

What's Your Compliance IQ?

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HIPAA News

2020 was the worst year yet for healthcare industry HIPAA breaches. There were 616 with 500 or more records breached. 28,756,445 healthcare records were exposed, compromised, or impermissibly disclosed in these breaches.

A new Check Point report shows a 45% increase of cyberattacks on healthcare organizations globally in November & December, 2020. While it is still common for ransomware to be distributed via spam mail & exploit kits, the healthcare attacks have been highly targeted with the main variants used in them delivered manually.

While most phishing attacks occur in the week during business hours, ransomware attacks commonly occur over the weekend & during hol-

idays when security staff monitoring is likely reduced.

A U.S. Court of Appeals has vacated a \$4.3M civil monetary penalty against the University of Texas M.D. Anderson Cancer Center in the wake of 3 breaches involving unencrypted mobile devices. The court called the penalty arbitrary, capricious, & contrary to law.

M.D. Anderson had provided the associates involved with an ironkey to encrypt & decrypt mobile devices & had educated them on its use. The court also took issue with whether PHI had actually been released to outside entities. Calculation of the penalty by HHS was also criticized & said other covered entities with similar breaches had zero financial penalties. The HHS OCR has revised interpretation of HI-

TECH Act penalty caps lowering fines for less egregious violations. The ruling sets forth entities & business associates must implement an encryption mechanism but is not responsible for violating the HIPAA Security Rule if the workforce does not use the mechanism. The ruling could trigger HIPAA regulation changes if HHS does not challenge the ruling.

Providers get mixed results for HIPAA compliance in the December OCR HIPAA audit. Most Covered Entities met timeliness for notification to individuals of breaches, prominently posted Notice of Privacy Practices (NPP). Bad news: most CEs failed to provide all required information in NPP & breach notifications to individuals & properly implement right to access & HIPAA Security Rule requirements.

Compliance News

The Price Transparency Rule began its rollout 1-1-21. The rule will require providers to post the rates they have negotiated with health plans.

The AHA warned CMS hospitals lack clarity on how to implement it. Unless there is court intervention, hospitals will be forced to devote staff time to comply with the rule.

CMS continues to work with Accrediting Organizations on providing some remote flexibilities in conducting surveys. Once the COVID Public Health Emergency is over, facilities must be ready for a survey. There will be no grace period. It will be operations as usual after the emergency is over.

Complying with Laboratory Ser-

vices Documentation Requirements has been revised clarifying documentation requirements and clarifying the term "standing orders."

A signed order, requisition, or medical record supporting the physician's intent to order tests satisfies the requirement for laboratory tests. All diagnostic laboratory services must include this as well as medical necessity documentation.

HHS has finalized a rule requiring the agency to review all existing regulations & sunset any not meeting certain criteria. The agency has 5 years to review regulations 10 years or older (estimated 2480 of them). The rule will also require review of rules every 10 years. If HHS does not review & assess a regulation, it will expire; rule does not apply to a

regulation jointly released with another agency. Regulations outlined annually for the ACA are also exempt.

The DOJ received \$1.8B in recoveries involving healthcare fraud & false claims in FY 2020. These are part of the \$2.2B from False Claim Act cases; over \$1.6B of these arose from lawsuits from whistleblower provisions under the act.

CMS has released guidance on how state surveyors will focus on COVID-19 testing reporting. That guidance is for CLIA-accredited laboratories and can be found at <https://www.cms.gov/files/document/gso-21-10-clia.pdf>. Ten probe questions have been suggested for surveyors. Insight into how to avoid citations is also provided.

Safety

When there is civil unrest outside a facility, education of staff regarding screening protocols for identifying people who should not be in your facility or on your property should be done.

Facilities should be prepared for patients from opposing sides in the Emergency Room or other facility sites. Frayed nerves from the pandemic will only serve to make matters worse. Staff must be prepared as the country continues to experience this unrest.

NIST has developed a free tool that estimates exposure to potentially infectious aerosols from people in a room. Calculations

are based on information from the aerosols themselves as well as the room's HVAC system & air filters. It is designed to help building managers to better identify strategies that could help reduce exposure to COVID-19 in indoor spaces.

Biohazard transport bags with a perforation going through the Biohazard symbol are designed to make them acceptable for the regular trash when the bag is torn there—cannot be visually bloody, etc. Some state agencies might not accept this & the state EPA individual should be consulted to be sure it can be used in the state.

CLSI's *Clinical Laboratory Safety*

states cell phones should not be used in the laboratory because of infection control issues; use in the lab has led to lab-acquired infections. If a cell phone is required, it should remain in the laboratory.

CDC lab safety guidance states carpets & rugs are not allowed in the laboratory; this is not a regulation but the document is considered best practice & is followed.

CAP (on checklist) states ALL chemicals need an assigned expiration data. If there is not one on the item, one should be assigned based on use frequency, storage conditions, & risk of deterioration. Lab should test usability/stability.

Miscellaneous

Can labs require their associates to take the COVID-19 vaccine? The answer is probably but not a 100% certainty YES. OSHA, arbitrators, & courts have upheld mandatory flu vaccine policies or a less restrictive mask-or-vaccination policy as a health & safety measure.

Forcing workers to take the vaccine would be invalid if it violates an employment contract or a collective bargaining agreement for

those in a Union. Any policy cannot violate any EOC grounds.

A 1-5-21 law requires the HHS Secretary to consider certain recognized security practices of Covered Entities & Business Associates when taking HITECH enforcement actions. Has the CE or BA used industry-standard cybersecurity practices for the required 12 months? If so, early and favorable termination of audits &/or the mitigation of fines & penalties may fol-

low. Each CE & BA will determine the security practices that fit best consistent w/the HIPAA Security Rule.

CMS is putting a general hold on hospital surveys except those dealing with immediate jeopardy situations, for at least 30 days because of COVID-19 surges. Accreditation organizations are being asked to do the same. Hospital compliant surveys will be limited to immediate jeopardy complaint allegations.

Fun Spot



December Puzzle Answer:

A White Carnation

January Puzzle:

What occurs once every minute, twice every moment, yet never in a thousand years?

Trivia:

- The bloodhound is the first breed of dog for which its evidence is legally admissible in some U.S. courts.
- Istanbul is located in both Asia & Europe.
- Banana cream was the original flavor of Twinkies filling.

- GeoCities is the name of the first social networking site launched on the internet in 1994.
- Water is the only substance on earth lighter as a solid than as a liquid.
- Australia is the only continent on earth without an active volcano.
- The ice cream cone was originally a way to hold flowers, not ice cream.
- It took 55 years for the telephone, invented in 1820, to be put into use in society.
- You speak 4800 words/day.