



ACCREDITATION ASSOCIATION  
for AMBULATORY HEALTH CARE, INC.

## Propofol shortage and AAAHC Standards

During the COVID-19 public health emergency, AAAHC is providing accredited organizations with necessary resources and communication to help our accredited organizations mitigate risk and adapt daily operations to meet ongoing challenges. The *1095 Strong, quality every day* philosophy is a commitment to providing quality health care all 1.095 days of the accreditation term, and AAAHC will continue to support your efforts with timely information and updates.

The US Food and Drug Administration (FDA) has received inquiries from health care professionals concerning the availability of propofol drug products used in the treatment and management of patients with complications related to COVID-19. There is currently reported difficulty in obtaining several drugs, including an adequate supply of 10 mg/mL vials of propofol, currently being used to sedate intubated patients with COVID-19. Propofol is on the FDA's shortage list with several presentations on backorder. Some pharmacies and outsourcing facilities that have access to certain presentations have asked to repackage or combine units of a finished, FDA-approved drug product to provide health care facilities with presentations needed for patients with COVID-19. The purpose of this is to provide the facilities with larger presentations of propofol to minimize exposure between patients and staff, as well as to preserve personal protective equipment (PPE).

To prevent the impact of the shortage, the FDA has indicated it will allow compounding pharmacies to repackage or combine propofol to meet the demand for these patients being treated with COVID-19. However, when an FDA-approved drug is repackaged, its characteristics may change in ways that could affect the safety and efficacy of the drug. FDA has issued guidance for pharmacies or outsourcing facilities to mitigate risks when repackaging certain drug products, including storage that does not conflict with the drug's approved labeling. FDA does not intend to act on violations if repackaging follows its guidance and under certain circumstances. For the full FDA guideline please see: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-repackaging-or-combining-propofol-drug-products-during-covid-19-public-health>

These *temporary* changes will affect the following v 41 AAAHC Standards:

11.D.3. Through interviews, staff demonstrates knowledge of prevailing pharmaceutical laws and regulations.

11.D.4. Direct access to current drug information and other decision support resources is available to all relevant staff.

11.I.6. Medications are stored and managed in accordance with manufacturer requirements, and state and/or CDC guidelines. (Standard 11.K.6 in the v41 *Medicare Deemed Status Handbook*)

11.K. If not administered immediately, all medications removed from the original container or packaging are labeled in a standard format in accordance with law, regulation, and standards of practice. (Standard 11.M in the v41 *Medicare Deemed Status Handbook*)

11.L. A written policy is present addressing the disposal or return of expired, damaged, and recalled medications in accordance with prevailing laws and regulations and accepted guidelines. [An addendum to the facility's current written policy should be made to be consistent with the FDA guidelines addressing the drug shortage.] (Standard 11.N in the v41 *Medicare Deemed Status Handbook*)

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