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JANUARY 2025

THE ADVISOR
MONTHLY COMPLIANCE COMMUNICATOR

The Right of Access Initiative

The Right of Access Initiative under HIPAA represents a crucial step toward empowering individuals with control over their health information. Launched in 2019 by the Office for Civil Rights (OCR) of the Department of Health and Human Services (HHS), this initiative aims to ensure that covered entities, including healthcare providers and health plans, comply with the HIPAA Privacy Rule's provisions on patients' right of access to their PHI. The initiative emphasizes timely, affordable, and transparent access, reinforcing patients' autonomy in managing their health.

Newsletter Content

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Understanding the Right of Access

The HIPAA Privacy Rule grants individuals the right to access their PHI maintained by covered entities, whether in paper or electronic format. This right includes:

1. Timely Access: Covered entities must provide access to PHI within 30 days of a request, with a one-time extension of 30 days allowed in specific circumstances.
2. Reasonable Costs: Fees for providing access must be reasonable and cost based. These fees may include the costs of labor for copying, supplies, and postage but cannot serve as a barrier to access.
3. Format of Access: Patients have the right to receive their records in the format of their choice, provided it is readily producible. This includes electronic copies when available.
4. Third-Party Access: Individuals can direct covered entities to send their PHI to a third party of their choice, such as another healthcare provider or a family member.

Enforcement Actions and Recent Developments

The Right of Access Initiative arose from OCR's observation of widespread noncompliance with the Privacy Rule's access provisions. Patients often faced delays, excessive fees, or outright denials when requesting their health records. To address these issues, OCR prioritized enforcement of the right of access through investigations and penalties for violations.

A notable recent development involves OCR, imposing a $100,000 civil monetary penalty against Rio Hondo Community Mental Health Center in California. The penalty resolved an investigation into Rio Hondo for failing to provide a patient with timely access to their medical records. The Privacy Rule's right of access provisions requires that individuals or their representatives have timely access to their health information (within 30 days, with the possibility of one 30-day extension) and for a reasonable, cost-based fee. This action marked OCR's 51st enforcement action to advance patient access to medical records under the Right of Access Initiative.

Importance of Patient Access

Access to health information is fundamental to patient empowerment and improved healthcare outcomes. When patients can review their medical records, they are better equipped to:

- Make Informed Decisions: Understanding their medical history and test results helps patients actively participate in their care.
- Identify Errors: Patients can spot inaccuracies in their records that could affect treatment.
- Facilitate Care Transitions: Access to records allows for seamless information sharing with new providers, enhancing continuity of care.

Overcoming Challenges in Compliance

Compliance with the Right of Access requires commitment and resources. Common challenges include outdated record systems, staff training gaps, and confusion over allowable fees. To address these issues, covered entities should:

1. Implement Efficient Systems: Use electronic health record (EHR) systems that ensure secure and efficient record access.
2. Educate Staff: Provide comprehensive training on HIPAA requirements and access procedures.
3. Establish Clear Policies: Develop and communicate policies that comply with HIPAA's access provisions.
4. Monitor and Audit: Regularly review processes to identify and address gaps in compliance.

The Path Forward

The Right of Access Initiative reflects OCR's dedication to patient rights under HIPAA. As the healthcare landscape evolves, this initiative aligns with trends toward patient-centered care and digital health innovation. Compliance is more than a legal requirement; it builds trust and enhances the patient experience.

It's Your Call – January 2025

OSHA/Infection Control: What are the three ways to sterilize instruments used on patients?

Sterilization of instruments achieves destruction of all forms of microbial life either by physical or chemical methods. There are different ways available to sterilize critical and semi-critical instruments/items utilizing either high or low temperature methods. Most instruments are heat stable and therefore undergo steam sterilization. Other ways to sterilize are utilizing dry heat or chemical sterilant/disinfectants.

HIPAA: Why is it important for practices to understand the Right of Access?

Understanding the Right of Access helps practices comply with HIPAA, avoid penalties, and build patient trust. Ensuring timely, affordable access to health records reduces legal risks, enhances patient satisfaction, and improves care coordination. It demonstrates a commitment to transparency and patient-centered care, strengthening the practice's reputation.

Instrument Processing Essentials: Key Steps for Sterilization and Storage

Instrument processing is critical to ensure sterility of instruments utilized on patients. There are four steps in processing instruments: cleaning, packaging, sterilization, and storage. This article will focus on the last two steps: sterilization and storage.

Earle H. Spaulding. PhD, devised a rationale for disinfection and sterilization of instruments and items. He categorized instruments and items into three categories: critical, semi-critical and non-critical.

- Critical items enter normally sterile tissues, including the vascular system.
- Semi-critical are instruments or items that contact mucus membranes or non-intact skin.
- Non-critical items contact intact skin and not mucus membranes.

All instruments and items are cleaned first.

- Once a critical item is cleaned, it is packaged and heat sterilized.
- Semi-critical items are cleaned, and heat sterilized; if the item is not heat stable it can be high-level disinfected.
- Non-critical items are to be low-level disinfected.

Sterilization of instruments achieves destruction of all forms of microbial life either by physical or chemical methods. There are different ways available to sterilize critical and semi-critical instruments/items utilizing either high or low temperature methods. Most instruments are heat stable and therefore undergo steam sterilization. Other ways to sterilize are utilizing dry heat or chemical sterilant/disinfectants.

Steam sterilization

Steam sterilization is most widely used and most dependable. Steam sterilization is moist heat in the form of saturated steam under pressure. There are several advantages of steam sterilization:

- it is non-toxic,
- the cycle is easy to monitor,
- it is inexpensive,
- rapidly microbicidal, and
- penetrates packaging.

There are also several disadvantages. These include:

- destroying heat or moisture sensitive instruments,
- dulling or rusting may occur, and
- the potential for burns of healthcare workers when removing the instruments from the sterilizer.

Types of steam sterilization
There are two types of steam sterilization. The first method of steam sterilization is gravity displacement sterilizer. With this type of sterilizer, steam enters the chamber, and unsaturated air is forced out of the chamber through a vent in the chamber wall. Most common items sterilized are unwrapped instruments, glassware, and solid waste.

The second method is a pre-vacuum sterilizer. These have a vacuum pump to create a vacuum in the chamber and ensure the air removal from the sterilizing chamber and load before the chamber is pressurized with steam. Wrapped items, surgical packs, and items with complex lumens are typically sterilized in a pre-vacuum sterilizer.

Sterilizer use
As with any method of sterilization, always use FDA approved devices and closely follow manufacturer's instructions for proper use. Follow these instructions for maintenance. Sterilizers will be cleaned weekly and monthly following the manufacturer's recommendations.

Loading instruments in the steam sterilizer should always be done in a manner to allow the steam to flow, should not be overloaded, instruments should be on the trays in a single layer, and not overlapping. Instruments packs can also be sterilized on their edge. Leave room between packs so the sterilizing agent can contact all sides of every pack. Follow the manufacturers' instructions on loading the sterilizer. Once the sterilization cycle is complete, allow instruments packs to dry completely and cool before handling. Instrument packs that are handled when wet are not considered to be sterile and therefore should not be used on patients.

Dry heat sterilizers
Dry heat sterilizers work by transferring heat energy from air inside the oven to the instruments. Simply put, it utilizes hot air to sterilize. Dry heat is good for items that are likely to dull or rust, powders, or ink that require sterilization. The packaging material must be able to withstand high heat. A disadvantage to dry heat is it is slow, and many instruments can't withstand the high heat.

Liquid chemical sterilant
Lastly, an alternative sterilization process for heat sensitive items is utilizing a liquid chemical sterilant cleared by the FDA. Liquid chemical sterilant is commonly referred to as cold sterile or a cold boat. The disadvantages to utilizing a chemical sterilant is exposure can be powerful and toxic and can be harmful to healthcare workers and patients if manufacturers' instructions for use are not followed closely. Items in a chemical sterilant cannot be stored because they are not wrapped. For this reason, CDC encourages the use of heat tolerant and disposable items.

Instrument storage
Now that we have cleaned, packaged and sterilized instruments, the last step is storage. Store instrument packs away from contaminants and leave instruments in packaging until ready to use. Removing instruments from the packs ahead of time is not recommended. Preferably, packs are stored in a closed drawer or cabinet; never under a sink where packs can become wet. Ensure the area used for storage will provide protection from moisture, dust, temperature, and humidity extremes. If a pack becomes compromised during storage, do not use the instruments for patient care. Instead, clean, repackage, and re-sterilize.

Items are stored utilizing either event-related or time-related storage.

- Event-related storage means the items will remain sterile and can be used indefinitely unless the packaging becomes compromised.
- Time-related storage means items remain sterile for varying periods depending on the type of material used and manufacturer instructions on shelf life. If utilizing time related, the pack should be labeled with date of sterilization and expiration date.

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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.

Newsletter Content

The Right of Access Initiative

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Instrument Processing Essentials: Key Steps for Sterilization and Storage

Need to contact us? Scan the QR code for all the ways to get in touch!