PREPROPOSAL STATEMENT
OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)
Do NOT use for expedited rule making

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: WAC 246-XXX - The Pharmacy Quality Assurance Commission (Commission) is considering revising its rules around licensing of pharmacies, facilities, and professionals that fall under the Commission's jurisdiction. The Commission will reevaluate current licensing standards, and will consider reorganizing licensing standards into a new chapter or chapters to address any changes identified as needed.

Statutes authorizing the agency to adopt rules on this subject: Chapters 18.64, 18.64A, 69.41, 69.50, and 69.51 RCW

Reasons why rules on this subject may be needed and what they might accomplish: The Commission is responsible for setting the standards for licensing of pharmacists, pharmacy interns, and facilities and locations where drugs are created, made, distributed, sold, and dispensed. A 2017 review of all of the Commission's rules has shown a majority are out of date. 60% of the Commission's 34 chapters of WAC have not been amended since the 1980s. Health care delivery and the role of pharmacists and other pharmacy personnel has changed dramatically over the last 30 years, and outdated rules have led to inconsistent application and interpretation of rules. Following the review and examination, the Commission determined it needed to reexamine and look to modernize the standards around licensing as part of an overhaul of all the outdated rules. Modernization will also align the rules with current pharmacy practice, trends and industry standards. Reexamining the standards may involve reorganizing or replacing standards in the licensing chapters currently in place.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Drug Enforcement Administration will need to be kept up to date throughout the rule making process to ensure they are apprised of any new licensing requirements.

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative rule making.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

Name: Tracy West
Address: PO Box 47850, Olympia, WA 98504-7850
Phone: (360) 236-4988
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Additional comments: Interested parties can sign up for and receive updates on all rule projects through the Commission’s GovDelivery email lists. Additional updates will be posted regularly on the Commission’s Rules In Progress website.
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<tr>
<th>Date:</th>
<th>12/19/2017</th>
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<tbody>
<tr>
<td>Name:</td>
<td>Tim Lynch, PharmD, MS</td>
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<tr>
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CR-101 (October 2017) (Implements RCW 34.05.310) Do NOT use for expedited rule making

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: WAC 246-XXX - The Pharmacy Quality Assurance Commission (Commission) is considering reevaluating the parameters around exercising its regulatory authority, specifically functions of the Commission, and other general provisions that apply to the regulation of the practice of pharmacy. The Commission will reevaluate current standards around its functions as a regulatory body, and will consider reorganizing standards in a new chapter or chapters to address any changes identified as needed.

Statutes authorizing the agency to adopt rules on this subject: Chapters 18.64, 18.64A, 69.40, 69.41, 69.50 and 69.51 RCW

Reasons why rules on this subject may be needed and what they might accomplish: The Commission is responsible for setting the standards and requirements for the practice of pharmacy in Washington state. A crucial part of the Commission's role in regulation is how it implements and functions under the rules and statutes that apply to the practice of pharmacy. A 2017 review of all of the Commission's rules has shown a majority are out of date, and 60% of the Commission's 34 chapters of WAC have not been amended since the 1980s. Health care delivery and the role of pharmacists and other pharmacy personnel has changed dramatically over the last 30 years, and outdated rules have led to inconsistent application and interpretation of rules. Following the review, the Commission determined it needed to reexamine and look to modernize the standards around its regulatory framework or other general provisions applicable to the pharmacy practice as part of an overhaul of all the outdated rules. The rules require modernization to better align with current pharmacy practice, trends and industry standards. Reexamining the current standards may involve reorganizing or replacing standards across multiple existing sections or chapters of WAC.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Drug Enforcement Administration will need to be kept up to date throughout the rule making process to ensure they are apprised of any requirement changes regarding controlled substances.

Process for developing new rule (check all that apply):

- [ ] Negotiated rule making
- [ ] Pilot rule making
- [ ] Agency study
- [X] Other (describe) Collaborative rule making.

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<tbody>
<tr>
<td>Name: Tim Lynch, PharmD, MS</td>
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PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)  
(Implements RCW 34.05.310)  
Do NOT use for expedited rule making

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: Title 246 WAC - The Pharmacy Quality Assurance Commission (Commission) is considering revising rules around operational standards for facilities under the Commission's jurisdiction and is considering reorganizing these standards into a new chapter or chapters to address any changes identified as needed.

Statutes authorizing the agency to adopt rules on this subject: Chapters 18.64, 18.64A, 69.41, 69.50, and 69.51 RCW

Reasons why rules on this subject may be needed and what they might accomplish: The Commission is responsible for setting the standards for licensing of pharmacists, pharmacy interns, and facilities and locations where drugs are created, made, distributed, sold, and dispensed. A 2017 review of all of the Commission's rules has shown a majority are out of date. 60% of the Commission's 34 chapters of WAC have not been amended since the 1980s. Health care delivery and the role of pharmacists and other pharmacy personnel has changed dramatically over the last 30 years, and outdated rules have led to inconsistent application and interpretation of rules. Following the review and examination, the commission determined it needed to reexamine and consider aligning existing standards with current pharmacy practice, trends and industry standards. Reexamining the standards may involve reorganizing or replacing standards in chapters currently in place.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: N/A

Process for developing new rule (check all that apply):
- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative rulemaking.

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Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: Title 246 WAC - The Pharmacy Quality Assurance Commission (Commission) is considering revising its rules around professional standards for pharmacy personnel under the Commission's jurisdiction and considering reorganizing these standards into a new chapter or chapters to address any changes identified as needed.

Statutes authorizing the agency to adopt rules on this subject: Chapters 18.64, 18.64A, 69.41, 69.50, and 69.51 RCW

Reasons why rules on this subject may be needed and what they might accomplish: The Commission is responsible for setting the standards for licensing of pharmacists, pharmacy interns, and facilities and locations where drugs are created, made, distributed, sold, and dispensed. A 2017 review of all of the Commission's rules has shown a majority are out of date. 60% of the Commission's 34 chapters of WAC have not been amended since the 1980s. Health care delivery and the role of pharmacists and other pharmacy personnel has changed dramatically over the last 30 years, and outdated rules have led to inconsistent application and interpretation of rules. Following the review and examination, the commission determined it needed to reexamine and consider aligning existing standards with current pharmacy practice, trends and industry standards. Reexamining the standards may involve reorganizing or replacing standards in chapters currently in place.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Drug Enforcement Administration, and the Washington state Attorney General's Office will be kept up to date throughout the rulemaking process to ensure they are apprised of any new standards.

Process for developing new rule (check all that apply):

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