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Board Members

Declining to Fill a Prescription

By Megan Flandro, Doctor of Pharmacy Student, Idaho State University College of Pharmacy

Can a Nevada pharmacist decline to fill a patient's prescription? The simple answer is yes. However, a pharmacist can only deny filling a prescription under certain circumstances. **Nevada Administrative Code (NAC) 639.753 Declination of pharmacist to fill prescription,** outlines these circumstances. It states that a pharmacist may decline to fill a prescription only if the pharmacist reasonably believes, in his or her professional judgment:

(a) The filling of the prescription would be unlawful;
(b) The filling of the prescription would be imminently harmful to the medical health of the patient;
(c) The prescription is fraudulent; or
(d) The prescription is not for a legitimate medical purpose.

Declining to fill a patient's prescription based on one of these reasons is justified, but it is also an interruption in patient care. The pharmacist must follow up with the patient's provider and explain why he or she is declining to fill the prescription. Clear and open communication between pharmacists and providers is vital to improving patient care. If a pharmacist declines to fill the prescription, what should he or she do with the prescription?

NAC 639.753 outlines a few options:

(a) Retain the prescription and not return the prescription to the patient;
(b) Return the prescription to the patient;
(c) Make a copy of the prescription and return the prescription to the patient; and
(d) Unless the prescription is for a controlled substance that is listed in schedule II, dispense a quantity of the drug prescribed, not to exceed a 3 days' supply . . .

The last option allows the pharmacist to have enough time to speak to the provider about his or her concerns with the prescription.

If the pharmacist has talked to the prescriber and used professional judgment to determine the prescription is lawful, not harmful to the health of the patient, not fraudulent, and for a legitimate medical purpose, he or she may fill the prescription. Documentation is critical in these types of situations, so pharmacists should make sure to record the outcome of their conversation with the practitioner. If they have spoken to the provider and have still decided not to fill the patient's prescription, they must keep the prescription and communicate with the patient their reasoning for not filling the medication.

New CS Theft or Loss Reporting Form

By Luis Curras, RPh, Inspector

Nevada's requirements for reporting **any** controlled substance (CS) theft or loss are set forth in Nevada Revised Statutes (NRS) 453.568:

"All loss or theft of [CS] must be reported on forms provided by the [Investigation] Division [of the Nevada Department of Public Safety] to the [Nevada State] Board [of Pharmacy] and Division within 10 days after the date of discovery of the theft or loss."

The Board requires "all loss or theft," meaning any loss or theft, to be reported to the Board within 10 days of discovery of the loss or theft. The 10-day reporting period

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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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permits the licensee sufficient time to investigate and more thoroughly report the circumstances surrounding the loss or theft.

CS loss or theft must be reported on the new **Licensee Record of ANY Controlled Substance Loss or Theft** form available here.

Once completed, the form must be forwarded to:

1. The Board (fax: 775/850-1444);
2. The Nevada Department of Public Safety, Investigation Division (fax: 775/684-7450, Attention: Coley)

Submitting a letter or corporate communication stating that a loss or theft has occurred does not satisfy the reporting requirements.

The new form is not intended to replace Drug Enforcement Administration (DEA) Form 106, and it does not meet federal reporting requirements, which require completion and submission of DEA Form 106 to DEA's Diversion Control Field Office. More information on DEA theft/loss reporting is available by visiting *https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.*

Meal Periods and Break Periods

Pharmacists regularly ask the Board members and staff whether pharmacists and pharmacy employees are legally entitled to rest periods and meal periods during their shifts. The Board's regulations do require pharmacies to provide both rest periods and meal periods, stating that "[t]he owner of a pharmacy shall permit each employee of the pharmacy to take meal periods and rest periods as required by NRS 608.019." See NAC 639.556(1)(a).

Nevada's regulation references NRS 608.019, a statute that is enforced by the Nevada Labor Commission. This gives the Board and the Commission concurrent jurisdiction over these issues. Before writing this article, Board staff contacted the Commission for additional guidance. The Commission affirmed that an employer must provide an employee with an uninterrupted meal period of no less than 30 minutes. The employer, likewise, must provide a 10-minute break period for every four hours the employee works. See NRS 608.019 and NAC 608.145.

During a meal period, a pharmacist may elect to remain on site at the pharmacy or to leave the pharmacy, at his or her sole discretion. See NAC 639.556(2). If the only pharmacist on duty wishes to stay on site, "the pharmacist may not be interrupted or disturbed to conduct his or her work as a pharmacist, unless the pharmacist has agreed to such an interruption," per NAC 639.556(3).

During a rest period, "[a] pharmacy may require a pharmacist to remain on the premises of the pharmacy . . . but may not require the pharmacist to serve the public during the rest period." The pharmacist may, at his or her discretion, agree to have the rest period interrupted. See NAC 639.556(5).

Additionally, an employer may request an exemption from the requirements of NRS 608.019, which the Commission may grant if "the employer has shown sufficient evidence that business necessity precludes providing such benefits," per NRS 608.019(4). A similar process exists whereby a group of employers may apply jointly for a categorical exemption based on the same standard. See NRS 608.019(5). No pharmacy in Nevada is currently exempt from the requirements of the statute.

If you have questions about rest periods, meal periods, or related issues you should refer directly to the applicable statutes and regulations referenced herein. Additionally, you may contact Board staff using the contact information on the Board's website or the Nevada Labor Commission using the contact information on its website.

Disclaimer: This information is provided as a courtesy by the Board. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

The *Nevada State Board of Pharmacy News* is published by the Nevada 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.

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