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RESPONSE TO PUBLIC COMMENTS RECEIVED TO PROPOSED RULES

(Including explanation of any amendments made to the proposed rule as a result of comments)

TITLE 15, SERIES 8 (WV CSR 15-8-1, et seq.) RULES OF THE BOARD OF PHARMACY FOR THE CONTROLLED SUBSTANCES MONITORING PROGRAM

The Board of Pharmacy filed proposed rules with the Secretary of State on June 15, 2017, making amendments to Title 15, Series 8. As a matter of information, the Board circulated the rule among wholesale drug distributor stakeholders during the drafting process and incorporated certain suggestions at that time, prior to filing for public comment. The public comment period ended on July 17, 2017, at 4:00 p.m. The Board received written public comments regarding the rules from the National Association of Chain Drug Stores (NACDS). The Board held a public meeting on July 26, 2017, to review the comments.

NACDS Offered one comment.

1. NACDS requests that pharmacies be granted an 18-month grace period to comply with the reporting requirements for the newly designated drug of concern product gabapentin. This grace period is to allow pharmacies to make changes to their current reporting software. After review, the Board determined that it was essential that the information be obtained right away, and that other state programs were already receiving the same data currently.

The Board then authorized this response and the proposed rules to be filed with the Secretary of State and the Legislative Rule-Making and Review Committee.

Prepared by:

Michael L. Goff
Acting Executive Director

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Mr. Mike Goff
Executive Director
West Virginia Board of Pharmacy
Series 14 Rule Comments
2310 Kanawha Boulevard East
Charleston, VW 25311

Re: Proposed Rule Addressing Controlled Substance Monitoring Program and Proposed Rule Addressing Central Fill/Central Processing

Dear Mr. Goff:

On behalf of the 303 chain pharmacies operating in the state of West Virginia, the National Association of Chain Drug Stores (NACDS) is submitting comments on the amendments to the Controlled Substance Monitoring Program Rule and Centralized Prescription Processing Rule. We appreciate the Board considering our views on these important matters.

Controlled Substance Monitoring Program Rule

NACDS appreciates the steps taken by the Board to enhance patient safety by extending reporting requirements to drugs of concern (Section 15.8.3.1) and requiring additional information about an individual who is picking up a prescription for a controlled substance for a patient (Section 15.8.3.1.h). However, we urge the Board to consider granting an 18-month grace period from the effective date of the proposed changes for compliance with the requirements in Section 18.8.3.1.h for the medication Gabapentin. As you know, Gabapentin is not a controlled substance but is a drug of concern. Pharmacies need time to make changes to their systems to accommodate this request as some systems do not capture the necessary information for non-controlled substances at the point of sale. We would appreciate the Board allowing time for pharmacies to comply with this requirement without penalty.

Centralized Prescription Processing Rule

NACDS has some recommendations we ask the Board to consider regarding the central fill provisions. The proposed language suggests that a centrally filled prescription must be returned to the original pharmacy and cannot be shipped directly to the patient from the central fill location. We believe that this requirement is unnecessary and antiquated in nature with regards to the extra step involved in the delivery of care. We further believe that the patient and pharmacist are in the best position to determine the most appropriate options to address the patient's care. Therefore, we urge the Board to consider the following changes to the verbiage:

3.4: Any filled prescription which was not picked up by or actually delivered to the patient must be put into the ~~originating~~ delivering pharmacy's inventory.

3.6. ~~The originating pharmacy, as~~ The delivering pharmacy, is responsible for making the offer to counsel the patient or patient's agent picking up the prescription on behalf of the patient.

3.8: The prescription label of a centrally filled prescription shall display the name, ~~and~~ business address and telephone number of ~~the originating pharmacy and may include the name of the central fill pharmacy~~ either the requesting pharmacy or delivering pharmacy or both, as well as all other information required by Rule Section 15-1-22.

3.9: Maintaining a mechanism for tracking the drug order during each step of the processing and filling procedures performed at the pharmacy. The central fill pharmacy must keep a record of the date the filled prescription was delivered to the originating pharmacy or patient and the method of delivery (i.e. private, common or contract carrier). The ~~originating~~ delivering pharmacy must keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (i.e. private, common or contract carrier). ~~and the name of the originating pharmacy employee accepting delivery.~~

NACDS supports the changes to the central processing requirements and appreciate the Board taking our suggestions into consideration on this important issue. We urge the Board to consider the following language for clarification:

4.1: Remote-order-entry or remote-order-review of prescription orders for prescriptions received at a pharmacy registered by this state is permitted to be performed by another pharmacy registered by the state where that pharmacy is located, provided that:

4.1a: for purposes of data entry, the data entry must be performed by a licensed pharmacist, licensed pharmacy intern, or registered pharmacy technician or pharmacy technician trainee who is located at the other pharmacy and licensed or registered by the state where that pharmacy is located which shares a common automated data processing system, and such system creates an audit trail of which pharmacist, pharmacy intern, or pharmacy technician or pharmacy technician trainee entered the data;

4.1b: for purpose of drug regimen review, the review must be performed by a licensed pharmacist or licensed pharmacy intern who is located at the other pharmacy and licensed by ~~registered~~ the state where that pharmacy is located which shares a common automated data processing system, and such

system creates an audit trail of which pharmacist or pharmacy intern provided the drug regimen review.

NACDS thanks the Board for considering our comments on these important issues. Please do not hesitate to contact me if I can provide more information or further assistance.

Sincerely,

Jill McCormack, Director
State Government Affairs
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