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THE ADVISOR
MONTHLY COMPLIANCE COMMUNICATOR

Regulated Waste Disposal: Protecting Against Bloodborne Pathogens through OSHA-Compliant Practices

Disposing of regulated waste, including blood, body fluids, and other potentially infectious materials (OPIM), is critical to workplace safety and health standards. Employers are responsible for adhering to regulations set by the Occupational Safety and Health Administration (OSHA) and other applicable federal, state, and local laws to ensure safe handling and disposal.

Understanding Regulated Waste

Regulated waste refers to various materials that could potentially harbor infectious pathogens, including liquid or semi-liquid blood, contaminated sharps, and items soiled with blood or OPIM. According to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), regulated waste is defined as:

- Liquid or semi-liquid blood or OPIM
- Items that would release blood or OPIM if compressed
- Items caked with dried blood or OPIM that can release these materials during handling
- Contaminated sharps
- Pathological and microbiological waste containing blood or OPIM

Regulated waste must be managed with utmost care during containment, storage, and transport to prevent exposure to employees and the public.

Disposal of Blood and Body Fluids

OSHA's Bloodborne Pathogens Standard stipulates that all regulated waste must be handled in accordance with specific guidelines. The waste must be placed in containers that are:

- Closable
- Constructed to contain contents and prevent leakage during handling, storage, or transport
- Labeled or color-coded to identify the materials
- Closed before removal to avoid spillage or exposure to contents

Newsletter Content

Septic Systems and Garbage Disposal
While it is generally discouraged to dispose of blood or body fluids in septic systems or regular garbage due to the risk of infection, it is ultimately the employer's responsibility to determine whether the waste meets the criteria for regulated waste. This determination is not based on the volume of blood or body fluids but on whether the waste poses a risk of releasing blood or OPIM during handling or compaction. For instance, even small amounts of blood in a waste container that could potentially leak or spill must be treated as regulated waste.

Handling of Feminine Products
OSHA does not typically consider discarded feminine hygiene products as regulated waste. Employers should utilize liners in restroom waste containers for feminine products to prevent direct physical contact with the contents.

Proper Handling of Contaminated Sharps
Contaminated sharps, such as needles or scalpels, present an additional risk due to their potential to cause puncture injuries. These items must be discarded in containers that are:

- Closable
- Puncture-resistant
- Leakproof on the sides and bottom
- Labeled or color-coded for identification

Sharps containers should be easily accessible to personnel and located near the area where sharps are used. They must be maintained in an upright position during use and replaced routinely to prevent overfilling. When moving sharps containers, they must be closed immediately before removal to prevent spillage.

Disposal of Regulated Waste
When it comes to the final disposal of regulated waste, the following guidelines must be followed:

- The waste must be placed in closable, leakproof, labeled, or color-coded containers.
- Containers should be closed before removal to prevent the risk of spills or exposure.
- If the container has external contamination, it should be placed inside a secondary container to contain any leakage during transport.

Federal and State regulations govern the proper disposal of regulated waste, ensuring that the materials do not pose a public health risk during disposal or transport. Familiarize yourself with your State and Local regulations to ensure compliance.

Contaminated Laundry

- Contaminated laundry, such as uniforms or linens, must also be handled carefully. Laundry should be bagged or containerized at the location and not sorted or rinsed.
- Containers must be labeled or color-coded to indicate the need for Universal Precautions.
- If the laundry is wet and could potentially leak, the containers must be designed to prevent soak-through or leakage.

Safely disposing of blood, body fluids, and other regulated waste is essential for protecting employees from exposure to potentially infectious materials. Employers must adhere to OSHA and State/Local regulations to mitigate risks. This includes using properly labeled and constructed containers, managing contaminated sharps and laundry, ensuring that all materials are handled and disposed of appropriately, and educating all staff on appropriate waste disposal. By following these regulations, employers can help maintain a safe and compliant workplace while protecting their employees from the risks posed by bloodborne pathogens.

Misinformation Surrounding the HIPAA Security Rule Notice of Proposed Rule Making

In December 2024, the Department of Health and Human Services (HHS) released a Notice of Proposed Rule Making (NPRM) regarding potential changes to the HIPAA Security Rule. This notice opened for a period of public comments, allowing healthcare professionals, organizations, and other stakeholders to voice their opinions on the proposed updates. The comment period closed on March 7, 2025, but the rulemaking process is still far from over.

As often happens with complex regulatory changes, misinformation has begun to spread, leading to confusion and, in some cases, unnecessary alarm. Understanding where we are in the process, what changes may come, and what steps need to be taken is critical for everyone in the healthcare space to avoid falling victim to this confusion.

The Current Status of the NPRM and Public Comments

- The period for submitting public comments has ended, but the next steps are just beginning.
- After reviewing the 4,745 comments submitted, the Office for Civil Rights (OCR) at HHS, which oversees HIPAA compliance, will carefully analyze the feedback.
- Tim Noonan, Deputy Director of Health Information Privacy at OCR, provided an update during the Virtual 42nd National HIPAA Summit, confirming that OCR has received a large volume of comments.
    - Noonan did not provide specific details on how OCR plans to proceed once the comments are reviewed, but he emphasized that OCR is committed to reading every single comment.
    - He also explained that OCR organizes the feedback by category to understand the public's response to the proposals:

"We will categorize everything, try to understand it, and then work within HHS, as with any rulemaking, on what future actions to take."

- This process of categorizing and understanding the comments helps ensure that the final rule considers the concerns and recommendations of stakeholders across the healthcare industry.
- However, until HHS completes its review and finalizes the rule, there are no immediate changes to the existing Security Rule.

What the Proposed Changes Could Mean

The proposed revisions to the HIPAA Security Rule aim to modernize the regulation in response to new technological risks, such as:

- The increasing use of cloud computing
- The rise of remote work environments
- The growing threat of sophisticated cyber attacks

Key updates could include:

- Clarifying the definitions of electronic protected health information (ePHI)
- Refining risk analysis requirements
- Ensuring that third-party vendors are held to clearer security expectations

Despite the significance of these changes, it's important to remember that these are merely proposed modifications at this stage. There will be no immediate changes to HIPAA compliance requirements until the final rule is published in the Federal Register.
Once that happens, healthcare entities and business associates will have 240 days to implement the new rules.

Executive Orders and the Future of HIPAA Changes
In parallel with the proposed Security Rule changes, several Executive Orders were released calling for a reduction in federal regulations. These orders may influence:

- The timeline and scope of the proposed updates.

While it is uncertain how much these orders will impact the process, there is speculation that they could delay or reshape the final rule. However, until HHS makes its final decision, healthcare organizations should continue adhering to current compliance standards.

Debunking the Misinformation
Amid all the speculation, it's easy for misinformation to spread. Some claims have inaccurately stated:

- That the changes are already in effect.
- That drastic shifts in compliance requirements are imminent.

These claims are misleading and can cause unnecessary stress for healthcare professionals and organizations. The reality is:

- There are no immediate changes to HIPAA until the final rule is published.
- While it's important to stay informed and understand the proposed updates, it's equally crucial to avoid reacting prematurely based on incomplete or incorrect information.

HHS has made a helpful fact sheet available to explain the key points of the proposed rule changes. This is a great resource for those who want accurate and up-to-date information.

Conclusion
The proposed changes to the HIPAA Security Rule, while important, have not yet been finalized, and no immediate action is required by healthcare organizations at this stage. Misinformation can be a barrier to clear understanding, so it's essential to rely on official updates from HHS and to be cautious about unverified claims. With OCR carefully reviewing public comments and planning future actions, the healthcare community will have time to prepare once the final rule is published.
Until then, maintaining awareness and staying grounded in facts will help organizations avoid unnecessary anxiety and confusion.

Sterilization Monitoring: A Critical Step in Infection Prevention and Patient Safety

Having proper sterilization processes in place is crucial in preventing the transmission of infection. Monitoring the sterilization process ensures that it is effective. The methods used to monitor sterilization are physical (mechanical) monitoring, chemical indicators, and biologic monitoring. Mechanical and chemical indicators don't guarantee sterilization; however, they are the first indicator that something may be wrong with the process. Biological indicators are the best assurance that sterilization has been achieved.

Monitoring the sterilization equipment, procedures, and recordkeeping are essential to ensure patient safety. The monitoring results must be documented and kept according to local and state regulations. Several regulatory agencies, including the Joint Commission and Centers for Medicare and Medicaid mandate documentation.

Mechanical/physical monitoring

Mechanical, or physical, monitoring consists of observing the cycle time, temperature, and pressure of each load. The sterilizer gauges or displays are observed for each of these parameters and those results are documented. Some sterilizers have a recording device or printout that can be used for documentation. If these parameters have not been met during the process, this could be the first indication of a problem. Documentation of these parameters should be maintained for a certain duration according to your state's regulations.

Chemical monitoring

Chemical monitoring uses sensitive chemicals or inks that change colors when exposed to temperatures or a combination of time and temperature. Chemical monitoring consists of indicator tape, strips, tabs, or markings on packaging materials. These indicators measure time and temperature parameters. They also measure pressure in autoclaves.

Chemical indicators

Chemical indicators are placed on the inside of each package to ensure the sterilizing agent has reached the instruments inside the package. If the indicator is not seen from the outside, place an additional indicator on the outside of the package. The indicators validate the sterilant penetrated the packaging material.

These indicators show that the item has been exposed to the sterilization process, but they do not prove sterilization. There are different classes of these indicators based on their ability to monitor one or multiple sterilization parameters (time, temperature, pressure). Inspect the indicators at the end of the sterilization cycle. If they don't turn colors or suggest inadequate processing, the item should not be used.

Biological monitoring/spore testing

Biological monitoring, also known as spore testing, is the only way to prove sterilization. This method includes placing a strip or vial of spores in the sterilizer to ensure those spores are killed. If the spores are killed, the sterilization process is successful. There are mail-in test strips or in-house vials of spores used with an incubator. Spore testing should be performed at least weekly and with each implantable device. Spore testing may need to be performed more frequently if the sterilizer is used multiple times throughout the day. This would allow for early detection of equipment malfunctions or procedure errors. In turn, this would minimize the extent of instrument retrieval and possible patient surveillance.

The Center for Disease Control (CDC) and the Association of Perioperative Registered Nurses (AORN) have steps to follow in the event a spore testing is positive. Following positive spore testing from steam sterilization, the sterilizer should be removed from service. Once this is done, sterilization logs should be reviewed, and procedures to determine any potential reason for the failed test should be implemented. If the logs show that physical and chemical monitoring was met, there is no need at this point to retrieve instruments for re-sterilization. However, any implantable device should be retrieved and not used until they are shown to be sterile. The sterilizer should then be retested, using the same type of spore testing that failed and the same cycle. If the additional spore test is negative, the sterilizer can be returned to service.

If the repeat spore test is positive, remove the sterilizer from service and have it inspected or repaired. Retrieve instruments, insofar as possible, from the last negative spore test and re-sterilize. After the sterilizer is repaired, perform spore testing until three consecutive negative testing is achieved. Once spore testing results are favorable, put the sterilizer back into service.

If using a method of sterilization that is not steam, and having a single positive spore test, treat all instruments as nonsterile. All instruments should be retrieved and reprocessed.

Sterilization monitoring and documentation are important aspects of an effective infection prevention and control program. If you have questions or need help with infection control, reach out to us at Total Medical Compliance. We will be happy to tell you about our NEW infection control, sterilization, and disinfection program.

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Instructions

Print and post newsletter in office for staff review. Each member should sign this form when completed. Keep on file as proof of training on these topics.

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