

What's Your Compliance JG?

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(COMPLIANCE HOTLINE 1-888-235-7554;
Deltapathology.ethicspoint.com)



HIPAA NEWS

Almost all organizations experienced at least one cyberattack in the past 12 months according to a Sophos study. Dealing with these is compounded by a shortage of expertise due to the global lack of cybersecurity professionals.

New research indicates virtually all hospitals have been using tracking software on their websites that captures visitor data, including health information, & transfers that data to third parties. HIPAA does not prohibit use of these technologies unless certain conditions are met as the code can capture individually identifiable health information.

The third party receiving this information is typically not a HIPAA-regulated entity meaning uses & disclosures of that information is largely unregulated. The OCR recently

released guidance for HIPAA-regulated entities that use of these codes is not permitted unless the third party is a legitimate Business Associate with a signed Business Associate Agreement in place.

An American Data Privacy & Protection Act draft is close to being released which is edging closer to being the first, comprehensive federal privacy legislation to become US law. There is a clear need for privacy protections with big tech firms collecting huge volumes of sensitive information & few restrictions on how consumer data can be collected, used, & shared.

Whether the new version of this bill will address the sticking points sufficiently to retain the current bipartisan support as required to get it signed into law is uncertain.

In March there were 63 breaches of 500 or more records reported to DHHS which is a 46.5% increase over February. There were 22 involving more than 10,000 people; 4 of these involved use of a tracking code on websites that collected individually identifiable website visitor data. These codes are not prohibited by the Privacy Rule but consent must be obtained before they are used

There were 3 10,000+ record data breaches involving hacking email accounts through phishing or other means. The majority of breaches were due to hacking/IT events.

With an increased Russian cyberthreat, there is a Senate bipartisan bill aiming to improve the cybersecurity of the healthcare/public health sector

Compliance News

Labs should be wary of improper billing of G0483 testing—definitive drug test billing. Unlike previous OIG audits, the new ones will include drug testing provided to ALL Medicare beneficiaries 2016-20. Providers deemed “at risk” are those using G0483 for 75% or more of those drug tests provided & for which they received \$5000 or more during the audit period.

High frequency billing of G0483 is not illegal but is enough to raise a red flag w/MMACs & OIG. It is imperative to have documentation justifying these bills to Medicare by showing medical necessity for definitive testing as well as tests targeting 22 or more different drugs.

The No Surprises Act took a controversial turn in February when a TX

Federal Court sided w/physicians & struck down parts of the regulation as being unfairly weighted in favor of insurers. As a result, implementing the independent dispute resolution has been put on hold until there is a fix for the court's concerns.

CMS issued a proposed rule in 12-22 to make the False Claims Act (FCA) regarding reporting & returning overpayments to Medicare (also called a “reverse false claim”). This proposed rule puts labs & other providers in a more precarious position for liability for failing to report & repay overpayments. The “knowingly” requirement eliminates the current regulatory “reasonable diligence” buffer for providers not only to determine the existence of overpayments but also quantify their amount w/in 60 days. Labs will need a robust process for

identifying potential overpayments to Medicare or there will be risk liability under both the ACA & the FCA.

The ABN form, CMS-R-131, has been approved by the OMB. The current form can be used until 6-30-23. On that date, the renewed form with the expiration of 1-31-26 becomes mandatory.

A recent survey indicated only 1/5 of organizations enforce their cybersecurity protocols. 31% of respondents said they were unsure of what to do in the event of a breach. Organizations continue to have challenges with hiring talent as the biggest issue. There is a global shortage of cybersecurity professionals. Once hired, retention is then a problem. A lack of data inventory is another cybersecurity issue for some.

Safety

An OSHA letter of interpretation strongly suggests the use of gloves when reading microbiology plates. OSHA's Chemical Hygiene standard requires gloves if chemical reagents (oxidase, catalase, etc.) are used while reading plates. It is a best biosafety practice when also considering these plates were handled with contaminated gloves during culture setup.

Some labs with a large volume of small containers of methanol have the chemical waste hauler remove them. The local wastewater treatment center may allow methanol to be poured down the drain in small amounts but the lab should get permission first.

Some cleaning products have a GHS labeling exemption, but these products may be used in different settings like homes where the OSHA Hazard Communication standard is not applicable. Since there is a SDS with each, hazard warnings are available; the SDS must be accessed if one of these products is involved in a spill or exposure.

The laboratory must use Standard Precautions when handling specimens in the laboratory. With open specimens face protection, gloves & fastened lab coats are required. If a specimen undergoes a procedure that can cause an aerosol (e.g., vortexing), it should be done in a hood.

Washable & disposable lab coats should be worn for a week provided nothing is splashed on them. Some disposable coats can be washed or autoclaved for reuse but the manufacturer must be consulted to ensure such an option is permitted.

OSHA's Bloodborne Pathogen Standard prohibits the storage of food or drink with specimens but does not specifically mention medications or vaccines. A JJC-accredited hospital does not permit storage of meds or vaccines with specimens. Either way, it is an unsafe practice & should not be done.

Phlebotomy cart-NO food or drink.

Miscellaneous

Every year CMS issues a list of Proprietary Laboratory Analysis (PLA) reimbursable by Medicare Part B under the fee schedule.

Among those for 2023 are assays produced by major companies like Thermo Fisher Scientific, DiaCarta, & Adaptive Biotechnologies. There is a good chance a lab provides some of the newly recognized PLA codes tests for Medicare. When a PLA code is available to report such a service, that same service

should not be reported with any other CPT codes & other CPT codes may not be reported with that PLA code. There are 22 newly recognized PLA codes officially billable April 1, 2023.

Magellan Diagnostics executives were accused of FDA violations as well as fraud & conspiracy. The charges involved the LeadCare Ultra, LeadCare II, & LeadCare Plus devices used to detect lead poisoning & lead levels in adults & children. These devices apparently had a serious defect

affecting the accuracy in venous samples; both clients & the FDA were misled resulting in tens of thousands receiving inaccurately low lead results. It is believed the executives know-about this for years.

An employee fired after raising COVID-19 safety concerns will receive \$45,000 in damages for OSHA Act whistleblower protections violations by the employer. The Dept. of Labor is dedicated to safe, healthy conditions required by federal law.

Fun Spot



Ever notice how
THE IRS
when put
together
spells
"THEIRS"?

March Puzzle Answer:

Your breath

April Puzzle:

What breaks but never falls & what falls yet never breaks?

Trivia:

- Competitive art used to be in the Olympics (sculpture, music, painting, architecture)
- Koala fingerprints are so close to humans' they can taint crime scenes.
- A grizzly bear's bite is strong enough to crush a bowling ball.
- Zebra stripes act as a natural bug repellent.
- Medical studies have shown red

heads tolerate pain better than those with other hair colors; they also need 19% more anesthesia than dark-haired people

- Apples are usually picked between August & November, covered in wax, hot-air dried, & sent to cold storage; after 6-12 months they land on grocery shelves.
- Adolph Hitler was nominated for a Nobel Peace Prize in 1939, but the nomination was withdrawn.
- 3 Musketeers used to come in 3 flavors (vanilla, chocolate, or strawberry)-hence the name.