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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 2 (WV CSR 15-2-1, et seq.)
RULES OF THE BOARD OF PHARMACY FOR
THE UNIFORM CONTROLLED SUBSTANCES ACT

The Board of Pharmacy filed proposed rules with the Secretary of State on May 12, 2017, making amendments to Title 15, Series 2. 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 June 12, 2017, at 4:00 p.m. The Board received written public comments regarding the rules from two entities: one from the Healthcare Distribution Alliance (HDA), and one from the National Association of Chain Drug Stores (NACDS). The Board held a public meeting on June 26, 2017, to review the comments.

HDA's comments offered three separate comments.

1. First, HDA requests that the language be clarified to indicate that submitting information by electronic and internet-based means would satisfy the requirement of submitting information "in writing" to the Board. After review, the Board determined that the request was reasonable, and language was added to include the reporting by electronic or web-based means.

2. Second, HDA requests that the Board include language that would grant wholesale drug distributors immunity against claims by those persons or entities identified as terminated customers, and from those that may be rejected from a contracting relationship for wholesale drug distribution based upon suspicious orders. HDA indicates that its membership has "legitimate concerns of retaliation when they terminate or flag a customer." After review, the Board determined that it is something more properly left for the legislature.

3. Third, HDA requests that the Board remove the requirement that wholesalers report the absence of any suspicious orders in a calendar month (zero reporting). In support, HDA states in part that ". . . the 'zero reporting' requirement is redundant since the Board could derive this same information when the distributor

would not submit a report." After review, the Board determined that this is something that creates accountability as to who is or is not submitting the reports, and provides the Board a tool for enforcement.

NACDS' comment echoes HDA's third comment, stating in relevant part that requiring zero reporting of suspicious orders in a calendar month is unnecessary and onerous for its members, and is burdensome for both the wholesale distributor and the Board. NACDS indicates that this creates an administrative burden for both the wholesale distributor and the Board, ". . . generating paperwork for the Board to review that offers little added value." As such, NACDS requests the Board to remove the zero reporting requirement from the rule. As this comment is relatively the same as HDA's third comment, after review, the Board determined that this is something that creates accountability as to who is or is not submitting the reports, and provides the Board a tool for enforcement.

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

HDA
Healthcare Distribution Alliance

PATIENTS MOVE US.

June 9, 2017

West Virginia State Board of Pharmacy
Attn: David Potters, Executive Director & General Counsel
2310 Kanawha Boulevard East
Charleston, WV 25311

RE: Healthcare Distribution Alliance (HDA) Comments on Amendment to Division 065 Wholesaler Rules to Reflect Changes in DEA Law for Reporting Suspicious Orders.

Dear Mr. Potters:

The Healthcare Distribution Alliance (HDA) and our primary wholesale distributor members are pleased to provide the following comments on the draft rule addressing suspicious order reporting in West Virginia. We appreciate the West Virginia Board of Pharmacy's continued desire to work collaboratively with the primary wholesale distribution industry to address this important issue, and hope our comments are used to help the Board achieve its goals in the most effective and efficient manner possible. HDA and our member companies are committed to working closely with all state and federal enforcement entities to address the prescription drug abuse epidemic impacting our nation, and to serving as a resource to the West Virginia Board of Pharmacy.

Primary pharmaceutical distributors are the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDA member companies work around the clock to ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and other healthcare settings nationwide. The most important goal for all HDA members is to provide medication delivery in the most safe, secure and efficient manner possible.

The prescription drug abuse and diversion epidemic is a serious healthcare challenge that threatens both patient safety and the security of the healthcare supply chain. The manner in which primary wholesale distributors analyze customer orders for suspicious activity has evolved significantly in recent years. Today, the pharmaceutical wholesale industry supports and employs a multilayered approach to help combat the epidemic including employing sophisticated analytical systems to monitor customer orders for any "suspicious order" activity. This information must be provided regularly to federal enforcement entities.

HDA offers the following comments to the Board of Pharmacy, which we believe will assist the Board in achieving their objective of implementing an effective suspicious order reporting system. We emphasize that the following comments reflect the views of the entire HDA membership.

1. HDA respectfully requests that the proposed language be clarified to indicate that submitting information by electronic and internet-based means would satisfy the requirement of submitting information "in writing" to the Board of Pharmacy.

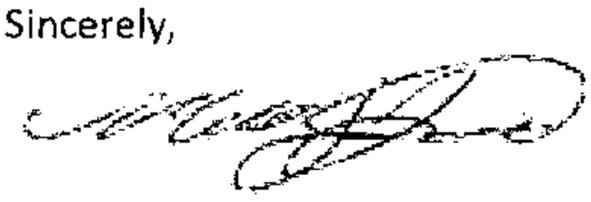
2. HDA respectfully requests that the Board include a provision granting wholesale distributors immunity from legal retaliation from those persons or entities identified as terminated customers, and from those that may be rejected from a contracting relationship based on suspicious orders. Wholesalers have legitimate concerns of retaliation when they terminate or flag a customer. Particularly considering the current opioid epidemic, wholesalers should not be subject to retaliation for completing responsible due diligence based on a state directive. Immunity will protect wholesalers from these unfair and punitive business practices. HDA has previously provided the Board with draft language to achieve this goal, and understands conversations have/will occur to determine its acceptance.

3. HDA members request the Board remove the requirement that wholesalers report the absence of any suspicious orders in a calendar month. HDA maintains that the federal reporting requirements wholesalers comply with for the Drug Enforcement Administration (DEA) are sufficient and as such, do not require reporting when there is an absence of suspicious orders. Furthermore, the "zero reporting" requirement is redundant since the Board could derive this same information when the distributor would not submit a report.

Conclusion:

HDA offers these comments to summarize the primary wholesale distribution industry's position and provide recommendations to the West Virginia Board of Pharmacy's draft regulations. Again, HDA greatly appreciates the ongoing, open dialogue with the West Virginia Board of Pharmacy and appreciates the Board's acceptance and understanding of previously negotiated provisions. We feel the above requests will improve the existing proposed language without diminishing the information provided to the Board. HDA continues to be committed to working with the West Virginia Board of Pharmacy to reach an agreeable solution that achieves the Board's goals.

Sincerely,



Matthew J. DiLoreto
Vice President - State Government Affairs

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 12, 2017

Mr. David Potters, Esq., Executive Director
West Virginia Board of Pharmacy
Series 2 Comments
2310 Kanawha Boulevard East
Charleston, VW 25311

Re: Proposed Changes to the Uniform Controlled Substances Act

Dear Mr. Potters:

On behalf of the 303 chain pharmacies operating in the state of West Virginia, the National Association of Chain Drug Stores (NACDS) is writing to express our concerns with the proposed changes to the Uniform Controlled Substance Act (Proposed Rule) by the West Virginia Board of Pharmacy (Board). We appreciate the Board considering our views on this important matter.

NACDS supports the reporting of suspicious orders in the interest of public safety and appreciates the Board updating its rules to conform with Drug Enforcement Agency (DEA) Rules. However, Section 4.4 of the Proposed Rule imposes what we deem an unnecessary and onerous requirement on our members. It requires that wholesale distributors, to inform the Board in writing if **no** suspicious orders are detected in a calendar month (i.e. zero reporting). We believe this requirement to be burdensome for both the wholesale distributor and the Board. Per the proposed rule, copies of suspicious reports submitted to the DEA will be provided to the Board. The addition of zero reporting creates an administrative burden for the distributor as well as an administrative burden for the Board; generating paperwork for the Board to review that offers little added value. We urge you remove this requirement from the Proposed Rule. If the Board believes that this information must be reported to the state, we urge you to consider allowing distributors to file such information electronically.
NACDS thanks the Board for considering our comments on this important.

Please do not hesitate to contact me if I can provide more information or further assistance.

Sincerely,

Jill K. McCormack

Jill McCormack, Director
State Government Affairs

Potters, David E

From: Jill McCormack <JMcCormack@NACDS.org>
Sent: Monday, June 12, 2017 10:55 AM
To: Potters, David E
Subject: NACDS Comments UCSA
Attachments: nacds comments UCSA june 2017.docx

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 12, 2017

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West Virginia Board of Pharmacy
Series 2 Comments
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NACDS thanks the Board for considering our comments on this important issue. Please do not hesitate to contact me if I can provide more information or further assistance.

Sincerely,

Jill K. McCormack

Jill McCormack, Director

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