



PQAC NEW RULES LIVE IMPLEMENTATION PLAN

PHARMACY QUALITY ASSURANCE COMMISSION

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Vision

The Pharmacy Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health system.

As a result, the citizens of Washington State:

Are well informed about their medication therapy;
Take responsibility and actively participate in their health outcomes;
Utilize pharmacists and other healthcare providers appropriately; and
Experience the highest level of health and wellness.



Left to Right: Sepi Soleimanpour, Commissioner,
and Tim Lynch, Commission Chair

Mission

The mission of the Washington State Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, governor and the legislature.

Rules Background

- The Pharmacy Quality Assurance Commission (Commission) has adopted one new chapter of administrative rules that covers four areas in the practice of pharmacy including:
 - (1) General Provisions
 - (2) General Licensing
 - (3) Professional Standards
 - (4) Operational Standards
- By creating this new chapter, the Commission is repealing all currently existing WAC chapters under the Commission's jurisdiction.
- The standards addressed were publically discussed over the course of two and a half years with participation from stakeholders and members of the public.
- Stakeholders participation allowed for thoughtful discussions around the evolving practice of pharmacy and foster a truly open process that benefits everyone, especially patients.

Rules Overview: 246-945 WAC

- The New Rules Incorporate:
 - Current WACs, amended WACs, and newly created WACs.
 - Hospital Pharmacy Associated Clinics emergency rules, and make those rules permanent.
 - Current practice, including some current policy and interpretative statements, while allowing for flexibility as the practice evolves.
 - Updates outdated practices, eliminate redundancies, and allows for pharmacists to use professional judgment while still ensuring patient safety and access to quality care.



Rules Overview: 246-945 WAC

- Part one of the new chapter covers general provisions that apply to the practice of pharmacy as well as all drugs under the Commission's authority. This will include operations for the Commission including inspection requirements, prescriptions and refill requirements, labeling requirements, record retention, advertising, legend drugs, controlled substances, precursors, and home dialysis. In addition, this section contains a single definition list that applies throughout the pharmacy WAC chapter.
- Part two of the new chapter covers general licensing for all personnel, facilities, and production or distribution under the Commission's authority. This will include licensing and registration requirements, continuing education, qualifications, renewals, and associated fees.
- Part three of the new chapter covers professional standards for all pharmacy personnel under the Commission's jurisdiction. This will include professional responsibilities, unauthorized conduct, delegation and non-delegable tasks, counseling, refills and continuity of care, prescription modification, substitution and transfers, as well as Collaborative Drug Therapy Agreements, monitoring of drug therapy, patients' rights and sexual misconduct rules.
- Part four of the new chapter covers operational standards for all facilities under the Commission's jurisdiction. This chapter will include building standards, dispensing and reporting requirements, technology implementation, and the management of drugs. Proposed rules for this chapter also include requirements for animal control agencies, wholesalers, and distributors.

Rules Overview: 246-945 WAC

- Much of this new chapter is taking current WACs and updating them to meet current practice, but there are a few sections of significant change. This includes mandating electronic recordkeeping for all facilities, refilling and adapting of prescriptions by pharmacists, and requiring that all prescriptions be electronically transferred among pharmacies.

Licensing and Reporting Changes

OLD

- 1 year renewal cycles for pharmacy personnel licensing
- 1500 internship hours are required documentation for pharmacists graduating
- No limits on Pharmacy Intern registrations renewals
- Appoint a replacement Responsible Pharmacy Manager immediately once the position has been vacated
- The new Responsible Pharmacy Manager must report their appointment to the Commission immediately
- There is no state requirement for conducting a controlled substance inventory



NEW

- 2 year renewal cycles for pharmacy personnel licensing [WAC 246-945-178]
- 1500 internship hours are no longer required documentation for pharmacists graduating after July 1, 2020 [WAC 246-945-162(1)(b)]
- Pharmacy Intern registrations may only be renewed twice [WAC 246-945-155 (3)]
- Appoint a replacement Responsible Pharmacy Manager within 30 days after the position has been vacated [WAC 246-945-410]
- The new Responsible Pharmacy Manager must report their appointment to the Commission within 10 days [WAC 246-945-480]
- Controlled substance inventory is required for incoming Responsible Pharmacy Manager within 30 days of appointment [WAC 246-945-420]

Significant Changes

- Easy open cap authorizations have no documentation requirements
- Pharmacist must offer to counsel on new drug therapy or changes in therapy [WAC 246-945-325]
- Required elements of a prescription are now specified in regulation [WAC 246-945-010]
- Requiring that all prescriptions be transferred by electronic means or facsimile (except in emergency situations)
- If a prescriber cannot be reached, prescriptions may be refilled by the pharmacist one time within 6 months for chronic drug therapy [WAC 246-945-330]

Significant Changes

- Prescription adaptation rules allow pharmacists to make changes to quantity, package size, and dosage form without prior provider approval [WAC 246-956-335]
- Differential hours requirements are no longer in rule
- Commission approval of pharmacy technician specialized functions is no longer required
- Sets standards for drugs stored outside of a pharmacy
- New reporting requirements for a wholesaler who receives a suspicious order

Chapter 246-945 WAC Pharmacy Quality Assurance Commission

- **Definitions**
- **Subpart A – PQAC Operations**
 - 246-11 Adoption by Reference
 - 246-12 Adoption by Reference
 - Inspections
- **Subpart B – Prescription Labeling, Records and Advertising**
 - Prescription Format
 - Labeling
- **Subpart C – Legend Drugs & Controlled Substances**
- **Subpart D – Home Dialysis**

Part 1 – General Provisions

Part 2 – General Licensing

Part 3 – Professional Standards

Part 4 – Operational Standards

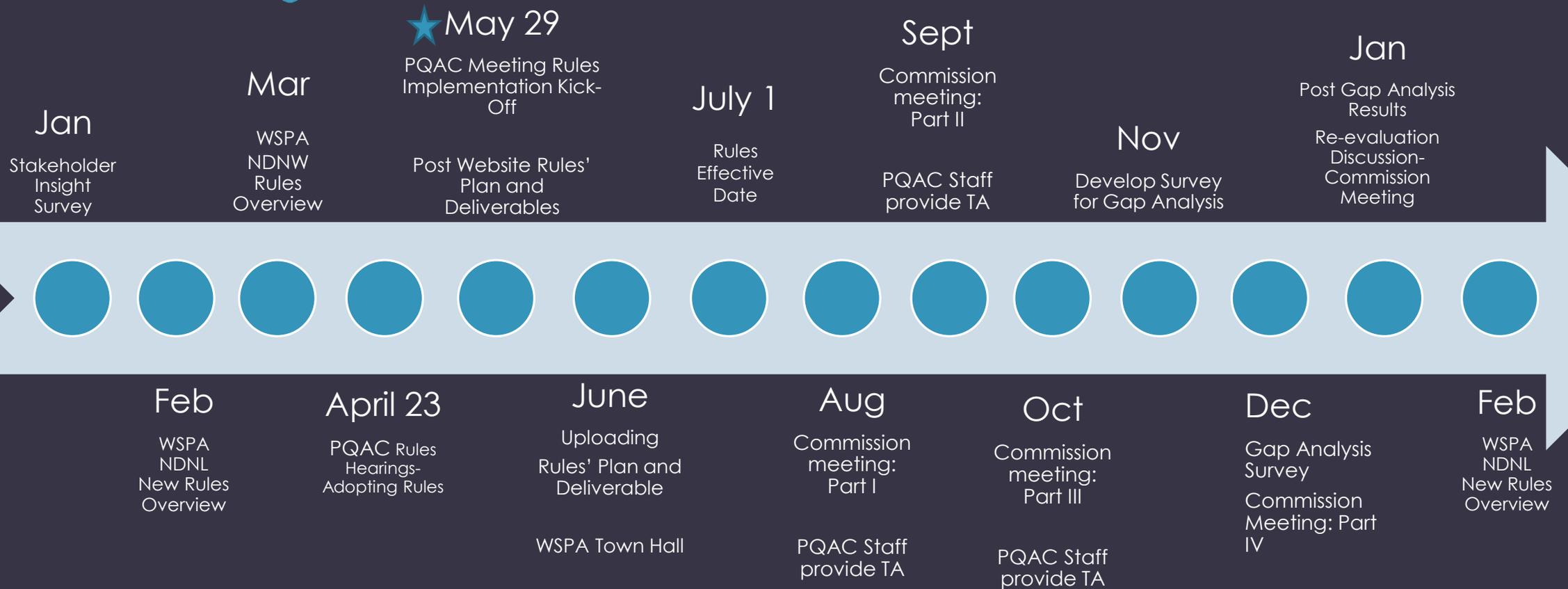
- **Subpart A – Pharmacies, Health Care Entities; and Hospital Associated Clinics**
 - Staffing/Supervision
 - Access
 - Drug Security/Storage
 - Recordkeeping
 - Dispensing (Onsite/Offsite)
 - Offsite Pharmacy Services
 - Destructions/Return of Drugs
- **Subpart B – Registrations**
 - Chemical Capture (WDFW)
 - Dog Handlers
 - Researchers
 - Humane Societies
 - Other Controlled Substance Registration
- **Subpart C – Drug Distributors**
 - Manufacturers,
 - Wholesalers
 - Virtual M/W; 3PLs; Outsourcing 503B

- **Subpart A – Pharmacy Interns & Pharmacists**
 - Licensing & Exams
 - Continuing Education
- **Subpart B – Pharmacy Assistants & Technicians**
 - Certification Requirements
 - Technician Training Programs

- **Subpart C – Pharmaceutical Firm Licensing**
 - Pharmacies and HPACs
 - Non-resident pharmacies
 - HCEs
 - Wholesalers/Manufacturers (including virtuals)
- **Subpart D – Registrations**
 - Researchers
 - Shopkeeper
 - Animal Control/Humane Societies and Chemical Capture

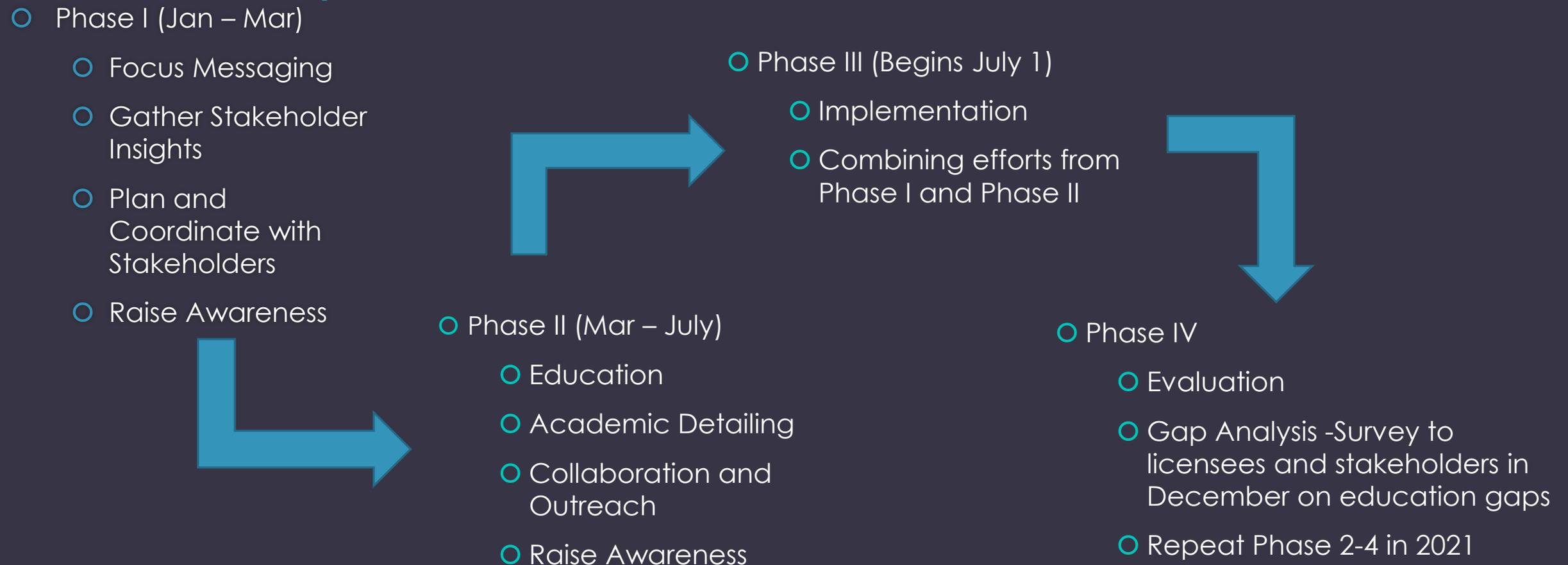
Timeline

News Rules At-A-Glance (2020-2021)



Rules Implementation Phases

Rules Implementation Phases



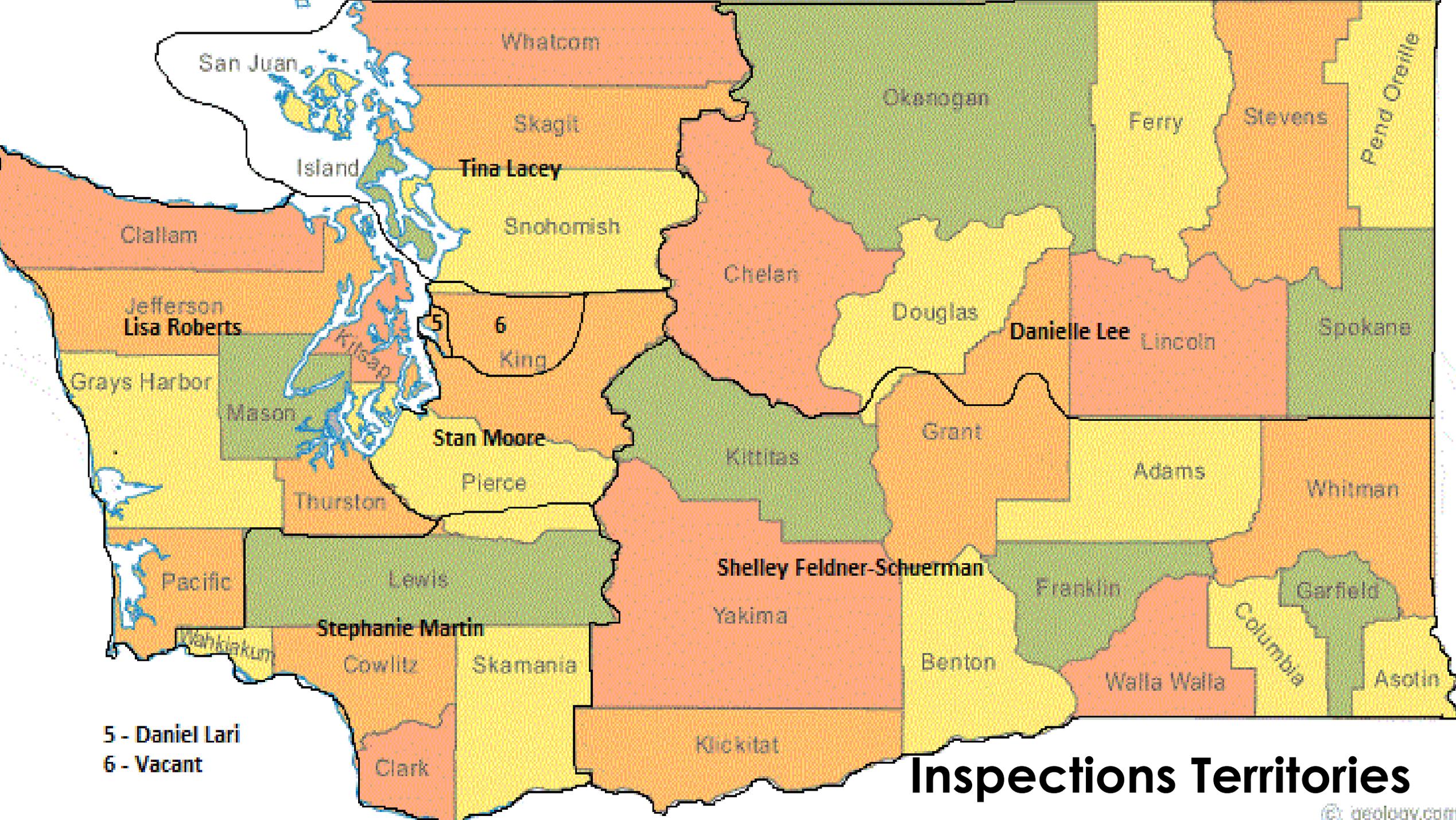
Inspections Under New Rules

Inspections Process Under New Rules

- The Inspection process will continue with Self-Inspections, technical assistance, plans of correction and appeal process to:
 - Promotes continued improvement of pharmacy practice
 - Engages pharmacies with Department of Health to learn together
 - Increase patient safety

Inspections Process Under New Rules

- The self-inspection worksheet must be completed annually during the month of March. Updated forms can be found [here](#) or if there is a change in Responsible Pharmacy Manger.
- The Responsible Manager must sign each self-inspection worksheet.
- The self-inspection worksheet must be maintained for two years from the date of completion according to established rule.



Stakeholder Insights

What words best describe the purpose for the updated rules? (3 max.)

Mentimeter



24

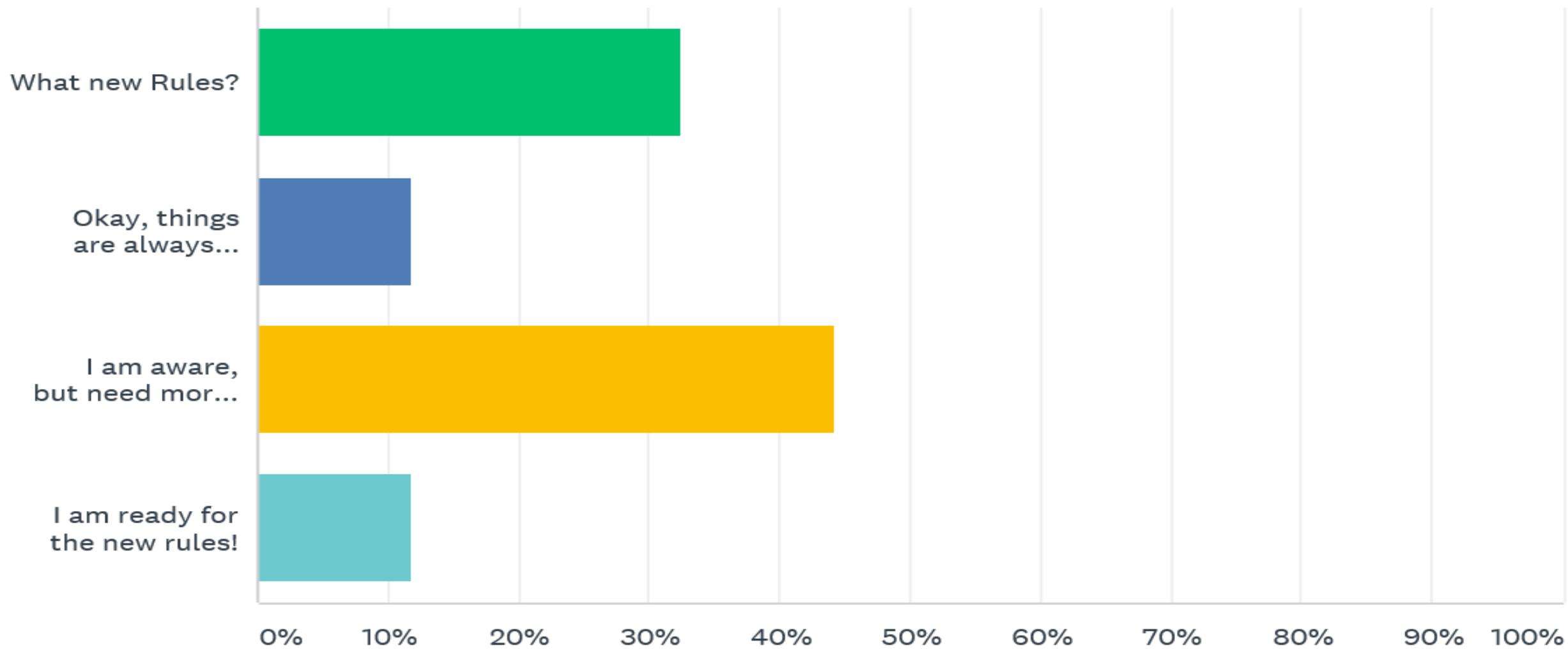
Action: PQAC gathered preliminary insights at January's Commission Meeting.

Rules Implementation Survey Results

<https://www.surveymonkey.com/stories/SM-QG5NL89D/>

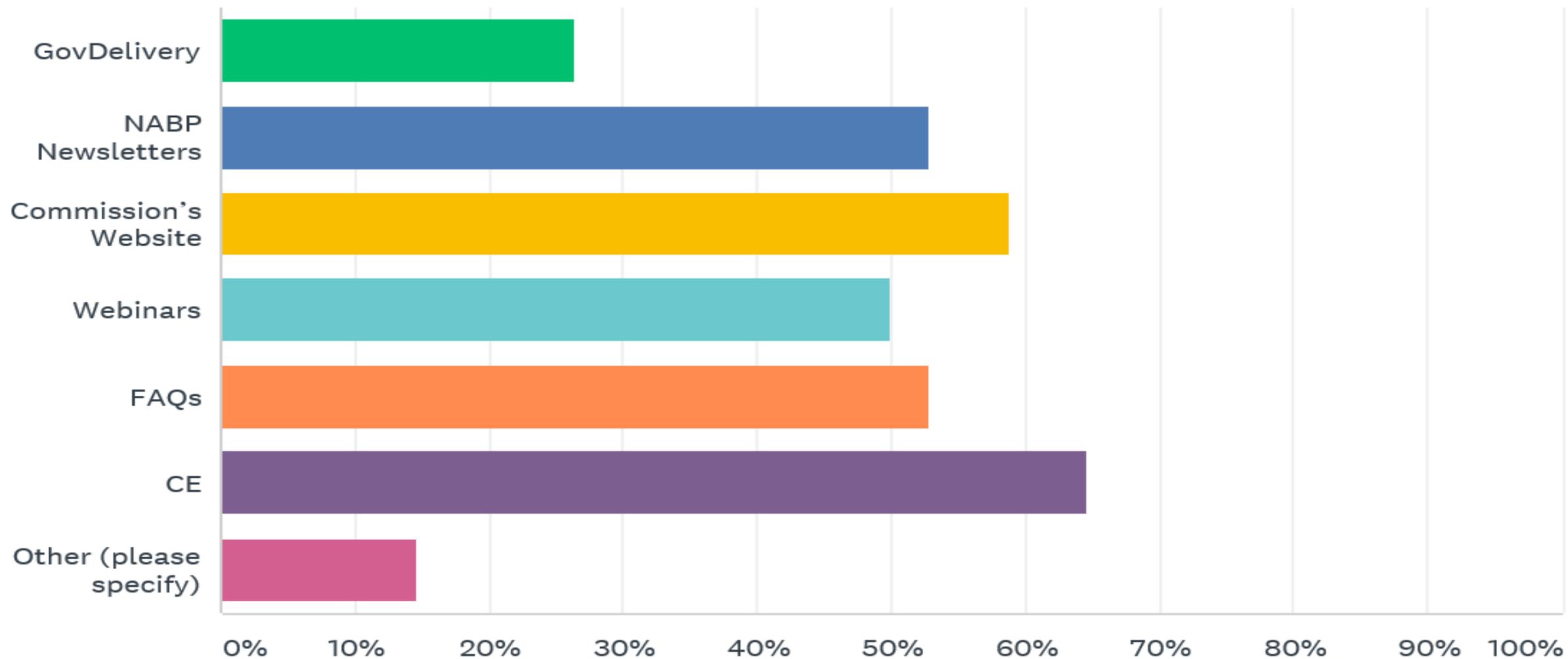
How do you currently feel about the new rules?

Answered: 34 Skipped: 0



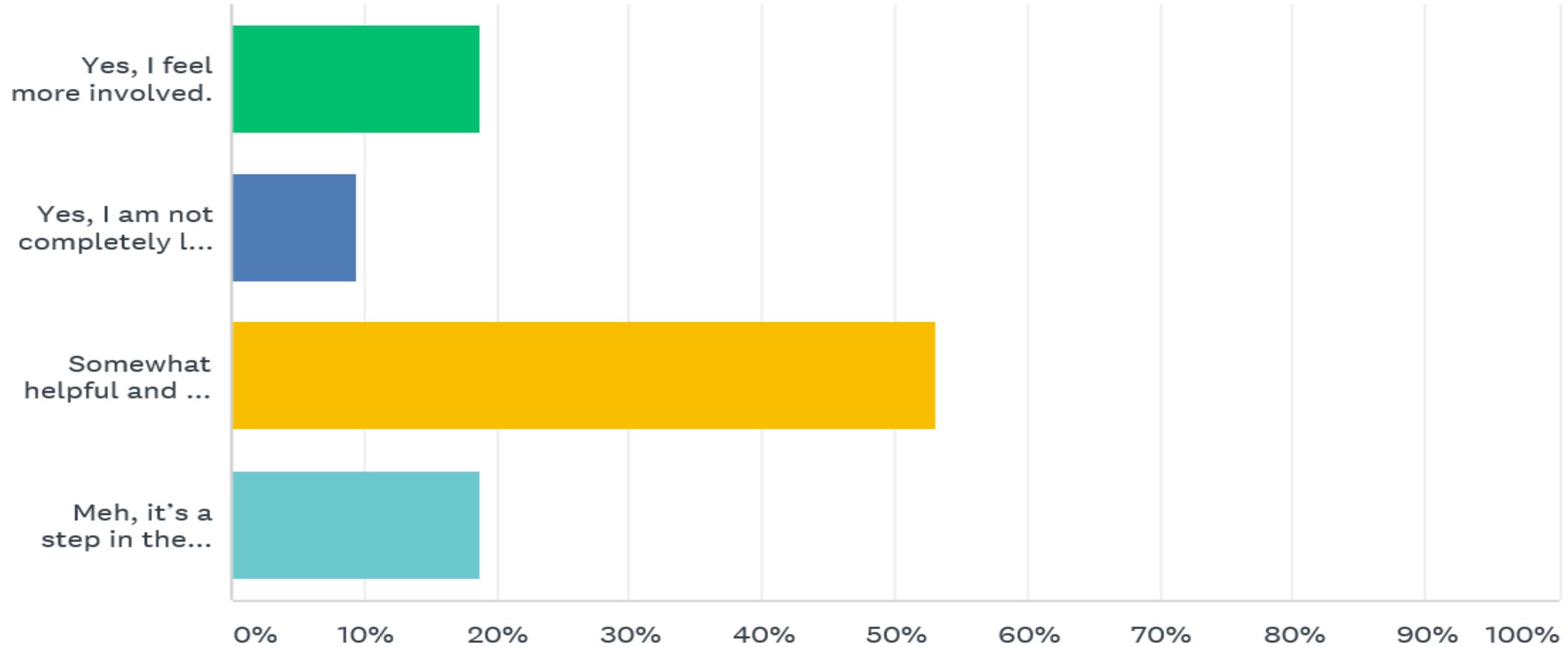
How would you like to best stay informed and educated on the Commi...

Answered: 34 Skipped: 0



Was sharing the Commission's Implementation Strategy helpful?

Answered: 32 Skipped: 2



Rules Implementation Proposed Deliverables

○ Pharmacy Commission Webpage

- Letter from the Chair
- Adopted Rules
- PQAC Postcard/Brochure – online and vial mail
- Revised Significant Analysis
- Rules Updates via GovDelivery

○ Pending:

- FAQs
- Old Vs. New WAC Cross-Walk
- Rules Webinar
- 2020 Pharmacy Facts Sheet

○ Pharmacy Commission Collaboration

- Webinar with WSPA
- WSPA New Drug New Law Presentations
- NW Virtual Pharmacy Conference
- Town Halls
- Webinars or Town Hall with WSHA
- Schools of Pharmacy Presentations

FAQs

- What was the Commissions' purpose for updating the Rules? **To modernize the Rules, remove redundancies, and transition to standards of care.**
- How long was the Rules Re-write process? **2.5-3 years**
- When do the proposed Rules go into effect? **July 1, 2020**
- Where is the best place to find helpful information about the Rules? **Pharmacy Commission Webpage under Rules In Progress. Once the rules are in effect, they will listed under [LAWs](#) and [What's New](#).**

How to contact the Commission

- Pharmacy Commission mailbox: WSPQAC@doh.wa.gov
- Pharmacy Commission rules mailbox: PharmacyRules@doh.wa.gov
 - Any questions regarding the new rules, please send to the rules mailbox.
- Main number: 360-236-4946
- Fax number: 360-236-2260
- Credentialing People – HSQACredentialingReview@doh.wa.gov
- Credentialing Facilities – HSQAFacilitiesCredentialing@doh.wa.gov
- Complaint Intake mailbox: HSQAcomplaintintake@doh.wa.gov
- Mail: PO Box 47852, Olympia, WA 98504-7852
- Subscribe to the email distribution: Click green “Subscribe” button at the bottom of any [Pharmacy Commission](#) or [DOH](#) web page.
<https://public.govdelivery.com/accounts/WADOH/subscriber/new>
 - Check your SPAM box.

Important Resources

- [Adopted New Rules](#)
- [Rules Significant Analysis](#)
- [Commission Website](#)
- [Letter from Commission Chair](#)





THANK YOU

PHARMACY QUALITY ASSURANCE COMMISSION