



September 9, 2022

The Honorable Elizabeth Warren
309 Hart Senate Office Building
U.S. Senate
Washington, DC 20510-2105

Dear Senator Warren:

On behalf of the American Pharmacists Association (APhA), we would like to thank you for your correspondence on August 9, 2022 and focus on ensuring continuity of care for patients across the country following the U.S. Supreme Court decision in *Dobbs v Jackson Women's Health Organization*. Optimizing patient access to FDA-approved medications and pharmacist provided patient care services are key strategic goals of our organization's vision and mission. We appreciate the opportunity to provide our perspective on press reports of restrictions to patients' access to their medications.

Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

As noted in your letter, APhA shares your concerns with the troubling reports of delays in care or lost access to medications following the *Dobbs* decision. The impetus of these reports has been: 1) Lack of clarity in state laws and rules, 2) Lack of clarity in federal laws, rules, and guidances, and 3) conflicts between state and federal law. These obscurities and conflicts have resulted in an environment, post-*Dobbs*, in which many health care professionals, including, but not limited to pharmacists, are unsure of their professional, financial, and legal liability when providing necessary care to their patients. APhA has spoken publicly of these concerns and requested action from policymakers to ensure patients' continuity of care is not interrupted,^{1,2,3,4,5} and most recently in a joint-statement with the American Medical Association (AMA), Society of Health-System Pharmacists (ASHP), and National Community Pharmacists Association

¹ Breaking: APhA issues statement in response to Supreme Court's *Dobbs v Jackson* decision. July 25, 2022. Available at <https://www.pharmacist.com/APhA-Press-Releases/breaking-apha-issues-statement-in-response-to-supreme-courts-dobbs-jackson-decision>

² New Federal Guidance confuses an already complicated landscape for pharmacists. July 13, 2022. Available at <https://www.pharmacist.com/APhA-Press-Releases/new-federal-guidance-confuses-an-already-complicated-landscape-for-pharmacists>

³ Abortion Restrictions May Be Making It Harder for Patients to Get a Cancer and Arthritis Drug. *Time Magazine*. Available at <https://time.com/6194179/abortion-restrictions-methotrexate-cancer-arthritis/>

⁴ Women with chronic conditions struggle to find medications after abortion laws limit access. *CNN*. July 22, 2022. Available at <https://www.cnn.com/2022/07/22/health/abortion-law-medications-methotrexate/index.html>

⁵ Post-Roe drug delays weigh on patients, providers. *Axios*. July 26, 2022. Available at <https://www.axios.com/2022/07/26/post-roe-drug-delays-weigh-on-patients-providers>

(NCPA).⁶ In the joint statement, the organizations call on state policymakers to ensure through guidance, law, or regulation that patient care is not disrupted and that physicians and pharmacists shall be free to continue to practice medicine and pharmacy without fear of professional sanction or liability. Through the joint statement, we strongly urge state medical and pharmacy boards, agencies, and policymakers to act to help ensure that our patients retain continuity of care and that our members clearly understand their legal and licensing obligations.

In response to your questions, please see the below answers:

1. **How have state-imposed restrictions on abortion care affected patients?**
 - a. **Have state-imposed restrictions on abortion care resulted in diminished access to pregnancy care, reproductive care, or any other form of health care? If so, please explain.**
 - b. **Have state-imposed restrictions on abortion care resulted in delays in care for patients? If so, please explain.**

State-imposed restrictions on abortion care have affected patients in multiple ways. Most directly, patient access to elective abortion care services has become illegal or has been severely restricted in many states. Although this impacts the entire population capable of becoming pregnant in the state, these policies disproportionately impact individuals who face issues related to social determinants of health and do not have the ability, or access to travel to a state where they could receive elective abortion care and related health care services.

Indirectly, state-imposed restrictions on abortion care have impacted pregnancy care, reproductive care, and other forms of health care. Many of these issues have been the result of vaguely worded state policies that could be interpreted as being more broadly applied to patients even if they are not receiving care related to an abortion. For example, see the below definitions of “abortion-inducing drug,” medical abortion, or other comparable terms:

Wisconsin: “Abortion-inducing drug” means a drug, medicine, oral hormonal compound, mixture, or preparation, when it is prescribed to terminate the pregnancy of a woman known to be pregnant.”⁷

Idaho: “Abortifacient” means mifepristone, misoprostol and/or other chemical or drug dispensed with the intent of causing an abortion as defined in section 18-604(1), Idaho Code. Nothing in the definition shall apply when used to treat ectopic pregnancy;”⁸

Texas: “Medical abortion--The use of a medication or combination of medications to induce an abortion, with the purpose of terminating the pregnancy of a woman known to be pregnant. Medical abortion does not include forms of birth control.”⁹

⁶ AMA, APhA, ASHP, NCPA Statement on State Laws Impacting Patient Access to Medically Necessary Medications. September 8, 2022. Available at: <https://www.pharmacist.com/APhA-Press-Releases/ama-apha-ashp-ncpa-statement-on-state-laws-impacting-patient-access-to-medically-necessary-medications>

⁷ Wis. Stat. § 253.10

⁸ Idaho Code § 18-617

⁹ 25 TAC § 139.2

The definitions from these three states exemplify the variability in defining these terms which is seen in many more state laws and regulations. This variability adds further confusion to an already complicated situation for health care professionals to navigate.

Without clear guidance from federal and state policymakers, pharmacists in many states are uncertain of the professional, financial, and legal liability they may face when providing care to their patients regardless if the care is related to abortion care services. One example is a lack of clarity of the federal and state liability for a pharmacist in a state where abortion is legal and may face penalties if they provide care or dispense a medication, regardless if the care or medication is related to abortion care services, to a patient that has traveled from a state where abortion is illegal or severely restricted.

These restrictions have resulted in limited access, delays in care, and confusion for numerous health care professionals and organizations as they attempt to follow obscure and conflicting federal and state laws and regulations.

2. **How have state-imposed restrictions on abortion care affected pharmacists?**
 - a. **Have state-imposed restrictions on abortion care affected pharmacists' ability to independently exercise their medical judgment? If so, please explain.**
 - b. **Have state-imposed restrictions on abortion care affected pharmacists' ability to provide the full range of care necessary for their patients? If so, please explain.**

State-imposed restrictions on abortion care have significantly impacted pharmacists and their ability to care for their patients in multiple ways, including, an inability to practice evidence-based health care, an increase in administrative burden, and uncertainty about their liability. First and foremost, the issue most concerning to pharmacists is that state-imposed restrictions are limiting or delaying their ability to provide evidence-based therapies to their patients. Restricting or limiting access to FDA-approved therapies that the pharmacist has identified as medically necessary based on their extensive education and training conflicts with the Oath of a Pharmacist¹⁰ and the Code of Ethics for Pharmacists.¹¹ These professional standards hold pharmacists to ensuring optimal care and outcomes for their patients, which is jeopardized when state-imposed restrictions limit their ability to provide needed care to their patients.

For example, take a patient that has been taking methotrexate, referenced in your letter, for an extended period of time for their rheumatoid arthritis (RA). Although methotrexate is commonly used for RA, it is also used off-label for the termination of intrauterine pregnancy. In many states,

¹⁰ Oath Of A Pharmacist. Available at <https://www.pharmacist.com/About/Oath-of-a-Pharmacist>

¹¹ Code of Ethics for Pharmacists. Available at <https://aphanet.pharmacist.com/code-ethics>

such as Alabama^{12,13,14}, Arkansas^{15,16,17,18,19}, Kansas²⁰, Kentucky²¹, Louisiana^{22,23}, Montana²⁴, Oklahoma^{25,26}, South Carolina^{27,28}, Tennessee²⁹, Texas³⁰, and Virginia³¹, methotrexate is specifically mentioned in state laws and regulations related to abortion care services. Due to the lack of guidance in interpreting laws in many states, pharmacists are unsure of the liability they would face in dispensing methotrexate, despite it being used for RA. This limits or delays patients from receiving their needed care and affects pharmacists' ability to independently exercise their professional judgement.

Complicating the current environment following the *Dobbs* decision has been President Biden's Executive Order (EO) on Securing Access to Reproductive and Other Healthcare Services³² and the guidance³³ from the U.S. Department of Health and Human Services' Office for Civil Rights (OCR) that interprets pharmacists' obligations under federal civil rights laws, conflicting with some state laws, and raising concerns for our nation's pharmacies and pharmacists. The EO perpetuates existing confusion in an already complicated landscape for our patients and profession. While we understand the intent, without consultation with our nation's pharmacists the OCR's guidance, as written, has language in conflict with a pharmacists' professional judgment to make "determinations regarding the suitability of a prescribed medication for a patient; or advising patients about medications and how to take them."

The OCR's guidance lists potential examples when a pharmacist's refusal to dispense a drug to a patient "may be" a violation of federal law. As you know, the practice of pharmacy is regulated by the states and State Boards of Pharmacy, which provide and oversee pharmacy and pharmacist licenses. In addition, OCR's guidance does not address all federal conscience protections for health

¹² Ala. Admin. Code r. 420-5-1-.01

¹³ Code of Ala. § 22-9A-13

¹⁴ Code of Ala. § 26-23E-3

¹⁵ 060 00 CARR 001

¹⁶ 007 05 CARR 004

¹⁷ A.C.A. § 20-16-1503

¹⁸ A.C.A. § 20-16-1702

¹⁹ A.C.A. § 20-16-2502

²⁰ K.A.R. § 28-56-2

²¹ KRS § 311.7731

²² La. R.S. § 14:87.1

²³ La. R.S. § 14:87.1

²⁴ 50-20-703, MCA

²⁵ 63 Okl. St. § 1-756.2

²⁶ 63 Okl. St. § 1-757.2

²⁷ S.C. Code Ann. § 40-47-37

²⁸ S.C. Code Ann. § 44-41-460

²⁹ Tenn. Code Ann. § 63-6-1102

³⁰ Tex. Health & Safety Code § 171.061

³¹ 18 VAC 110-30-20

³² Executive Order on Securing Access to Reproductive and Other Healthcare Services. Available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/>

³³ U.S. Department of Health and Human Services. Office for Civil Rights. Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services. Available at <https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf>

care professionals.³⁴ More than just the Church Amendments applies because the scope and impact of this federal guidance goes beyond health care services only related to abortion. Pharmacists cannot ignore state law if a pharmacy and pharmacist licenses would be in jeopardy, even with OCR's interpretation of a limited number of existing federal statutes. The implications of OCR's federal guidance also has the potential to cause widespread unintended consequences beyond reproductive health care services which could force pharmacists to dispense any medication that could impact the safety of our patients. For example, if there is a drug-drug interaction, drug allergy, drug-condition interaction, or other clinical concern that may impact patient safety.

Additionally, state-imposed restrictions have increased administrative burden on pharmacists and other health care professionals. Due to the obscurities and conflicts in state and federal law, pharmacists must take additional steps to ensure they are not violating any laws when providing care to their patients. This increase in administrative burden has the potential to delay care for multiple patients as it interrupts the workflow of the pharmacist.

State-imposed restrictions on abortion care and the response from the federal government are both contributing to legal confusion and impacting health care professionals, including pharmacists, ability to independently exercise their professional judgement.

3. What guidance have you provided to your members, if any, about how to perform their duties in light of state-imposed restrictions on abortion care? Do you plan to issue any future guidance to your members about how to perform their duties in light of state-imposed restrictions on abortion care?

We have provided information³⁵ to our members on relevant terminology differences related to reproductive health care services, guidance to assist on navigating conflicting interpretations of federal and state laws, state and federal³⁶ conscience protections for health care professionals along with APhA policy on the topic³⁷, and resources to guide their practice following the *Dobbs* decision. Additionally, APhA is gathering members' feedback through a series of listening sessions as existing APhA policy does not explicitly contemplate the complexities and sensitivities that the *Dobbs* decision brings to light. This input will feed into APhA's deliberation on these issues at the next seating of the APhA House of Delegates.

Unfortunately, due to the 1) Lack of clarity in state laws and rules, 2) Lack of clarity in federal laws, rules, and guidances, and 3) conflicts between state and federal law, additional guidance to our members has been limited to educating pharmacists to follow state and federal laws - while urging action from policymakers to ensure patients' continuity of care is not interrupted. As more laws, rules, and guidances are published in the future we plan to interpret and update our members.

³⁴ HHS. Conscience Protections for Health Care Providers. Content last reviewed September 14, 2021. Available at: <https://www.hhs.gov/conscience/conscience-protections/index.html#:~:text=Federal%20statutes%20protect%20health%20care,moral%20objections%20or%20religious%20beliefs>

³⁵ Reproductive Health Care: Navigating The Dobbs Decision. Available at <https://www.pharmacist.com/Advocacy/Issues/Reproductive-Health>

³⁶ Conscience Protections for Health Care Providers. Content last reviewed September 14, 2021. Available at <https://www.hhs.gov/conscience/conscience-protections/index.html>

³⁷ Pharmacist Conscience Clause. Available at <https://aphanet.pharmacist.com/policy-manual?key=Pharmacist+Conscience+Clause&op=Search>

4. How can the federal government help protect and expand access to pregnancy care, reproductive care, and other forms of health care in response to state-imposed restrictions on abortion care?

APhA respectfully requests federal policymakers ensure through guidance, law or regulation recognition of a pharmacist's professional judgement and that patient care is not disrupted. Pharmacists and other health care professionals should be free to continue to meet the health care needs of our patients without fear of professional sanction or liability. We strongly urge federal policymakers to work with state policymakers to prevent further confusion and act to help ensure our patients retain continuity of care and that pharmacists clearly understand their legal and licensing obligations under both state and federal laws, as well as FDA, state and State Board of Pharmacy regulations.

We deeply appreciate your focus on these important and urgent issues. We hope that this correspondence can foster a positive collaboration with your office, APhA, and the pharmacy community to address the many issues impacting patients' continuity of care and provide helpful guidance from state and federal policymakers to assist our nation's pharmacists. We welcome and encourage Senator Warren to meet with us to discuss these many issues facing our nation's pharmacists and our patients in advance of any future correspondence. Please contact Michael Baxter, Senior Director, Regulatory Policy at mbaxter@aphanet.org with any additional questions and/or to arrange a meeting with us.

Sincerely,



Ilisa BG Bernstein, PharmD, JD, FAPhA
Interim Executive Vice President and CEO

cc: Theresa Tolle, BPharm, FAPhA, APhA President