



Public Comments

Issue Assessment - Accountability

Draft 2-For Public Comment - May 15, 2015

From:	Comment:
<p>[REDACTED]</p>	<p>In regards to accountability, I whole-heartedly agree with the training requirements as I did not receive training before becoming a PIC myself. Also, many pharmacists in my company are becoming PICs as soon as they finish college - even though they may be talented, without giving them experience or proper training, I feel that is really unfair to the young graduate.</p> <p>All patients who receive prescriptions (including mail order) in Washington state should receive their medications from a Washington state licensed pharmacist - no exceptions and they should be counseled.</p> <p>Terms of businesses practices that compromise patient safety - that needs to be clarified for corporations ... mainly because at retail corporations, one pharmacist is asked to check off prescriptions in less than 15 minutes, and do immunizations and MTM services and counsel by himself. If a pharmacist is trying to do 10 different things at the same time, that leads to patient safety issues.</p> <p>It would be appreciated to make specific rules for retail pharmacy operations due to lack of emphasis on patient safety.</p>
<p>[REDACTED]</p>	<p>I agree that the owner who has the permit should share in the responsibility when a PIC has informed them about a violation and hasn't done anything about it. I worked in a pharmacy where the drive through speaker would project into the volume. It would be incredibly easy to violate HIPPA. I asked if they had asked anyone to fix it, but they said they did have someone come by and 'fix it', but it was pretty obvious that it was still projecting in the lobby.</p>
<p>[REDACTED]</p>	<p>Regarding the consideration of "accountability", the management & upper management of these large pharmacy operations should be held accountable also. Their feet should be held to the fire just as the individual pharmacist is held responsible. Due care on everyone's part should be considered.</p>
<p>[REDACTED]</p>	<p>The comment regarding Arizona elimination of the non-resident PIC licensure requirement is inaccurate. The removal of the requirement is permanent, not temporary. The AZ Board felt it had enough jurisdiction over the permit holder to protect Arizona citizens. If the PIC was found in violation, the complaint would be sent to the home state board for action.</p>
<p>[REDACTED]</p>	<p>111 Consider requiring businesses to have a pharmacy regulations compliance officer who is responsible for all operations of the company to the Commission and who is licensed as a pharmacist in Washington</p>

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	<p>State.</p> <p>lil Consider requiring all managers or corporate officers involved in any aspect of pharmacy operations who reside in or maintain a permanent office in Washington State and who make, apply, enforce, or are responsible for policies that affect the safety of patients or compliance with federal or state pharmacy laws and regulations in pharmacies operating in the state of Washington, to be licensed in Washington State as pharmacists or pharmacy assistants. Or pharmacy technician</p>
	<p>(abbreviated- full text distributed to committee May 15)</p> <ul style="list-style-type: none"> • Absent a thorough training program I certainly could support anywhere from a 3-5 year waiting period before a new pharmacist could be appointed a PIC (and actually would like to submit that the same should also apply to anyone seeking a preceptor license). • Regarding the need for whistleblower protection, I'm not sure what additional safeguards the P-QAC would need to provide that isn't available elsewhere in state or federal laws. Having said that, I wonder how much of a problem would be left if the P-QAC tackled the rather onerous practice of prescription and immunization quotas set by corporate bean counters which may increase that "revolving door" of staff that was discussed? One simple sentence in a WAC that says "No pharmacy corporation or non-pharmacist shall require a quota of prescriptions to be filled or immunizations to be provided in any given time frame." • shared responsibility should be chief among the priorities for the Committee to pursue. I've been a PIC in several past incarnations of my career and, frankly, the thought of being held 100% accountable for what might be the actions of others (who could be acting without my knowledge and outside of acceptable practice or corporate procedure) is somewhat frightening. Especially since any disciplinary action shows up in an on-line (and very public) database essentially forever no matter how trivial the matter. Shared responsibility seems a logical application of looking at systems, not people when seeking to right a wrong.
	<p>We appreciate the chance to share our perspective with the Pharmacy Quality Assurance Commission (PQAC) on two issues: meal and rest breaks and accountability. Odessa Memorial Healthcare Center acknowledges and supports the Commission's efforts to promote high-quality care and access to pharmacy services, as well as their efforts to address issues of adverse drug events. We have concerns, however, around PQAC's proposed action on meal and rest breaks and accountability.</p> <p><i>We also understand the Commission is considering enhancing accountability by adding requirements for the Pharmacist in Charge (PIC). The changes under consideration could have a detrimental impact on access while driving up the cost of care. The requirement for three</i></p>

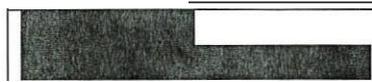
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	<p><i>years of post-licensure practice would make it difficult to hire P/Cs while the 30 hours per week requirement in each setting under the license could limit our ability to be innovative and use staff across facilities . Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts, driving up the cost of care while diverting pharmacist's time from patient care.</i></p>
	<p>We appreciate the chance to share our perspective with the Pharmacy Quality Assurance Commission (PQAC) on two issues: meal and rest breaks and accountability. Coulee Medical Center acknowledges and supports the Commission's efforts to promote high-quality care and access to pharmacy services, as well as their efforts to address issues of adverse drug events. We have concerns, however, around PQAC's proposed action on meal and rest breaks and accountability.</p> <p><i>We also understand the Commission is considering enhancing accountability by adding requirements for the Pharmacist in Charge (PIC). The changes under consideration could have a detrimental impact on access while driving up the cost of care. The requirement for three years of post-licensure practice would make it difficult to hire P/Cs while the 30 hours per week requirement in each setting under the license could limit our ability to be innovative and use staff across facilities. Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts, driving up the cost of care while diverting pharmacist's time from patient care.</i></p>
	<p>We also understand the Commission is considering enhancing accountability by adding requirements for the Pharmacist in Charge (PIC). The changes under consideration could have a detrimental impact on access while driving up the cost of care. The requirement for three years of post-licensure practice would make it difficult to hire PICs while the 30 hours per week requirement in each setting under the license could limit our ability to be innovative and use staff across facilities. Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts, driving up the cost of care while diverting pharmacist's time from patient care.</p> <p>Please consider spending Commission time on updating our Pharmacy WAC's. I do not need my Commission to micromanage how I manage my time in my work day.</p>
	<p>In the attachment you provided, specifically under section 'Other States', bullet point #7. It stated that the Committee welcomes information on applicable provisions regarding shared accountability, possibly like those in Arizona. Therefore, I would like to provide some Statute and Rule information, from the Arizona State Board of Pharmacy Act and Administrative Code, that may contain language the committee can use to formulate it's new regulations.</p> <p>Under ARS 32-1904(B)(8)...Powers and duties of the board; immunity</p>

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	<p>8. Investigate alleged violations of this chapter, conduct hearings in respect to violations, subpoena witnesses and take such action as it deems necessary to revoke or suspend a license or a permit, place a licensee or permittee on probation or warn a licensee or permittee under this chapter or to bring notice of violations to the county attorney of the county in which a violation took place or to the attorney general.</p> <p>Under ARS 32-1901.01(A)(24)...Definition of unethical and unprofessional conduct; permittees; licensees</p> <p>A. In this chapter, unless the context otherwise requires, for the purposes of disciplining a permittee, "unethical conduct" means the following, whether occurring in this state or elsewhere:</p> <p>24. Overruling or attempting to overrule a pharmacist in matters of pharmacy ethics or interpreting laws pertaining to the practice of pharmacy or the distribution of drugs or devices.</p> <p>Under ARS 32-1927.02(A)...Permittees; disciplinary action</p> <p>A. The board may discipline a permittee if:</p> <ol style="list-style-type: none"> 1. The board determines that the permittee or permittee's employee is guilty of unethical conduct pursuant to section 32-1901.01, subsection A. <p>Under AAC R4-23-608(B)(1)(2)(C)...Change of Personnel and Responsibility</p> <p>B. Responsibility of ownership and management. The owner and management of a pharmacy shall:</p> <ol style="list-style-type: none"> 1. Ensure that pharmacists, interns, and other pharmacy employees comply with state and federal laws and administrative rules; and 2. Not overrule a pharmacist in matters of pharmacy ethics and interpreting laws pertaining to the practice of pharmacy or the distribution of drugs and devices. <p>C. The Board may suspend or revoke a pharmacy permit if the owner or management of a pharmacy violates subsection (B).</p> <p>Also, I would recommend someone from the committee reviewing the Louisiana State Board of Pharmacy Regulation in Title 37, Chapter 14, Part E - 1241(Discipline) to show how they financial impact the permit holder for statute or rule violations, which is something I think needs to be done in Washington State in order to make an impact on the corporate permit holders in making changes. (PLEASE SEE EXAMPLES OF DISCIPLINARY ACTIONS AGAINST PERMIT HOLDERS IN LOUISIANA BOARD OF PHARMACY NEWSLETTERS)- On NABP website under Boards of Pharmacy</p>
	<p>A PIC should be fully aware of what the employees are doing and how they are handling various situations in the pharmacy. While making policies can help with this, being physically present will increase the level of awareness of this individual and make them more likely to</p>

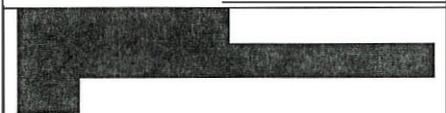
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	<p>address issues that may arise from employees or patient complaints. In Wyoming, PICs are required to be physically present in the pharmacy for 32 hours per week, except for time periods of less than 30 days when absent due to illness, family illness or death, scheduled vacation, or other authorized absence, every week, or eighty (80) percent of the time the pharmacy is open, if opened less than forty (40) hours per week. This facilitates patient access to the person in charge when problems occur and allows the PIC to see what beneficial changes should commence regularly as opposed to having a part-time or one with fewer hours who is less able to help patients and work flow issues due to their lack of familiarity with the situation . I believe this is a reasonable requirement for a PIC and prevents recent graduates from being excluded from this position.</p>
	<p>We appreciate the chance to share our perspective with the Pharmacy Quality Assurance Commission (PQAC) on two issues: meal and rest breaks and accountability. Navas acknowledges and supports the Commission's efforts to promote high-quality care and access to pharmacy services, as well as their efforts to address issues of adverse drug events. We have concerns, however, around PQAC's proposed action on meal and rest breaks and accountability.</p> <p>We also understand the Commission is considering enhancing accountability by adding requirements for the Pharmacist in Charge (PIC). The changes under consideration could have a detrimental impact on access while driving up the cost of care. The requirement for three years of post-licensure practice would make it difficult to hire PICs while the 30 hours per week requirement in each setting under the license could limit our ability to be innovative and use staff across facilities. Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts, driving up the cost of care while diverting pharmacist's time from patient care.</p>
	<p>We appreciate the chance to share our perspective with the Pharmacy Quality Assurance Commission (PQAC) on two issues: meal and rest breaks and accountability. Kittitas Valley Healthcare Pharmacy <i>acknowledges</i> and supports the Commission's efforts to promote high-quality care and access to pharmacy services, as well as their efforts to address issues of adverse drug events. We have concerns, however, around PQAC's proposed action on meal and rest breaks and accountability.</p> <p>We also understand the Commission is considering enhancing accountability by adding requirements for the Pharmacist in Charge (PIC). The changes under consideration could have a detrimental impact on access while driving up the cost of care. The requirement for three years of post-licensure practice would make it difficult to hire PICs while the 30 hours per week requirement in each setting under the license</p>

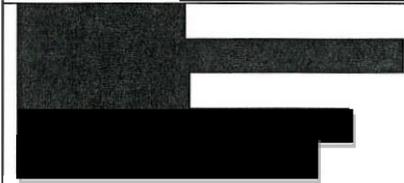
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	<p>could limit our ability to be innovative and use staff across facilities. Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts, driving up the cost of care while diverting pharmacist's time from patient care.</p>
	<p>However, I am concerned that appropriate balance in enforcement must exist. There are many good PICs out there, and no matter how responsible the PIC may be, there will be at times subordinates who will at times violate rules in some aspect, and the PIC should not be held accountable for a subordinate's actions where the PIC has not contributed any wrongdoing. This issue may not be an issue, but reading this document gives me the impression that extreme enforcement could inappropriately go to this end.</p> <p>I am also concerned that firms (owners and non-pharmacist managers) can not be pragmatically held accountable for their practice policies contributing to violations of law that are imposed on professional staff without significant fining authority. This will require legislative action and needs to be actively pursued, but will be opposed at many levels.</p> <p>Again, thank you for taking on these difficult issues. They need to be dealt with. Please take your time, and continue to do a quality job that will be fair and appropriate for all involved, patient included.</p>
	<p>On behalf of the 18 chain pharmacy companies operating in the state of Washington, the National Association of Chain Drug Stores (NACDS) thanks you for the opportunity to submit comments on Pharmacy Business Practices Committee's ("Committee") draft assessments and recommendations for rule updates regarding pharmacy business practices related accountability in the pharmacy setting.</p> <p>NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly. In Washington, there are about 1,093 pharmacies, of which 820 are chain pharmacies. Those chain companies employ approximately 101,810 Washington residents, including 3,186 pharmacists, and pay about \$811 million in state taxes annually. As a group, Washington chain and independent pharmacies employ approximately 103,794 full- and part-time workers including about 3,644 pharmacists, paying almost \$827 million in state taxes annually.</p> <p>NACDS recognizes and appreciates the appropriate role of the pharmacist in charge (PIC) in the operation of pharmacies. If the Committee is committed to pursuing rule changes to better delineate PIC vs. pharmacy license holder/pharmacy owner responsibilities, we</p>

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	<p>believe that the Committee should adopt policies similar to those used in Texas and West Virginia and assign accountability according to the appropriate roles of the PIC and the permit holder/pharmacy owner. Because the PIC is usually an employee who is in charge of the day to day activities within the pharmacy, the PIC should not be held accountable for administrative and operational functions that are generally controlled by the permit holder/pharmacy owner. Requiring the PIC to be fully responsible for every aspect of a pharmacy operation presents concerns as they would be held responsible for actions and duties beyond their authority and overall control. Therefore, we strongly urge the Committee to consider the development of rules that would appropriately assign accountability standards that coincide with the individual roles and responsibilities of the PIC and the permit holder/pharmacy owner.</p> <p>NACDS and our members understand the Committee's goals for developing standards that serve to protect public health, safety, and welfare in the pharmacy setting. However, we have concerns that if not developed properly, these standards would create undue barriers for the PIC and could hinder patient safety goals. We appreciate the Committee's consideration of our comments and ask for the opportunity to work with the Committee in the development of proposed rules to develop accountability standards that would create the appropriate balance between the responsibilities of the PIC and the permit holders/pharmacy owners.</p>
	<p>I understand the Commission is considering enhancing accountability by adding requirements for the Pharmacist in Charge (PIC).</p> <p>I do not understand the rationale for this. I am the PIC for East Adams Rural Hospital, Columbia Basin Hospital and North Valley Hospital.</p> <p>These are small Critical Access Hospitals. For these hospitals, the average daily census is two to three patients at the most. Some of these small Critical Access Hospitals have an average daily census of less than one patient a day. The Critical Access Hospitals are unable to afford to hire a pharmacist for 30 hours a week. Annual drug expenditures can be less than the salary of a pharmacist. The changes under consideration could have a detrimental impact.</p> <p>Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts, driving up the cost of care while diverting pharmacist's time from patient care.</p> <p>How can this work for the smallest of hospitals?</p> <p>We also understand that PQAC is considering adding requirements for</p>

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	<p>the Pharmacist in Charge (PIC).The proposed changes would negatively impact access to care while driving up the cost. The requirement for three years of post-licensure practice would make it difficult to hire PICs while the 30 hours per week requirement in each setting under the license could limit our ability to be innovative and use staff across facilities. Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts - driving up the cost of care while diverting pharmacist's time from patient care.</p> <p>Legacy Health urges PQAC not to take any action on these issues.</p>
	<p>We also understand the Commission is considering enhancing accountability by adding requirements for the Pharmacist in Charge (PIC). The changes under consideration could have a detrimental impact on access while driving up the cost of care. The requirement for three years of post-licensure practice would make it difficult to hire PICs while the 30 hours per week requirement in each setting under the license could limit our ability to be innovative and use staff across facilities. Further requirements for a Pharmacy Regulations Compliance Officer would have similar impacts,driving up the cost of care while diverting pharmacist's time from patient care. Thank you for your attention to our concerns.</p> <p>We look forward to working with PQAC to ensure that patients can access pharmacy services and high-quality care.</p>