Washington State Department of Health

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# Report to Commission: Proposed Process, Pharmacy Business Practices Committee

**Presented by: Dan Rubin, Chair, Pharmacy Business Practices Committee, July 10, 2014**

The committee's other members are Steven Anderson, Gary Harris and Elizabeth Jensen. I regret that my understanding of requirements of the Open Meeting Act made it impossible for me to consult with them individually while I developed this recommendation in consultation with commission staff members over the past month. I seek input today from all commission members on the proposal.

## History

- In fall of 2011 the then- Board of Pharmacy began a pharmacy rules rewrite project. Over the following year members and staff participated in a rule scan and gap analysis process to identify areas that likely need revision.
- This rule scan was input to a Board Planning Session on November 9, 2012. Four workgroups were formed, including an "Operations Workgroup" (name later modified to Business Practices).
- In January 2013 the board adopted resolutions authorizing filing a CR-101 for this area of rule making (along with resolutions covering three other rule-making areas (Compounding; Pharmacists and Pharmacy Interns; and Pharmacy Technology).
- Soon after this a moratorium was placed on non-essential rule making, leading to interruption of planned work sessions with stakeholder input.
- The priority areas were reviewed again at the April 16, 2014 Commission Planning Session without formal change and membership of the committee was reaffirmed except for the appointment of Steven Anderson to replace Emma Zavala-Suarez, who had left the commission. Dan Rubin was named chair at this point.

## Scope of Issues to be Considered

- Official scope of rule making will be stated in a CR-101 that needs to be filed to initiate the formal rule-making process under the state Administrative Procedures Act (APA).
- Based on work through the conclusion of the November 2012 Planning Session, **priority topics** related to Pharmacy Business Practices were identified. The output document dated December 17, 2012 is attached, but more briefly, the priorities fall in three areas:
    - Priority Area: Workload and staffing levels (sufficient personnel, quotas, workflow metrics, appropriate staffing to provide for counseling)
    - Priority Area: Prescription transfers (and other advertising/soliciting issues that may affect public safety).[1]
    - Priority Area: Appropriate time, space and privacy for clinical pharmacy functions (including immunizations).

[1] Commitment to address this issue was reinforced at the April 17, 2014 Business Meeting. The commission denied a petition for immediate rulemaking to prohibit the use of financial awards or offers of other benefits (incentives) for prescription transfers from one pharmacy to another, but we stated our intent to include this topic within the broader rule-making process.

- The topics above were reviewed during the commission's April 16, 2014 Planning Session. No official modifications were made in the list above but I believe a brief period should be provided for further input on the scope of Pharmacy Business Practice rulemaking by both commission members and interested parties before filing a CR-101.
- I recommend consideration of at least the following addition topics, without predetermination of whether any will be added:
    - My personal notes from the April 2014 Planning Session listed "contributory responsibility of the business" as another very important topic.
    - Other issues that I have heard come up during recent discussion include:
        - Adequacy of rules addressing secondary and "gray market" methods of drug distribution and "white bagging";
        - Quality improvement and quality assurance processes; and
        - Access to necessary references and compendia (including for veterinary drugs).

## Proposed Process

1. Immediately after today's business meeting, the Pharmacy Business Practices Committee will convene to agree on a process for the committee's work (Committee Meeting 1). The door will be open to modification of process later based on experience and/or further input.
2. My goal is for the CR-101 identifying general scope of consideration for rulemaking to be issued by the end of August at latest. Process:
    - Request written input by July 25 on additional topics for consideration (beyond the priority topics previously identified by the commission).
    - Schedule a second committee meeting by August 15 to determine scope of CR-101. (The scope of issues to be considered can be changed if necessary by filing a new CR-101.)
    - Staff prepare and issue a CR-101 as soon as possible, in consultation with committee.
3. I believe even the existing priority areas cover too much ground to have a single developmental discussion about them all simultaneously. I recommend we separate distinct broad issues within the scope to allow focused discussion, public comment and evolution of potential rulemaking content ideas on a rolling basis.
    - I would like the committee to determine at its second meeting (by August 15) how to subdivide the agreed scope into three or more broad issue clusters that can be discussed separately with greater focus. The three priority areas identified to date are a first cut but this may change with addition of other topics and appropriate combination.
    - The order for consideration of issues also should be determined (for the rolling process discussed in item 5 below).
4. I suggest a rolling process where each issue cluster moves through certain steps before all rule content is integrated. For each issue cluster:
    - Committee carry out preliminary discussion to further define the problem(s) which may require rule development. This step should include brief consideration of available research, issues as seen by inspectors, input previously received, and identification of

specific questions for stakeholder input. For the first cluster, this step should occur at Committee meeting 3 (late August or early September)
    - If it wishes the committee may invite public comment at this first session, but the focus will be on a formal request for comment in the next step.
- Immediate follow-up to the initial discussion of each issue cluster should include a formal request for stakeholder comments, including a request for relevant research on problems, evidence of potential solutions achievable by rule and examples of effective or promising policies from other jurisdictions. The working deadline for this initial request for comments should precede a future meeting selected to address the issues, with enough time for committee members to review comments and if possible, for a summary of the comments by staff, Chair or another committee member.
- At the designated follow-up meeting, review written input and solicit oral comments and discussion. More than one meeting may be necessary depending on complexity, number of comments and meeting length. This is the stage of the process at which multi-site teleconferences are likely to be of the highest value, when feasible.
- Committee consider evidence and input and either identify additional questions for input, or proceed to discussion of a "trial balloon" reflecting the sense of the committee as to general direction or options. The purpose of this "trial balloon" is to obtain more focused comments prior to the CR-102 stage. Substantial changes from the "trial balloon" may occur at later stages; it does not constitute a proposal to the commission.
- One committee meeting may contain different steps in the work on distinct issues, in order to keep the process moving. There will be an agenda for each committee meeting.

5. Comments on Specific Topics
    - Timing for work on the Workload and Staffing Levels issue cluster must be coordinated with the planned survey of pharmacy professionals, which will provide information.
    - Proponents of the rule petition on prescription transfer (who were then University of Washington pharmacy students) will be invited to present when that topic is addressed.
6. When the Committee has developed all issue clusters planned for rule-making, the committee will turn its attention to working with staff to draft a proposed rule. Procedures for consultation with the full commission at this stage, before filing a CR-102, need further discussion.
7. Note that provisions of that Administrative Procedures Act govern all rule development processes and the work of the Pharmacy Business Practices Committee must always comply.

## Commission Comments on Recommendations

- I look forward to hearing comments on these recommendations by commission members (including members of the Pharmacy Business Practices Committee) during the rest of this Business Meeting agenda item. I request that process detail decisions rest with the committee.
- Public comment will not be sought as part of this agenda item, to reduce the risk of this process discussion moving into substantive discussion about the rules, which should be made part of the official rule-making file after issuance of the CR-101. There will be many opportunities for public comment after the official rule-making process begins.