







June 18, 2020

Shauna White, PharmD, RPh, MS
Executive Director
District of Columbia, Board of Pharmacy
899 North Capitol Street, NE – 2nd Floor
Washington, DC 20002

RE: DEPARTMENT OF HEALTH EMERGENCY RULEMAKING - COVID-19 TESTING BY PHARMACISTS

Dear Director White,

The National Community Pharmacists Association (NCPA), the National Association of Chain Drug Stores (NACDS), the National Grocers Association (NGA), and the Food Industry Association (FMI) is writing you today in regards to the recently adopted Department of Health (DOH), Board of Pharmacy (BOP) emergency rule - § 6516, COVID-19 Testing by Pharmacists. We commend the DOH's efforts to curb the spread of the 2019 novel coronavirus disease (COVID-19) while protecting the health, safety, and welfare of the District's residents. However, the adopted rules for safe and effective operation of pharmacies that participate in COVID-19 testing entails restrictive requirements on types of COVID-19 tests authorized to use for the service, restrictions on personal protective equipment (PPE), exclusion of certified pharmacy technician participation in testing efforts, and inaccurate classification of all testing as the same, notably requiring testing outdoors, regardless of the differences in testing processes. These requirements create inefficiencies in the District's efforts to expand COVID-19 testing and negatively impacts patient access to testing. As such, we request the Department of Health to approach this opportunity for pharmacists to provide the service from a broad standards of care approach instead of implementing prescriptive rules to provide quality patient care. In addition, the emergency rules as written, may expire before the HHS public health emergency declaration.

NCPA represents the interest of America's community pharmacists, including the owners of more than 21,000 independent community pharmacies across the United States and 44 independent community pharmacies in the District of Columbia (D.C.) that employ about 488 full-time employees who filled over 2.5 million prescriptions last year. Our members are small business owners who are among America's most accessible health care providers in many communities and are critical for the expansion of testing and eventually to furnish a COVID-19 vaccine to D.C. residents once available.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Our members operate nearly 40,000 pharmacies and include regional chains, with as few as four stores, and national companies. 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.

FMI represents the entire food industry – from producers that supply food and other products, to food retailers that sell to consumers as well as supermarket pharmacies – to amplify the collective work of the industry. Health and wellness, including pharmacy-specific programs, is of the utmost importance to our industry. In total, FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. The reach and impact of our work is extensive, ultimately touching the lives of over 100 million households in the United States and representing an \$800 billion industry with nearly 6 million employees.

The National Grocers Association (NGA) is the national trade association representing the retail and wholesale grocers that comprise the independent sector of the food distribution industry. An independent retailer is a privately owned or controlled food retail company operating a variety of formats. The independent grocery sector is accountable for close to one percent of the nation's overall economy and is responsible for generating \$131 billion in sales, 944,000 jobs, \$30 billion in wages, and

\$27 billion in taxes. NGA members include retail and wholesale grocers – including over 3,000 grocery pharmacies, state grocers associations, as well as manufacturers and service suppliers.

Pharmacist COVID-19 Testing Authority

We applaud the DOH and BOP for enacting this emergency rule, granting pharmacists the authority to conduct COVID-19 testing. However, rule 6516.2 requires pharmacists to use COVID-19 tests that have been "approved by the United States Food and Drug Administration (FDA)." The U.S. Department of Health and Human Services (HHS) advisory opinion clarified that pharmacists are authorized to order, administer, and perform COVID-19 tests, including serological tests, *authorized* by the FDA. HHS and the majority of other states that have addressed COVID-19 testing authority have used authorized instead of approved because, to date, no COVID-19 diagnostic or serologic tests have been approved by the FDA, but several have been authorized via emergency use authorization (EUA). We strongly urge the DOH and the BOP to amend rule 6516.2 to align with federal guidance and expand pharmacist testing access to neighborhoods across the District.

PPE Requirements

We support ensuring the safety of patients, pharmacists, and pharmacy staff during testing but rule 6516.7 requirement for pharmacy personnel involved in testing to be fully gowned, including having a face shield, regardless of direct or non-direct test administration, is counterproductive to the efficient use of PPE. During the process of a COVID-19 drive-up test, the patients remain in their vehicle with their windows rolled up during the collection process, and the pharmacy staff does not get within the recommended distance of six (6) feet from the patient.

Furthermore, the adopted rules go far beyond the CDC¹ PPE guidance, and even the FDA² relaxed its PPE rules due to shortages and increased demand. Moreover, the CDC takes the position that face shields are to be used during procedures and activities that could generate splashes, body fluids, secretions, and excretions.³ Thus, we recommend that the minimum PPE requirements, including wearing face shields be required only when the testing protocol could expose the pharmacy personnel to patient excretions while performing COVID-19 testing (i.e. performing a nasal swab).

Pharmacy Technician Participation

Rule 6516.12 prohibits the pharmacist from authorizing a certified pharmacy technician to assist in the COVID-19 testing process. All members of the pharmacy team should be leveraged to their fullest capability in order to effectively deliver quality patient care. Pharmacists should focus their time on patient care activities, and they have the flexibility to do so when other members of the pharmacy team can step up and support administrative pharmacy roles, including administrative aspects of COVID-19 testing. Much like the pharmacist's scope of practice, certified pharmacy technician roles have advanced from pill counting to remote data entry, taking medical histories, vaccine administration, and administering pharmacist-authorized tests. In a number of states, including Ohio⁴ and Vermont⁵, certified pharmacy technicians are authorized to administer COVID-19 tests under pharmacist supervision. The increased role of the certified pharmacy technicians is a natural progression to be embraced for its part in supporting a better standard of pharmacy care. We urge the DOH to allow the pharmacist in charge to utilize their highly trained certified pharmacy technicians in COVID-19 testing to increase testing capacity while managing the pharmacy's daily workflow to serve all patients well.

¹CDC, Strategies to Optimize the Supply of PPE and Equipment

²FDA, <u>Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding</u>

³CDC, https://www.cdc.gov/hicpac/recommendations/core-practices.html

Testing Categories and Location

Rule 6516.2 incorrectly categorizes all testing as the same. A distinction taking into account the test type and location is necessary for administering COVID-19 diagnostic tests, antibody tests, and self-administered sample collection. These processes vary in safety concerns and warrant separate considerations in how and where they are carried out. Rule 6516.4 requires that all testing occurs outdoors. Given that outdoor space is hard to find in urban settings, requiring all testing to occur outdoors may prevent pharmacies from participating. Employers are also well aware of the importance in taking the necessary safety precautions when providing patient care services, adhering to CDC guidance and developing the necessary protocols to ensure healthcare workers and patient safety. They are well-positioned to determine the appropriate location to conduct testing, without additional burdensome requirements. Additionally, CDC states that asymptomatic patients who test positive via serological testing and do not have recent COVID-19 compatible illness have relatively low likelihood of active infection. Thus, we recommend the DOH and BOP give pharmacies the option of choosing to test indoor or outdoor when performing COVID-19 antibody tests, while requiring facemasks and ensuring that social distancing standards are maintained during testing, as well as remove unnecessary distance and location requirements to provide the service.

Accessible COVID-19 Testing Services

In order for D.C. to reopen safely, testing capacity must be increased significantly. The accessibility and convenience of community pharmacies allows D.C. residents the ability to receive quality COVID-19 testing services within their own neighborhood. However, rule 6515.5 limits pharmacies' ability to extend their patient reach by requiring appointments for patients to receive COVID testing. Pharmacists are well-positioned and capable of conducting COVID-19 testing services without the need of an appointment. In fact, just recently 8 fire houses across D.C. offered residents walk-up testing delivered by paramedics and EMTs with no appointment needed. Given pharmacists' extensive educational background and training adequately qualifies them to provide testing services and we would posit similar flexibility should be extended to pharmacy healthcare destinations. Thus, we strongly urge the DOH and the BOP to remove rule 6516.5 in an effort to expand access to COVID-19 testing and protecting D.C. residents.

Conclusion

Frontline community pharmacists stand ready to continue helping in their authorized capacity, and they remain well-positioned to play an essential role to expand testing and provide mass vaccination to D.C. residents once a vaccine is available. The recommendations above will remove existing restrictive barriers to testing and enhance patient care in D.C. Thank you for your time and consideration, please do not hesitate to contact NCPA's Ronna Hauser, Vice President – Policy & Government Affairs Operations at ronna.hauser@ncpa.org with any questions you may have.

⁴Expansion Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician Testing Authority During COVID-19

⁵Pharmacis Ordering and Administration of Testing for COVID-19 in Vermont

⁶ CDC, Interim Guidelines for COVID-19 Antibody Testing

Sincerely,

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CC:

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