July 2020

Louisiana Board of Pharmacy News

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COVID-19 Public Health Emergency (20-07-639)

Governor John Bel Edwards declared a statewide public health emergency on March 11, 2020, in response to the threat posed by the coronavirus disease 2019 (COVID-19). Since then, the governor has issued multiple proclamations suspending certain provisions of laws and authorizing various state agencies to issue waivers of certain regulations as they deem appropriate. The Louisiana Board of Pharmacy issued its first guidance document on March 13, and has issued approximately 20 additional guidance documents since then. To facilitate the communication of these and other related documents, a COVID-19 Public Health Emergency page has been established on the Board's website. If you have not already done so, please make sure that the Board has an email address in your licensure record; the Board emails links to these documents as soon as they are published.

Louisiana implemented phase 2 of its reopening plan on June 5 and will remain in phase 2 until July 24. The current exit strategy for transitioning out of the public health emergency will include advance notice of the termination of various waivers granted by the Board, pursuant to the gubernatorial proclamations and guidance for resuming compliance with the various laws and rules governing the practice of pharmacy.

CPE Requirements for Renewal of Pharmacist License for Calendar Year 2021 (20-07-640)

During its April 2 meeting, the Board took note of the reduced number of offerings of live continuing pharmacy education (CPE) programming during 2020, subsequent to the stay-at-home orders issued during the COVID-19 pandemic. As a result, the Board determined it appropriate to modify the CPE requirements for pharmacist license renewal for calendar year 2021, such that a total of 15 hours of Accreditation Council for Pharmacy Education (ACPE)-accredited pharmacist-specific CPE will qualify for license renewal without regard to whether the CPE is acquired through live or home study methods.

Board Member Nomination Election (20-07-641)

The legislature has declared a vacancy in the member position representing District 1-A. The Board will conduct a special nomination election among the pharmacists residing in District 1, which is composed of the parishes of Jefferson and St Tammany.

Address changes in District 1 received in the Board office after July 17, 2020, will not be reflected in the mailing list for this special election. On or by July 30, 2020, the Board will mail election ballots to all pharmacists residing in the district who hold an active license. A pharmacist may participate in the election by recording the name of his or her nominee on the ballot, completing the signature slip, and mailing both items to the Board office in the manner indicated on the ballot. The nominee may be any pharmacist residing in the district who holds an active license and has been licensed in this state for at least two years. The deadline for the return of completed ballots is August 28, 2020. The ballot communication will state the time and place for the counting of the ballots; that gathering will be open to the public.

The Board's secretary will certify the names of the three nominees receiving the highest number of votes and will forward that information to the governor. The person appointed to the Board will complete the remainder of the current term, which is scheduled to expire on June 30, 2025. Should any pharmacist in the district need a list of pharmacists in the district for purposes related to this special election, the Board office will supply one complimentary list upon receipt of a written request by the pharmacist.

National Pharmacy Compliance News

July 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.*

Disciplinary Actions (20-07-642)

During its April 2, 2020 meeting, the Board took action on several items of business, including:

William Coleman Honeycutt (PST.010643): Board granted his request for modification of previous orders, then removed Article 2-e from his February 2016 Probation Board Order, which had restricted him from accepting an appointment as the pharmacist-in-charge of a pharmacy; and further, continued all other restrictions for the remainder of the probationary period, which is scheduled to conclude on February 24, 2021.

In the interim between its April 2 and May 27 meetings, the Board took action on several items of business, including:

Heather Nicole Delatin (CPT.004276): Board granted her request for reinstatement of the previously lapsed certificate, contingent upon the satisfaction of the following requirements prior to April 7, 2022: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit, accompanied by a letter of competency from the pharmacist supervising those hours; (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE as documented on her CPE Monitor® transcript, which shall not include any of the hours previously submitted as part of her reinstatement application; and (3) successful completion of a Board-approved pharmacy technician certification examination (Exam for the Certification of Pharmacy Technicians (ExCPT) or Pharmacy Technician Certification Exam (PTCE)).

Miranda Lea Coon (CPT.005192): Board granted her request for reinstatement of the previously lapsed certificate, contingent upon the satisfaction of the following requirements prior to April 14, 2022: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit, accompanied by a letter of competency from the pharmacist supervising those hours; and (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE as documented on her CPE Monitor transcript, which shall not include any of the hours previously submitted as part of her reinstatement application.

Dixie Lee Duchesne (CPT.003300): Board granted her request for reinstatement of the previously lapsed certificate, contingent upon the satisfaction of the following requirements prior to April 21, 2022: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit, accompanied by a letter of competency from the pharmacist supervising those hours; (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE as documented on her CPE Monitor transcript, which shall not include any of the hours previously submitted as part of her reinstatement application; and (3) successful completion of a Board-approved pharmacy technician certification examination (ExCPT or PTCE).

Todd Michael Durham (PST.016962): Board granted request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of one year and stayed the execution of the suspension, then placed the license on probation for one year, effective April 21, 2020, subject to certain terms enumerated within the consent agreement.

Eva Marie Smith (CPT.007106): Board granted her request for reinstatement of the previously lapsed certificate, contingent upon the satisfaction of the following requirements prior to April 14, 2022: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit, accompanied by a letter of competency from the pharmacist supervising those hours; and (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE as documented on her CPE Monitor transcript, which shall not include any of the hours previously submitted as part of her reinstatement application.

Michael Wayne Lindsey (PST.015624): For his violation of probationary terms, the Board invoked Article 3 of his May 2019 Probation Board Order; however, in lieu of permanent revocation of the license, the Board ordered an emergency summary suspension of the license for an indefinite period of time, effective May 13, 2020, thereby terminating the probationary period originally scheduled to conclude on June 20, 2034.

During its May 27, 2020 meeting, the Board took action on several items of business, including:

LaKisha Lonitte Robinson (CPT.009561): For her alleged diversion of prescription drugs from her employer pharmacy and subsequent termination therefrom, the Board revoked the certificate, effective February 5, 2020, and further, prohibited the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board.

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Darren Michael Martin (PST.016954): Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective February 18, 2020.

Michael Paul Wilson (PST.016146): For his failure to disclose the May 2019 revocation of his Texas pharmacist license on his December 2019 application for the renewal of his Louisiana pharmacist license despite specific questioning for such information, the Board revoked the license; and further, conditioned the acceptance of any future application for the reinstatement of the license upon the prior reinstatement of his Texas pharmacist license.

Steven's Pharmacy, LLC, dba Steven's Pharmacy (Port Allen, LA) (CDS.038660): Board accepted the voluntary surrender of the credential, resulting in the active suspension of the controlled dangerous substance license for an indefinite period of time, effective March 9, 2020.

Joseph Lee Wiley, II (PST.015533): Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective March 19, 2020.

Ricky Allan Chambers (PST.021312): Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective May 14, 2020.

During the same meeting, the Board issued letters of reprimand to 13 pharmacists and four pharmacies.

Calendar Notes (20-07-643)

The Board office will be closed on July 3 in observance of Independence Day and on September 7 for Labor Day.

Special Note (20-07-644)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. Electronic copies dating back to 1998 are posted on the Board's website.

Louisiana Lagniappe (20-07-645)

"Whatever course you decide upon, there is always someone to tell you that you are wrong. There are always difficulties arising which tempt you to believe that your critics are right. To map out a course of action and follow it to an end requires courage." – Ralph Waldo Emerson

The *Louisiana Board of Pharmacy News* is published by the Louisiana 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.

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