

Pharmacy Quality Assurance Commission

**Inspection Subcommittee
March 21, 2016**

Background

- Commission established two subcommittees to look at the inspections process.
- After these two subcommittees held their first meetings, it was determined by the Commission it would be best to join the two subcommittees.
- The combined subcommittee held a meeting on August 4th, 2015. Initially, the Commission and staff had gathered information that stakeholders may want to move away from the current point system. At the August meeting other ideas and concerns were discussed.
- Commission and staff took stakeholder comments and have since been discussing different inspection models and what the rule review process should look like going forward.

Why are we here today?

- **Objective:** Gain an understanding of what you think the inspection process should look like.
- **How to:**
 - Discuss other inspection/survey models for DOH facilities.
 - Discuss out-of-state research on alternative inspection models.
 - We have a number of options staff and the Commission members on the committee have discussed.
 - Receive additional feedback from you!

Current Process

WAC 246-869-190 Pharmacy inspections.

- (1) All pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.
- (2) Each inspected pharmacy shall receive a classification rating which will depend upon the extent of that pharmacy's compliance with the inspection standards.
- (3) There shall be three rating classifications:
 - (a) "Class A" - for inspection scores of 90 to 100;
 - (b) "Conditional" - for inspection scores of 80 to 89; and,
 - (c) "Unsatisfactory" - for inspection scores below 80.
- (4) Any pharmacy receiving a conditional rating shall have sixty days to raise its inspection score rating to 90 or better. If upon reinspection after sixty days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.
- (5) Any pharmacy receiving an unsatisfactory rating shall have fourteen days to raise its inspection score rating to 90 or better. If upon reinspection after fourteen days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.
- (6) The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced.
- (7) Noncompliance with the provisions of chapter [18.64A](#) RCW (Pharmacy assistants) and, chapter [246-901](#) WAC (Pharmacy assistants) resulting in a deduction of at least five points shall result in an automatic unsatisfactory rating regardless of the total point score.
- (8) Pharmacies receiving an unsatisfactory rating which represent a clear and present danger to the public health, safety and welfare will be subject to summary suspension of the pharmacy license.

Washington State Health Care Facilities Inspection Overview

- There are 6 health care facility types staff looked at within WA state.
 - Ambulatory Surgical Facilities (ASF)
 - Child Birth Centers (CBC)
 - Hospitals
 - In-Home Services Agencies (Hospice, Home Health, Home Care)
 - Medical Test Sites
 - Residential Treatment Facilities (RTF)
- All of these facility types use some form of Notice of Deficiency/Plan of Correction as their survey/inspection model.
 - Primary differences revolve around timelines, mandated inspections, and mandatory or discretionary notice of survey findings.

Other States

Oregon follows NOD/POC, inspections are conducted annually

- NOD states rule numbers violated
 - 1st deficiency noted on inspection
 - If same deficiency occurs the following year, NOD is completed.
 - If deficiency occurs a third time, a notice of non-compliance is issued, and sent to the Board.
- PIC must provide a response to any deficiency within 30 days
 - 14 days for more serious violations
- Educational components –
 - Licensees emailed a self-inspection form in December, and are required to complete it by February.
 - Monthly PIC classes
- Still have a “scored” system
 - “Pass”, “pass with notes”, “pass with deficiency”, “pass with compliance”

Idaho follows NOD/POC

- NOD must be corrected promptly
- Board can request notification of corrective measures taken, and can require one follow-up inspection. If an additional follow-up inspection is required after the first allotted follow-up, licensee must pay for all related expenses.

Other States (continued)

Texas follows NOD/POC

- System is pass/fail. Warning notices are provided when a new rule is implemented, this allows a collaborative educational relationship between inspector and licensee.
- All facilities inspected the same, except for sterile compounding facilities which have additional requirements.
- Three deficiency severity levels
 - 1st time/1st tier – violation is noted on inspection form
 - Found a second time, facility may be required to submit a written correction. The requirements of this correction depends on the violation and its severity.

California complaint based model.

- Annual inspections of all sterile compounding sites.
- Pharmacies must file a self-assessment form by July 1st every odd year. This must be kept on-site in case of an inspection.
- When a complaint comes in, a routine inspection is performed in conjunction with the complaint inspection. If additional violations are seen, everything is fair game to be documented.
- Inspector lists all findings from the routine inspection and the Board decides what fines, if any, are imposed.

Other Organizations

NABP Verified Pharmacy Program (VPP)

- Unannounced inspection, follows corrective action model.
- Inspection report is posted in VPP system and sent to facility.
- Facility must prove compliance, and can respond to inspection report detailing how noncompliance has been remedied, or why there is no need to remediate.
- State boards of pharmacy use this information to determine licensure of the nonresident pharmacies.
- The VPP has an extensive inspection checklist.

Accreditation Commission for Health Care (ACHC)

provides a hybrid model (NOD and Points) for their accreditation process.

- In performing a survey in response to an accreditation application, and for a facility to receive accreditation, ACHC goes to the facility to assess standards, it is the responsibility of the pharmacy to show compliance.
- This process is education focused, if a pharmacy shows a deficiency, the inspector educates on what is exactly not in compliance, and informs the pharmacy how it can be corrected.
- An inspection may enter into a plan of correction to help with identifying fix and making facility better, both in compliance and understanding of compliance standards.
- The facilities are then provided a score associated with the deficiencies and an internal decision is made to present to accrediting committee

Possible Inspection Models

1. No action. Leave the point system in place. Work on updating the WACs to be more reflective of current pharmacy practices in the field that protect and enhance patient safety.
2. Maintain the point system, but allow points to be attributed differently; i.e., more points based on clearly articulated activities related to patient safety.
3. Adopt a hybrid of points for based on clearly articulated activities related to patient safety and Notice of Deficiency/Plan of Correction for administrative issues.
4. Change to a NOD/POC.
5. Other – based on further research regarding other state practices; or stakeholder ideas



Laws, Rules and Standards for Rule Making

- Administrative Procedure Act (APA) – chap. 34.05 RCW
- Significant Legislative Rule (Cost/Benefit Analysis) – RCW 34.05.328
- Regulatory Fairness Act (Small business economic impact) – chap. 19.85 RCW
- Code Reviser – chap. 1-21 WAC
- Department of Health Rules Manual
- HSQA Procedure 1-1-03 Rules Process (Operating Agreement)

Rule Development

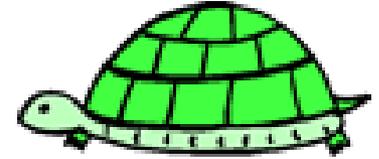


Notice and public comment opportunity required:

- CR-101 - Announces possible rule making
- Stakeholder work – Most of the work / time involved
- CR-102 - Formal proposed rules
- Public hearing and written comments
- Written response (Concise Explanatory Statement)
- CR-103 - Final adoption notice

“CR” means Code Reviser

Why does rule making take so long?



Most rules take 12 to 18 months

- Waiting periods
- Public involvement is valued, but takes time
- Input helps you draft a better rule
- Data, research, economic analyses
- Coordination with Department of Health, Boards or Commissions
- Board / Commission meeting schedules

Questions

