2640

October 21, 2007

Melanie Zimmerman
Executive Secretary
State Board of Pharmacy
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Zimmerman,

On behalf of the P-3 class of Wilkes University Nesbitt School of Pharmacy, I am pleased to submit comments related to the proposed changes to 49 PA. Code, Chapter 27 as outlined in 37 Pa. B. 5260. For convenience, the class comments are listed in blue directly below the affected section in the proposed regulations. Please let us know if you have any questions or comments related to the submission. Thank you for the opportunity to contribute to these important changes.

Respectfully Submitted,

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§ 27.12 (relating to practice of pharmacy and delegation of duties)

The Board proposes to amend § 27.12 to delete the prohibition on pharmacy interns accepting and transcribing oral orders and telephone prescriptions. The purpose of a pharmacy internship is to prepare a pharmacy student to function as a pharmacist. One of the pharmacist's duties is to receive telephone prescriptions and other oral orders. Pharmacy interns are well prepared to assume this responsibility and, with direct supervision by a pharmacist required for all pharmacy interns, there is no increased risk to the public.

The class applauds this proposed change which recognizes the importance of the pharmacy interns' ability to accept and transcribe oral orders and telephone prescriptions. However, in addition to deleting the prohibition, we also think that it is important to affirmatively express the ability to accept and transcribe oral orders and prescriptions as outlined below:

§ 27.12. Practice of pharmacy and delegation of duties.

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(c) *Pharmacy interns.*

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(2) **[A pharmacy intern may neither accept nor transcribe an oral order or telephone prescription.**

(3)] A pharmacy intern may neither enter nor be in a pharmacy if a pharmacist is not on duty.

[(4)] (3) A pharmacy intern working under the direct, immediate, personal supervision of a pharmacist may perform procedures which require professional skill and training. Examples of these procedures include: accepting and transcribing oral orders and prescriptions, verifying ingredients, weighing ingredients, compounding ingredients and other similar processing of ingredients.

§ 27.17. Security for Schedule II controlled substances.

(a) **[From the time that a Schedule II controlled substance is received for storage in the prescription area until the time that controlled substance has been prepared and compounded into an individual prescription, no person except a licensed pharmacist or a licensed pharmacist intern or, in an institution, a licensed physician or registered nurse, may have access to the controlled substances or work in an area where open containers of the controlled substances are shelved or stored. The Board**

will consider the following measures as adequately controlling access to the controlled substances:

(1) A safe, vault or other storage facility in compliance with storage requirements for BNDD Schedule II drugs.

(2) A chest or cabinet of sound construction secured to a wall or floor and able to be securely locked.

(3) A wire cage with a door able to be securely locked.

(b) The Board may approve alternative security measures proposed by an applicant upon a showing that a degree of security would be provided equal to or greater than that set forth in subsection (a).] Schedule II controlled substances shall be stored in securely locked, substantially constructed cabinets. However, Schedule II controlled substances may be dispersed throughout the stock of noncontrolled substances in a manner that obstructs the theft or diversion of the controlled substances.

[(c)] (b) The occasional entry of other persons into an area where the controlled substances are accessible **[in order]** to clean, deliver or perform other necessary functions shall be allowed only when a licensed person is present and supervising.

[(d)] (c) The pharmacist manager shall be responsible for assuring that licensed persons, **[employes] employees** and others who enter the prescription area know and abide by the standards of security and that the other measures are taken as may be necessary to insure their enforcement.

The above proposed changes clarify the Board's position that CII controlled substances may be dispersed throughout the stock in a manner that obstructs theft or diversion. To further support this clarification, the class would like to suggest a slight modification in wording above

FROM: **Schedule II controlled substances shall be stored in securely locked, substantially constructed cabinets. However, Schedule II controlled substances may be dispersed throughout the stock of noncontrolled substances in a manner that obstructs the theft or diversion of the controlled substances.**

TO: **Schedule II controlled substances may be stored in securely locked, substantially constructed cabinets; alternatively, Schedule II controlled substances may be dispersed throughout the stock of noncontrolled substances in a manner that obstructs the theft or diversion of the controlled substances.**

In addition, the proposed changes as written state:

[(c)] (b) The occasional entry of other persons into an area where the controlled substances are accessible **[in order]** to clean, deliver or perform other necessary functions shall be allowed only when a licensed person is present and supervising.

The reference to the "occasional entry of other persons" needs to be restated since there is no prefatory reference to any other persons in the proposed changes as written. In addition, if there is an intent to affirmatively express the ability of a pharmacy technician to be able to assist in the processing of CII prescriptions, then it might be useful to affirmatively express those duties in the clause "to [count medications,]clean, deliver or perform other necessary functions....

In addition, the Board proposes to amend § 27.18(j) to prohibit the filling of Schedule II prescriptions after 6 months have passed from the date of the prescription. Currently, there is no time limit as to how long a prescription for a Schedule II controlled substance is valid. The Board believes there should be a limit and proposes 6 months as a reasonable time during which a Schedule II controlled substance prescription may be filled. The Board believes that this requirement will bring the time restriction in line with the restriction for filling of Schedule III, IV and V substances

One concern here is to initially verify that this suggested change is not under the purview of the Dept of Health which is vested with the authority for enacting regulations associated with the Controlled Substance Drug Device and Cosmetic Act. Assuming that the Board of Pharmacy has the authority to propose this change, the class feels that it might be more appropriate to limit the time frame to 90 days. Restricting the time period to 90 days is more in keeping with the DEA stated belief that Congress clearly mandated greater prescription controls for CIIs than CIII or CIV prescriptions. The DEA has introduced a proposed regulatory change to limit an individual practitioner to issue multiple prescriptions authorizing the patient to receive a total of up to a 90 day supply of a Schedule II controlled substance under certain circumstances. Since the DEA has set 90 days as a reasonable outer limit beyond which physician involvement is required to provide additional CIIs, it seems prudent to follow that direction and limit the ability of a patient to present a prescription no later than 90 days after it was written.

27.18 s

(s) The following provisions are applicable to paraphernalia and accessories: (1) Sale of accessories, such as empty capsules, quinine, sugar of milk or a similar product found in illegal traffic when sold in unusually large quantities shall be immediately reported to the Board. A pharmacist who sells, gives away or otherwise disposes of accessories, chemicals or proprietary products when the pharmacist knows or has reason to know of their intended use for illegal purposes shall be guilty of unprofessional conduct and in violation of this chapter.

Though not specifically addressed by the Board in its proposed changes, this section might be eligible for some revision. While this section properly notes the unprofessional conduct associated with selling, giving away,... accessories, capsules, etc, it is vague in the initial section that mandates to report to the Board sales in unusually large quantities, etc. The class noted that it might be better to simply note the prohibitory nature of such conduct. Otherwise, without further clarification, one is left to wonder who reports whom, etc.

§ 27.19. Prospective drug review and patient counseling.

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(b) *General.* This section requires a pharmacist to perform a PDR before filling, delivering or sending a new **[retail or outpatient]** prescription **or drug order, except when a physician dispenses a drug to a patient being treated in the emergency room**. The PDR requires that the pharmacist review a profile of the patient maintained in the pharmacy in accordance with subsection (g) prior to dispensing the medication to the patient or caregiver **[and the pharmacist or designee of the pharmacist make an offer to counsel the patient or caregiver]**.

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(d) *Scope.*

(1) The PDR is required for **[retail or outpatient]** prescriptions **and drug orders**. The PDR does not extend to the following:

(i) **[An order for a drug for an inpatient of an institution, as the term "institution" is defined in this chapter.**

(ii)] A drug dispensed in an emergency room.

[(iii)] (ii) A drug dispensed by a medical practitioner.

[(iv)] (iii) A drug dispensed by a pharmacist to a medical practitioner which the practitioner will administer to a patient.

(2) The following are examples of situations in which a PDR is required:

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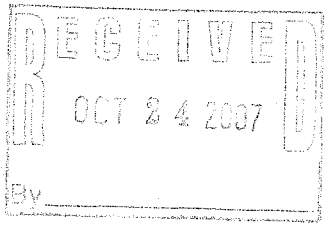
(v) A pharmacist fills a prescription for a patient in a nursing home.



(vi) A pharmacist in a hospital dispenses a drug which will be administered to a patient in the hospital.

(3) The following are examples of situations in which a PDR is not required:

(i) **[A pharmacist fills a prescription for a patient in a nursing home.**

(ii) A pharmacist in a hospital dispenses a drug which will be administered to a patient in the hospital.

(iii)] A physician dispenses a drug to a patient being treated in the emergency room.

[(iv)] (ii) A pharmacist dispenses a radiopharma- ceutical to a physician who will administer it to a patient.

This section begins by stating "This section requires a pharmacist to perform a PDR before filling, delivering or sending a new **[retail or outpatient]** prescription **or drug order, except when a physician dispenses a drug to a patient being treated in the emergency room**." then proceeds to list directly below other examples where PDR is not required. In addition, this section flips unnecessarily between where PDR is not required, then where it is required, then again where it is not required. The class would suggest to start out with the general section then start with the affirmative (i.e. where PDR is required and then to state where it is not required. Instances where PDR is and is not required can be limited to one section respectively. In addition, in the proposed regulations, it appears that the second set of situations where PDR does not apply are already addressed by the first set of situations where PDR does not apply. At any rate, they can certainly be combined.

27.16 (7) addresses the prohibition on a tv set within the viewing area of the pharmacy. Even though not addressed in the proposed regs, the class would suggest the following changes in the context of the "clean up" of the existing regulations. The existing regulations in New Jersey provide a more expanded view of the use of the television in today's pharmacy and can be used as a basis for proposed changes:
No commercial television, other than for security measures, pharmacy training or patient counseling, may be operated in a prescription area or in any location outside of a prescription area such that its operation may be viewed from the prescription area.

27.18 (a) ...in refilling....pharmacist may reuse the original container of that prescription if the container is clean and reuseable. The refill requires a new label containing the information specified in subsection (d). Pharmacies and

pharmacists shall comply with the Poison Prevention Packaging Act of 1970 (15 U.S.C.A. §§ 1471—1476) which includes the use of child resistant containers.

This is another section that is not specifically addressed in the proposed changes, but may want to be revisited by the Board since it seems to be in direct contravention of the CPSC guidelines: The CPSC states in the Q & A section of its *Poison Packaging: A Guide for Healthcare Professionals*:

Q. In the case of refills, can prescription bottles and vials be reused?

A. As a general rule, no. This prohibition is based on the wear associated with a plastic vial, which could compromise the package's effectiveness. Since such wear or undetected damage with a glass container is negligible, the CPSC staff has indicated that it would have no objection to the reuse of a glass container, provided a new closure is used. This same consideration would be given to any other package type that is not prone to wear.

27.18 (v) A drug order in an institution is not required to conform to the labeling requirements of subsection (d) as long as the drug is dispensed in unit dose. A drug not in unit dose shall be labeled to indicate the patient name, drug name, drug strength, dosing instructions and lot number. The label of a parenteral, enteral or total parenteral nutrition product shall contain the name of the patient; the ingredients, including the name, strength, quantity of each, the diluent and expiration date; and the initials of the pharmacist.

This is another section that is not specifically addressed but could use some clarification. The above section delineates labeling requirements for non-unit dose products, as well as for parenteral, enteral and TPN products. However, other than stating that unit dose products are not required to conform to the labeling requirements of subsection (d), there is no discussion of what labeling requirements apply to unit-dose products. The class proposed that the Board adopt the FDA guidelines for unit dose labeling.