OCTOBER 2021

VIRGINIA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Dispensing Biosimilars

When dispensing a Food and Drug Administration-approved biosimilar, please be aware of the dispensing and labeling requirements found in §54.1-3408.04 of the Code of Virginia. Such requirements include:

> [informing] the patient prior to dispensing the interchangeable biosimilar[;] unless otherwise directed by the prescriber, [recording] on both the record of dispensing and the prescription label, the brand name or, in the case of an interchangeable biosimilar, the product name and the name of the manufacturer or distributor of the interchangeable biosimilar; [and labeling] "the drug with the name of the interchangeable biosimilar followed by the words 'Substituted for' and the name of the biological product for which the prescription was written.

Virginia Attorney General's Opinion on the Definition of 'New Prescription'

Virginia Attorney General Mark Herring recently opined that a subsequent prescription "for the same medication without a change in dose, directions, or drug formulation is considered a 'new prescription' under §54.1-3319 of the Code of Virginia for which a pharmacist must offer counseling." Since the term "new prescription" is not defined in the Code of Virginia or in Virginia Board of Pharmacy Regulations, the attorney general's opinion relies upon the "plain and ordinary meaning" of the word "new."

Virginia Code §54.1-3319 requires pharmacists to offer to counsel any person who presents a new prescription for filling. "The offer to counsel [can] be made in any manner the pharmacist deems appropriate . . . and may include any one or a combination of the following: face-to-face communication with the pharmacist or the pharmacist's designee; a sign posted in such a manner that it can be seen by patients; a notation affixed to or written on the bag in which the prescription is to be delivered; a notation contained on the prescription container; or by telephone."

"If the offer to counsel is accepted, the pharmacist [is required to] counsel the person presenting the prescription to the extent the pharmacist deems appropriate in his professional judgment." Read the attorney general's full, official opinion here.

Transitioning Security Systems to 5G

Pharmacies upgrading their wireless security systems that communicate via cellular networks may need to submit a remodel application depending upon the actions necessary to upgrade the system to 4G or 5G. Per Board guidance, if the security system upgrade requires only a change to the circuit board, then a remodel application will not need to be submitted to the Board office. However, please be aware that if the upgrade involves any other type of action, including replacement of the alarm panel, then a remodel application must be submitted to the Board office along with the appropriate fee, as the modified or new alarm system must be reinspected. Additionally, the Board advises pharmacists to maintain documentation on file that indicates if 3G, 4G, or 5G technology is currently being used, if and when an upgrade was performed, and what action was necessary to upgrade the security system. This documentation should be readily available for review by an inspector. At all times, the security system shall comply with regulation 18 Virginia Administrative Code (VAC) 110-20-180.

DEA Clarifies Supplier DEA Registration Number on the Single-Sheet DEA Form 222

Drug Enforcement Administration (DEA) has issued a direct final rule to amend DEA regulations that either the purchaser or the supplier may enter a supplier's DEA registration number on the Single-Sheet DEA Form 222, effective October 18, 2021.

In September 2019, DEA issued a final rule to implement a new Single-Sheet DEA Form 222 (single-sheet form) to replace the three-part carbon copy form (triplicate form). On the single-sheet form, the field for the supplier's DEA registration number is located directly above a section titled "to be filled in by purchaser," which has led to some confusion regarding who must record the supplier's DEA registration number on the single-sheet form. Therefore, DEA is amending its regulations to clarify that either the purchaser or the supplier may fill in this information on the single-sheet form.

DEA also notes that the single-sheet form has been modified – and approved by the Office of Management and Budget – by the addition of a line that separates the field for the supplier's DEA registration number from the field titled "Part 2: To be filled in by the purchaser," in which the supplier's business name and address are recorded. The revised version of the form is being provided to any registrant requesting paper DEA Forms 222 pursuant to Title 21 Code of Federal Regulations §1305.11.

Furthermore, DEA notes that this rule does not impose any new requirements as the supplier's DEA registration number is already required to be entered on the single-sheet form. This direct final rule is effective on October 18, 2021.

Board Welcomes New Member; Election Results

On July 30, 2021, Governor Ralph Northam announced the appointment of **Cheri Garvin, RPh,** of Leesburg, VA, to the Board. Ms Garvin is a pharmacist and owner of The Compounding Center in

Leesburg. She is replacing Ryan Logan, who previously served approximately eight years on the Board before joining Board staff in May of this year.

Additionally, congratulations are extended to **Cheryl Nelson, PharmD, RPh,** and **Dale St Clair, PharmD, RPh,** who were elected to the positions of Board chairperson and vice chairperson, respectively. Elections were held at the Board's June 4, 2021 meeting.

Pharmacist CE Credit for Volunteering

Board Regulation 18VAC110-21-120 requires pharmacists to obtain 15 contact hours for annual renewal of their pharmacist license. Per the regulation, "at least three hours [must] be obtained in courses or programs that are live or real-time interactive." Included in the three hours, a maximum of two hours may be credited for providing volunteer pharmacy services, "without compensation, to low-income individuals receiving health services through a local health department or a free clinic. One hour of continuing education [CE] may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic." The form for documenting these hours may be accessed here. Please note that this form does not need to be submitted to the Board office unless selected for the annual CE audit.

Board Member and Staff Member Named to NABP Task Force

Board Member Kris Ratliff, DPh, RPh, and Deputy Executive Director Ellen Shinaberry, PharmD, RPh, have been appointed to the National Association of Boards of Pharmacy® (NABP®) Task Force on Workplace Safety and Well-Being. The task force will meet in November 2021 to examine the topic of pharmacy workplace safety and well-being and the effects on patient safety. The task force will include members with experience overseeing investigative activities related to these topics to develop suggested guidelines and objective tools that may be used by state boards of pharmacy.

Coronavirus Disease 2019 Vaccine Administration

The Board has received several inquiries regarding the ability to use pharmacy technician trainees to administer vaccines to patients. The Board wishes to remind the pharmacy community that in order to be considered a "qualified pharmacy technician," as indicated on page two of the United States Department of Health and Human Services (HHS) Guidance issued on October 20, 2020, an individual authorized to administer vaccines must be registered with the Board as a pharmacy technician. Registration with the Board as a pharmacy technician trainee does not meet the requirement to be considered a "qualified pharmacy technician."

HHS Guidance – October 20, 2020:

> Similarly, states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. For purposes of this guidance, to be a 'qualified pharmacy technician,' pharmacy technicians working in states with licensure and/

or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association.

Verification of CE Credits

Pursuant to 18VAC110-21-120 and 18VAC110-21-180, the Board is authorized to conduct a random CE audit each year to ensure that licensees and registrants are compliant with the Board's CE requirements. Pharmacists and pharmacy technicians are encouraged to periodically check their continuing pharmacy education (CPE) transcripts on CPE Monitor® to verify that all CPE credits have been accurately posted to their e-Profiles. All Accreditation Council for Pharmacy Education (ACPE)-approved CPE credits are required to be reported to CPE Monitor within 60 days of completion of a course. If it is discovered that the CPE Monitor transcript does not contain all the CPE credits as expected, contact the CPE provider to inquire.

An e-Profile ID number is required to receive credit for an ACPE-approved CPE activity and may be obtained from CPE Monitor. The e-Profile ID number is available free of charge from NABP and facilitates the exchange of information between the Board and NABP necessary for licensure processes. To establish an e-Profile ID, please visit the NABP e-Profile dashboard, select the "Individual or Business Customers" tile, and follow the instructions for setting up a new account.

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