



July 21, 2023

Rulemaking Staff
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

**RE: ATA ACTION CONCERNS WITH PROPOSED RULE DIVISION 115:
PHARMACISTS AND DIVISION 125 PHARMACY TECHNICIANS**

Dear Oregon Board of Pharmacy rulemaking staff,

On behalf of ATA Action, I am writing to express our concerns with certain proposed requirements in the Notice of Proposed Rulemakings regarding Division 115: Pharmacists issued June 16, 2023. We are concerned that, if implemented, the proposed rules could erect unnecessary barriers to patient care.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth coverage and fair payment policies to secure telehealth access for all Americans, including those in rural and underserved communities. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

Many members of the ATA and ATA Action offer patients the option to receive their medication through mail-order fulfillment. This option can increase patient access to medication and improve patient adherence to treatment, leading to better patient outcomes.

Proposed Counseling Requirements

Proposed Rule 855-115-0145 includes a number of new requirements related to pharmacist counseling, which would impose substantial and unique burdens on pharmacists who deliver care into Oregon and on patients who choose to have their medications delivered at home.

Specifically, the rules redefine counseling to be “interactive,” suggesting that the provider-patient interaction must be a real-time discussion and forecloses the use of (currently permitted) offers to counsel or written interactions. The proposed rules would also mandate pharmacists *to initiate* such interactive counseling prior to delivery of medication and by the end of the next business day (often within 24 hours) after delivery if the patient is not reached initially. Finally,

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the rules would require the pharmacist to document each counseling attempt and the outcome “at the time of the attempt or interaction.”

ATA Action echoes other stakeholders and has significant concerns with these proposed rules, which would make Oregon the first state in the country to mandate pharmacists provide “interactive” counseling and prohibit written counseling and offers to counsel for remote delivery.

First, the new requirement for real-time interactive counseling will require pharmacies offering mail-order or delivery to invest significant time and resources – some estimates in the millions of dollars – without any corresponding benefit to patient safety. ATA Action is aware of no safety data, study, or clinical evidence showing that current practice – such as an offer to counsel or written counseling – are insufficient for safely managing prescription medications. If the Board believes there is data to support a mandate for proactive counseling, ATA Action questions why the rules regarding dispensing and drug delivery for Community Health Clinics (CHC)¹ and Dispensing Practitioner Drug Outlets (DPDO)² will still allow for delivery or mail prescription with a written offer to provide counseling.

Second, ATA Action is not aware of any other state that requires the pharmacist to proactively initiate contact with a patient regarding their prescription prior to delivery as well as within a strict 24-hour time limit after delivery. There is a good reason why: 8-in-10 Americans do not answer calls from unknown telephone numbers,³ meaning other states understand the futility of such a requirement. Furthermore, the proposed rule does not require any interactive contact to occur before dispensing the medication, meaning most of these proposed patient counseling contact attempts will merely function as a new, expensive administrative burden without any counseling occurring.

Third, the proposed rules’ documentation requirement piles on these new unnecessary administrative burdens on pharmacists. Pharmacists will now be required to not only make dozens of unanswered phone calls, but must also file rote and often blank documentation that offers no discernable value to patients or pharmacies. If the Board insists on keeping this recordkeeping requirement, ATA Action sees no reason why the pharmacist must personally do this administrative task, rather than other members of the pharmacy team.

In contrast to how the above rules impose counseling mandates and unnecessarily restrict patient choice, ATA Action requests the Board rely instead on the proposed rule language that

¹ Board of Pharmacy, 855-043-0740 Community Health Clinic (CHC) - Dispensing and Drug Delivery.

<https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=290866>

² Board of Pharmacy, 855-043-0545 Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery.

<https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=290863>

³ Pew Research Center, *Most Americans don't answer cellphone calls from unknown numbers*, Dec. 14, 2020,

<https://www.pewresearch.org/short-reads/2020/12/14/most-americans-dont-answer-cellphone-calls-from-unknown-numbers/>.



empowers pharmacists to use their judgement as to the patient and his or her circumstances. Specifically, the rules state: “for each prescription, the pharmacist must *determine the manner* and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.” ATA Action agrees that licensed practitioners should be able to utilize the full range of available modalities while delivering care, so long as the technologies being used are appropriate to meet the standard of care presented by the patient. It should be pharmacists, relying on their extensive education and clinical experience, who should have the ability to determine if written counseling and written offers to provide direct counseling meet the patient’s needs, or if more direct or proactive real-time counseling is necessary.

Indeed, written offers to counsel or written counseling might be *more appropriate* for engaging many patients who have chosen mail-order fulfillment, particularly those in the telemedicine setting. Many of the reasons patients choose to receive medical care in the telehealth setting are the same reasons patients choose to receive medications via home delivery methods. Both care settings offer solutions for patients with limited mobility or transportation challenges, who cannot take time off work, who reside in underserved or rural areas who may not have convenient or easy access to a pharmacy to fill their prescription in person, or are part vulnerable or stigmatized populations, such as those seeking reproductive or sexual health care. While a pharmacist can easily counsel a patient (or attempt to) at the time they come to pick up their prescriptions in a brick and mortar pharmacy, initiating a separate interaction with patients for counseling in a mail-order delivery setting will be far more burdensome and is misaligned with patients’ expectations.

Patients will be the ones who bear the burden of this rule being implemented. The potential confusion it would create for providers and patients alike, coupled with the fiscal impact to be borne by members, could have legitimate and sizable negative impacts upon the speed, cost, and availability of mail-order prescription fulfillment. For all these reasons, ATA Action requests the Board of Pharmacy consider revising 855-115-0145 to better reflect and account for the differences in patients accessing medications at their homes:

Division 115, 855-115-0005 Definitions

(1) "Counseling" or "Counsel" means an interaction, including through written communication, ~~interactive communication~~ between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

Division 115, 855-115-0145 Counseling

(2) The pharmacist must counsel or offer to counsel the patient or patient's agent on the use of a drug or device:¶
 (a) Upon request;

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- (b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;
 - (c) When there has been a change in the dose, formulation, or directions;
 - (d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or
 - (e) For any refill that the pharmacist deems counseling is necessary.
- (5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation **or does not respond to an offer to counsel**. If refused,
- (a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required.
 - (b) The pharmacist may choose not to release the prescription until counseling has been completed.
- ...
- (7) The pharmacist **must ensure the offer attempt** to counsel, ~~provides counseling, or accepts the request not to be counseled~~ is documented **their identity, each attempt to counsel and the outcome at the time of the attempt or interaction**.

Pharmacy Technician Licensing Requirements (Division 125)

ATA Action appreciates that the Board's proposed rules in Division 115 clearly outline pharmacy activities in that a pharmacist located in another state who is working for an out-of-state pharmacy can perform without holding an Oregon pharmacist license. (see 855-115-0001(3)).

ATA Action seeks further clarity in the Division 125 rules, however, to ensure there are equivalent licensure exemptions extended to pharmacy technicians working under the supervision, direction, and control of a pharmacist operating under these exemptions. As drafted, the proposed rules in 855-125-0001(2-3) state that "only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may assist a Pharmacist in the practice of pharmacy..." and that "only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification when delegated to do so by a Pharmacist." ATA Action believes these proposed rules create confusion when read with 855-115-001 and could unintentionally suggest that *every pharmacy technician* working at an out-of-state pharmacy needs an Oregon license if the facility dispenses to an Oregon patient. We respectfully request the Board clarify these rules to ensure parity and consistency for licensure exemptions between out-of-state pharmacists and pharmacy technicians.

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Rules Effective Date

Finally, the proposed rules currently do not include an effective date. ATA Action requests the effective date for compliance be at least a year from Board approval, as covered pharmacies will need sufficient opportunity to hire staff and implement frameworks to comply with these resource-intensive requirements.

We encourage you and your colleagues to reconsider these proposed rules to protect Oregon patients' access to affordable, high-quality care. Please let us know if there is anything that we can do to assist you in your efforts to adopt practical policy in Oregon. If you have any questions or would like to engage in additional discussion regarding the telehealth industry's perspective, please contact me at kzebley@ataaction.org.

Kind regards,

A handwritten signature in black ink, appearing to read "Kyle Zebley", is written over a light gray circular watermark.

Kyle Zebley
Executive Director
ATA Action