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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.) LICENSURE AND PRACTICE OF PHARMACY

The Board of Pharmacy filed proposed rules filed with the Secretary of State on July 1, 2016, making amendments to Title 15, Series 8. As a matter of information, the Board circulated the rule among stakeholders during the drafting process and incorporated certain suggestions at that time as well, prior to filing for public comment. The public comment period ended on August 4, 2016. The Board received two written public comments regarding the rules. One Comment was from the National Association of Chain Drug Stores (NACDS); the other was from Fruth Pharmacy. The two comments are relatively the same. The Board held a public meeting on August 17, 2016, to review the comments.

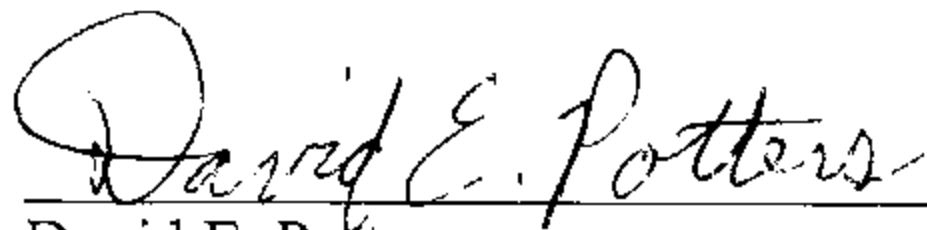
First, NACDS and Fruth both comment on § 15-8-2.2.3 and the new proposed definition of “date filled”. The Controlled Substances Monitoring Program (CSMP) legislation in West Virginia Code § 60A-9-4 requires, among other things, the reporting of the “date filled”. To many consumers, this means the date a prescription is actually picked-up or delivered. However, to the industry, this term means the date that the prescription was prepared and placed into will-call or otherwise while waiting to be picked-up or delivered. The dispensers report the data to the CSMP in accordance with national automated reporting standards called ASAP formats. The ASAP formats include fields for both “date filled” and “date sold”. The Board’s goal in writing the definition of “date filled” was to make the term mean the date that a prescription is actually delivered to a patient. As we as a State try to get more accurate information in the CSMP as to exactly when a prescription became available to a patient, and if we eventually go to real-time reporting, then we will need point-of-sale reporting, i.e. when actually delivered to the patient, not when prepared (filled) and placed into will-call. Nonetheless, per the commenters, the definition of “date filled”, given the way that terminology is used to mean something different in the industry, is causing confusion with pharmacies. They ask the Board to use the term “date sold” as the defined term. However, the statute uses the term “date filled”, so the Board, in complying with the statute, cannot on its own substitute “date sold”, so instead attempted to define the statutory term. Further, the Board would rather avoid using the term “date sold” in statute or rule, and would prefer to use the term “delivered”, since not all dispensings are “sold”. The Board could then by rule make “date sold” mean date delivered to comply with the ASAP format fields. All this being said, a statutory solution changing “date filled” to “date delivered” in West Virginia Code § 60A-9-4 may be the most logical solution. (Alternatively, the term

“date delivered” could be added in addition to “date filled” if the Legislature wants both fields captured). Given the complexity of the situation, the Board has given the suggestion much thought, and concluded (1) that the definition of “date filled” should be changed to “date sold” and be defined as follows: “‘date sold’ means, for purposes of ASAP reporting formats, the data a filled prescription is delivered to the patient or the patient’s caregiver or agent on behalf of the patient, Provided that, for prescriptions delivered by mail or other common carrier, it is the date placed in the mail or for delivery”, and (2) to seek a legislative change as described above.

The second comment from both NACDS and Fruth is that, in § 15-8-5, dispensers be given 7 days rather than just 24 hours to correct errors in reporting upon discovery. The Board received this suggestion during drafting, and accepted it at that time, and already made that change prior to filing the rules for public comment. So, the comment is well-taken, and no change is necessary at this time as it was already drafted that way.

Having reviewed the comments in full, no further substantive changes were made except as described above. 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:



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