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August 29, 2024

SUMMARY OF COMMENTS RECEIVED REGARDING
PROPOSED RULE FOR 15 CSR 1 AND
RESPONSES OF THE WV BOARD OF PHARMCY

The proposed rules for 15 CSR 1 were filed for a Notice of Comment Period of proposed rule 15 CSR 1 on July 23, 2024, 4PM and the comment period closed August 22, 2024, at 5PM. The Board received three comments on the proposed rule (all exactly the same.) A copy of this summary is being provided to the three commenters.

Commenter 1: Jordan Carter, PharmD, MS
Director of Pharmacy, Acute Care Operations
WVU Medicine – WVU Hospitals
1 Medical Center Drive, PO Box 8045
Morgantown, WV 26506

Commenter 2: Chad Foreman, RPH
Director of Pharmacy
Jackson General Hospital Pharmacy
122 Pinnell Street
Ripley, WV 25271

Commenter 3: Todd Karpinski, PharmD, MS, FASHP, FACHE
Chief Pharmacy Officer & System Vice President - WVUHS
Hospital Administration
WVU Medicine
Box 8059
Morgantown, WV 26506-8059

Comment 1 (on Section 20.3.2 Beyond-use-date for non-aqueous solid dosage forms shall not exceed 180 days or the expiration date of the drug being repackaged, whichever is shorter. WVU Hospitals and WVU Hospitals Jackson General Hospital oppose this change for 2 reasons: USP-NF (1178) Good Repackaging Practices does state similar timelines to the proposed language, however, there is no scientific evidence referenced by USP to support this BUD determination

1. There is no publishable data stating that a non-aqueous solid dosage form routinely loses any potency or stability when repackaged from a bulk bottle into unit dose (assuming all appropriate repackaging practices are followed)
2. Instead of classifying BUD's (or expiration dates) for repackaged medications by theoretical rationale, we should instead be using the EXP date listed on the original manufacturer's bottle as this is the only timeframe with actual scientifically studied data to support the dating (assuming all appropriate repackaging practices are followed)

Response 1: The Board appreciates this recommendation and recognizes the difficulty change in processes of repackaging can cause. However, this proposed change brings WV Rules into compliance with the federal United States Pharmacopeia repackaging standards (USP Chapter 1178) as acknowledged by the commenters and into compliance with the U.S. Food and Drug Administration Guidance *Repackaging of Certain Human Products by Pharmacies and Outsourcing Facilities* available here. The USP standards and FDA are recognized and a requirement of WV law (§15-1-11.1.2 and §15-1-15.2.1). The FDA explains the rationale for not using the expiration date on the original manufacture's bottle because the medication is now being removed from a manufacturing facility that is using current Good Manufacturing Practices (pharmacies do not meet these standards) and are exposing the medications to air, humidity, thus initiating the medication decomposition process. While the previous language in the rule was in compliance with an older version of USP Chapter 1178, USP Chapter 1178 and USP 795 have been reevaluated and updated to the current approved version. Therefore, the United States Pharmacopeia (who for over 200 years have been evaluating evidence and establishing standards) have determined that the standard needs to be a shorter dating than for the original packaged product and previous guidelines. To make the language clearer, the Board is making the modification below:

20.3.2. The expiration date shall not exceed: ~~Expiration dates may be no more than twenty five percent (25%) of the time between the day of packaging and the expiration date on the stock bottle, not to exceed twelve (12) months in any case.~~

20.3.2.a. Six months from the date of repackaging; or

20.3.2.b. The manufacturer's expiration date; or

20.3.2.c. Twenty-five percent of the time between the date of repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.

20.3.2.d. Except as modified in W.Va. Code R. § 15-5-1 *et seq.*

Comment 2: Reducing the maximum expiration date (or BUD as proposed) from 12 months to 180 days will result in substantial cost increase due to:

a. Facilities being forced to purchase unit-dose products directly from manufacturers for low usage items that otherwise would expire (often 5-10x more expensive for a unit dose NDC than a bulk bottle NDC)
b. Facilities seeing increased medication waste due to expiration dating / BUD being cut in half

Not only is this rule change is based on zero scientific, data-driven rationale, it is one that will lead to substantial cost increases for our facility when purchasing

medications. More importantly, ultimately the patients of West Virginia will be the ones to incur the downstream impact of this increased cost.

Response 2: The Board appreciates this recommendation and wishes to keep costs low while also ensuring optimal patient safety. This rule modification is prompted by the change made in both the USP Chapter 1178 and the FDA guidance document cited above. When national standards and guidelines change, WV facilities that provide care to WV citizens should meet those same standards. Pharmacy facilities are still able to repackage medications; nothing in this rule modification forbids repackaging. Regarding the comment's 12-month suggestion, under the current rule, a 12-month expiration date would be used rarely. The current rule limits any expiration date time period to "no more than twenty five percent (25%) of the time between the day of packaging and the expiration date on the stock bottle, not to exceed twelve (12) months in any case." Therefore, for the 12-month dating to be used, there would need to be 48 months left from the date of repackaging to expiration date on the bottle—a rarity with the numerous drug shortages occurring at present. While a few products might be impacted due to having an expiration date that long, most would not.

This proposed rule change also does not force a health system to purchase unit dose directly from the manufacturer. For example, a health system could run a report to estimate the number of that product that will be used in 6 months and repackage in a phased manner. If the health system uses 10 bottles of the drug in a year, the health system could unit dose package 5 bottles and then complete the unit dose repackaging again in another 6 months. This would limit waste, meet the USP and FDA national standard guidance of a 6-month expiration date, and not require the purchase of unit dose direct from the manufacturer as the comment suggests. Most importantly, this would ensure that the drug maintains potency and safety for the patient as determined by the repackaging national standards.

Capehart, Krista D <krista.d.capehart@wv.gov>

FW: WV BOP July 2024 Newsletter

1 message

Carter, Jordan <jordan.carter1@wvumedicine.org> Fri, A
To: "Capehart, Krista D" <krista.d.capehart@wv.gov>

Good afternoon,

Please see comments below from WVU Medicine – WVU Hospitals related to these proposed changes. Please let me know if there is any additional clarification I can provide.

Thanks!

§15-3 **Comments due in writing by 8/22/24 5PM**

- **20.3.2 Beyond-use-date for non-aqueous solid dosage forms shall not exceed 180 days or the expiration date of the drug being repackaged, whichever is shorter**

WVU Hospitals is opposed to this change for two reasons:

1. USP-NF (1178) Good Repackaging Practices does state similar timelines to the proposed language, however, there is no scientific evidence referenced by USP to support this BUD de
   a. There is no publishable data stating that a non-aqueous solid dosage form routinely loses any potency or stability when repackaged from a bulk bottle into unit dose (assuming a repackaging practices are followed)
   b. Instead of classifying BUD's (or expiration dates) for repackaged medications by theoretical rationale, we should instead be using the EXP date listed on the original manufactur the only timeframe with actual scientifically studied data to support the dating (assuming all appropriate repackaging practices are followed)
2. Reducing the maximum expiration date (or BUD as proposed) from 12 months to 180 days will result in substantial cost increase due to:
   a. Facilities being forced to purchase unit-dose products directly from manufacturers for low usage items that otherwise would expire (often 5-10x more expensive for a unit dose N NDC)
   b. Facilities seeing increased medication waste due to expiration dating / BUD being cut in half

Not only is this rule change is based on zero scientific, data-driven rationale, it is one that will lead to substantial cost increases for facilities when purchasing medications. More importantly, ul of West Virginia will be the ones to incur the downstream impact of this increased cost.

§15-3 **Comments due in writing by 8/22/24 5PM**

- **9.2.3 – Destruction of "abandoned" individual patient medications not supplied by the hospital**

WVU Hospitals has a policy around abandoned medications left at the facility following patient discharge from their hospital stay. For reasons outside of the patient's control, sometimes medic returned to the patient prior to discharge, and they return to the hospital to retrieve them. We consider patient's own medications "abandoned" 30 days post-discharge, and at that point destro

We agree that documentation of destruction should occur. However, it is routinely not possible to document each of the proposed items, such as when medications are brought into the facility

Currently, WVU Hospitals documents:

1. Patient Medical Record Number (MRN)
2. Medication name
3. Medication strength
4. Amount destroyed
5. Date of destruction
6. Pharmacist
7. Witness (licensed pharmacy employee)

WVU Hospitals requests the documentation requirements be the seven items above, not including the prescription number and the filling pharmacy. Signatures should also not be required as be stored electronically through vendor automation that does not permit signature capture (employee and witness identity maintained through biometric identification within vendor automation

Additionally, we request the requirement of two pharmacists to document destruction be modified to the following: two pharmacists, or one pharmacist and one certified pharmacy technician, and one nurse.

WVU Hospitals also requests the addition language against storage of controlled substance medications at the bedside during admission of a hospital stay.

- Reference the verbiage below from California:
  - 22 CCR § 70263
    § 70263. Pharmaceutical Service General Requirements.
    (j) Medications shall not be left at the patient's bedside unless the prescriber so orders. Such bedside medications shall be kept in a cabinet, drawer or in possession of the patient. Drugs shall not be left at the bedside which are listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended, unless the hospital permits bedside storage of medications, written policies and procedures shall be established for the dispensing, storage and records of use, of such medications.

Jordan Carter, PharmD, MS

Director of Pharmacy, Acute Care Operations

WVU Medicine – WVU Hospitals

1 Medical Center Drive, PO Box 8045

Morgantown, WV 26506

Office: (304) 598-4000 Ext. 79758

WVUMedicine
PHARMACY

From: Jordan Carter <jordanfrcarter@gmail.com>
Sent: Friday, August 16, 2024 10:31 AM
To: Carter, Jordan <jordan.carter1@wvumedicine.org>
Subject: Fwd: WV BOP July 2024 Newsletter

Jordan Carter

Begin forwarded message:

From: noreply.boardofpharmacy@wv.gov
Date: July 31, 2024 at 1:56:09 PM EDT
To: jordanfrcarter@gmail.com
Subject: WV BOP July 2024 Newsletter

Good afternoon!

I hope this finds you all well and having a good summer 2024! Attached please find the "New Look" for the WV BOP Newsletter July 2024 Ed. Excited to feature new up-to-date content, frequ
questions, and WV photos taken by our own pharmacists & pharmacy staff who love photography!

Also, we have entered the Notice and Comment period for the 2025 Legislative session. There are proposed rule changes for 15-1, 15-2, and 15-15. These can can be viewed at the links b
be submitted in writing either to the WV BOP address to my attention or via email at krista.d.capehart@wv.gov

§15-1 Comments due in writing by 8/22/24 5PM

§15-2 Comments due in writing by 8/22/24 5PM

§15-15 Comments due in writing by 8/23/24 9AM

Finally, I hope you enjoy the rest of the summer and the July Newsletter. *I am out of the office until Monday, August 5, 2024.* Should you have questions, I will be able to address any questions th
information in the Newsletter etc after Monday, Aug 5, 2024.

Thanks!
Krista Capehart, PharmD

Director of Professional and Regulatory Affairs, WV BOP

WVBOPQuarterlyNewsletterJuly2024FINAL.pdf
891K

Capehart, Krista D <krista.d.capehart@wv.gov>

20.3.2 Beyond-use-date for non-aqueous solid dosage forms

1 message

Foreman, Chad <dennis.foreman@wvumedicine.org> Tue, Aug 20, 2024 at 1:30 PM
To: "krista.d.capehart@wv.gov" <krista.d.capehart@wv.gov>

Hello Krista,

With regards to comments for:

- **20.3.2 Beyond-use-date for non-aqueous solid dosage forms shall not exceed 180 days or the expiration date of the drug being repackaged, whichever is shorter**

Jackson General opposed to this change for two reasons:

1. USP-NF (1178) Good Repackaging Practices does state similar timelines to the proposed language, however, there is no scientific evidence referenced by USP to support this BUD determination
    1. There is no publishable data stating that a non-aqueous solid dosage form routinely loses any potency or stability when repackaged from a bulk bottle into unit dose (assuming all appropriate repackaging practices are followed)
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    2. Facilities seeing increased medication waste due to expiration dating / BUD being cut in half

Not only is this rule change is based on zero scientific, data-driven rationale, it is one that will lead to substantial cost increases for our facility when purchasing medications. More importantly, ultimately the patients of West Virginia will be the ones to incur the downstream impact of this increased cost.

Thank you for considering our input. Have a blessed day!

Chad Foreman, RPH
Director of Pharmacy
Jackson General Hospital Pharmacy
122 Pinnell Street
Ripley, WV 25271
P: 304-373-1604
F: 304-373-1512

New email: dennis.foreman@wvumedicine.org

Capehart, Krista D <krista.d.capehart@wv.gov>

15-1 Comments

1 message

Karpinski, Todd <todd.karpinski@wvumedicine.org> Tue, Aug 20, 2024 at 1:17 PM
To: "krista.d.capehart@wv.gov" <krista.d.capehart@wv.gov>

Hi Kristy. As you know our System is going forward with a drug warehouse where we will do quite a bit of repackaging. The change in expiration date from 12 to 6 months would be very impactful for us and not in a good way. We would like the Board to consider the following—

§15-1 **Comments due in writing by 8/22/24 5PM**

- **20.3.2 Beyond-use-date for non-aqueous solid dosage forms shall not exceed 180 days or the expiration date of the drug being repackaged, whichever is shorter**

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Not only is this rule change is based on zero scientific, data-driven rationale, it is one that will lead to substantial cost increases for facilities when purchasing medications. More importantly, ultimately the patients of West Virginia will be the ones to incur the downstream impact of this increased cost.

Todd Karpinski, PharmD, MS, FASHP, FACHE

Chief Pharmacy Officer & System Vice President - WVUHS

Hospital Administration

WVU Medicine

Box 8059

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todd.karpinski@wvumedicine.org