FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE FOR EMS, CQI, COUPONS, AND LEGISLATIVE PROPOSALS

May 12, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:05AM.

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Empsy Munden
Dinny Li
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented.

PUBLIC COMMENT: Ms. Warriner announced that board counsel recently advised that the Board should accept all public comment at the beginning of the meeting and not throughout the meeting as individual agenda topics are discussed. Ms. Warriner then called for public comment.

Battalion Chief Jennie Collins with Prince William County Department of Fire & Rescue provided a handout of slides indicating there are 258 emergency boxes currently in- use in Northern Virginia. Currently the county exchanges Schedule VI drugs on a 1:1 basis as informally condoned by the Board for the past several years. She stated if the Board prohibits 1:1 exchange of Schedule VI drugs and requires box for box exchange, the region will need 644 boxes to meet demand. Concerns expressed by Chief Collins for a box to box exchange include: increase in pharmacy and EMS workload based on need to inventory contents of every box upon exchange; increase need for hospital storage of boxes awaiting exchange; increase demand of drug inventory amidst drug shortages; increase in time associated with exchanging boxes which will delay EMS ability to respond to 911 calls. Chief Collins requested Board allow a 1:1 exchange of Schedule VI drugs and that Schedules II-V drugs are exchanged box for box.

Sam Dahl, Executive Director of the Northern Virginia Emergency Medical Services Council emphasized the importance of EMS personnel spending as little time as necessary at the hospital when transporting patients, because the demand on EMS increases substantially when ambulances are out of service.

Gill Abernathy, Pharmacy Manager, Regulatory & Quality at Inova Health System expressed concern for pharmacy staffing and time constraints if the Board required box for box exchange of all drug schedules. Additionally, she requested the Board consider allowing a second EMS provider to witness the wasting of drugs and pleaded for ability to perform 1:1 exchange of Scheduled VI drugs. She is also concerned that stand-alone emergency departments must obtain a limited-use pharmacy permit to stock and exchange emergency kits, albeit she stated that she did not have a specific recommendation at this time.

Annette Reichenbaugh, Pharmacy Director at Reston Hospital Center expressed the following concerns for requiring box to box exchange of all drug schedules: currently facing drug shortages; insufficient space to currently store boxes; and, additional responsibility for pharmacy staff to monitor expiration dates of boxes.

Greg Rauch, President of the Northern Virginia Emergency Medical Services Council supported comments provided by others. Sam Dahl further stated that these concerns are not limited to northern Virginia.

Hunter Jamerson, Esq., representing EPIC Pharmacies expressed support for the petition recently submitted to the Board to prohibit incenting patients to transfer prescriptions as it creates polypharmacy. Additionally, he stated the practice creates difficulty for pharmacists to maintain a bona fide pharmacist-patient relationship and an inability for pharmacists to review a complete patient record. He suggested the Board consider reviewing current prohibitions in New York and New Jersey. He further stated that his comments were not intended to address the use of pharmaceutical manufacturer coupons.

EMS REGULATION:

After discussion, the motions below were offered.

MOTION:

The Committee voted unanimously to recommend to the full board that it amend the proposed draft of Regulation 18VAC110-20-500 as follows:

- **Subsection A,10 - add "if the kit contents include Schedule II, III, IV, or V drugs" to the end of the second sentence;**
- **Subsection B – replace first sentence with "A licensed EMS agency may obtain a controlled substances registration pursuant to §54.1-3423 D for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices";**
- **Subsection B, 3 – replace "intravenous and irrigation fluids" with "Schedule VI drugs and devices". (motion by Thornbury, second by Adams)**

MOTION:

The Committee voted unanimously to recommend to the full board that it further amend the proposed draft of Regulation 18VAC110-20-500 subsection A, 6 by allowing a pharmacy technician or a second EMS provider to participate in the destruction of partially used Schedule II-V drugs and to adopt the amended EMS regulations as a fast-track regulatory change. (motion by Thornbury, second by Munden)

MOTION: **Mr. Adams moved to recommend to the full board that it consider requiring the printed name and signature when documentation is required within Regulation 18VAC110-20-500. (Motion died for lack of a second.)**

CQI REGULATION: The Committee discussed the proposed replacement regulations for continuous quality improvement programs. Ms. Juran reported that she had spoken with R. Brent Rawlings who submitted public comment on behalf of the Virginia Hospital and Healthcare Association during the last public comment period. Mr. Rawlings stated his clients had not expressed specific concerns regarding the proposed replacement regulations, however, he was slightly concerned that once the dispensing error is reported to a patient safety organization that it cannot be used to defend a possible lawsuit. He acknowledged to Ms. Juran that not requiring the submission of a dispensing error to a patient safety organization may not be consistent with the intent of the statute. Ms. Thornbury later questioned the intent of the proposed definition for "dispensing error" and whether an error that was corrected prior to the patient receiving it but after the pharmacist's final verification should be treated as a dispensing error. The consensus of the Committee was that such a "near miss" should be treated as a dispensing error since the error was not found during the pharmacist's final verification process.

MOTION: **The Committee voted unanimously to recommend to the full board that it amend the proposed definition of "dispensing error" in Regulation 18VAC110-20-10 by adding "regardless of whether the patient received the drug" following the phrase "after the final verification by the pharmacist" and to adopt the proposed CQI regulations as amended. (motion by Thornbury, second by Adams)**

PHARMACY COUPONS: The Committee discussed the information contained in the agenda packet with a focus on whether a prohibition against incenting patients to transfer prescriptions could be construed as a restraint of trade. Ms. Juran reported that New York is currently defending a law suit for its current prohibitions against incenting patients. She also stated that the executive director of Oregon indicated its language prohibits pharmacies from incenting the transferring of prescriptions, but allows the incenting of patients to retain their prescriptions at a single pharmacy such as through loyalty programs. Board counsel stated that he did not believe Oregon's language could be construed as a restraint of trade. The Committee reviewed a proposed amendment to unprofessional conduct found in Regulation 18VAC110-20-25 that staff prepared using language similar to Oregon.

MOTION: **The Committee voted unanimously to recommend to the full board that it adopt a Notice of Intended Regulatory Action regarding the use of coupons to incent patients to transfer prescriptions. (motion by Adams, second by Munden)**

LEGISLATIVE PROPOSALS:

- WHOLESALE

DISTRIBUTION NOTIFICATION REQUIREMENT

Ms. Yeatts and Ms. Juran provided an overview of the legislative proposal that was adopted by the Board in 2013 but not included in the administrative packet to the General Assembly. The proposal resulted from the Enforcement Working Group during the 2013 National Governor's Association Prescription Drug Abuse policy grant initiative in which Virginia participated.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal requiring wholesale distributors to notify the Virginia State Police and the Board of Pharmacy when ceasing or restricting distribution of controlled substances based on suspicious activity. (motion by Munden, second by Adams)

- AUTHORITY TO LICENSE PHYSICIAN DISPENSING FACILITIES

Ms. Yeatts explained that the Board has the authority to license individual physicians dispensing controlled substances, but not the facilities from where the drugs are dispensed. Because there has been a significant increase in the number of physician selling licenses issued by the Board in the past few years, it has become increasingly more difficult for staff to manage the oversight of these unlicensed facilities. Ms. Juran reminded the Committee of its desire to implement a routine inspection process for physician selling that is similar to the routine pharmacy inspection program. Currently, the pre-hearing consent order resulting from a routine inspection would have to be issued against the responsible physician as the Board does not have jurisdiction over the facility unlike its jurisdiction over a pharmacy. Ms. Yeatts stated the Board adopted this legislative proposal in 2013 but that it was not included in the administrative packet sent to the General Assembly.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal authorizing the Board to license the facility associated with the practitioners of the healing arts to sell controlled substances. (motion by Adams, second by Li)

- PHARMACIST POSSESSION AND ADMINISTRATION OF EPINEPHRINE AND OXYGEN

Ms. Juran explained that under a Board of Nursing-approved immunization protocol, pharmacists are required to recognize and administer epinephrine when warranted. This legislative proposal would provide the necessary authorization in law for pharmacists to possess and administer epinephrine and oxygen.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal authorizing pharmacists to possess and administer epinephrine and oxygen. (motion by Munden, second by Adams)

- PLACMENT OF ALFAXOLONE INTO SCHEDULE IV

Ms. Yeatts reported that effective March 31, 2014, DEA placed a new animal drug, alfaxalone, into Schedule IV. The proposed legislative proposal would place alfaxalone into Schedule IV of the Drug Control Act to conform to federal scheduling.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt the legislative proposal to place alfaxalone into Schedule IV of the Drug Control Act. (motion by Munden, second by Adams)

- LICENSING AND REGULATING OF OUTSOURCING FACILITIES

Ms. Juran provided a brief overview of the compounding requirements in the recently passed federal legislation, the Drug Quality and Security Act. She then explained the concepts of the proposed legislative proposal acknowledging that she and Ms. Yeatts would need to continue editing the language. The proposal would create a new licensing category for outsourcing facilities and nonresident outsourcing facilities, require compliance with federal law, and require those outsourcing facilities that compound pursuant to patient-specific prescriptions to also obtain a pharmacy permit. There was discussion of whether §54.1-3410.2 should be amended to eliminate compounding for office use since the FDA has indicated the federal law prohibits pharmacies from compounding for office use. According to the FDA, compounding for office use must be performed by an outsourcing facility. The Committee did not reach consensus on this topic.

MOTION:

Based on the concepts of the proposed legislative proposal, the Committee voted unanimously to recommend to the full board that it adopt the legislative proposal to create a new licensing category for outsourcing facilities and nonresident outsourcing facilities, to regulate such facilities by requiring compliance with federal law and require those outsourcing facilities to also obtain a pharmacy permit prior to compounding pursuant to patient-specific prescriptions. (motion by Thornbury, second by Adams)

ADJOURN:

With all business concluded, the meeting adjourned at 1:05PM.

Cynthia Warriner, Committee Chairman

6/4/14
Date

Caroline D. Juran, Executive Director

6/4/14
Date