References for Multi-use Medications


Guidelines for Use of Ophthalmic Eye Drops and Ointments

Campbell, R, TJC, email to Palmer, D, Robin, A, June 3, 2021

Chambers, W, Letter to Drs. Robin and Palmer, May 14, 2021

CDC, email to Robin, A, June 14, 2021

Figy, A. AAAHC, email to Palmer, D, June 3, 2021.

Wolff, I, AAAASF, email to Robin, A, June 3, 2021
Dr. Palmer request for answers from AAAHC for O OSS article – needed by May 31

1. Consistent with Pharmacy Practice Act regulations and AAAHC Standards, how can patients go home with their topically applied OR meds if a pharmacy or label printer is not on premises?
AAAHC Response:
These medications should be prescribed through the clinic (physician’s office) for the patient at their pharmacy of choice. Then, the patient can bring the medications in their original packaging to the surgery center on the day of the procedure. This will ensure the medications are correctly labeled, and the nursing staff can verify that the patient has obtained their post-op eye drops.

Our standards and interpretive guidance will be updated with our upcoming overhaul process.

Thank you for allowing us to contribute.

Respectfully,

Ilana Wolff, RN
Director of Clinical Compliance

AAAHC- Accreditation Association for Ambulatory Healthcare

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2. Can patient-own medications from a Registered Pharmacist/retail pharmacy be allowed into the ASC OR and be provided to patients post-discharge?
If a Medicare Designated facility, is there a difference?
AAAHC Response:
Yes, if the medication is in the original packaging, correctly labeled by pharmacy, and only used for the patient they have been prescribed to. These medications would always need to stay with the patient. Typically, this is not the practice, most ASC’s use their own eye drops pre-op, intra-op, and post-op, while the patient is in the ASC.

3. Please differentiate AAAHC vs The Joint Commission Survey Standards in approving a facility.
AAAHC Response: AAAHC prefers to decline commentary.
4. Are multidose eyedrops, for example dilating drops, on multiple patients allowed if the Standards approved by AAAHC are followed? If yes, what are the Standards?

AAAHC Response: Yes, provided that the medication is labeled, handled, administered, and stored according to policies, manufacturer instructions, and best practice guidelines.

Staff must understand safe practice and apply infection control techniques with rigor.

Consider mandatory training, competency, and monitoring programs to teach and validate safe eye drop handling.

Anna Figy, AAAHC

CDC- Centers for Disease Control

Thank you for your inquiry to CDC-INFO.

Your request for information was forwarded to the CDC Division of Healthcare Quality Promotion. We hope you find their reply helpful.

Thank you for your inquiry.

CDC does not have specific guidance for ophthalmic solutions; however, the following recommendations apply to injectable medications.

Medication vials should always be discarded whenever sterility is compromised or cannot be confirmed. In addition, the United States Pharmacopeia (USP) General Chapter 797 recommends the following for multi-dose vials of sterile pharmaceuticals:

- If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and **discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.**

- If a multi-dose vial has **not** been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer’s expiration date.

The manufacturer’s expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer’s original expiration date.

Additional information is available at https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html

Thank you again for contacting us. We hope the information provided is helpful to you,

Sincerely,

CDC's Division of Healthcare Quality Promotion's Public Inquiries Team
CMS Letter to Scott Haber, AAO legislative affairs and public health director 12/2/21:

CMS expects all providers and suppliers to comply with nationally recognized standards of practice for infection control, and medication preparation and administration. Drugs and biologicals must be handled and provided in accordance with applicable State and Federal laws as well as with standards established by organizations with nationally recognized expertise in the clinical use of drugs and biologicals. The CFCs do not explicitly prohibit the use of multi-dose eye drop bottles for multiple patients if done in accordance with national standards of practice. The ASC infection control worksheet contains content related to the use of injectable medications. The questions related to multi-dose vials should not be used as the sole basis of citations related to handling of eye drops as these relate to CDC guidelines for injectable medications. ASCs using multi-dose eye drop bottles for multiple patients must follow the instructions on the labeling to minimize inadvertent contamination of any medications through direct contact with potentially contaminated surfaces that could then lead to infections in subsequent patients. If surveyors observe eye drops known to be contaminated and/or using eye drop medications labeled as single patient use only on multiple patients, the facility should be cited under the appropriate infection control requirement for ASCs. Eye drop medications labeled as multi-dose may be used for more than one patient if, and only if, aseptic technique and standard precautions are followed. Any medication labeled as single-use must be discarded immediately after use on a single patient.

TJC- The Joint Commission email to Palmer, Robin

“An email to our committee from Robert Campbell, PharmD, BCSP, Director of Clinical Standards Interpretation Group and Medication Management at TJC confirmed that the 28 day expiration dating used for multi dose injectable medications does not apply to topical agents such as ophthalmic drops/ointments. The manufacturers package insert provides expiration dates for the particular product.”

Robert Campbell, PharmD, BCSCP
Director, Clinical Standards Interpretation Group
Director, Medication Management

The Joint Commission
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