



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

July 7, 2020

Elena Kemp
Regulatory Coordinator
Department of Regulatory Agencies
1560 Broadway, Suite 1550
Denver, CO, 80202

Via: dora_dpo_rulemaking@state.co.us

RE: Proposed Rule to Expand Pharmacy Practice under 3 CCR 719-1

Dear Ms. Kemp:

On behalf of our members operating more than 600 stores and employing more than 70,000 residents within the state of Colorado, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to express support for the current proposed rule to make permanent changes under the April 30, 2020 emergency rules. NACDS applauds the Colorado Department of Regulatory Agencies- Board of Pharmacy (the "Board") for recognizing the value of eliminating burdensome and unnecessary existing requirements and expanding accessible and convenient patient care throughout the state. Pharmacies have risen to the challenge during the COVID-19 pandemic as destinations for frontline care, and all healthcare professionals should be leveraged to practice at the top of their license to engage in response efforts and beyond.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. NACDS members operate nearly 40,000 pharmacies and include regional chains, with as few as four stores, and national companies. Nationally, chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. For more information, please visit nacds.org.

In an effort to expand pharmacy practice and allow pharmacists to deliver quality care, NACDS recognizes the Board's tremendous efforts to do so. NACDS is in general support of the Board's actions via emergency rule, with strong support for the Board's removal of specific pharmacist qualifications under section 17.00.30 for pharmacy collaborative practice agreements and section 19.01.10 for vaccine administration. Pharmacists are highly qualified healthcare professionals who undergo a rigorous pharmacy curriculum focused on medication therapy and delivery of patient care services. In addition to our general support for making existing emergency rules pertaining to pharmacy practice permanent, NACDS also proposes minor modifications below for the Board's consideration.

Board Rule 1.00.00- RULES OF PROFESSIONAL CONDUCT. NACDS applauds the Board for recognizing pharmacists' ability to order and administer COVID-19 tests, including serology tests, and fully supports permanent enactment of this emergency rule. As states and local economies begin to reopen, testing capacity must be ramped up significantly to meet the demand and to protect Colorado residents. Along with making this emergency rule permanent, NACDS strongly urges the Board to grant broader authority for pharmacists to order and administer point-of-care tests in a similar manner as deemed for COVID-19 tests. Currently, Colorado rules authorize pharmacists to conduct physical assessments or order and evaluate laboratory or other tests pursuant to a statewide protocol, if testing is noted within the protocol. Explicit authorization to conduct testing for specific conditions pursuant to statewide protocols results in a

delay in the delivery of essential patient care. Pharmacists are trained and capable to independently order and administer point-of-care tests and should be leveraged accordingly to provide the service within neighborhoods. Specifically, as the nation prepares for a potential additional wave of COVID-19, possibly around influenza season, states such as Colorado should expand current pharmacist testing authority to include all appropriate point-of-care pharmacy tests (e.g. influenza, strep throat, HIV, hepatitis C, tuberculosis, etc.). Community pharmacies provide accessible care, as nearly 90% of Americans live within 5 miles of a pharmacy. Thus, NACDS proposes the following edit for Rule 1.00.25, expanding current pharmacist authority to broadly allow for the administration of point-of-care tests would be of great benefit to Colorado residents.

NACDS' Proposed Edits (in red text):

1.00.25 Colorado-licensed pharmacists may **independently** order and administer COVID-19 tests, including serology tests, that have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA), or equivalent regulatory authorization, subject to the disclaimers and limitations required by the FDA for such tests, **in addition to any CLIA-waived point-of-care tests.**

Board Rule 5.00.00- OUTLETS. NACDS is supportive of the Board's decision to remove unnecessary requirements for pharmacy openings and hours. In light of COVID-19 and other unexpected events, pharmacies should have the flexibility to determine the appropriate hours of operation. Requiring pharmacies to submit a statement to the Board documenting the days and hours when the pharmacy will operate at least 30 days before the intended date is not always possible. As such, NACDS proposes removing section 5.01.40.b as shown below:

NACDS' Proposed Edits (in red text):

~~5.01.40 Minimum Hours of Operation.~~

~~ab. In the event that the principal compounding/dispensing area is open less than thirty-two hours per week, the pharmacist manager shall submit to the Board a written statement of the designated days and hours when the principal compounding/dispensing area will be open for business, and this statement shall be submitted at least thirty days prior to the date on which the hours of operation will be less than thirty-two hours per week.~~

Board Rule 19.00.00- ADMINISTRATION. The Board's recent efforts to remove administratively burdensome and unnecessary pharmacist qualifications for vaccine administration are invaluable to the delivery of effective vaccination services. Community pharmacists are valuable and highly educated to provide accessible and cost-effective health services including immunizations to their local communities. The ability to leverage pharmacists and pharmacies as vaccine destinations – especially during significant disease outbreaks that can or will eventually be preventable through vaccination – will be critical to meeting public health goals. However, in an effort to fully leverage all members of the pharmacy team to meet the increased demand for vaccination, there is a corresponding need for pharmacists to delegate administrative, nondiscretionary tasks such as vaccine administration to pharmacy technicians and pharmacy interns to provide high quality, dedicated care to the communities they serve. The highly anticipated upcoming influenza season has the potential for increased consumer demand for flu and pneumonia vaccines, in addition to COVID-19 vaccines when available. The Centers for Disease Control and Prevention's pandemic plans include pharmacies as a central partner in distribution of pandemic vaccine, and as such, it is essential to fully utilize all pharmacy staff to meet the demand of Americans.

Research supports pharmacy technicians to successfully perform the technical task of administering vaccinations. Upon pharmacist review of vaccine appropriateness and patient counseling, authorization of pharmacy technicians to administer vaccines results in more time for pharmacists to focus on tasks requiring clinical judgment, which is no different than support staff administering vaccines in physician offices. To date, Utah, Idaho, and Rhode Island have

incorporated the ability for technicians to perform this technical task.ⁱ In a recent pilot, pharmacy technicians delivered over 950 vaccinations between December 2016 and May 2017 without adverse effects.ⁱⁱ Given the technical nature of vaccine administration, pharmacy technicians should be authorized to administer all types of vaccinations. Further, the training program developed for pharmacy technicians in Idaho included both intramuscular and subcutaneous administration routes and techniques, equipping technicians to offer a wide range of vaccinations.ⁱⁱⁱ Importantly, even when pharmacy technicians administer vaccinations, pharmacists continue to maintain all aspects of clinical decision-making. Thus, NACDS strongly urges the Board to authorize pharmacists the ability to delegate administration of any vaccine, including the forthcoming COVID-19 vaccine, to pharmacy technicians via the proposed modification below.

NACDS' Proposed Edits (in red text):

19.01.20 A trained pharmacist may delegate the administration of **any** vaccines and immunizations, **including vaccines authorized by the Food and Drug Administration related to COVID-19, only** to a trained pharmacy intern **or pharmacy technician**.

Board Rule 26.00.00 REMOTE PHARMACY PRACTICE. NACDS applauds the Board for recognizing the value of fully leveraging pharmacy staff, especially to support Colorado's COVID-19 pandemic response. Specifically, Colorado authorized pharmacy technicians to conduct remote processing during the global pandemic, resulting in increased safety of personnel and pharmacy continuity. Additionally, the removal of an administratively burdensome requirement such as requiring pharmacies to submit a Policy and Procedure Manual and sample Written Agreement to the Board expands pharmacies' reach to patients and the surrounding community. However, the use of remote processing tools safely enhance patient access to care every day, beyond the pandemic and, thus, these emergency rules should be made permanent.

NACDS also recommends that the Board allow members of the pharmacy team to conduct appropriate remote pharmacy practices from home given the current COVID-19 pandemic, as it provides increased protection and flexibility for members of the pharmacy team. Authorizing pharmacists, pharmacy interns, and pharmacy technicians to conduct remote practices at home will still allow for quality care delivery as pharmacists and pharmacy technicians are able to provide dedicated focus to their responsibilities. Currently, thirty-three (33) states recognize the benefits of allowing pharmacists and pharmacy technicians to work at home during the COVID-19 pandemic. Additionally, employers are capable of determining appropriate security and privacy controls. And, pharmacists will still be required to review data entry performed by pharmacy technicians, resulting in multiple layers of quality control and minimize errors as similarly observed in the physical pharmacy. Please see below for NACDS' proposed modification to Rule 26.00.10.

NACDS' Proposed Edits (in red text):

26.00.10 Definitions d. "Remote Pharmacy Practice" means initial interpretation and/or final evaluation of orders which is conducted at a location other than a registered prescription drug outlet or other outlet, **including offsite locations such as a pharmacy staff member's residence, ~~registered with the Board.~~**

e. "Remote Pharmacy Practice" may include, but is not limited to, duties conducted by pharmacists, pharmacy interns, or pharmacy technicians at a location other than a registered prescription drug outlet or other outlet, **including offsite locations such as a pharmacy staff member's residence, ~~registered with the Board.~~**

NACDS appreciates the Colorado Department of Regulatory Agencies- Board of Pharmacy's consideration of our comments. We strongly support the finalization of existing emergency rules that will leverage all members of the pharmacy staff as well as eliminate burdensome requirements that hinder the full practice of pharmacy. NACDS acknowledges the tremendous efforts of the Board and strongly urges the Board to consider these recommendations in an effort to provide Coloradoans seamless, accessible, and convenient care within their neighborhood. If you have any

questions regarding this letter, or if we can be of any assistance, please contact NACDS' Mary Staples at mstaples@nacds.org or 817-442-1155.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a large initial "S" and "A".

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

ⁱ <https://www.pharmacytimes.com/publications/supplements/2019/March2019/an-update-on-technicians-as-immunizers>

ⁱⁱ McKeirnan KC, Frazier KR, Nguyen M, MacLean LG. Training pharmacy technicians to administer immunizations. J Am Pharm Assoc (2003). 2018;58(2):174–178.e1. doi:10.1016/j.japh.2018.01.003

ⁱⁱⁱ <https://pharmacy.wsu.edu/pharmacy-technician-immunization-training/>