



Pharmacy Business Practices Interested Parties Comments/Input

August 1, 2014

As well as the 3 items mentioned at the meeting, I would like to focus on...

- 1) Innovative use of ancillary staff given technological advances (this will necessarily cause overlap with the technology workgroup)
- 2) How to mitigate/evenly distribute the culpability to guilt of a pharmacist in charge when the pharmacy involved is owned and managed by a non-pharmacist entity. If the owner/manager is making policies that the pharmacist in charge has to comply with to maintain their employment, and that policy that causes harm to a patient, we need to have a structure to discipline the non-pharmacist owner/manager (besides suspend/revoke).
- 3) How to deal with white bagging in institutions/clinics, when it is mandated by the PBM.
- 4) Regulating PBMs licensed to offer pharmacy services in our state (requiring mail order)
- 5) Increasing requirements on mail order pharmacies, to mirror retail pharmacies
- 6) Require closure for lunch if pharmacy just staffs one pharmacist
- 7) Provide adequate staff to do required patient care, do away with performance metrics

July 31, 2014

Pharmacy Business Practices

1. Dual licensure issue: currently, a pharmacy technician may be dual licensed as a pharmacy assistant. I have one facility, at least, that has gotten their techs licensed as assistants. The pharmacist did not know who were the techs for that day. How can they supervise ancillary staff if they don't know which "hat" each staff member is wearing?
2. Counseling: Clear guidelines on counseling requirements. Pharmacists are not counseling; pharmacy staff "protect" the pharmacist or do not alert the pharmacist to counsel. During inspections, I have seen new rx's go out without the pharmacist having the opportunity to counsel, or staff accepting decline of counsel.

Other concerns :workload expectations, including number of rx's per hour, and time from input to will-call; long hours with no breaks; no pharmacist overlap for many pharmacies; inadequate staff; immunization expectations.

July 31, 2014

One of the most important problems all pharmacies have is enough room to operate. I have built a large compounding pharmacy and we are growing into the facility. I am so glad I over-bought space, because when I was "on the road" doing "relief", I saw huge potential for errors due to inadequate workspace. The committee may wish to establish some minimum guidelines if a pharmacy is going to be incorporated into a building. So often pharmacies are later add-ons and we all know big corporations, and now because of high rent, even small independants design the pharmacies too restrictive for safety, and they don't plan for growth! I would be honored to help with these "rules" especially in the design of pharmacies doing compounding "on the side". Thanks for allowing my input.

July 31.2014

1. I believe that in order for a pharmacist to become a PIC, they should have a minimum of 3 to 5 years' experience of active pharmacy practice.
2. **closing a pharmacy: Commission** should be notified of a pharmacy closing 40 days prior to event; Patients must be notified within 30 days of closure; Rewrite the details of WAC 246-869-250. This is a patient access issue if a pharmacy closes and the patients have no notice or redress. The pharmacy that receives files and documents from a purchase and closure shall be responsible for all documentation regarding the pharmacy closing.
3. Each business that utilized interns as part of their workflow should be required to submit an intern utilization plan that focuses on the educational aspects of the intern's training and discourages their use as cheap labor or 'pharmacist lite'. The interns should be supervised and scheduled by their preceptor and not the corporation/business.
4. No quotas on prescription processing, clinical services, or other professional services.
5. No metrics or time measurements on professional services or prescription services.
6. Clinical space for clinical services ("Private Space" means a physical area separated from the pharmacy and the non-pharmacy area of business that is no less than 8 feet by 8 feet 48 square feet and has at least an 8 feet tall partition that is completely solid from the floor to the top to ensure patient safety and confidentiality. The partition cannot be a curtain.) from Board of Pharmacy of Wyoming 2014
7. Remote entry site must have prospective review of all prescriptions PRIOR to submission to facility.
8. Mandate **prospective** prescription review prior to all dispensing by the pharmacist.
9. Patient counseling: require that pharmacist counsel on ALL new and ALL refilled prescriptions.
10. A pharmacist must have a minimum of three years' experience before becoming a preceptor and supervising interns.
11. All PIC's or directors of pharmacy should have full and complete control of their departments (WAC 246-873-040)
12. Pharmacy operations must have **direct** supervision of a pharmacist at all times.
13. Need to consider WAC 246-873-070 on physical requirements of pharmacies and if they are contemporary to the current practice.
14. Need to address WAC 246-873-110 regarding Medication history reviews by staff/ techs .
15. Advertising needs to include both drug pricing information AND clinical service pricing information to give patients a clear idea of services offered.

July 30, 2014

Pharmacies

- WAC 246-901-010 Pharmacy Ancillary Personnel Definitions
 - (11) defines immediate supervision as being in "visual and/or physical proximity to a licensed pharmacist" – change the rule to read "visual and physical proximity to a licensed pharmacist"
2. Define direct supervision (cite?) (other Boards and Commissions, such as Nursing, have defined this term)
3. WAC 246-869-190 Pharmacy Inspections
 - Re-writing this rule to create a mechanism for handling failed inspections via a Plan of Correction (POC) or a Directed Plan of Correction (DPOC), follow-up inspections and then enforcement action (i.e. notice of intent to revoke/suspend) if the POC or DPOC is not followed
 - Adding a subsection that states pharmacies are subject to a fine for inspections that show repeated violations of the same laws or rules

4. Develop a rule that sets forth how the Commission will take enforcement action against pharmacies (i.e. issue a Notice of Intent, allow for a certain number of days for the licensee to respond, hold a hearing etc.)
5. Developing a rule that requires pharmacies to have quality improvement programs (other faculties such as hospitals or ambulatory surgical facilities have such rules)
6. Develop rules to prevent pharmacies from issuing enticements to get customers to switch pharmacies and to prevent coupon swapping
7. Develop rules that allow pharmacists to exercise their training, experience, and judgment and prevent pharmacies from taking away a pharmacist's discretion and increasing the pharmacist's workload (i.e. pharmacists having to run through a checklist before dispensing a prescription, eliminating quotas etc.)

Non-Resident Pharmacies

1. Developing a rule that would allow the Commission to take action against a non-resident pharmacy who had action taken against it by another state similar to RCW 18.130.180(5) for professions ("suspension, revocation, or restriction of the individual's license to practice any health care profession by competent authority in any state, federal, or foreign jurisdiction, a certified copy of the order, stipulation, or agreement being conclusive evidence of the revocation, suspension, or restriction" RCW 18.130.180(5))

July 30, 2014

I would like to draw your attention to a couple of things directly related to these subjects. The first is regarding the conditions at 24 hour pharmacies. In my work situation, staffing level calculations ignore the extended hours of the pharmacy, lumping them all together just as though the night pharmacist is there to answer the phone, council patients, give injections, check prescriptions, etc. right along with the day crew when, of course, they are not. The resulting short staffing during daytime hours is clearly felt by all, including the customers/patients.

The second issue regards state mandated work breaks. While pharmacy assistants and technicians are generally accorded their necessary breaks, in practice, pharmacists are often shorted. The heavy demands on pharmacist's time seems to encourage many to forgo their breaks and, especially in "no overlap" situations including the scheduling of 12 hour shifts, lunch. Laws regulating these employment practices could certainly be enforced by board inspectors right along with other pharmacy regulations.

July 29, 2014

While I am chair of the Commission's Pharmacy Business Practices Committee, this is personal input on areas that should be considered by the committee. In the interest of a fair and transparent process I will make my suggestions in the same manner as a member of the public would need to follow.

As indicated in my July 10 "Process Proposal" to the Commission, three "buckets" for pharmacy business practices rule making have already been established:

- Workload a staffing levels (including sufficient personnel, quotas, workflow metrics, appropriate staffing to provide for counseling) -- There are many examples of concerns in this area.
- Prescription transfers and other advertising/soliciting issues that may affect public safety
 - I would like to add to this area advertising claims that may affect public welfare, such as deceptive claims about pharmaceutical products, convenience, delivery and cost/pricing. Safety is not the only consumer interest. In investigating this area the committee should coordinate with the Consumer Protection (fair business practices) program of the state Attorney General's Office. There is statutory authority there for action on consumer complaints but complaints having anything to do with prescription drugs routinely are referred to the Pharmacy Commission and consumers can end up feeling they have no recourse.
 - I notice that one public comment recommends consideration of certain practices of Pharmacy Business Manager (PBM) firms. The most actionable issue appeared to be related to PBMs steering to their own mail order pharmacies and difficulties accessing a pharmacist. These may be marketing and communication issues or they may be more substantive business practices that are the responsibility of the mail order entity. PBMs themselves are not within PQAC authority and are lightly regulated by the Office of the Insurance Commissioner.
- Appropriate time, space and privacy for clinical pharmacy functions (including immunizations).

I support the committee moving forward in all three of the above areas, in whatever timing.

I also recommend the committee take up three additional areas of scope:

1. Accountability and "contributory responsibility" of pharmacy businesses (the firms): Washington statutes have some weaknesses in establishing intermediate sanctions for pharmacy business entities. Putting this aside as a legislative matter, there also may be weaknesses in the basis for assigning shared responsibility between businesses and professionals (pharmacists and ancillary staff) and between multiple pharmacy businesses that participate in processing from presentation of the prescription through to dispensing and counseling. The complexity of such accountability issues is increased by technologies (such as for work sharing or distant processing) but the issue of assigning accountability to firms itself is a separate matter that should be addressed in this committee.
 - Related: The role of the Responsible Pharmacy Manager may need to be clarified in relation to the variety of business models and the scale of some business operations. While this is closely tied to professional pharmacist responsibilities, it also is integral to assignment of responsibilities to firms. The RPM may not be a good surrogate for the firm's accountability.
 - Potentially related: The meaning of "direct supervision" of ancillaries by pharmacists has likewise become somewhat unclear as technologies and business models change. I believe this should be defined in rule, whether through the work of this committee or another.
 - I believe the issue of allowable technician (or ancillary) ratios ideally will be considered as part of the work on Technicians and Ancillaries (which has been put on a slower track) rather than as business practices. However, the committee is welcome to consider whether this is integral to accountability.
2. Affirmative responsibilities for Quality Assurance and Quality Improvement: Rules do not now set out consistent responsibilities independent of type of pharmacy. In addressing the Commission, large pharmacy firms often have noted that they have robust QA and QI should

be relied on to assure quality and safety, in preference to very detailed regulatory requirements. This line of thought would suggest QA and QI responsibilities be clear and accountable, and access to relevant data assured in the course of investigations (whether or not for general public release).

3. Access to pharmaceuticals in emergency situations: The recent wildfires in Central Washington disclosed that there are some issues of legal authority for emergency measures needed to cope with disruptions of normal means of pharmaceutical supply and access. I would let the Chief Inspector and other staff speak to the details.

July 25, 2014

I have attended meetings of the Washington Board, now WSPQA for over 5 years. I have seen first-hand the lack of current rules, member turnover, change of Executive director and the stampede of practice and technology innovation. The commission is in a difficult position to protect the citizens of Washington, while not impeding the rapidly changing practice of pharmacy. In 2012 the American Pharmacists Association stated that "state boards of pharmacy must accept that many aspects of pharmacy practice will be done in a virtual environment, that crosses state lines". The boards must develop practice rules that protect the public without burdensome licensure requirements or restrictions on creativity that produce quality pharmacy practices. At the NABP annual meeting this past May, Executive Director Carmen Catizone, in his address, stated that the practice of pharmacy is now regularly done across jurisdictions and much of the historical paradigm of the individual pharmacist in a local store has changed forever. He challenged the Association to address these changes in a meaningful manner and maintain the safe practice of pharmacy in light of the technological and geographical changes.

Due to the rapid expansion of the Commission, and the lack of members with significant rule writing experience, it is critical that the committee utilize successful models of rules from states that have addressed shared services (workload balancing) technician supervision ratios (not one size fits all practice models) and use of technicians and support personnel.

July 25, 2014

Pharmacist in Charge:

Restrict appointments to PIC to those pharmacist who have 3 years working experience in Washington State.

Limit the PIC to sites where the PIC is currently working at least 20 hours per week, and to one location only.

Require Continuous Quality Improvement (CQI) or QA programs for all pharmacy practice sites. Require that all medication errors or discursions be tracked, and that Staffing and training requirements, production metrics and production quotas be related be justified under the required CQI rules for the protection of public.

Require that any production metrics be incorporated into required CQI rules and coordinated with medication errors and medication discursions to reflect the best interests of patients and public health. If production quotas and metrics are to be used.... And they will be used, then the system must be able to justify the metrics and quotas under the CQI requirements, and

that the pharmacy staff be able to reasonably accomplish their legal responsibilities.

Quality improvement needs to be an on-going process, continually looking at the systems and process in place, to identify quality discursions where they take place and opportunities for process improvement and the protection of the public health.

All CQI/QA material should be available to the Commission for inspection, and should be referred to when medication discursions occur for evaluation

July 24, 2014

Prescription Transfers: I don't see the need for any rule(s) prohibiting the use of coupons or discounts for services or products. Competition between physical stores is probably healthier than regulating it away.

I'm much more concerned with the Pharmacy Benefits Manager's (PBM) ability to require or induce patients to use their mailorder pharmacies, many patients tell us that they can no longer use our pharmacies because their insurance will only pay if they use the PBM's mailorder. This service integration allows the PBM to change the benefit provided to insured individuals rather than competing on price or service. Patient's sometimes come to our stores to get advice because they cannot get to a pharmacist via the PBM's phone tree. I view this as both an economic and patient safety hazard.

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July 23, 2014

I strongly urge the Pharmacy Business Practices Committee to undertake rulemaking in the following areas:

- 1) Eliminate prescription wait time guarantees.
- 2) Eliminate prescription transfer coupons and any incentives that entice patients to switch pharmacies to obtain a reward.
- 3) Eliminate production quotas of any type including immunization shot quotas, prescriptions filled per hour or shift and staffing on demand.
- 4) Require pharmacies that offer immunizations and other clinical services to provide a dedicated room that meets a set of standards for size, cleanliness and security before such services can be provided.
- 5) Require pharmacies to provide a work environment that protects the health, safety and welfare of the patient including, opportunities for uninterrupted rest periods and meal breaks, adequate time for the pharmacist to complete professional duties and responsibilities

and sufficient staff to prevent fatigue, distraction and other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.

- 6) Limit the number of pharmacies a pharmacist can be a Responsible Pharmacy Manager to one pharmacy.

July 23, 2014

Could we add another broad category addressing LTC pharmacy best practices and consider rule making to license these pharmacies under a separate license other than retail or hospital. Could we add another broad category addressing LTC pharmacy best practices and consider rule making to license these pharmacies under a separate license other than retail or hospital.

July 23, 2014

Given the increasing complexity of laws and consequently the rules and regulations in support of those laws and that rules and regulations, to be valid, must have statutory authorization, all rules and regulations, whether in progress or adopted should cite the law, including section, subsection, etc, that is deemed to authorize such rules and regulations.

July 22, 2014

It is my conclusion after 24 years of working in Washington State pharmacies and 12 years of management level operation of the same that without legislative intervention the upper echelons of pharmacy management will continue to make dangerous staffing decisions that become the declining standard of practice in all of our retail settings. I am strongly in favor of a state mandated lunch break for pharmacists with the provision that the pharmacy must close to accommodate this. My recent experience has been mandatory 12 hour days. I did get a 30 minute break (10 of which were eaten up walking to and from the break area) and then 7 hours with no break. This shows how much the industry is antagonistic to the spirit of the law which is to allow adequate human replenishment to persons involved in licensed health care functions for the safety of the population. Sure we comply with a half hour lunch break but then require what in most settings is a full shift after that without any chance to restore your capacity. I would like to see this end of the spectrum addressed in the legislation as well. Also the need for technicians needs to be quantified so managers are not balancing their budgets on the back of pharmacists by making the, answer every phone call, take customers with no connection to the services of the pharmacy to find things like ground beef, ring up every order in the midst of taking verbal prescription orders or making interventions on behalf of a patient.

July 22, 2014

I hope work load, staffing levels, and quotas are seriously evaluated regarding the new business practices being considered by the Pharmacy Commission. As it stands now at many pharmacies, staffing is controlled by the store manager, not the responsible pharmacist in charge. The hours scheduled for personnel in the pharmacy are often based on whole store sales for the prior week or month, etc. and not on the work load in the pharmacy. This means if deli hours or cashier hours are cut, so are pharmacy hours.

I also hope that breaks and lunches are addressed in these considerations. I have never understood why, just because a pharmacist is considered a "professional", a pharmacist can be forced to work 12 hours straight with no breaks or lunches and barely have time to literally run to the rest room.

Thank you for taking the time to consider these topics.

July 14, 2014

"1) Eliminate the designation of "Responsible Manager" in pharmacies not owned by a pharmacist. The short version of my rationale is simply that "Responsible Manager" means almost nothing in the chain pharmacy as well as Institutional Pharmacy and other corporate pharmacy worlds. The Responsible Manager in these situations rarely is able to implement any unique practice decisions or effect changes in these environments. It seems very unfair to those individuals to impart on them responsibility for processes or outcomes which they truly have no control over.

2) Recognize the 800-pound gorilla in the room, i.e. pharmacist wages are behind many of the exemption requests you see for off-site order verification, technician ratio and duty protocols, et al. It strikes me that a lot of the requests you get (especially those that seek to relocate the pharmacist elsewhere after hours) are due to the business' reimbursement model not reflecting the true cost of running a pharmacy. Is this the WS-PQAC's problem? I don't want to sound cynical but are these requests really in the best interest of a patient's health or the best interest of the corporate bottom line? If a facility operates a pharmacy there should be adequate local staff to maintain the pharmacy, including provision for on- call, after hours local service. In the coming years we're going to see an excess of pharmacists in the work environment so duties currently defined as being "pharmacist- only" won't need to be allocated to another licensed individual, there'll be a pharmacist available to do the work."

July 14, 2014

I would like to see a regulation that REQUIRES a pharmacy to transfer a prescription when the request is made, whether from a patient or another pharmacy. Too often, a pharmacy will refuse to cooperate when asked, forcing us to contact the doctor who will sometimes refuse to give us a new rx because he/she knows that there is still a valid prescription out there already. This causes confusion, extra (unnecessary) work and inconvenience for the patient, if not an outright dangerous situation for the patient.

This has been an ongoing and increasingly difficult occurrence that should be addressed for the safety and convenience of the patient. The patient has the right to get his/her prescription filled wherever they would like and it is extreme arrogance on the part of the pharmacy who capriciously complies or not.

Thank you for your consideration of this potentially dangerous situation.

July 13, 2014

Oregon has addressed the "lunch break" issue finally by making it "law" to have a 30

min. uninterrupted lunch break. A concept for any other employee in any other work setting which is not considered a "privilege."

Wondering how we can implement this new concept of an "official" lunch break even if it means closing the pharmacy for a half hour and the "whole staff" takes their lunch break say between 1-1:30 or etc.. May actually create fewer errors and happier pharmacies and in response happier patients for the retail sector which is not the case in the majority of pharmacies currently. Just creating "conversation" for excellent pharmacy business practices. Thank You for your response on this subject matter.