

What's Your Compliance IQ?

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HIPAA News

The Government Accountability Office (GAO) recently reviewed Medicare telehealth services provided during the pandemic. Under normal circumstances, Medicare covers telehealth services only in limited circumstances.

OCR encouraged covered providers to inform patients about potential privacy & security risks associated with these services but specific language to use nor direction to help explain the risks were given. There were a number of complaints about HIPAA Privacy & Security Rule violations. The GAO is recommending HHS strengthen oversight of Medicare telehealth & help providers communicate privacy risks.

The government is taking steps to improve cybersecurity in healthcare as one of the next steps for focus areas by the White House.

Businesses realize cybersecurity is a top priority with 71% making new hires for this in the last year. Even with additional staff added, there is concern about keeping up with the fast-evolving cyber threat landscape. The frequency with which data breaches are being reported does indicate many businesses are struggling to keep pace.

A Trend Micro study indicates 25% of all data breaches now involve ransomware. From 2017-2021, these attacks rose by 109% & 2022 has seen a 13% increase & the attacks are having a major impact on healthcare organizations. 25% of those experiencing an attack had to completely halt operations & recovery time can be considerable.

Mid-year, the healthcare industry has the largest rise in cyberattacks of all industries increasing by 69% com-

pared to 2021. 63 breaches of 500 or more were reported to OCR in September but for the third month the number of records decreased. 30 breaches of 10,000 or more records were reported all of which were hacking/IT incidents. The largest breach involved more than 542,000 patients & saw database & system configuration files deleted & more than 3.6M individuals were affected.

Most September incidents were IT/Hacking incidents w/exposure or theft of >2.4M records. The next highest cause was ransomware. There were 7 unauthorized/access disclosure incidents (24,639 individuals) & 4 involving theft or loss of electronic devices. Email remains the most common way to access with ransomware. 10 breaches were reported by business associates & 7 by health plans.

Compliance News

The Joint Commission has a new health equity standard effective 1-1-23. The standard requires hospitals & other accredited providers to take meaningful measures to improve health care equity. The standard states "reducing health care disparities for the organization's patients is a quality & safety priority." There are 6 things labs must do to comply"

- Designate a health disparities officer
- Screen patients' needs
- Use stratified data to identify disparities
- Implement a written plan to eliminate disparities
- Take follow-up action
- Provide annual progress reports.

The lab should also create a written statement committing to eliminating health disparities in its services.

CA-based Arrayit offered diagnostics on dried blood on a paper card to then be mailed to the company lab. In March, '20, it claimed this unapproved test could rapidly detect COVID-19 when used with the allergies test kit. Just like Theranos, it was a lie & the test did not exist.

The DOJ had sounded the alarm on fraudulent COVID-19 tests from the outset of the pandemic. In addition to this, the company president was alleged to have run an illegal kickback scheme involving fraudulent claims to Medicare & insurances for allergy tests not medically necessary. Doctors were also paid kickbacks to use their provider numbers to charge insurances & Medicare for patients never seen by the doctor.

HHS has dished out its first penalties for hospital price transparency violations. Hospitals were slow to act & many calculated the cost of compliance vs. potential penalties. CMS then increased the penalties & after months of warning, took action in June against 2 GA health systems. More penalties are to come.

A HIPAA gap is OCR has followed a leniency policy of enforcements for HIPAA violations often favoring voluntary compliance & technical assistance ahead of civil money penalties or financial settlements. As of 9-22 OCR has only imposed one of these in 126 cases. In 2 rounds of HIPAA audits, widespread noncompliance was identified yet no financial penalties were issued & some entities actually ignore requirements entirely because of this.

Safety

There should be no use of gloves in hallways to transport specimens. Specimens should be in transport bags, the outside of which should be handled with no gloves. Wearing even just one glove in the hall is unacceptable.

The date/lot numbers for reagents used in slide strainers do not have to specifically be on each container in the stain line but safety hazard information required can be displayed on a nearby sheet or poster. A paper or electronic log can be used to provide the expirations/lot numbers as long as the stain line containers are labeled so they can be traced to the appropriate data in the log.

OSHA requires shoes worn in the lab be made of materials that will not absorb chemicals, blood or body fluids. They should also be able to prevent sharps into contact with feet. Canvas & mesh shoes are not acceptable. CLSI's *Clinical Lab Safety* document states lab shoes should be made of leather, vinyl, or some other solid material covering the entire foot. If shoes are not of these materials, fluid resistant shoe covered are needed.

There is no specific standard requiring cleaning the phlebotomy chair between each patient. However, it is considered best practice to clean the chair after each day of use.

Education for signing waste mani-

fest for DOT covers both regulated medical waste & hazardous waste. It is unusual for a laboratory associate to sign these manifests, but it does happen & the DOT still requires education.

Venipuncture needles should never be pre-assembled (i.e., put the needle on the hub before the patient is present). The CLSI Venipuncture Standard clearly states this should never be done. There are many reasons for this, but opening sterile needles long before use is not good practice.

Some spill kits state if kept intact & stored dry, cool they are "good" for years. It is recommended that spill powder not be kept more than 5 yrs.

Miscellaneous

HHS has authorized the FDA to issue EUAs for *in vitro* diagnostic tests for Monkeypox. The first EUA has been issued to Quest Diagnostics for an automated PCR test designed to detect 2 different DNA targets related to monkeypox & the closely related non-variola orthopoxvirus from skin lesion swab samples.

FDA tactics are a little different this time allowing the use of monkeypox antibody tests developed &

performed by CLIA-certified labs operating under academic medical centers as long as test results are used with other diagnostics for direct medical care of the patient.

Surprise Act update. A final rule has been issued but the Qualifying Payment Amount (QPA) remains the primary factor. The final rule does alleviate some providers' concerns but is far from a total victory. The new rule does not tell arbitrators how to weigh the QPA against the "qualitative" fac-

tors. As a result, arbitration decisions in out-of-network price disputes are likely to be unpredictable & inconsistent case to case. This casts uncertainty over the process & whether it will generate fair decisions.

CMS will continue to exercise enforcement discretion under CLIA for the duration of the COVID-19 public health emergency for the use of authorized COVID-19 molecular & antigen POC tests on asymptomatic patients outside test authorization.

Fun Spot



September Puzzle Answer:
His horse's name is Friday

October Puzzle:
What English word retains the same pronunciation even after you take away 4 of its 5 letters?

Trivia:

- Candy corn was originally called "chicken feed" when marketing it first started—at the time many Americans did not consider corn to be food for humans.
- Halloween is the 2nd. most commercially successful holiday, after Christmas.

- Original jack o' lanterns were made from turnips.
- Halloween colors, orange, & black—orange is for pumpkins & harvest & black represents night, death, & darkness.
- The most popular adult Halloween candy—M & M's.
- The most popular kid's Halloween candy—Reese's peanut-butter cups.
- A warlock is a male witch.
- Wizards are different from warlocks—wizards use magic & are called sorcerers & warlocks use witchcraft.
- Ouija boards patented in 1800.