

What's Your Compliance IQ?

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HIPAA News

Various HIPAA Notifications of Enforcement Discretion expired at the end of the Public Health Emergency (PHE). OCR will no longer exercise enforcement discretion of not imposing penalties on Covered Entities (CE) and Business Associates (BA) for:

- Their use & disclosure of PHI for public health & health oversight activities under designated regulations if certain parameters were met
- "In connection with good faith participation in COVID specimen collection & testing sites" in the community

A Yakima, WA hospital was investigated regarding allegations associates had impermissibly snooped into the medical records of 419 patients. The facility voluntarily agreed to settle for \$240,00 & put a

place to update its policies & procedures to safeguard PHI & to educate staff to prevent this type of behavior in the future.

May, '23 was a particularly bad month for healthcare breaches of 500 or more healthcare records reported to the OCR. It was also one of the worst-ever months in terms of breached records. 23 data breaches of 10,000 or more & including the 2 largest breaches in '23 to date.

The vast majority of breaches in May were hacking/IT incidents & the average size was 310,756 records. There were 57 breaches involving ePHI stored on network servers & 9 breaches involving ePHI in email accounts.

The HIPAA Conduit Exception Rule allows HIPAA Covered Entities (CE)

to use certain vendors w/o having a Business Associate Agreement (BAA). It applies to entities that transmit PHI but lack access to the transmitted information & do not store copies of the data. They simply act as conduits through which PHI flows (e.g., UPS, USPS, FedEx).

Misclassifying a vendor as a conduit rather than a BAA can result in a significant financial penalty. Many CEs have been penalized when found to disclose PHI to a vendor w/o a BAA.

A slew of changes to the Privacy Rule were announced 12-10-20 & the Final Rule is expected to be published in the Federal Register now that the comment period has closed. A grace period will be given to CEs to make necessary changes before compliance with the new rules is mandatory & enforceable.

Compliance News

With the end of the PHE:

- Price transparency for COVID testing & imposition of civil penalties for failure to comply ended
- COVID testing billed to Medicare must now be ordered by an authorized Medicare provider
- Higher payment rates for high throughput technologies for COVID testing ended & have reverted to the Clinical Lab Fee Schedule
- Insurance companies no longer must cover COVID testing without cost sharing
- HHS no longer has the authority to require myriad data surveillance reporting requirements & results but labs are still subject to state requirements.
- Blanket waivers for certain Anti-

Kickback & Stark Law provisions are no longer applicable.

- CMS intends to extend enforcement discretion to facilitate remote pathologist reads without a separate CLIA certificate
- Medicare will no longer provide Free at-home COVID tests (OTC) but Medicaid & CHIP patients will continue to have access through 9-30-24 after which states will decide their own coverage rules.

As the PHE ends, labs should review current policies & procedures & take any needed action to implement compliance.

The last significant changes to the personnel requirements under CLIA were made in 1992. On 7-22-22 there was a proposed rule to update

these to better reflect current knowledge, academic context changes, & advancement in laboratory testing. To do this, CMS is essentially proposing to water down credentials required for LD, TS, & testing personnel roles. The addition of nursing degrees to perform moderate & high complexity testing is proposed making it equivalent to a biological science BS.

Also proposed is allowing one with a "professional doctorate or master's equivalency" to qualify as lab directors. The final rule has not yet been published but the comment period has long since closed. The final rule could be published at any time & changes could officially take place 90 days from the date of publication. Watch for the publishing of the rule.

Safety

If an associate is wearing goggles while opening specimens & then moves to a workstation such as reading slides, the goggles have to be removed to look into the scope. Associates must be aware of the need to first wash their hands & then remove the goggles & to place those goggles onto a clean surface to avoid contamination the next time they are picked up & put on. This process applies to any situation when moving from a workstation requiring goggles to one that does not require them.

What is a Safety Stand Down? Because of a number of incidents in several national high containment labs in 2016, this was recom-

mended. OSHA defines this as an event for employers to talk directly to associates about safety. Because of the danger to associates, more specifically it means work stops until the issue is corrected & all involved associates have been educated to be sure the issue does not recur.

In the real world a lab does not shut down unless someone is in imminent danger. These sessions can still be run successfully. First develop the education focusing totally on the point(s) at hand. Then decide if meetings will be individual, in small groups or with everyone together. Then develop a plan for periodic checks to be sure new processes are being followed.

Document the education, take attendance & subject matter for future reference.

Labs should be sure lab vendors & service representatives use good safety practices in the lab. Some reps bring their own lab coats on site & this is an OSHA violation; PPE used in the lab should not be taken out of the lab; provide a disposable one for use. Use of cell-phones & laptops is another safety concern. These should be decpm-taminated prior to leaving the lab; see if a landline phone can be used. Make sure reps wear gloves as well. Provide face protection when instruments must be opened. Explain these are required by OSHA.

Miscellaneous

CMS may return or reject Medicare Parts A & B claims inappropriately if it appears there is a mismatch between the procedure or diagnosis code & the reported sex of the patient. Organizations & clinicians are reminded Part B professional claims need a condition code or modifier to allow these claims to be processed correctly effective July 1, 2023.

The Supreme Court has ruled against the government meaning

federal prosecutors will have to curb identity theft charges & restrict them to cases where the misuse of another person's ID is the crux of a criminal offense rather than the current broad interpretation allowing ID theft charges for fraudulent billing where another person's ID is merely an ancillary feature of a billing method.

24 state attorneys general have confirmed their support for the proposed update to the HIPAA Privacy Rule to strengthen reproductive

health information privacy. The state AGs recommend creating a separate definition of "reproductive health" in addition to the proposed rule's broad definition of "reproductive healthcare" as a subcategory of health care. The state AGs also call for HHS to define "birth" & "death" separately to clarify termination of pregnancy is not a public health reporting event. &, therefore, not subject to the HIPAA Privacy Rule reporting requirements & to tighten language regarding obtaining PHI for a prohibited purpose.

Fun Spot



May Puzzle Answer:

They are both in the middle of water

June Puzzle:

What starts with a "T." ends with a "T" & has "T" in it?

Trivia:

- The 2 tiny holes in every BIC pen ensure the air pressure is the same both inside & outside the pen which helps ink flow to the tip.
- Walmart sells more bananas than any other item in stock.
- lbs comes from the Latin word "Libra" which means pound.

- People do not sneeze in their sleep because the brain shuts down the reflex.
- The brain is the fattiest organ & is composed of almost 60% fat.
- Almonds are in the peach family.
- No one is entirely sure why a duck quack does not echo.
- There are parts of Africa in all 4 hemispheres.
- Cartilage & the cornea are the only human tissues without blood vessels.
- The brand name "Spam" is a combination of spice & ham.