What are the Joint Commission's expectations for managing multi-dose vials of vaccines ?

Any examples are for illustrative purposes only.

Storage and Expiration Dating:
Vaccines are exempt from the 28-day requirement. The CDC Immunization Program states that vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission applies this approach to all vaccines - whether a part of the CDC or state immunization program or purchased by healthcare facilities - with the expectation that vaccines are managed in accordance with the product manufacturer's instructions for use (correct temperature, frequency of temperature checks, etc.) and any applicable regulatory requirements.

IMPORTANT: If you are a Vaccine for Children (VFC) provider or receive other vaccines purchased with public funds, consult your state or local immunization program to ensure you are meeting all mandatory storage and handling requirements that are specific or tailored to your jurisdiction

Preparation:
The setting in which vaccines are prepared and administered should have adequate space to prepare a vaccine using aseptic technique to prevent vial contamination. Consider the following:

- There is clear physical separation of the medication storage / preparation area from the administration area. A barrier, such as a wall, etc., is NOT required.
- The multi-dose vaccine vial remains in the medication preparation area and does not cross into the patient administration area.
- Any item taken into the administration area (e.g. needle, syringe, medication vial, band-aid, etc.) does not return to the medication storage/preparation area.
- Staff utilizing the room have been trained on procedures required to prevent cross contamination.
- All vaccination and administration supplies are secured or under constant visual surveillance to ensure cross contamination does not occur.

Ordering and Protocols

Influenza and Pneumococcal Vaccines:
Unless your state is more specific, these two vaccines are not required to have a physician's order in the medical record as long as the following conditions are met:

- There must be a hospital policy and procedure approved by the medical staff which allows Influenza and Pneumococcal Vaccines to be given without a physician's order.
- There must be an evidence-based evaluation of the patient to ensure that no contraindications exist preventing the patient from the receiving the vaccine.
- The medical record must contain evidence of the vaccination administration to include the Manufacturer Lot # and expiration date as well as the publication date of the Vaccine Information Statement (VIS) given to the patient.

If all criteria are met and an order would not be required, then pharmacy would not be required to review.

For all Vaccines *except* Influenza and Pneumococcal Vaccines:

Since vaccines are considered medications, they are subject to the requirements found in the Medication Management (MM) chapter of the accreditation manual. Regarding patient-specific orders and pharmacy review, there are a number of states that allow vaccines to be administered based on a standing order that can be

implemented when a patient meets certain pre-defined criteria (age, medical condition, etc), thus eliminating the need for an individual physician order.

Each organization would need to determine if their state permits the use of such standing orders for vaccine administration. However, a pharmacist will still need to review this standing order in regards to the particular patient in which it was ordered for evaluation of contraindications, etc.

Our standards do not address issues related to payer source, when patients are covered under entitlement programs, such as Medicare, an order to implement a protocol may be required to be entered into the medical record. Regardless of the payer source, to ensure compliance with RC.02.01.01, a copy of the standing order/protocol etc., should be included in the medical record.

Documentation Requirements:
The following information must be documented on the patient's paper or electronic medical record **OR** on a permanent log: (The HCO determines if documentation will be in the medical record **OR** on a permanent accessible log).

- The vaccine manufacturer
- The lot number of the vaccine
- The date the vaccine is administered

- The name, office address, and title of the healthcare provider administering the vaccine
- The Vaccine Information Statement (VIS) edition date located in the lower right corner on the back of the VIS. When administering combination vaccines, all applicable VISs should be given and the individual VIS edition dates recorded.
- The date the VIS is given to the patient, parent, or guardian.

The federally required information should be both permanent and accessible.
Federal law does not require a parent, patient, or guardian to sign a consent form in order to receive a vaccination; providing them with the appropriate VIS(s) and answering their questions is sufficient under federal law.

Resources:
Center for Disease Control (CDC):
One and Only Campaign
Frequently Asked Questions (FAQs) regarding Safe Practices for Medical Injections
Safe Injection Practices to Prevent Transmission of Infections to Patients
CDC Vaccination Resources
Vaccine Information Statement (VIS) - General Information
Vaccine Information Statement (VIS) FAQs
Vaccine Storage and Handling Toolkit (2019)
At-A-Glance: Vaccine Administration, Storage and Handling

Last updated on February 29, 2024 with update notes of: Editorial changes only

First Published Date: January 23, 2019