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North Carolina Board of Pharmacy News

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Item 2406 – Northeastern District Board Member Election Results

Congratulations to Wallace Nelson, who was elected to the North Carolina Board of Pharmacy from the Northeastern District. Mr Nelson received the most votes in a runoff election with Cornelius Toliver. Board members and staff thank Mr Nelson and Dr Toliver for a great campaign.

Mr Nelson hails from Hertford, NC, and he is a graduate of the University of North Carolina Eshelman School of Pharmacy. Mr Nelson previously served with distinction as a Board member from 2000-2010.

The Board also thanks Russell Boratko, Dave Catalano, Ned Clark, Chad Cobus, Tony Mitchum, and Tara Torrence for their candidacies.

Board members and staff thank and salute Gene Minton, who has now completed two five-year terms serving the Board from the Northeastern District. Mr Minton remains deeply involved with public health regulatory issues in North Carolina, having been appointed last year by Governor Roy Cooper to the Public Health Commission.

Item 2407 – COVID-19 Response

The public health crisis wrought by the coronavirus disease 2019 (COVID-19) pandemic continues to dominate our lives. Board members and staff again thank pharmacists who, as always, have demonstrated courage, perseverance, and compassion throughout this difficult time.

At press time, the Board office remains closed to the public. Board services to licensees, permittees, registrants, and the public continue without interruption, however. Board meetings continue to be held by teleconference. Interested members of the public and the profession should continue to monitor the Board's website at *www.ncbop.org*, where instructions for logging in to, and participating in, Board meetings are posted.

Board members and staff continue to provide updates, links, waivers, and other services to pharmacists and the public. The environment is fast- and ever-changing. Updates appear on the front page of the Board's website. Staff also consolidate and index these materials on the COVID-19 Updates and Resources page at *http://www.ncbop.org/COVID19.html.*

The COVID-19 Updates and Resources page includes information on:

- Emergency declarations
- Temporary pharmacy closures and relocations
- Emergency rules
- Board waivers and guidance documents
- North Carolina Department of Health and Human Services resources, licensure/registration/volunteer resources, federal guidance, and guidance from other state and local agencies

Pharmacist-managers are, of course, at the forefront of ensuring that their pharmacies remain safe for both pharmacy personnel and the public. North Carolina law requires that a pharmacy, among other things, be "kept in a clean, orderly, and sanitary condition." See 21 North Carolina Administrative Code (NCAC) 46.1601. "Sanitary" conditions plainly include conditions sufficient to minimize the risk of transmission of communicable disease within a pharmacy.

Under North Carolina law, the pharmacist-manager is the person to whom the Board issues a pharmacy permit (North Carolina General Statutes §90-85.21) and is, therefore, "the person who accepts responsibility for the operation of a pharmacy in conformance with all statutes and rules pertinent to the practice of pharmacy." See 21 NCAC 46.1317(27).

Throughout this crisis, the Board has strongly supported efforts by pharmacies and pharmacists to adjust workflows and processes within a pharmacy to reduce the

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National Pharmacy Compliance News

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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.*

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risk of person-to-person COVID-19 transmission. Such efforts have included, but not been limited to:

- not physically handling patient identifications at the point of dispensing,
- not requiring a physical signature for pickup of a prescription,
- increasing use of prescription delivery service,
- limiting the number of patients physically entering a pharmacy,
- enforcing social distancing within a pharmacy, and
- requiring personnel and the public to wear masks.

The Board emphasizes that the pharmacist-manager is the person authorized by law to ensure compliance with these standards. Improper interference with a pharmacist-manager's carrying out of these duties and responsibilities subjects a pharmacy permit to potential disciplinary action, up to and including revocation. Likewise, a person licensed by, or registered with, the Board, who improperly interferes with a pharmacist-manager's carrying out of these duties and responsibilities, is subject to potential disciplinary action, up to and including revocation.

Pharmacists and the public are encouraged to consult the resources on the COVID-19 Updates and Resources page frequently. As always, Board staff are grateful for feedback and content suggestions.

Item 2408 – Licensees, Permittees, and Registrants May Donate to the L. Stanley Haywood Recovery Fund

The Board and the North Carolina Professionals Health Program (NCPHP) established the L. Stanley Haywood Recovery Fund in April 2018. The fund provides financial support to qualifying pharmacists and pharmacy personnel in need of substance use assessment, treatment, and monitoring services. Stan Haywood, who passed away in May 2018, served for 13 years as a member of the Board and well understood the public health toll of untreated substance use disorders. He championed proactive efforts to lessen this toll, including spearheading the fund's creation.

In coordination with NCPHP, Board staff created a way for individuals licensed or registered with the Board to contribute to this fund at any time and in any amount. Simply log in to the Board's Licensure Gateway and select the blue tile labeled Donate to Stan Haywood Recovery Fund to be taken directly to NCPHP's donation site. Members of the public who wish to contribute may do so by visiting here.

Item 2409 – What Should Pharmacies Do If They Suspect a Supplier of Price Gouging?

Board staff have received messages from some pharmacists concerned about offers for sale of medication or supplies (including, especially, personal protective equipment) at prices that beggar belief. Crises bring out the absolute best in a lot of folks. Unfortunately, there are always folks who are less public-minded in times of crisis. Other adjectives come to mind, but you get the point.

North Carolina has a strong price-gouging statute that operates during emergency declarations. Attorney General Josh Stein is aggressively enforcing it. Effective enforcement, though, depends on reporting from those suspicious of price-gouging behavior. The attorney general's COVID-19 resource page includes information on how to report suspected price gouging at *ncdoj.gov/covid19.* Any pharmacy, pharmacist, or durable medical equipment supplier who suspects this behavior is strongly encouraged to contact the attorney general's office.

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