

What's Your Compliance IQ?

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HIPAA News

There are new regulatory requirements & compliance initiatives due to *Dobbs* & Pixel use & lawsuits against healthcare organizations over privacy violations. Hacking incidents are increasing & these organizations are facing increased scrutiny on their data security practices & compliance programs. Over the next 12 months there will likely be an increase in enforcement actions & lawsuits over privacy violations. A study suggests 99% of non-federal acute care hospital websites use pixels capable of transmitting sensitive data & only a handful have disclosed Pixel-related data breaches to OCR so far.

There are also likely to be enforcement actions against HIPAA-regulated entities & non-regulated entities in the healthcare space for privacy violations involving reproductive health information privacy viola-

-tions.

One of the largest data breaches of the year was reported in April; it affected 3,037,303 individuals—the 19th largest breach reported by a single HIPAA-regulated entity to date. There were 52 breaches of 500 or more records reported to the OCR—less than the 12-month average of 58. Hacking & other IT incidents continue to dominate the reports accounting for 69.2% of April breaches & most breached records.

Business Associate Agreements (BAA) are not always the fault of the Business Associate (BA). HHS guidance implies Covered Entities (CE) need only obtain “satisfactory assurances” BAs will only use PHI for the purposes for which it was engaged prior to the BAA & the CE does not have to do due diligence to ensure these are backed up with pol-

cies, safeguards & procedures.

The AHA is urging the HHS OCR to reconsider its guidance on online tracking technologies & to stop considering an IP address as a unique identifier under HIPAA with respect to pixels & other website tracking technologies.

The AHA considers the IP address tying health information to an individual too broad an interpretation & warns it will result in significant adverse consequences for hospitals, patients, & the public at large. It also says by considering a mere IP address as PHI under HIPAA, the guidance will reduce public access to credible health information. The guidance puts hospitals & health systems at risk things such as class action suits, HIPAA enforcement actions or loss of millions of dollars invested in websites, apps, & portals.

Compliance News

CMS expects hospitals to fully comply with hospital price transparency & is enforcing these rules to ensure patients know charges for items & services.

CMS has 3 main avenues for monitoring & assessing hospital noncompliance:

- Evaluate complaints made by the public.
- CMS’s review of individuals’ or entities’ analysis of noncompliance
- Internal audits of hospitals’ websites

The case cycle consists first of a warning notice with instructions to correct the deficiencies within 90 days. If these are not corrected within that timeframe, CMS issues a Corrective Action Plan (CAP) request with a 45-day deadline. Hospitals then must submit a pro-

posed completion date to CMS for approval. If a facility is still out of compliance after the CAP deadline, a Civil Monetary Penalty is issued. The average case cycle time is 195-220 days & as of 4-23, more than 730 warning notices & 269 requests for CAPs have been issued & CMPs have been imposed on 4 facilities for noncompliance.

On 3-28-23, Congress reintroduced the Saving Access to Laboratory Services Act (SALSA to clean up the Protecting Access to Medicare Act (PAMA) issues with pricing & reporting. Unless Congress acts, 800 Clinical Laboratory Fee Schedule tests (CLFS) will be subject to PAMA payment cuts of 15% 1-1-24. SALSA is a bi-partisan bill which provides hope reform could be coming.

Labs struggling to understand billing

& coverage requirements are advised to proactively seek guidance from CMS or its Medicare Administrative Contractor. The Supreme Court was to hear arguments 4-18-23 in a False Claims Act case which has potential impact on labs. Regardless of the outcome, labs must be careful submitting claims to MC for tests without a full understanding of the billing & coverage regulations involved.

The CMS Specimen Collection policy was updated 1-1-23 raising the general collection fee from \$3 to \$8.57 for CY 2023. This fee amount will be updated annually by the percent change in the CPI-U. Specimen collection from a Medicare patient in a skilled nursing facility by the lab on behalf of a Home Health Agency increases by \$2 making that fee \$10.57.

Safety

Bronchial lavage specimens should be processed in a Biosafety Cabinet (BSC) to avoid aerosols. Once the counting chamber for WBC counts & differentials is loaded, it can be moved to the microscope for counting; respiratory protection is not necessary at the scope.

The bottle type of eyewash does not meet OSHA standards because it cannot be used hand free & will not flush for the full 15 minutes. When an eyewash is needed, it must meet OSHA standards.

If dry ice cannot be disposed of by letting it sublimate outside, it should be placed in a location where there is good ventilation & as far away as

possible from staff

NFPA does not mandate location of fire extinguishers except to say they should not be blocked & they must be hung at least 4 inches above the floor so they can be accessed easily. Local fire authority officials designate the number needed in a laboratory & where they must be located.

All large & small waste generators must register with the EPA. In 2021 small waste generators were required to reregister every 4 years thereafter using the required form.

While OSHA requires protection of associate feet, it does not spell out how to do it very well. CLSI states,

however, laboratorians should wear shoes that protect from blood, body fluid, sharps, & chemicals & need to completely cover the foot (no clogs, straps, etc.) & they need to be made of non-absorbent material like vinyl or leather. There are now many sneakers available on the market acceptable for laboratory use.

The same chemical from different vendors will have different hazard ratings sometimes because they come up with these different ratings. The NFPA rating on the original container or vendor secondary bottles must always be used. The same reagent may contain a different formulation or contain an additive that, for example, changes the flash point.

Miscellaneous

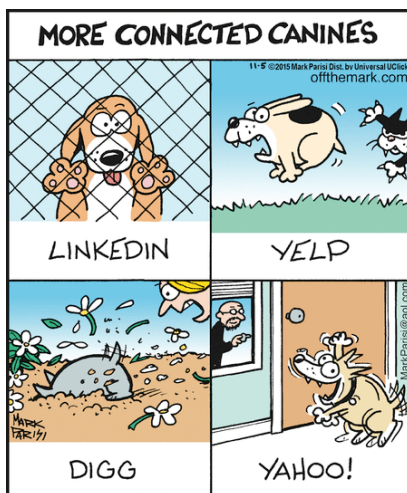
Laboratories need to be prepared for any potential whistleblower activity. A whistleblower lawsuit can do significant damage to a lab & its reputation. Under the False Claims Act (FCA), whistleblowers are protected & are entitled to reinstatement with the same status they had plus 2 x the amount of back pay & compensation for any special damages as a result of discrimination including litigation & reasonable attorney fees. Being found liable can cost millions of dollars.

Facilities should have policies that encourage rather than discourage associates to come forward & report any wrongdoing. Facility leadership should listen, & investigate any problems brought forward or identified. It is only when you stonewall, ignore, suppress & intimidate that associates with concerns become whistleblowers.

The 2021 Census report indicated 21.5% of people in the U.S. speak a language other than English at home. 8.2% of these meet the definition of lim-

ited English proficient (LEP). LEP healthcare disparities are more pronounced with adverse events affecting them & more frequently caused by communication problems. HHS is undertaking rulemaking to better align regulation with the statutory text of the Affordable Care Act to reflect recent developments in Civil Rights case law under Title VI, Section 504, & better address discrimination issues. The proposed rule specifically requires covered entities to have written language access procedures.

Fun Spot



April Puzzle Answer:
Day & Night

May Puzzle:
What do an island & the letter "T" have in common?

- Trivia:**
- Daydreamers are better at solving complex problems.
 - An iceberg contains more heat than a lit match.
 - We are born with only two innate fears: fear of falling & fear of loud sounds.
 - The longest 1-syllable words in English all start with "s."

- Bamboo grows so fast, it is measured in MPH.
- Your nostrils work one at a time.
- The healthiest place in the world is in Panama.
- Bee hummingbirds are so small they get mistaken for insects.
- Leonardo Da Vinci invented scissors.
- Men can read smaller print than women; women can hear better.
- Opossums "playing possum" are not playing; they have passed out due to fear.
- All polar bears are left handed.