NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 26, 2019

Mr. Malcolm J. Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700

By Fax: 225-925-6649
By Email: info@pharmacy.la.gov

RE: Louisiana Board of Pharmacy Rule Review

Dear Mr. Broussard:

On behalf of our members operating in Louisiana, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the Board of Pharmacy's (Board) review of existing rules related to the practice of pharmacy. We applaud the Board for accepting comments on its rules as it is critical to keep them current to best serve patients in the state. NACDS requests the Board to view the rules through the lens of a standard of care approach. Our extensive comments are aimed at reducing prescriptive rules and in consideration of a standard of care approach, like our medicine and nursing counterparts. We ask the Board to consider this approach as it applies to the utilization of technology, scope of practice, supervision, personnel, facility and notification requirements.

COMMENTS AND RECOMMENDED AMENDMENTS

Chapter 5. Pharmacists

Subchapter A. Licensure Procedures

§511. Employment Change (A)
We recommend striking this section as very few states require notification of employment changes as we believe this is unnecessary and an administrative burden for all licensees.

§521. Prescription Orders to Administer Medications
Subsection (B): We recommend eliminating the properly executed Authority to Administer and allow the prescriber to authorize administration on the prescription. If a pharmacist meets the criteria to administer the medication and the prescriber has issued the order, the pharmacist should be allowed to administer such medication. Additionally, we recommend eliminating the 180 days requirement as this should apply to the life of the prescription.

Chapter 7. Pharmacy Interns

§709. Scope of Practice– (B)

We recommend striking section B, eliminating the intern to pharmacist ratio. Limiting the number of assistants that a pharmacist may leverage in the dispensing process has not demonstrated a positive impact on patient safety. The advanced training and education of pharmacy interns should make this a clear rule that is open for change.

We believe that interns work better and can learn more with other interns, especially in non-drug dispensing or research rotations/internships. We support eliminating the limitation of pharmacy interns that may assist in the prescription filling process. We recommend allowing the precepting pharmacist to determine the appropriate ratio based on their workplace and job duties.

A. Pharmacy interns may perform any duty of a pharmacist provided he is under the supervision of a pharmacist.

B. ~~The ratio of pharmacy interns to pharmacists shall be 1:1. However, the ratio of pharmacy interns on rotation with a board-approved college of pharmacy to pharmacists shall be no more than 3:1.~~

~~C.~~ A pharmacy intern may not:

1. present or identify himself as a pharmacist;
2. sign or initial any document which is required to be signed or initialed by a pharmacist unless a preceptor cosigns the document;
3. independently supervise pharmacy technicians; or
4. administer immunizations unless properly credentialed as required by the board.

Chapter 9. Pharmacy Technicians

§901. Definitions

Employer-based training programs prepare technicians for their practice setting. If an employer can show that the core elements of a program are met, they should be allowed the flexibility to provide their own program. Understanding that employee turnover is a reality of any business, we believe there is a potential resolution to the challenges associated with staffing while technicians work towards achieving national certification. Chain pharmacies have a comprehensive training regimen that covers the pertinent competencies required to fulfill the allowed tasks of a Louisiana technician. We believe Louisiana Statute 37:1212 grants the Board the authority to approve company-based training programs as a method of certification, which will be focused on the actual activities being performed at that practice site. We recommend this amendment.

Training Program—a pharmacy technician training program that is currently nationally-accredited and has been approved by the board. ***The Board may***

approve an employer-based training program that is not nationally accredited if deemed acceptable by the Board.

§903. Pharmacy Technician Candidates

Subsection (A)(2)(c)(i): We believe that the Board should allow for both board-approved or nationally accredited programs. If a program is nationally accredited, there is no purpose in also requiring it to be "board-approved". Instead, we recommend a process to allows for employer-based programs that are not necessarily nationally accredited. Therefore, we suggest changing "and" to "or" to allow for both board-approved or nationally accredited programs. If the Board wishes to mandate national accreditation, then we recommend striking "and board approved". We also suggest similar changes throughout the chapter to ensure consistency of all rules pertaining to certification programs and requirement.

Subsection (A)(3)(f): We recommend striking the change of employment requirement. We believe this requirement to be administratively burdensome and is overly unnecessary to notify the Board of a change in employment. Under current regulations the candidate is already required to notify the Board regarding mailing address changes. Removal of this requirement would not only lessen the administrative burden on the Board and the candidate, it would also align with current requirements in most states.

Subsection (B)(2): We recommend striking this section regarding notification of failure by the technician from a training program. The burden of notifying the Board when a trainee is no longer enrolled in a training program should not be the responsibility of the training program. If a technician candidate attempts to become employed elsewhere, the new place of employment has a responsibility to ensure proper credentialing of the candidate prior to hire and engagement in all technician activities. Additionally, it should be the responsibility of the candidate, not the training program, is to notify the Board of a change in program. This is an unnecessary administrative responsibility that has no significant impact on patient safety.

Subsection (D)(1): The Board should amend "board-approved" and instead indicate that any exams conducted by organizations accredited by NCCA (National Commission for Certifying Agencies) are acceptable as these are currently the exams conducted by PTCB or NHA only. This is a general standard across the nation. In addition, it does not require the board to specify exam names in the rule nor create a potential bias towards one exam or another.

Subsection (D)(2): We recommend striking time frames for retesting. Currently, both the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA) have minimum time-periods in which a candidate must wait prior to re-taking the exam to ensure the integrity of the exam. Additionally, we believe that a one year waiting period is a lengthy time frame in which it is likely to diminish the candidate's chances of passing this exam as well as decrease interest in gaining certification.

§905. Pharmacy Technician Certificate

Subsection (A)(3)(a): We recommend striking "and board-approved" or amending it to "or board-approved" for the same reasons provided in section 903.

Subsection (A)(3)(b): We recommend reducing the 600-hour requirement to 320 hours, or 8 weeks full time, which we think is enough to appropriately train pharmacy technicians. If the Board is not willing to decrease the required hours to 320, at minimum, we suggest revising the existing language to align with the current PTCB training requirements of 440 hours for entry level pharmacy technicians.

§907. Technician Scope of Practice

Subsection (A)(2): We recommend that the Board eliminate pharmacy technician ratios. Our experience in states with similar ratio requirements to the current Louisiana rule, staffing issues arise due to the limited number of certified technicians available to meet the high end of the ratio allowance. There is no evidence that limiting the number of technicians promotes the safety of pharmacy practice. Conversely, states that place a cap on the number of technician candidates leave pharmacists with the decision to either staff their location without adequate support or violate ratio regulations.

Pharmacists are professionals who can manage their pharmacies. Dictating a technician ratio is an antiquated policy in the present pharmacy practice environment. Arbitrary ratios prevent pharmacies from maximizing use of pharmacy technicians to provide a broader set of patient care services to the public. Many Boards of Pharmacy, recognizing this to be true, have over the years relaxed or removed restrictive ratios to allow for optimal use of pharmacy technicians. Notably, the National Association of Boards of Pharmacy (NABP) has long supported the complete elimination of the pharmacist to technician ratio.

Given the growing demand for pharmacist-provided patient care services in community pharmacies, there is a corresponding need to deploy pharmacy technicians for administrative and non-judgmental duties. Furthermore, elimination of technician to pharmacist ratios will enable pharmacists to focus more on counseling patients, performing MTM, providing disease management programs, engaging in other important patient care services, and collaborating with other health care professionals, thus integrating more fully in a patient's care. These services also help patients better adhere to their medication regimens and ultimately serve to improve patients' health and wellness and reduce our nation's health care costs. Therefore, we strongly urge the Board to eliminate technician ratios to maximize the utilization of technicians by pharmacists.

Subsection (B): The current rules do not delineate specific tasks pharmacy technicians may perform. Instead, it outlines limitations for the duties performed by pharmacy technicians

and allow pharmacists to determine what duties may be performed by technicians within those limitations. NACDS strongly supports pharmacists practicing at the top of their profession to allow for optimal patient care and improved health outcomes. When considering an enhanced role for pharmacy technicians in collaborative health settings, several duties can be reasonably delegated from these two categories: (1) medication dispensing support; and (2) technical support for clinical services provided by pharmacists and other health professionals. As such, where appropriate, we recommend that the Board strongly considers adopting changes that would allow pharmacy technician to perform duties in the following areas:

Medication Dispensing:

Some pharmacist duties related to medication dispensing can be delegated to pharmacy technicians, thus allowing pharmacists to devote more time to patient care. The following tasks are related to medication dispensing and can be performed by a technician:

- ***Accepting a verbal prescription***: Allows the technician to accept a verbal prescription by phone. Currently, 16 states permit this activity for certified technicians.[1]

- ***Transferring a prescription*****:** Allows the technician to transfer a patient's prescription to another pharmacy. Currently, 13 states permit this activity for certified technicians.[2]

- ***Consulting with a prescriber for clarifications***: When information on a prescription is incomplete, a pharmacy technician can contact the prescriber and appropriately obtain the needed information. However, if the inquiry regarding the missing information requires the professional judgment of a pharmacist, then the pharmacist would contact the prescriber. Currently, six states permit this activity for certified technicians.[3]

- ***Final product verification*****:** A new optimizing care practice model is emerging that allows technicians to verify the accuracy of another technician's work and eliminate the final verification of a prescription by a pharmacist. Currently, this task is allowed in the community setting in Arizona, Idaho, and North Dakota. Iowa is currently soliciting comments on a proposed rule regarding technician product verification.

    - Arizona: Qualified technicians may perform a final technology assisted verification of a product and subsequently type and affix a label for the

[1] Currently allowed in ID, IL, IA, LA, MA, MI, MO, NH, NC, ND, OH, PR, RI, SC, TN, and WI. National Association of Boards of Pharmacy; *Survey of Pharmacy Law*; 2018; pp. 50.

[2] Currently allowed in AZ, ID, LA, MA, MI, MO, NC, ND, PR, RI, SC, TN, and WY. *Id.* at 51.

[3] Currently allowed in DE, IL, ID, IA, MI and SD.

prescription medication. A pharmacist, or graduate or pharmacy intern must verify the accuracy of the label.[4]

- Idaho: A certified technician may perform final verification on prescription drug orders that have previously undergone prospective drug review by a pharmacist.[5]

- Iowa: Proposed rule would allow certified technicians provide drug product verification.[6]

- North Dakota: Allows the preparation of a prescription or order for dispensing or administration to be performed by one registered pharmacy technician and verified by another registered pharmacy technician working in the same licensed pharmacy, under specific conditions.[7]

- ***Checking the Prescription Monitoring Program (PMP)*:** Technicians should be allowed to initiate a check of the PMP, but not be allowed to make decisions on whether a medication should be dispensed based on the findings in the PMP report. Technicians are currently allowed to check the PMP in Maine and Idaho.[8]

Assisting with Clinical Services:
The following are potential tasks that may be delegated to a technician with proper training to augment the role of pharmacists in providing direct patient care services. It is important to note that these tasks would not allow technicians to perform clinical services, but to perform steps that are part of a clinical service that do not require professional judgment. Except for Idaho, which now allows technicians to administer vaccines, these tasks are not expressly allowed in any state. However, it has been suggested that pharmacy technicians can be trained to perform the following:

- ***Perform basic physical assessment*:** Performing basic assessments such as taking a patient's temperature or blood pressure can be considered non-judgmental tasks

[4] Arizona Admin. Code R4-23-1104(A) and (B), https://apps.azsos.gov/public_services/Title_04/4-23.pdf.
[5] Rules of the Idaho State Board of Pharmacy, 27.01.01.410
[6] Technician Product Verification Programs, Proposed Rule, Nov 2018, https://pharmacy.iowa.gov/sites/default/files/documents/2018/11/draft_tpv_ch_40_pre-notice.pdf.
[7] North Dakota Administrative Code, Section 61-02-07.1-12. Conditions require that: there are policies and procedures outlining pharmacy technician scope of practice, including training for the specific activity and appropriate recordkeeping; the pharmacy has a continuous quality improvement system in place to periodically verify the accuracy of the final product; any error must trigger pharmacist review of the process; the pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient; and the pharmacist-in-charge and permit holder are jointly responsible for the final product dispensed or released for administration from the pharmacy.
[8] Idaho Statute, Title 37, Article III, Section 2726 (12). In Idaho, House Bill 374 was recently signed into law allowing technicians to check the PMP as a delegate of the supervising pharmacist as of July 1, 2016. The law provides practitioners with a new tool to streamline access to the PMP and allows for the designation of up to four delegates to access the PMP on their behalf. The bill amends the existing definition of "delegate" to include a registered pharmacy technician. A delegate may access information to the extent the information relates specifically to a current patient to whom the practitioner is prescribing or considering prescribing any controlled substance. Presently, regulations have not been proposed to implement this change in the law.

and may be tasks that pharmacists can delegate to pharmacy technicians. Allowing pharmacy technicians to perform such assessments may leverage scarce healthcare resources to improve efficiency in pharmacies that offer point-of-care testing. For example, if a pharmacy technician can check a patient's temperature and administer a screening for influenza, then the pharmacist may assess the results and initiate treatment if appropriate.[9]

- ***Conduct medication reconciliation*:** Properly trained technicians can compile an initial medication list based on an interview with the patient. Assessing that information and making clinical recommendations would be performed by the pharmacist using his or her professional judgment.

- ***Administer vaccines*:** Prescribers routinely delegate vaccine administration to healthcare paraprofessionals. Similarly, there is an opportunity to allow pharmacists to delegate this task to a properly trained and certified pharmacy technician. In Idaho, technicians who are appropriately trained and certified may administer vaccines.[10]

- ***Administer CLIA-waived laboratory tests*:** CLIA-waived tests are "simple and have a low risk for erroneous results"[11] with most having diagnostic capabilities. Under federal law, CLIA waived tests can be performed by laypersons. Consequently, performing a CLIA-waived test is a task that may be delegated to a properly trained technician. The decision to order, interpret, and act on the results of the test, however, requires professional judgment and would remain the duty of the pharmacist.

Chapter 11. Pharmacies

§1101. Pharmacy

Subsection (C)(1): We recommend not requiring the signature of the PIC on the initial application as it is an unnecessary administrative burden for the pharmacy. Instead of the PICs signature, we recommend that the Board accept the name of a PIC on the application.

Subsection (C)(2): We recommend changing from annual to biennial renewals for pharmacy permits.

§1103. Prescription Department Requirements:

[9] Pharmacy Today*; The Promise of Point of Care Testing*; Volume 22, Issue 2, pp 34-37; February 2016. In Nebraska, a Hy-Vee pharmacist is authorized through a collaborative practice agreement with a local primary care physician to dispense amoxicillin, azithromycin, or oseltamivir to treat influenza.

[10] Rules of the Idaho State Board of Pharmacy, 27.01.01.330.02(b)(3)

[11] Clinical Laboratory Improvement Amendments, Center for Disease Control, https://wwwn.cdc.gov/clia/resources/waivedtests/, last visited November 22, 2016.

Pharmacy practice has changed over the years and many requirements in this section are outdated. Some pharmacies today do not even stock medications, but rather only provide pharmacy services. Many of the requirements in this section are overly prescriptive, outdated, and unnecessary. We recommend eliminating these three subsections:

~~C. Square Footage. A prescription department that is new or remodeled on or after January 1, 2004 shall be not less than three hundred (300) total square feet, and shall be inaccessible to the public.~~

~~D. Prescription Counter. A prescription counter on which to compound or dispense medications shall have a working surface of not less than a minimum of twenty-four (24) total square feet. The minimum unobstructed free working surface shall be kept clear at all times for the compounding or dispensing of prescriptions.~~

~~E. Prescription Aisle Space. The aisle space behind the prescription counter shall be not less than thirty (30) inches in width.~~

Subsection H)(1): We recommend striking the first sentence and leaving only: "Drugs that require special storage shall be properly stored."

H. Drug Inventory.

1. Storage. ~~The pharmacy shall provide sufficient space on-site for proper storage of labels,~~

~~prescription containers, and an adequate prescription inventory in order to compound and dispense prescription orders.~~ Drugs that require special storage shall be properly stored.

Subsection (K): References - The requirement to keep hardcopies of the Louisiana Board of Pharmacy Laws and Regulations is outdated and should be eliminated. Electronic copies of the laws and regulations are available and can be updated automatically, whereas paper copies must be manually considering laws/rules constantly change. Therefore, we recommend revising this section to allow electronic copies of Louisiana laws and regulations.

§1105. Pharmacist-in-Charge

Subsection (A)(1)(b): Under current rule, a licensed pharmacist is not be able to serve as PIC until they have obtained a minimum of two years of experience practicing pharmacy in Louisiana or another state. We believe that this requirement is problematic for community pharmacies. While we recognize the important role of the PIC in the operation of pharmacies and appreciate the Board's intent for developing standards that serve to protect public health, safety, and welfare in the pharmacy setting, this requirement unfairly disadvantages skilled pharmacists and pharmacies who have to wait until the arbitrary timeline requirements are met. Additionally, it potentially exacerbates staffing issues in areas where pharmacies already have challenges recruiting pharmacists.

We believe that the designation of a PIC should be made on a case-by-case basis and should be based on the level of knowledge and training that a pharmacist has without regard to the number of years in practice. Pharmacists who are appointed to this position are those who are motivated and dedicated to protecting patient safety while upholding the statutes and rules under which they practice. Careful consideration is made prior to appointing a PIC and we believe each institution should have the right to determine if a pharmacist can perform as their PIC. We recommend the Board amend this provision in the proposed rule to require six months to one year of experience.

Subsection (A)(2): We recommend eliminating the minimum hours requirement. The Board rules have made clear that the PIC is accountable for the pharmacy following all laws and regulations, therefore a minimum hours requirement is unnecessary and overly prescriptive.

Subsection (I): The current rules require the notification in writing to the Board within 10 days of any discharge or termination of the licensed pharmacist or change of the status of the PIC. Additionally, the current rules require the permit holder to designate a new pharmacist-in-charge within 10 days of the departure of the prior pharmacist-in-charge. We disagree with the current language and recommend for notification of only the PIC. Staffing changes occur on a regular basis as pharmacists acquire new employment within the industry. We believe that this level of notification provides no additional patient protection and instead creates an additional administrative burden on the PIC as well as the Board staff.

In addition to making changes to only require notification of changes for the PIC, we also ask the Board to increase the report time from 10 days to 30 days to prevent unintended notification consequences. Currently most states allow the pharmacy license holder 30 days to find an adequate replacement for the PIC. We believe that given the level of responsibility of the PIC, the 10-day requirement is unrealistic and unreasonable. We recommend the Board allow more time for this process to be adequately completed.

§1109. Pharmacist Temporary Absence, and §1111. Pharmacist Absence

We suggest amending the current rule to enable a pharmacist to assist a patient in a clinical capacity from outside of the pharmacy department without being considered absent. It is important to not obstruct safe pharmaceutical care practice in the evolving world of pharmacy services.

§1113. Mechanical Drug Dispensing Devices

We recommend striking this rule. This rule prohibiting the dispensing of medications directly to patients by mechanical devices or machines may create confusion and/or potentially limit opportunities for increased access. Furthermore, we believe that this technology has been prohibited without evidence of public safety concern, as well as an

inhibition of patient access to pharmaceutical care. If the Board will not consider elimination of the rule, instead we recommend that the Board considers incorporating an approval process to enable the expansion of patient access to pharmacy care.

A. Dispensing of prescription drugs directly to a patient or caregiver by mechanical devices or machine is prohibited***, unless the device is approved by the Board***. This prohibition shall not apply to automated medication systems as defined and provided for in Chapter 12 of these regulations.

§1123. Records

We ask the Board to strike the requirement to retain a prescription hard copy for a year. Digital images of prescriptions for legend drugs have enabled pharmacies to utilize their software system to receive faxed prescriptions, without utilizing paper, and to scan written and oral transcribed prescriptions into the system for secure record keeping. The requirement to retain the hard copy for a year creates the unnecessary use of paper and limits the storage space within a pharmacy. We recommend the Board consider adopting these amendments:

K. Filing and Retention of Prescription Forms

1. Written prescription forms ***not stored in accordance to paragraph J*** (including transcriptions of verbal prescriptions received in the pharmacy, prescriptions received by facsimile in the pharmacy, as well as written prescription forms presented to the pharmacy) shall be assembled and stored in prescription number sequence. Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately from all other prescriptions. Where multiple medications are ordered on a single prescription form and includes one or more controlled dangerous substances listed in Schedule II, then such forms shall be filed with other Schedule II prescriptions. These original hard copy prescription forms shall be retained in the prescription department for a minimum of two years following the most recent transaction.

~~2. For those pharmacies utilizing an electronic imaging system as described in Paragraph J of this Section, written prescription forms may be assembled and stored in prescription number sequence, or in the alternative, a date scanned sequence. Further, these original hard copy prescriptions shall be retained in the prescription department for a minimum of one year following the most recent transaction.~~

3. Prescription forms ***stored in an electronic imaging system shall be retained within the system in a readily retrievable manner for a minimum of two years from the last transaction.*** ~~received as an electronic image or electronic facsimile directly within the pharmacy information system shall be retained within the information system for a minimum of two years following the most recent transaction. Further, the pharmacy~~

~~may produce a hard copy of the prescription form but shall not be required to do so merely for recordkeeping purposes.~~

§1131. Pharmacy Opening Procedures

Subsection (A)(1): We recommend the Board amend this section to allow for the signature of appropriate authorized representative of the pharmacy versus the signature of the PIC on the initial pharmacy permit application and Louisiana Controlled Dangerous Substance License application. As stated previously, staffing changes occur on a regular basis as pharmacists acquire new employment within the industry. When a new PIC is designated, the signature and documents are outdated. Allowing the appropriate authorized representative of the pharmacy to sign the initial permit application removes any inaccuracies with frequent employment changes of the PIC, and allows for more accuracy in the application and records processes.

Subsection (A)(4): This requirement is unnecessary in rules as it appears to be advisement to the applicant vs. a mandatory requirement.

Chapter 12. Automated Medication Systems

§1201. Definitions, and §1207. Pharmacist Review

Technology has enabled the utilization of automated product checks that ensure the correct product on the label is dispensed. This has enabled Boards of Pharmacy to safely enable barcode scanning validation actuated by a technician or automated system to meet the requirements of a final pharmacist check. The dispensing pharmacist would be designated as the responsible pharmacist, with the duty of ensuring the accuracy of the technological verification system utilized. In line with these comments, we recommend the following amendments:

§1201. Definitions

Final Checks of Work – the requirement that only a pharmacist supervises and releases the completed product prepared by a pharmacy technician, ***unless otherwise noted in this Section***

§1207. Pharmacist Review

A. ***The Pharmacist-in-Charge or verifying pharmacist shall be responsible for the accuracy of medication produced by the*** ~~S~~***system*** ~~shall be used in settings that ensure medication orders are reviewed by a pharmacist prior to administration and~~ ***The system must be maintained*** in accordance with established policies and procedures and good pharmacy practice. A policy and procedure protocol shall be adopted to retrospectively review medications which cannot be reviewed prior to administration, as provided in LAC 46:LIII.1209.2.

We also recommend that clarifying language be added to indicate that indicates “counting machines” to not be included as automated dispensing systems.

Chapter 23. Nonresident Pharmacy

§2307. Pharmacist-in-Charge

Similar to Section 1105 which requires a pharmacist to practice for two years prior to becoming a PIC, creating a determining factor of pharmacy management by time of practice is not a holistic view of who can take the responsibility of a PIC. Time of practice is not a holistic view of who can take the responsibility of a PIC. This requirement forces the selection of an individual based on years of practice rather than their individual capabilities to manage a pharmacy. With respect to mandating this of nonresident PICs, the state is, in some instances, prohibiting the domicile PIC of the nonresident pharmacy from being responsible for the actions of his or her pharmacy. In exchange, the rules seek to assign responsibility to another individual simply on the merits of that individual’s tenure being in excess of two years. Consistent with the suggestion made above for Section 1105, we recommend that the Board delete this provision in the rules.

A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege:

1. The acquisition of the PIC privilege shall require:

a. Possession of an active Louisiana pharmacist license;

b. Possession of an active license in the state in which the pharmacy is located, and further, said license shall not have any restrictions which prohibit the position of pharmacist-in-charge;

~~c. Active practice as a pharmacist for a minimum of two years under the jurisdiction of any board of pharmacy in the United States;~~ and

c~~d~~. …

Chapter 24. Limited Service Providers

§2425. Telepharmacy Dispensing Site

Subsection (A)(1): We recommend reducing the mileage requirement to 10 miles. For those patients that lack transportation or have other mobility issues, even a few miles may create an access barrier. As currently written, 20 miles does not resolve the access concerns that these rules are intended to fix.

Subsection (A)(6): We recommend striking this section of the rule that requires the closing of a dispensing site if a new community pharmacy opens within 20 miles of the existing telepharmacy dispensing site. This section creates an unnecessary barrier for telepharmacies to open. Telepharmacy continues to grow nationally and will have a significant impact on rural areas. Where primary care physicians may be scarce, 91.7% of

the country's population lives within 5 miles of a pharmacy. We applaud Louisiana for having a telepharmacy platform in the state, however we request that the relevant rule be reevaluated to ensure that telepharmacy allows for flexibility to accommodate the inevitable changes in technology.

To reevaluate the rule comprehensively, we suggest looking at actions taken by the Indiana Board of Pharmacy (which has established a subcommittee to develop telepharmacy rules that meet the needs for patient population in Indiana) and the Illinois State Board of Pharmacy (which has developed industry leading rules that are currently used in Illinois).

Subsection (E)(2)(c): We recommend eliminating this section of the rule. The economics/business aspects of the pharmacy should dictate the number of personnel required to staff a telepharmacy location. In addition, as stated above, we recommend striking any ratio references in this rule.

Subsection (E)(3)(g): We recommend counseling requirements only on new prescriptions and an offer to counsel requirement on all refills. The vast majority of patients do not require nor want counseling on refills.

Chapter 25. Prescriptions, Drugs, and Devices

§2511. Prescriptions

Subsection (C): We recommend the following changes to align with current electronic technology for transmitting prescriptions as well as to remove provisions that are administratively burdensome and unduly unnecessary.

- Striking the size requirements of a written prescription.
- Expanding the rule to allow for electronic capture of facsimile prescriptions. With increased technology, facsimile prescriptions may now be received and stored electronically without a requirement to be in paper format.
- Striking the expiration date of 12/31/2016 of this section of this rule, thereby allowing for prescriptions received by the pharmacy that bears the electronic signature of a prescriber to be construed as a validly formatted prescription for non-controlled prescriptions.

Subsection (D): We recommend adding language that would allow a pharmacy intern or technician to initial the form or add an identifier in the electronic record keeping system. Additionally, we suggest adding language that states that the verifying pharmacists would assume the responsibility for the accuracy of the order received by the technician or the pharmacy intern.

1. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a

written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, ~~a pharmacist~~ ***they*** may enter the prescription information directly into the pharmacy's dispensing information system. In the event a pharmacy intern or pharmacy technician transcribes such a prescription, ***the intern or technician must initial the form, or add an identifier in the electronic record keeping system. The verifying pharmacists assumes responsibility for the accuracy of the order received by a technician or pharmacy intern.*** ~~supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.~~

§2513. Prescription Receipt and Verification

Written, oral and electronic transmission of prescriptions as well as the verification of a prescription are all basic standards of practice and otherwise identified and throughout various Board laws and rules. We recommend the Board delete this section as it is redundant and unnecessary.

§2519. Prescription Refills; Medication Synchronization and Refill Consolidation

Subsection (B)(2): We recommend that the Board amend this section to align with the §1306.22 of the Federal Code. Currently, under Federal Regulation, the DEA only specifies that C-III and C-IV prescriptions to be refilled up to 5 times. We recommend amending (B)(2) to strike C-V's from this section of the rule to align with these requirements.

§2521. Emergency Refills

Continuity of chronic care is essential for patients. Pharmacists should be enabled to assist a patient with demonstrated chronic therapy by providing an ample supply of medications when the prescriber cannot be reached for renewal. The current provision of 72-hours is on the low end of allowable quantities and may not bridge the gap being experienced by the patient. In the pharmacist's clinical judgment, a patient should be enabled to receive a month supply of their chronic medication. This should follow a reasonable attempt by the pharmacist to reach the prescriber. It is also important to note that medications such as inhalers and oral contraceptives cannot be broken down into a 72-hour supply. Regardless of the Board's desire to extend the day supply allowed for an emergency refill, a carve out for unit dosed packaging that cannot be separated into a 72-hour increment should be enabled. We recommend the Board adopt this amendment:

A. Using sound professional judgment, a pharmacist may provide a refill ~~adequate~~ of medication ~~for a seventy-two (72) hour regimen~~ when an emergency ~~for medication~~ has been adequately demonstrated and the prescribing practitioner is not available. This refill should not exceed a 30-day supply, or the previously prescribed quantity, whichever is less.

§2525. Prescription Expiration

Subsection (B)(2): We recommend that the Board amend this section to align with the §1306.22 of the Federal Code. Currently, under Federal Regulation, the DEA only specifies that C-III and C-IV prescriptions to expire 6 months from the date written. Therefore, we recommend amending (B)(2) to strike C-V's from this section of the rule to align with these Federal Code requirements.

DEA: §1306.22 Refilling of prescriptions.

> No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times

DEA FAQ's: Question: Can controlled substance prescriptions be refilled?

> Answer: Prescriptions for schedule II-controlled substances cannot be refilled. A new prescription must be issued. Prescriptions for schedules III and IV controlled substances may be refilled up to five times in six months. Prescriptions for schedule V controlled substances may be refilled as authorized by the practitioner.

Chapter 27. Controlled Dangerous Substances

§2733. Inventory Requirements

Subsection (C)(1)(a): This subsection is unnecessary since annual inventory is required and shall include all stocks of controlled substances medications.

§2747. Dispensing Requirements

Subsection (B)(5): We recommend that the Board review the current rules and amend as necessary to align with Section 702 (21 U.S.C 829(f)) of the Comprehensive Addiction and Recovery Act (CARA) to allow partial fills at the request of the prescriber or patient.

Conclusion

We thank the Board for the opportunity to provide input and proposing changes to your rules. We look forward to working with you to ensure that patients in Louisiana continue to receive optimal healthcare at their community pharmacy. If you have any questions or need additional information, please contact me at mstaples@nacds.org or 817-442-1155.

Sincerely,

Mary Staples

Mary Staples
Regional Director, State Government Affairs