Multi-dose Vials

Q. What types of vials are considered to be “multi-dose”?
A. According to Safe Injection Practices Coalition (2010):
A multi-dose vial is a bottle of liquid medication (injectable) that contains more than one dose of medication and is approved by the Food and Drug Administration (FDA) for use on multiple persons. A new, sterile needle and syringe should always be used to access the medication in a multi-dose vial. The reuse of needles or syringes to access multi-dose vial medication can result in contamination of the medicine with microbes that can be spread to others when the medicine is used again. (Retrieved on June 18, 2010 from http://www.oneandonlycampaign.org/Post/sections/8/Files/SIPCProviderBrochure.pdf)

Q. When do multi-dose vials that have been punctured or opened need to be discarded?
A. Multi-dose vials are to be discarded 28 days after first use unless the manufacturer specifies otherwise (shorter or longer). Manufacturers are only required by law to test the effectiveness of the bacteriostatic agent used in the multi-dose vial for a period of 28 days. Manufacturers are allowed by the FDA to provide extended dating in the package insert if they have conducted testing beyond the 28 days. Multi-dose pens, such as those used to inject medications such as insulin and Byetta, are included.

Q. Does the multi-dose vial need to be labeled with a new expiration date once it is opened or punctured?
A. Yes. Standard MM.03.01.01, EP 7 requires that all stored medications are labeled with the expiration date. The Joint Commission defines the expiration date as “the last date that the product is to be used”. The manufacturer’s expiration date is based on the fact that the product has not been opened. Once the vial cap is removed or the vial is punctured, the manufacturer’s expiration date is no longer valid and a revised date (also called the “beyond use date” in pharmaceutical terminology) needs to be determined. **To be in compliance with MM.03.01.01 EP 7, The Joint Commission requires organizations to re-label multi-dose vials with a revised expiration date once the multi-dose vial is opened or punctured.**
If the manufacturer’s original expiration date is shorter than the revised expiration date then the shorter date must be used. Also, if sterility is questioned or compromised the multi-dose vials should be discarded regardless of the date.
Labeling the multi-dose vial with the date opened will **not** meet the intent of this requirement.
Q. Do vaccines need to follow the 28 day rule?
A. Currently, vaccines are exempted from this requirement. The CDC Immunization Program states that vaccines are to be discarded per the manufacturer’s expiration date. The Joint Commission is applying this approach to all vaccines (whether a part of the CDC or state immunization program or purchased by healthcare facilities) with the understanding that the vaccines are stored and handled appropriately (correct temperature is maintained, frequency of temperature checks, etc.). Following the guidelines provided in the package insert is very important to assure integrity of the vaccine.
The CDC has excellent resources regarding the use, storage and handling of vaccines at:
http://www.cdc.gov/vaccines/hcp.htm

Q. Where can I locate additional information on safe medication practices for multi-dose vials?
A. The Safe Injection Practices Coalition has developed the One & Only Campaign which is: “A public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices”. The website for this campaign provides excellent resources for staff and patients. For more information see:
http://www.oneandonlycampaign.org/about/default.aspx