ASHP Crosswalk of Guidances and Standards for Managing Single (SDV) and Multi-Dose Vials (MDV)

July 2013

This guide is an ASHP member resource prepared jointly by the **Section of Pharmacy Practice Managers Advisory Group on Quality and Compliance** and **ASHP's Division on Medication Safety and Quality.**

Contact:
David Chen
Director, Pharmacy Practice Sections
and Section of Pharmacy Practice Managers
DChen@ashp.org

Disclaimer:

The information contained in this guide is provided for informational purposes. It is not to be considered as medical, legal or other professional advice. The information contained in this guide is provided solely on an "as is" basis, without any representations or warranties, express or implied. No recipients or readers of this guide should act or refrain from acting on the basis of any content included in this guide. The content of this guide contains general information only, and may not reflect the most current standards, legal developments, regulations or laws.

ASHP makes no representation or warranty with respect to this guide and the information contained herein, and expressly disclaims any and all liability with respect to it, including, but not limited to, a) the accuracy and/or completeness of the information contained in this guide; and b) the consequences of actions taken or not taken based on any or all the contents of the guide. The contents of the guide address topics of interest to our membership and other audiences, and are offered solely on a blind basis, without any knowledge as to specific circumstances. The application and impact of relevant laws and regulations will vary from jurisdiction to jurisdiction. The content of this guide should not be relied upon or used as a substitute for consultation with professional advisers.

	CMS	TJC	USP	CDC	FDA
MDV **(Used in Pharmacy)**	Expects compliance with nationally recognized standards (e.g., CDC, USP).	Expects compliance with nationally recognized standards (e.g., CDC, USP). (NOTE: PPD skin test is NOT exempt from 28 BUD limit upon opening)	BUD per USP 797, normally 28 days unless manufacture label specifies otherwise or evidence of visible contamination. (Exception: Vaccines) (Exception: 96 hours under refrigeration for acetylcysteine)	USP 797 requirements: BUD of 28 days, unless manufacturer label specifies. See http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html CDC safe injection practices FAQs also state: "A needle or other device should never be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid." Therefore, if a spiking or other device is used to puncture the MDV, the vial should remain in the ISO Class 5 environment for subsequent uses. See http://www.cdc.gov/injec	Does not regulate practice.

	CMS	TJC	USP	CDC	FDA
				tionsafety/providers/provider_faqs_med-prep.html Vaccines: BUD per manufacturer instructions See CDC's Vaccine Storage and Handling Guide for specific vaccine product info at http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf Also, the CDC Vaccine and Storage Handling Toolkit says to mark the date the vaccine is opened (date and time for vaccines requiring reconstitution). See http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf	
SDV **(Used in Pharmacy) (includes Single use items like SVP and LVP)**	Original vial: Six hours after initial puncture assuming USP 797, with date/time and vial remains in ISO Class 5	Expects compliance with nationally recognized standards (e.g., CDC, USP).	Repackaged items: BUD per 797 low risk compounding USP 797:	Original vial: Discard according to the time the manufacturer specifies for the opened vial. Do not store for further use.	Does not regulate practice.

	CMS	TJC	USP	CDC	FDA
	(i.e. the IV hood) Repackaged items: BUD per 797 low risk compounding See CMS Survey and Certification Group memorandum at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-35.pdf		BUD of six hours after initial puncture unless otherwise specified by manufacturer provided 1) the container is penetrated only once after constitution with a sterile transfer device or dispensing set and 2) the container is used and remains in a laminar airflow hood or equivalent clean air compounding area BUD of 1 hour after puncture in worse than ISO Class 5 air ***Note: does not apply to opened ampules***	Repackaged items: Per USP 797 Safe Injection Practices FAQs at http://www.cdc.gov/injectionsafety/providers/provider_faqs.html states although the use of aseptic technique when preparing injectable medications is applicable to all healthcare settings, (including pharmacy areas) the CDC document is not intended to reflect the standards and recommended practices for handling medication vials and related products in pharmacy settings. These should be determined in accordance with the state BOPs, USP, FDA, and DEA. ** Do not use LVP or SVP for more than one patient in areas such at cath lab **	

	CMS	TJC	USP	CDC	FDA
Pharmacy Bulk Packages **(Used in pharmacy) (e.g., electrolytes, antibiotics)**	Expects compliance with nationally recognized standards (e.g., CDC, USP) and manufacturer's recommendations.	Expects compliance with nationally recognized standards (e.g., CDC, USP) and manufacturer's recommendations.	Restricted to pharmacy admixture programs; labeled "not for direct infusion;" BUD per manufacturer instructions Note: must be punctured only one time and maintained in an ISO Class 5 environment		
MDV **(used outside pharmacy)**	Expects compliance with nationally recognized standards (e.g., CDC, USP).	Expects compliance with nationally recognized standards (e.g., CDC, USP).	BUD per USP 797, normally 28 days unless manufacture label specifies otherwise or evidence of visible contamination. Examples of exceptions: PPD skin test; vaccines	Date and discard within 28 days, unless manufacture label specifies. CDC safe injection practices state MDVs should be dedicated to a single patient as much as possible. If MDVs are used for more than one patient, they must not enter the immediate treatment area. Challenge: use of bedside bar coding	

	CMS	TJC	USP	CDC	FDA
				Challenge: anesthesia carts are in immediate treatment areas See http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html CDC safe injection practices FAQs also state: A needle or other device (e.g., spiking device) should never be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid. See http://www.cdc.gov/injectionsafety/providers/provider_faqs.html Vaccines: BUD per manufacturer instructions See CDC's Vaccine Storage and Handling Guide for specific vaccine product info at	

	CMS	TJC	USP	CDC	FDA
				http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf Also, the CDC Vaccine and Storage Handling Toolkit says to mark the date the vaccine is opened (date and time for vaccines requiring reconstitution). See http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf	
SDV **(used outside pharmacy)**	Expects compliance with nationally recognized standards (e.g., CDC, USP) See CMS Survey and Certification Group memorandum at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-35.pdf	Expects compliance with nationally recognized standards (e.g., CDC, USP)	"Immediate Use" One hour if not punctured in a ISO Class 5 environment	For use in a single patient for a single case/procedure/injection. Discard according to the time specified by the manufacturer for the opened vial or at the end of case/procedure for which it is being used, whichever comes first. Container should not be stored for future use. Expects CDC Safe Injection Practices to be	

	CMS	TJC	USP	CDC	FDA
	Also see CMS Surveyors Worksheet http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-32.pdf			followed. See http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html **Bags and bottles of intravenous solutions must not be used as a common supply for multiple patients. ** Also see the CDC Position on SDVs at www.cdc.gov/injectionsafety/PDF/CDC-SDV-Position05022012.pdf	
Pharmacy Bulk Packages **(used outside pharmacy) (e.g., contrast media)**	Expects compliance with nationally recognized standards (e.g., CDC, USP).	Expects compliance with nationally recognized standards (e.g., CDC, USP). (**NOTE**: The Joint Commission is allowing this practice for contrast media if injectors are used and handling and dating are consistent with manufacturer recommendations, since that is what has been approved by the FDA as part of the package insert. The Joint	If not punctured in a suitable clean air environment (e.g., laminar airflow hood) may only use for one patient and handled as a single use container. See USP definition of pharmacy bulk package at the end of this document.		

	CMS	TJC	USP	CDC	FDA
		Commission has stated that it is working with the FDA to evaluate this practice of use outside a pharmacy or laminar flow hood- which would impact the package insert- but until a decision has been reached – surveyors will not score this as non-compliant if organizations are using consistent with manufacturer recommendations.)			
MDV **(used in MD office or free-standing ambulatory care site)**	Expects compliance with nationally recognized standards (e.g., CDC, USP).	Expects compliance with nationally recognized standards (e.g., CDC, USP).	BUD per USP 797, normally 28 days unless manufacture label specifies otherwise or evidence of visible contamination.	Date and discard within 28 days, unless manufacture label specifies. CDC safe injection practices state MDVs should be dedicated to a single patient as much as possible. If MDVs are used for more than one patient, they must not enter the immediate treatment area.	

	CMS	TJC	USP	CDC	FDA
				If multi-dose vials enter the immediate patient treatment area they should be dedicated for single-patient use and discarded immediately after use. Also see- Checklist: http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care:* http://www.cdc.gov/HAI/pdfs/guidelines/standatds-of-ambulatory-care-7-2011.pdf	
SDV **(used in MD office or free-standing ambulatory care site)**	Expects compliance with nationally recognized standards (e.g., CDC, USP) See CMS Survey and Certification Group memorandum at	Expects compliance with nationally recognized standards (e.g., CDC, USP)	"Immediate Use" One hour if not punctured in a ISO Class 5 environment	For use in a single patient for a single case/procedure/injection. Discard according to the time specified by the manufacturer for the opened vial or at the end	

	CMS	TJC	USP	CDC	FDA
	http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-35.pdf Also see CMS Surveyors Worksheet http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-32.pdf			of case/procedure for which it is being used, whichever comes first. Container should not be stored for later use. Checklist: http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care: http://www.cdc.gov/HAI/pdfs/guidelines/standatds-of-ambulatory-care-7-2011.pdf	
Pharmacy Bulk Packages **(used in MD office or free standing ambulatory care site)** **(ex. Contrast media, antibiotics)**	Expects compliance with nationally recognized standards (e.g., CDC, USP).	Expects compliance with nationally recognized standards (e.g., CDC, USP).	If punctured in the MD office or ambulatory care site and not in a suitable clean air environment (e.g., laminar airflow hood), may only use for one patient and handled as a single use container. See USP definition of pharmacy bulk package at the end of this document.		

Notes

Acronyms:
BUD – beyond use date
CMS – Centers for Medicaid and Medicare Services
CDC – Centers for Disease Control
FDA – Food and Drug Administration
SVP – Small Volume Parenteral (e.g., 50 mL, 100 mL, 250 mL).
LVP – Large Volume Parenteral (e.g. 500 ml or greater volume)
TJC – The Joint Commission
USP – United States Pharmacopeia

USP's definition of a Pharmacy Bulk Package is as follows:
A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.

The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set which allows measured dispensing of the contents. The Pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

FDA's definition of a Pharmacy Bulk Package is as follows:
A container of a sterile preparation whose contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.

TJC Standard:
The hospital stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions