September 2020

North Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

1906 E Broadway Ave • Bismarck, ND 58501-4700 • Phone: 701/328-9535
Fax: 701/328-9536 • *www.nodakpharmacy.com*

Pharmacists Testing for COVID-19

By Kendrick Rummel, PharmD Candidate 2021

On March 13, 2020, President Donald J. Trump issued a declaration of national emergency due to coronavirus disease 2019 (COVID-19). In response to this, on March 21, Governor Doug Burgum signed Executive Order 2020-09. One of the powers that licensed pharmacists gained was the ability to administer COVID-19 tests in accordance to and under the guidance of the North Dakota Department of Health.

With the high number of North Dakotans that have been and will continue to need testing, pharmacists can take the opportunity to help their community, benefit their business, and advance their profession by testing patients. The North Dakota State Board of Pharmacy, with the North Dakota Pharmacists Association, and North Dakota State University School of Pharmacy – under the guidance of the Department of Health – have been working on a plan to help pharmacists collect specimens from patients to perform polymerase chain reaction (PCR) tests for COVID-19. Upon approval, the plan will be sent out to the public in the near future. The hope is that it will outline the process and guide pharmacists to become registered with the state lab to receive swab kits. It will also provide guidance on personal protective equipment, tests to perform and how to conduct them, how to send specimens to the lab for processing, screening procedures, and models for reimbursement of services.

The two main types of COVID-19 tests that are performed include PCR and antibody tests. PCRs test the patient for an active infection whereas testing for antibodies involves looking for a past history of infection. The majority of tests that are currently being performed are classified as PCR tests. The state lab has the ability to perform PCR testing from nasopharyngeal and throat swab specimen collection. The pharmacy profession would like to focus on the throat route of collection in asymptomatic individuals who would want or require testing. The pharmacist's role in PCR testing would be the collection of specimens, which would then be shipped to the state lab to perform the actual testing. Under recent United States Department of Health and Human Services guidance, pharmacists have the ability to order and perform COVID-19 PCR tests. Due to the lack of reliable antibody tests and the need for additional PCR collection, pharmacists' focus when starting will primarily be with PCR specimen collection. As testing technology and validation continues to improve, strategies may quickly change.

COVID-19 testing and specimen collection are not requirements for pharmacists in North Dakota but rather opportunities for those who are able to conduct testing or are interested in doing so. There are many other resources on the North Dakota Department of Health and the Centers for Disease Control and Prevention websites to guide you and your patients in this process.

If you have any interest or questions pertaining to pharmacists and their ability to test for COVID-19, please reach out to the Board.

Immunization and Medication Administration Guidance

As a result of House Bill 1498 from the 2019 legislative session and the Board's subsequent rule changes, the scope for a pharmacist or intern to administer medications, including immunizations, has been expanded. These changes removed the need for the Board to issue the two-year injection certificate based on an individual providing proof of the various requirements.

The new standards still maintain the need for an individual to stay up to date with CPR or basic cardiac life-support certification and obtain/maintain the continuing professional competencies necessary, according to the standard of care, for the administrations he or she intends to provide.

continued on page 4

National Pharmacy Compliance News

September 2020

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

continued from page 1

The Board has transitioned to a streamlined process for a pharmacist/intern to add the "administration authority" to his or her license issued by the Board. Once attestations are made and approved, this "administration authority" will be designated on the pharmacist's or intern's license, which will constitute his or her legal authority for providing administrations according to his or her practice.

There are two ways to update and maintain your "administration authority" on your license:

1. During your next license renewal, check the three statements (shown below) affirming each standard. There is no need to submit certificates unless specifically requested by the Board.
2. Outside of license renewal, may add the "administration authority" by using the "Change Address/Data/Administration Authority" function on the Board website and attest to the standards below.

- I affirm that I have and will maintain a current certification in cardiopulmonary resuscitation or basic life support.
- I affirm that I have successfully completed educational requirements set forward in section 43-15.31.5 according to the administrations that I intend to perform. (Requirement can be completed through formal doctor of pharmacy program or through external educational training.)
- I affirm that I have and will continue to maintain the appropriate continuing competency training on administrations in which I intend to perform.

If you have any questions, please feel free to contact the Board office directly.

North Dakota State Board of Pharmacy Licensure Statistics

Pharmacists	**2019**	**2020**
Active Status Pharmacists	1,185	1,215
Inactive Status Pharmacists	67	74
Out-of-State Status Pharmacists	908	887
Lifetime – 50-Year Pharmacists	138	156
Delinquent – yet to renew pharmacists		74
Pharmacy Technicians		
Active Pharmacy Technicians	819	844
Inactive Pharmacy Technicians	43	53
Technicians-in-Training	212	211
Delinquent – yet to renew technicians		60
Interns		
NDSU PharmD Student Interns	348	329
Pre-Pharmacy or Other PharmD Students	90	92
Pharmacies		
North Dakota Pharmacies	269	270
Out-of-State	649	706
Wholesale Licenses Issued	1,357	1,366
Third-Party Logistics	124	130
Veterinary Retail Facilities	14	16
Veterinary Dispensing Technicians	44	45
Delinquent Vet Techs – yet to renew		11

Annual Pharmacy Inspection Process for 2020-2021

As a result of COVID-19, the 2020-2021 inspection cycle will utilize a different process. The Board implemented an online inspection process last year. This new streamlined process gives pharmacies access to complete a self-inspection and the compliance officer access to finalize it – traditionally completed during a physical visit.

The Board will not be sending compliance officers/inspectors out into the field routinely, unless a compliance issue has been identified that would need investigating. However, this year, the compliance officer will reach out to the pharmacy to finalize the yearly inspection over the phone.

continued on page 5

continued from page 4

The inspection form is available on the Board's website. Pharmacies are expected to complete the self-inspection and submit it online to the Board office. A Board compliance officer will then contact your pharmacy to set up a time to connect by phone to answer any questions and finalize the inspection process.

As with anything new, the Board anticipates this online transition will be a learning process for the Board as well as you. Please feel free to offer feedback and reach out to the Board if you have any questions.

Help and Hope for Recovery From Addiction

North Dakota has taken major strides to address the opioid crisis. More people than ever before are seeking out help for recovery thanks to ONE Rx and other initiatives. In 2019, North Dakota Department of Human Services reported overdose deaths are down 13.2% from the record 77 deaths reported in 2016. This news is hopeful, yet the state continues to face the economic, social, and physical consequences of substance abuse.

In September 2018, FirstLink launched the Community Navigator program. Born out of the Mayors' Blue Ribbon Commission formed in Cass County, ND, and Clay County, MN, the program has helped hundreds of individuals, loved ones, and providers by offering support, information, and referrals. FirstLink has memorandums of understanding with nearly two dozen substance use treatment providers throughout the Fargo-Moorhead metro area to streamline the referral process with current information on availability and specialized treatment programs. Support is offered for individuals at every stage of use and recovery, both to those seeking help for their own substance abuse problem as well as those who are concerned about someone else. As the program grows, the network of providers in the resource database continues to grow across the state of North Dakota. This is especially important for individuals in rural areas who have limited options for treatment and recovery support services.

Visit the FirstLink website at *https://myfirstlink.org* for printable resources to share with the public or for more information about the Community Navigator program and other services provided by FirstLink. If you think you or someone you care about may have a problem with alcohol or other substances, please do not wait to get help. Dial 2-1-1 or 701/235-7335 for support 24 hours a day.

The *North Dakota State Board of Pharmacy News* is published by the North Dakota State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Mark J. Hardy, PharmD - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager