ACT
 - Expanded Privacy and Security Rules
 - Changed the breach standard (no more harm standard)
 - Increased penalties for violations
 - Business Associates (entities that create, receive, maintain, or transmit PHI on behalf of a CE) have increased obligations and independent liability

WHAT IS A BREACH?

- "an acquisition, access, use, or disclosure of protected health information in a manner not permitted under... [the Privacy Rule] is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment..."
 - A breach can only occur in connection with "unsecured protected health information" – essentially translates to unencrypted PHI
 - LIMITED EXCEPTIONS: (1) unintentional workforce access, (2) inadvertent disclosure to authorized person and (3) "good faith" belief that unauthorized person could not retain the data disclosed

HOW TO RESPOND TO A BREACH UNDER HIPAA

- Covered Entities and Business Associates can demonstrate a low probability that the PHI has been compromised based on a risk assessment that includes at least the following factors:
 - 1) The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
 - 2) The unauthorized person who used the PHI or to whom the disclosure was made;
 - 3) Whether the PHI was actually acquired or viewed; and
 - 4) The extent to which the risk to the PHI has been mitigated.
- This incident-specific risk assessment must be documented
- May consider additional factors

HOW TO RESPOND TO A BREACH UNDER HIPAA

IN THE EVENT OF A BREACH, NOTICE MUST BE GIVEN TO:

- 1) All affected individuals
 - notice should be written but can be electronic, telephonic or by substitute
 - notification must be provided without unreasonable delay and in no case later than 60 days following discovery of a breach
 - written notice must include
 - a brief description of the breach
 - a description of the types of data involved in the breach,
 - the steps affected persons should take to protect themselves from harm,
 - a brief description of what the CE is doing to investigate the breach, mitigate the harm, and prevent further breaches,
 - contact information for the CE (or BA, as applicable).

HOW TO RESPOND TO A BREACH UNDER HIPAA

IN THE EVENT OF A BREACH, NOTICE MUST BE GIVEN TO:

- 2) Prominent media outlets must be notified when more than 500 residents of a State or jurisdiction are affected
 - media notice must be provided without unreasonable delay and no later than 60 days following discovery, and must include the information that affected individuals receive
 - notice must be given to prominent media outlets within the State or jurisdiction more than 500 affected individuals reside

HOW TO RESPOND TO A BREACH UNDER HIPAA

IN THE EVENT OF A BREACH, NOTICE MUST BE GIVEN TO:

- 3) The Secretary of HHS, through OCR
 - In addition to notifying affected individuals and the media, CEs must notify the Secretary by completing the online HHS form
 - If a breach affects 500 or more individuals, CE must notify the Secretary without unreasonable delay and no later than 60 days
 - If a breach affects less than 500 individuals, CE may notify the Secretary on an annual basis, reports of breaches affecting fewer than 500 individuals are due within 60 days of the end of the calendar year in which the breaches are discovered

HOW TO RESPOND TO A BREACH UNDER HIPAA

OTHER REQUIREMENTS IN THE EVENT OF A BREACH:

- A CE must mitigate any ongoing or harmful effects of a breach
- A CE must conduct a breach-incident assessment that identifies
 the causes and vulnerabilities involved in the breach and
 develops an appropriate remedial plan and remedial actions to
 address the causes and vulnerabilities associated with the
 breach incident and improves the CE's privacy and security
 protections
 - this breach assessment should include an analysis of these four factors in assessing the probability of data compromise: (1) nature and extent of the PHI involved; (2) the unauthorized person who used/accessed the PHI; (3) whether the PHI was actually acquired or viewed; (4) the extent the risk to the PHI was mitigated.

WHY COMPLY WITH HIPAA

- Can be Criminal: It is a federal crime to obtain or disclose PHI
 without authorization knowingly, under false pretenses or with
 intent to sell, transfer, or use PHI for commercial or personal gain
 or malicious harm.
- Duty to Self-Report: Business Associates must report breaches to Covered Entities and Covered Entities must self-report HIPAA breaches of unsecured PHI to the individual affected, HHS, and, when the breach affects 500 or more individuals, to the media.
- Stiff Civil Penalties: Federal Office for Civil Rights is required to impose HIPAA penalties if the Covered Entity or Business Associate acted with willful neglect (i.e., with "conscious, intentional failure or reckless indifference to the obligation to comply" with HIPAA).

CIVIL PENALTIES UNDER HIPAA

CONDUCT OF CE OR BA

Did not know of violation and, by exercising reasonable diligence, would not have known

Violation is due to reasonable cause and not willful neglect

Violation is due to willful neglect but is corrected within 30 days after covered entity knew or should have known of violation

Violation due to willful neglect and not corrected within 30 days after covered entity knew or should have known

PENALTIES

\$100 to \$50,000 per violation; Up to \$1,500,000 per identical violation per year

\$1,000 to \$50,000 per violation; Up to \$1,500,000 per identical violation per year

Mandatory fine of \$10,000 to \$50,000 per violation; Up to \$1,500,000 per identical violation per year

Mandatory fine of at least \$50,000 per violation; Up to \$1,500,000 per identical violation per year

DATA SECURITY BREACH ACTION PLAN

- 1. Assign responsibility for breach response (Security Officer)
- 2. Train the assigned person and your workforce about breach reporting and applicable legal obligations
- 3. Create a breach response policy and procedure
- 4. Immediately collect all necessary data about the incident
 - names of involved workforce members and time of report
 - nature of the incident (systems, equipment and persons involved)
 - the way in which the incident was detected, including date/time the incident was first noticed
 - details about the origin of the attack or breach, IP address, name(s) and any information available about

DATA SECURITY BREACH ACTION PLAN

- 5. Designated breach response person or team must assess and begin documenting the incident:
 - Is the incident a reportable breach (real or perceived)
 - Is the incident still in progress and can it be quickly contained
 - The nature of the incident and whether outside assistance is needed (law enforcement, legal, information technology)
 - What data, assets and property is threatened and how critical is it, including impact an asset's loss would have on the business
 - The overall severity of the incident and its potential impact
 - The names and locations of the systems being targeted

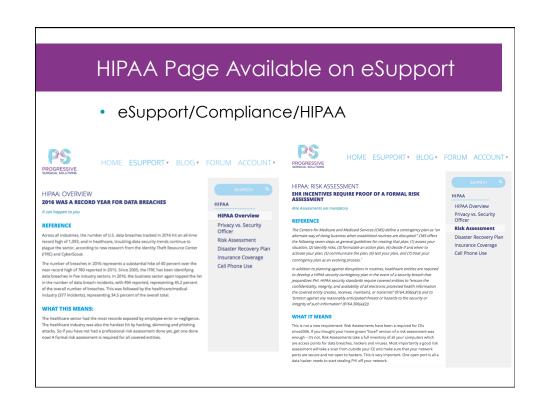
DATA SECURITY BREACH ACTION PLAN

- 6. Investigate the incident immediately
 - Begin compiling a spreadsheet with contact information for all affected individuals and the types of PHI involved in the breach
 - Review all evidence, system activity and logs for relevant data
 - Interview witnesses, including all BA or workforce members
- 7. Develop a plan to mitigate any negative effects and securing all systems and PHI that were compromised
- 8. Implement plan and restore compromised systems and data, make necessary notifications and reports

9. Document a risk assessment, including the following: • Summary of the incident, including key details, dates, discovery, etc. • If applicable, the origin of the breach or attack • Details of the response plan, mitigation efforts and investigation • Nature and extent that your PHI, data and records were involved • An assessment of the incident-specific risk • Conclusions and findings about whether the response was effective • Corrective and preventative actions taken 10. Take steps to make sure all evidence of the incident is preserved and not lost

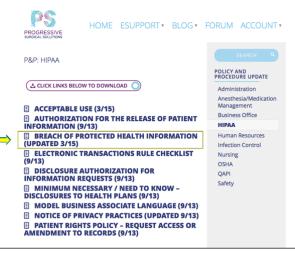






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Mark Your Calendars



July 24, 2017 11am PT/2am ET PURCHASING AND SUPPLY CHAIN

Brian Valley McKesson

September 18, 2017 11am PT/ 2am ET MINIMIZING THE RISK OF LEGAL CLAIMS/LIABILITY

Will Miller

Mark Your Calendars



August 25, 2017 11am PT/ 2am ET COMPOUNDING PHARMACIES

Prima Pharma

