DEPARTMENT OF HEALTH
PHARMACY QUALITY ASSURANCE COMMISSION
DIRECTIVE

Title:	Enforcement of WAC 246-871-030(2)(c) and WAC 246-871-080(1)(d) relating to parenteral products.	**Number:**	D002
Reference:	RCW 18.64.270(2), WAC 246-871-030, WAC 246-871-080, USP Chapter 797, and USP Chapter 795		
Contact:	Steven Saxe, Executive Director		
Effective Date:	June 8, 2018		
Supersedes:	**N/A**		
Approved:	**Chairperson, Pharmacy Quality Assurance Commission**		

This policy establishes the approach of the Pharmacy Quality Assurance Commission (Commission) as it relates to enforcement of two rules. Specifically, the Commission will not be enforcing the following:

- WAC 246-871-030(2)(c): which required the replacement and written recording of certain prefilters.
- WAC 246-871-080(1)(d): *only* as to the requirement for written documentation and the performance of quarterly end product testing.

The Commission will not find deficiencies or take enforcement action against its licensees for failure to adhere to these rules while this policy is in effect. The Commission has taken this position based on its intent to repeal these rules as part of its "Rules Rewrite" project, that the legislature's incorporation of United States Pharmacopeia (USP) chapters provide adequate safeguards for the citizens of Washington related to risks posed by compounded drugs, and the Commission's belief these two rules do not improve patient outcomes or promote public health.

BACKGROUND:

Following a 2012 a meningitis outbreak stemming from unsterile compounding at the New England Compounding Center in Massachusetts, several states worked to adopt standards around sterile and non-sterile compounding of medications. In 2013, the Washington State legislature adopted standards set by USP, a national leader in compounding standards, as the standards pharmacies must meet in order to compound medication. RCW 18.64.270(2) states "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

The Commission has performed a comprehensive review of chapters 246-871 and 246-878 WAC and compared them to the standards set in USP. In its review the Commission determined the vast majority of the standards set in WAC were equivalent or substantially equivalent to the standards in USP. As a result, the Commission has incorporated the repeal of these WAC chapters into the Commission's "Rules Rewrite" project.

During its review, the Commission also identified two rules: WAC 246-871-030(c) and WAC 246-871-080(1) which impose requirements, either in whole or in part, not provided for in the USP chapters. The Commission determined these requirements did not improve patient outcomes or promote public health. Consequently, the Commission decided these two rules should not be enforced.

CONCLUSION:

The Pharmacy Commission will not enforce WAC 246-871-030(c) in its entirety; and WAC 246-871-080(1) in part, as it relates to the performance and written documentation of quarterly end product testing. The Commission believes these rules do not improve patient outcomes or improve public health. Instead the incorporation of USP chapters into statute provide adequate safeguards to the citizens of Washington from any risks posed by compounded drugs.