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July 24, 2025

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

The proposed rules for 15 CSR 1 were filed for a Notice of Comment Period of proposed rule 15 CSR 1 on June 19, 2025, 2 PM and the comment period closed July 19, 2025, at 5PM.

Commenter: _____

§15-1-24.2.7 – “this subsection should either be removed, edited, clarified, or moved to a different section. In short, the rule in current form places an ambiguity on the prohibition of dispensing gender-affirming care medications to minors, which originally stems from the text of SB299.” The implementing rule is titled "Practice of Telepharmacy and Telehealth services", and outside of institutional settings, subsection 24.1 restricts telehealth and telepharmacy only when the patient is unable to be present in the pharmacy. This would seem to exclude the entire rule (§15-1-24) from applying to community retail pharmacies as long as the patient physically comes into the pharmacy.

The part that I request that the Board consider removing, editing, clarifying, or moving, is the dispensing prohibition inside §15-1-24.2.7, which just states "A pharmacist is prohibited from prescribing or dispensing gender altering medication to a person who is under 18 years of age" (emphasis mine). Unlike some of the other subsections (e.g. 24.2.4 and 24.2.5), it does not carry the qualifier "performing telehealth care service". There is ambiguity as to the scope of what this pertains: The restriction on prescribing certainly pertains to remote pharmacists, but what about the dispensing restrictions? Does it apply only to prescriptions written by telehealth prescribers? Or does it apply to all prescriptions at non-resident pharmacies? Or does it apply to all prescriptions at all pharmacies (including community retail pharmacies)? A look at the parent subsection (§15-1-24.2) seems to suggest it is only germane to telehealth service or non-resident mail order dispensing, as it simply states "The practice of the health care service occurs where the patient is located at the time the telehealth services are provided;".

While the Medical, PA, and APRN Practice Acts are modified to prevent the prescribing of gender-affirming care to minors by West Virginia providers, patients in West Virginia's border counties often get in-person medical care in our neighboring states. My pharmacy is located in Berkeley County, which borders Maryland and Virginia, and approximately half of our prescriptions originate in neighboring counties in Maryland or Virginia. Neither Maryland, nor Virginia, restricts the prescribing of gender-affirming care to minors. Depending on whether our community retail pharmacies are included in the restrictions in §15-1-24.2.7, the ambiguity could lead to situations where a WV pharmacy either wrongly dispenses a medication when they're prohibited from doing so, or a WV resident with a valid in-person script from a neighboring county is wrongly denied their medication.

Lastly, if this prohibition applies to every community retail pharmacy in the state, then this will create a burden and a delay in care. To be in compliance, every prescription for an estrogen-based oral contraceptive for patients under 18 would realistically require a phone call to the prescriber to ensure that the patient was in-fact born female and that it is being used for contraception. This may result in delays in the evenings or over the weekends, and by the time the office returns our messages, the patient may have missed their cycle.

Response 1: The Board appreciates the comment and recognizes the concerns of the commenter. The statute and rule reference "gender-altering medications" as defined in rule and statute as 2.1.25. "Gender altering medication" means the prescribing or administering of the following for the purpose of assisting an individual with a gender transition:

2.1.25.a. Gonadotropin-releasing hormone (GnRH) analogues or other puberty blocking medication to stop or delay normal puberty; and

2.1.25.b. Supraphysiologic doses of testosterone, estrogen, or other androgens than would normally be produced endogenously in a healthy individual of the same age and sex.

Hormonal contraception is not used for the purpose of assisting an individual with a gender transition, but rather for the original intent of the medication of oral contraception of regulating the menstrual cycle and to prevent pregnancy. Therefore, it should not create a burden or delay in care and cannot be stricken from the rule as the language is included in code. The other comments relate to requirements of statute and cannot be changed.

Comment 2: §15-1-8.6 - I am completely in favor of this as currently proposed.

Response 2: The Board appreciates the support for the proposed changes and the work being done to improve patient access to the services needed and medications.

Comment 3: §15-1-24.2.4 Recommend modifying the final "is" (located between "conduct" and "§15-1-15") to be "in".

Response 3: The Board appreciates this comment and accepts the recommendation.

Comment 4: §15-1-26.2.1 Recommend modifying "devise" to be "device".

Response 4: The Board appreciates this comment and accepts the recommendation.

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July 24, 2025

Travis J. Chapman, PharmD, MS
Submitted via TJ.Chapman@tjpharmd.com

Dear Dr. Chapman:

The West Virginia Board of Pharmacy thank you for taking the time to provide comments on the Board's proposed rule 15 CSR 1 (Licensure and Practice of Pharmacy).

The Board has met and carefully considered all the comments received. Enclosed please find the *Summary of Comments Received Regarding Proposed Rule for 15 CSR 1 and Responses of the WV Board of Pharmacy*.

The agency-approved proposed rule was filed Thursday, July 24, 2025, with the West Virginia Secretary of State's office. Both the proposed rule and comments in their entirety can be viewed there. Thank you for your time and participation in the rule-making process.

Professionally,

Krista Capehart, PharmD, MS, BCACP, FAPhA



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

WV CSR 15-01 Rule Change Comments

1 message

TJ Chapman <TJ.Chapman@tjpharmd.com>

Sat, Jul 5, 2025 at 10:35 PM

To: "krista.d.capehart@wv.gov" <krista.d.capehart@wv.gov>

Good Evening Dr. Capehart,

I have included my comments below regarding the changes to WV CSR 15-01. Comment 1 is regarding the wording in the rule that implements SB299, Comment 2 is in support to the faxed transfer changes, and Comments 3 and 4 are minor wording changes. Please let me know if you have any questions or need any clarifications.

Comment 1: §15-1-24.2.7 - I believe that this subsection should either be removed, edited, clarified, or moved to a different section. In short, the rule in current form places an ambiguity on the prohibition of dispensing gender-affirming care medications to minors, which originally stems from the text of SB299.

For background information, SB299 prohibits prescribing gender-affirming care to minors by modifying the Medical, PA, and APRN Practice Acts and ties it in to the other health professions via a section that states that health professions shall propose an emergency rule to regulate telehealth practice. The law states that one of those rules that the Board should propose is simply "[a] prohibition of prescribing or dispensing gender altering medication to a person who is under 18 years of age."

The implementing rule is titled "Practice of Telepharmacy and Telehealth services", and outside of institutional settings, subsection 24.1 restricts telehealth and telepharmacy only when the patient is unable to be present in the pharmacy. This would seem to exclude the entire rule (§15-1-24) from applying to community retail pharmacies as long as the patient physically comes into the pharmacy.

The part that I request that the Board consider removing, editing, clarifying, or moving, is the dispensing prohibition inside §15-1-24.2.7, which just states "A pharmacist is prohibited from prescribing or dispensing gender altering medication to a person who is under 18 years of age" (emphasis mine). Unlike some of the other subsections (e.g. 24.2.4 and 24.2.5), it does not carry the qualifier "performing telehealth care service". There is ambiguity as to the scope of what this pertains: The restriction on prescribing certainly pertains to remote pharmacists, but what about the dispensing restrictions? Does it apply only to prescriptions written by telehealth prescribers? Or does it apply to all prescriptions at non-resident pharmacies? Or does it apply to all prescriptions at all pharmacies (including community retail pharmacies)? A look at the parent subsection (§15-1-24.2) seems to suggest it is only germane to telehealth service or non-resident mail order dispensing, as it simply states "The practice of the health care service occurs where the patient is located at the time the telehealth services are provided;".

While the Medical, PA, and APRN Practice Acts are modified to prevent the prescribing of gender-affirming care to minors by West Virginia providers, patients in West Virginia's border counties often get in-person medical care in our neighboring states. My pharmacy is located in Berkeley County, which borders Maryland and Virginia, and approximately half of our prescriptions originate in neighboring counties in Maryland or Virginia. Neither Maryland, nor Virginia, restricts the prescribing of gender-affirming care to minors. Depending on whether our community retail pharmacies are included in the restrictions in §15-1-24.2.7, the ambiguity could lead to situations where a WV pharmacy either wrongly dispenses a medication when they're prohibited from doing so, or a WV resident with a valid in-person script from a neighboring county is wrongly denied their medication.

Lastly, if this prohibition applies to every community retail pharmacy in the state, then this will create a burden and a delay in care. To be in compliance, every prescription for an estrogen-based oral contraceptive for patients under 18 would realistically require a phone call to the prescriber to ensure that the patient was in-fact born female and that it is being used for contraception. This may result in delays in the evenings or over the weekends, and by the time the office returns our messages, the patient may have missed their cycle.

I respectfully request that the language be modified to better clarify to what this rule pertains. If the intention was for the prohibition on dispensing to apply to all prescriptions at all pharmacies (including community retail pharmacies), I would recommend that the Board instead move the restrictions on dispensing gender-affirming care medications from §15-1-24.2.7 (and abortifacients from §15-1-24.2.6) to a different location in series 15-1 (possibly §15-1-15 [the new Unprofessional Conduct rule]).

Comment 2: §15-1-8.6 - I am completely in favor of this as currently proposed. Although not expressly permitted, the practice of faxing transfers is already commonplace in the retail setting in West Virginia. More importantly, the transfer of prescriptions via fax improves patient safety by reducing potential sources of errors. The incidence of sound-alike errors, such as hydroxyzine/hydralazine or clomiphene/clomipramine, as well as mis-transcribed dosage forms (ER/DR/CR/XR) and directions of use, should be greatly reduced.

I am also in favor of maintaining the language "After direct communication between the pharmacist(s) and/or pharmacy intern(s)", as ultimately the pharmacists are responsible for the transfer process. This leads to accountability in situations where a prescription for an incorrect patient was transferred or a pharmacy requests a transfer without the patient's consent, the latter of which I have encountered on more than one occasion.

Comment 3: §15-1-24.2.4 - I recommend modifying the final "is" (located between "conduct" and "§15-1-15") to be "in".

Comment 4: §15-1-26.2.1 - I recommend modifying "devise" to be "device".

Sincerely,
TJ Chapman, PharmD, MS-HSA

Travis J. Chapman, PharmD, MS

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