

What's Your Compliance IQ?

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HIPAA News

HHS has proposed a new rule requiring adoption of standards for healthcare attachment transactions & electronic signatures used in conjunction with those transactions to support healthcare claims & prior authorization transactions. It will apply to all health plans, healthcare clearing houses, & providers currently lacking an efficient, uniform method of sending attachments.

Currently, additional information needed is sent by mail or fax requiring time & resources. This new rule will implement Administrative Simplification Requirements of HIPAA & the Affordable Care Act. The AHA has announced support of a new rule & adoption of a new HIPAA standard for attachments & electronic signatures.

HHS has proposed new privacy rules for Substance Abuse Patient

(SUD) Records. There are five changes affecting labs collecting, using, & disclosing SUD information:

- Most significant-programs may use a single patient consent permitting all current uses & disclosures of SUD for treatment, payment & healthcare purposes.
- This single TPO form is not a blank check-patient may request restrictions; restrictions are not binding except if the patient pays.
- Notice of Privacy Practices will require minor adjustments.
- Labs covered by the proposed rule will have to implement policies/procedures to notify HHS & affected patients of SUD breach.
- Criminal penalties not a great risk, but adding civil penalties will increase noncompliance risk

Multiple changes to the HIPAA Privacy Rule have been proposed for 2023 meant to ease the HIPAA

administrative burden for HIPAA covered entities, but the burden will be increased in the short term. Policy & procedure updates as well as changes to Notice or Privacy Practices will be required if enacted.

Cyberattacks increased 38% in 2022 over 2021 fueled mostly by a sizeable increase in healthcare entity attacks. Globally, healthcare had the highest increase in weekly attacks with an average of 1463 per week. An unwelcome milestone is more healthcare records have now been breached than the US population as well as there having been greater than 5000 data breaches.

Any impermissible use or disclosure of PHI is a breach unless there a low probability of compromise can be demonstrated via a privacy risk assessment. If not, notification of it must be done.

Compliance News

HHS OCR has announced a Notice of Proposed Rulemaking entitled *Safeguarding the Rights of Conscience Protected by Federal Statutes* which proposes to restore the longstanding process for the handling of conscience complaints & provide additional safeguards to protect against conscience & religious discrimination.

The proposed rule strengthens protections with religious or moral objections while also ensuring access to care for all in keeping with the law.

The 2023 OPPTS Payments Rule established a Medicare provider designation type called a rural emergency hospital (REH) into which entities currently designated as critical access hospitals (CAHs) & small rural hospitals may convert. The new

REH designation is designed to provide access to hospital care in rural & other underserved communities.

A REH is a hospital with not more than 50 beds providing outpatient, emergency, & observation care, but not acute care inpatient services-other than hospital extended care furnished in a distinct unit licensed as a skilled nursing facility. REHs may also provide services that OPPTS does not cover included, but not limited to, lab tests covered by the Clinical Lab Fee Schedule.

There were 13 data breaches of 10,000 or more records in 12-22. Five of these were due to ransomware (2 of which involved 600,000 or more records). There were 28 incidents due to hacking & other IT incidents. There were 10 unauthorized access/disclo-

tures breaches.

While it is hard to obtain accurate data on the number of ransomware attacks on healthcare organizations, available data suggest a decline. This does not mean the number will not increase again. A concern noted is that organizations are investing less in combating ransomware attacks. There is also a notable number of companies without an incident response plan specifically for ransomware attacks.

A reminder: shoes worn in the lab need to be made of a non-absorbent material (like leather or vinyl) & should cover the entire foot, including sole, instep, & the heel. Clog-style shoes with no back are not acceptable.

Safety

Wearing artificial nails in the lab is a bad idea. For gloves to properly fit & for good infection control, nails should be no longer than 0.25 in. beyond the end of the finger according to the CDC. Jewelry pasted to nails should also be avoided as these can cause tiny holes in gloves & allow contamination of hands & nails. Artificial nail safety risks span personal hygiene, infection control, & patient safety.

Workplace violence has become a national epidemic with hazards especially high in healthcare settings. Employers must provide a workplace free from violence as a Condition of Participation for Med-

care certified hospitals OSHA inspectors & state surveyors will be scrutinizing workplace violence programs, policies, & procedures. Eight basic measures are expected:

- Do workplace violence hazard assessment
- Implement measures to control identified violence risks
- Implement workplace violence response procedures
- Implement procedures for investigating violent incidents
- Provide appropriate support for victims
- Discipline associates who commit or threaten violence
- Provide appropriate education
- Monitor effectiveness of prevention measures.

It is acceptable to use clear plastic bags in a healthcare facility provided the bags stay in the facility & items inside are recognized as specimens.

“Hands-on” fire extinguisher education is strongly recommended by CAP but not required; it is, however, the best & recommended by Dan the Safety Man.

OSHA requires at least baseline monitoring of noise levels in the lab. If that is below the threshold, repeat monitoring is not necessary unless there are changes due to new equipment, construction or procedures affecting noise OR complaints. Doing it every 2 years is a good routine.

Miscellaneous

The FDA has granted EUA status to the Amazon Real Time-PCR test as part of the company's overall COVID-19 preparedness & response program.

Two OTC rapid home antigen COVID-19 tests, one manufactured by Roche & one by SD Biosensor, have been approved by the Biden Administration.

A new COVID-19 Omicron variant, XBB, shows a unique path into ex-

istence not seen with other variants giving it a more profound resistance to antiviral humoral immunity induced by breakthrough infections of prior Omicron subvariants. XBB is the first variant increasing its fitness through recombination rather than single mutations. XBB is not as lethal as the Delta variant, but is as lethal as the BA.2.75 variant.

OSHA is moving ahead with a permanent standard to protect healthcare workers from COVID-19 on the job. A final

rule was submitted in December; the details are not yet public.

Workplace violence has become a national epidemic. A 11-28-22 CMS memo alerted facilities to this & their intention to enforce safety expectations. State surveyors will be scrutinizing facility workplace violence prevention policies, programs & procedures. Labs must implement assessments, risk control measures, procedures, victim support, investigations, effectiveness monitoring, & victim support, etc.

Fun Spot



December Puzzle Answer:

All are pronounced differently when the first letter is capitalized

January Puzzle:

Something is filled with keys, but has no locks. There is space but no extra room. You can enter but there is no exit. What is it?

Trivia:

- ¼ of the bones in the body are in the feet.
- On average, 12 newborns given to the wrong parents. during hospital stay
- Months beginning on a Sunday always have a Friday the 13th.

- Humans have the same number of vertebrae in their necks as giraffes.
- Blueberries will not ripen until picked.
- A mole can dig a tunnel 300 ft long in only one night.
- A single cloud can weigh more than 1M pounds.
- Malaria was once used to treat syphilis—caused a very high fever that ultimately killed it.
- Schizophrenia can be diagnosed with 98.3% accuracy by tracking eye movement abnormalities