

# Updates on Activities Related to Single-dose Vials

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HICPAC  
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## **What is a Single-dose/Single-use Vial?**

- ❑ **Vial of liquid medication intended for parenteral administration that is meant for use in a single patient for a single case/procedure/injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.**

[http://www.cdc.gov/injectionsafety/providers/provider\\_faqs\\_singlevials.html](http://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html)

## **CDC/HICPAC Guidelines Address Single-dose Vials**

# **2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings**

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Committee**

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<http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

## **Single-dose Vial Recommendations in CDC/HICPAC Guidelines**

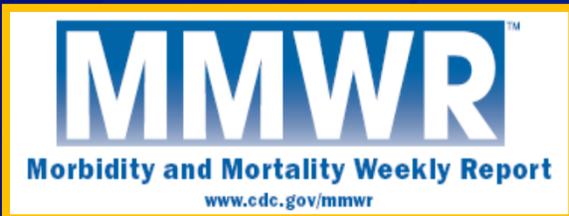
- ❑ Use single-dose vials for parenteral medications whenever possible. Category IA**
- ❑ Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use. Category IA**

## Outbreaks Associated with Single-dose Vials

- **Since the CDC Safe Injection Guidelines were published in 2007:**
  - At least 19 outbreaks associated with single-dose vials or single use IV solutions
  - 7 outbreaks of hepatitis B and/or C
  - 12 outbreaks of bacterial infections
    - High rates of hospitalization for BSIs
  - Nearly all occurred in outpatient settings
    - Pain clinics (n=8) and cancer clinics (n=5)

# HCV Outbreak at Las Vegas Ambulatory Surgical Center (ASC)

May 16, 2008 / Vol. 57 / No. 19



## Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic — Nevada, 2007

On January 2, 2008, the Nevada State Health Division (NSHD) contacted CDC concerning surveillance reports received by the Southern Nevada Health District (SNHD) regarding two persons recently diagnosed with acute hepatitis C. A third person with acute hepatitis C was reported

- Re-entered medication vials with used syringe
- Used single-dose vials of propofol for more than one patient

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm>

# Infection Control Worksheet Used by CMS in ASCs

Exhibit 351

*Ambulatory Surgical Center*

## INFECTION CONTROL SURVEYOR WORKSHEET

*(Rev. 68 Issued: 11-24-10, Effective: 11-24-10, Implementation: 11-24-10)*

*Agency or AO (please print at right)*

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Directions: The following is a list of items that must be assessed during the on-site survey to determine compliance with the infection control Condition for Coverage. Items are to be

- |  |                           |                                   |
|--|---------------------------|-----------------------------------|
| F. a. Single dose (single-use) medication vials are used for only one patient (A "No" response must be cited in relation to 42 CFR 416.48(a).) | <input type="radio"/> Yes | <input type="radio"/> Observation |
|  | <input type="radio"/> No  | <input type="radio"/> Interview   |
|  | <input type="radio"/> N/A | <input type="radio"/> Both        |
| b. Manufactured prefilled syringes are used for only one patient   | <input type="radio"/> Yes | <input type="radio"/> Observation |
|  | <input type="radio"/> No  | <input type="radio"/> Interview   |
|  | <input type="radio"/> N/A | <input type="radio"/> Both        |
| c. Bags of IV solutions are used for only one patient  | <input type="radio"/> Yes | <input type="radio"/> Observation |
|  | <input type="radio"/> No  | <input type="radio"/> Interview   |

[http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107\\_exhibit\\_351.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf)

## Contact Congress Today!

### ■ Critical Shortage of Essential Drugs Due to Single Dose Vial Policy

The American Society of Interventional Pain Physicians (ASIPP) is very concerned about the single dose vial policy for infection control. There is currently a national emergency of a critical shortage of essential drugs used in managing patients including drugs for sedation, pain relief, and

id...the single dose vial policy for infection control which, as currently written, is not only very expensive, but causes numerous problems related to patient access, further it has not been proven through evidence to be necessarily or medically indicated.”

and Alfentanil. Along with these we are also experiencing shortages and increased costs for contrast material. It is essential that CMS modify this rule as soon as possible to avoid further crisis.

We ask for your assistance in contacting Congress for their support. We encourage you to personal the letter or if you prefer you may send it as it is written. Either way your letter(s) will help in the fight to save health care, your practice, and patient access.

[Capwiz Letter](#)

**Injection Safety Recommendations  
for 2007 CDC/HICPAC Guidelines**

**ASIPP Draft “Consensus Statement  
of Infection Control Measures of  
Single-dose Vials for Multiple  
Patients”**

IV.H.1. Use aseptic technique to avoid contamination of sterile injection equipment. Category IA

All doses must be drawn up by licensed professionals whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.

IV.H.2. Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed. Needles, cannulae, and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient. Category IA

Not mentioned in ASIPP Draft Consensus Statement.

**Injection Safety  
Recommendations for  
2007 CDC/HICPAC  
Guidelines**

**ASIPP Draft “Consensus Statement of Infection  
Control Measures of Single-dose Vials for Multiple  
Patients”**

IV.H.5. Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use. Category IA

2. All doses from a given vial should be drawn-up and administered within a 12-hour period.
3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.
4. Any opened vials or filled syringes (contrast medium, local anesthetic, steroids, or other drugs) must be discarded if not used within 12 hours of the vial's first puncture. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) when not in use.
5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.

# CDC Position Statement on Single-dose Vials

Centers for Disease Control and Prevention  
National Center for Emerging and Zoonotic Infectious Diseases  
Division of Healthcare Quality Promotion  
Single-dose/Single-use Vial Position and Messages  
May 2, 2012

In an effort to ensure clinicians are clear about CDC guidelines, the Agency is restating its position on the use of single-dose/single-use vials and also seeks to dispel inaccuracies being disseminated to healthcare providers.

## CDC's Position

### Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials

The Centers for Disease Control and Prevention's guidelines call for medications labeled as "single dose"

<http://www.cdc.gov/injectionsafety/CDCposition-SingleUseVial.html>

## CDC Position Statement on Single-dose Vials

- ❑ In times of critical need, contents from unopened single-dose/single-use vials can be repackaged for multiple patients. However, this should only be performed by qualified healthcare personnel in accordance with standards in United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Following the USP standards is imperative, as medication contamination and patient harm can occur when repackaging (e.g. splitting doses) is not done properly.

## **CDC Ongoing Activities Related to Single-dose Vials**

- ❑ **Discussions with partners including USP, FDA, and CMS**
- ❑ **Outreach to provider community to**
  - Educate about ongoing experience with outbreaks associated with multi-patient use of SDVs
  - Learn more about factors that that make dedicating SDVs to individual patients challenging
    - Reimbursement
    - National Drug Shortage
    - Access to the “right-sized vial” which may not be produced by the manufacturer

# Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

National Center for Emerging and Zoonotic Infectious Diseases  
Division of Healthcare Quality Promotion

