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8 **UNITED STATES DISTRICT COURT**
EASTERN DISTRICT OF WASHINGTON
9 **AT YAKIMA**

10 STATE OF WASHINGTON,

NO. 2:19-cv-00183-SAB

11 Plaintiff,

DECLARATION OF STEVEN
SAXE IN SUPPORT OF STATE OF
WASHINGTON'S MOTION FOR
PRELIMINARY INJUNCTION

12 v.

NOTED FOR: July 17, 2019
With Oral Argument at 1:30 p.m.

13 ALEX M. AZAR II, in his official
capacity as Secretary of the United
States Department of Health and
14 Human Services; and UNITED
STATES DEPARTMENT OF
15 HEALTH AND HUMAN
SERVICES,

16 Defendants.
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18 I, Steven Saxe, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

19 1. I am over the age of 18, competent to testify as to the matters herein,
20 and make this declaration based on my own knowledge.

21 2. I am the Executive Director for the Washington State Pharmacy
22 Quality Assurance Commission (Commission). I have held this position from

1 2004 to 2006, 2007 to 2009 (in an Acting Executive Director capacity), for six
2 months in 2012, and from 2016 until present. Since 2004, I have worked for the
3 Washington State Department of Health (DOH) in a number of leadership roles
4 including Director of the Office of Facilities and Services Licensing, Director of
5 the Office of Health Professions and Facilities, and the Director of the Office of
6 Community Health Services. Prior to working for DOH, I worked in hospitals
7 and health systems for over twenty-five years. I hold a Master of Healthcare
8 Administration from Duke University and a Bachelor of Pharmacy from the
9 Washington State University. Since 1977, I have held an active pharmacist
10 license in Washington and North Carolina.

11 3. The Commission is composed of fifteen members appointed by the
12 Governor. Wash. Rev. Code 18.64.001. The members include: (i) ten
13 pharmacists, (ii) four public members, and (iii) one pharmacy technician. *Id.* The
14 Commission has a number of powers and duties granted by the legislature to
15 support its mission of protecting and promoting public health and safety by
16 issuing licenses, registrations, and certifications to qualified persons and entities,
17 and responding to complaints or reports of unprofessional conduct. For 2018, this
18 included, but is not limited to, the regulation of: (i) 10,784 pharmacists, (ii) 8,817
19 pharmacy technicians, (iii) 8,018 pharmacy assistants, and (iv) 1,462 in-state
20 pharmacies.

21 4. Primarily, the Commission protects the public health, safety, and
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1 welfare of the citizens of the State of Washington by regulating the practice of
2 pharmacy. Wash. Rev. Code 18.64.005. The practice of pharmacy includes the
3 distribution, manufacturing, and delivery of pharmaceuticals in the State of
4 Washington. Wash. Rev. Code 18.64.011(28). The Commission also has
5 regulatory authority over the Legend Drug Act, Uniform Controlled Substances
6 Act, and other laws relating to poisons or drugs. Wash. Rev. Code 69.04; Wash.
7 Rev. Code 69.38; Wash. Rev. Code 69.40; Wash. Rev. Code 69.41; Wash. Rev.
8 Code 69.43; Wash. Rev. Code 69.50; Wash. Rev. Code 69.60. DOH provides
9 administrative support for the Commission to perform its powers and duties.
10 Wash. Rev. Code 18.64.310.

11 5. The Commission regulates the practice of pharmacy by
12 promulgating administrative rules, conducting inspections of pharmaceutical
13 firms, investigating complaints filed against its license holders, and taking
14 enforcement action against licensees who have engaged in unprofessional
15 conduct. Wash. Rev. Code 18.64.005, .163, .165, .310; Wash. Rev. Code 18.130.

16 6. In January 2006, the predecessor to the Commission, the State of
17 Washington Board of Pharmacy (Board),¹ became aware of media coverage
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19 ¹ In 2013, the State of Washington Board of Pharmacy was renamed to the
20 State of Washington Pharmacy Quality Assurance Commission. Board of
21 Pharmacy—Pharmacy Quality Assurance Commission, Laws of 2013, ch. 19.
22 This session law increased the Commission’s membership from seven members

1 highlighting the confiscation and destruction of lawful prescriptions by
2 pharmacists in other states who objected to dispensing and delivering
3 medications lawfully prescribed to patients. Members of the public asked
4 whether the Board could take licensing action against Washington licensed
5 pharmacists who similarly confiscated and destroyed lawful prescriptions. The
6 Board reviewed their laws and determined the law did not directly prohibit a
7 Washington licensed pharmacist from confiscating and destroying lawful
8 prescriptions. Based on this determination, the Board decided to open rulemaking
9 to consider whether rules should be adopted to address the public's concern. After
10 considerable public input, reaffirming the importance of providing Washington
11 patients timely access to all lawfully prescribed medications, the Board adopted
12 two rules by unanimous vote on April 12, 2007.

13 7. The first rule, an amendment to Wash. Admin. Code 246-863-095,
14 regulates the conduct of pharmacists. Under this rule, a pharmacist may be
15 subject to professional discipline for: (i) delegating to ancillary staff the decision
16 to not dispense or deliver lawfully prescribed drugs, (ii) destroying or refusing to
17 return an unfilled lawful prescription, (iii) violating a patient's privacy, or (iv)
18 unlawfully discriminating against, or for intimidating or harassing a patient. The
19 rule does not require an individual pharmacist to dispense and deliver lawfully
20 _____
21 to fifteen members and required one of the members to be a pharmacy technician.
22 It did not modify the Commission's regulatory authority.

1 prescribed medication to which they object.

2 8. The second rule, Wash. Admin. Code 246-869-010, regulates the
3 operation of pharmacies. Under this rule, a pharmacy is required “to deliver
4 lawfully prescribed drugs or devices. . . *in a timely manner consistent with*
5 *reasonable expectations for filling the prescription.*” Wash. Admin Code
6 246-869-010(1) (emphasis added). The italicized language reinforced the
7 Board’s position that complaints alleging a violation of this rule would be
8 reviewed on a case-by-case basis and should include an evaluation of the
9 potential risk of harm to the patient caused by a delay in the delivery of their
10 lawfully prescribed medications.

11 9. Under the second rule, a pharmacy may substitute a “therapeutically
12 equivalent drug” or provide a “timely alternative for appropriate therapy,” but is
13 prohibited from refusing to deliver a lawfully prescribed or approved medication
14 unless one of the following exceptions applies:

15 (a) Prescriptions containing an obvious or known error,
16 inadequacies in the instructions, known contraindications, or
17 incompatible prescriptions, or prescriptions requiring action in
accordance with WAC 246-875-040.

18 (b) National or state emergencies or guidelines affecting
availability, usage or supplies of drugs or devices;

19 (c) Lack of specialized equipment or expertise needed to safely
20 produce, store, or dispense drugs or devices, such as certain drug
compounding or storage for nuclear medicine;

21 (d) Potentially fraudulent prescriptions; or

22 (e) Unavailability of drug or device despite good faith compliance
with WAC 246-869-150.

1 Wash. Admin Code 246-869-010(1)(a)-(e).

2 10. A pharmacy is also prohibited from destroying or refusing to return
3 an unfilled lawful prescription, violating a patient’s privacy, unlawfully
4 discriminating against, or intimidating or harassing a patient. Wash. Admin Code
5 246-869-010(4).

6 11. In the Concise Explanatory Statement issued by the Board as part of
7 the rulemaking process as required by Wash. Rev. Code 34.05.325, the Board
8 noted that it created a right of refusal for individual pharmacists by allowing a
9 pharmacy to accommodate a pharmacist who has a religious or moral objection.
10 A pharmacy may not refer a patient to another pharmacy to avoid filling a
11 prescription because the pharmacy has a duty to deliver lawfully prescribed
12 medications in a timely manner. A pharmacy may accommodate a pharmacist’s
13 personal objections in any way the pharmacy deems suitable, including having
14 another pharmacist available in person or by telephone.

15 12. My understanding is that the rule, Protecting Statutory Conscience
16 Rights in Health Care Delegations of Authority, published in the Federal Register
17 on May 21, 2019 (Final Rule), permits health care entities to refuse to provide
18 services if they have a religious or moral objections. I understand that the Final
19 Rule defines “health care entity” to include pharmacies. Final Rule § 88.2. Thus,
20 under the Final Rule, as I understand it, Washington pharmacies will be able to
21 refuse to provide prescription drugs and devices to their customers if they assert
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1 a religious or moral objection to the medical care or such characteristics of the
2 patients such as their sexual or gender identity.

3 13. The Final Rule will negatively impact the Commission's mission to
4 safeguard the health, safety, and welfare of the people of the State of Washington.
5 Specifically, the Final Rule will preempt most, if not all of, Wash. Admin. Code
6 246-863-095 and 246-869-010 (WACs), which struck a balance between timely
7 patient access to healthcare and the religious or conscience objection of the
8 pharmacist. The WACs struck this balance by requiring the pharmacy to ensure
9 patients have timely access to all lawfully prescribed drugs and devices.
10 However, the Final Rule would allow pharmacies the right to turn away patients
11 with a variety of lawful prescriptions, many of which are time sensitive. The Final
12 Rule would also potentially allow pharmacists to simply turn away these patients
13 without referring them to another pharmacist available to consult with the patient
14 in person or by phone. An example of some, but not all, of the time sensitive
15 prescriptions that I anticipate a pharmacy may refuse to fill based on a religious
16 or conscience objection includes:

- 17 a. Psychotropic medications for mental health diagnoses;
- 18 b. Antibiotics for, among other things, sexually transmitted diseases;
- 19 c. Antiretroviral therapy medication for HIV/AIDS diagnoses;
- 20 d. Medications for treatment of opioid use disorder;
- 21 e. Medications for reversal of an opioid overdose;

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- 1 f. Contraceptives;
- 2 g. Mifepristone for the medical termination of a pregnancy;
- 3 h. Medication for erectile dysfunction;
- 4 i. Hormone therapy for individuals engaged in long term hormone
- 5 replacement as part of gender transition;
- 6 j. Medications traditionally only prescribed to individuals of one
- 7 gender; or
- 8 k. Syringes or other drug paraphernalia used for administration of a
- 9 drug intramuscularly or intravenously.

10 14. It is likely the Final Rule will heavily undermine the Commission's
11 duty to promote the health, safety, and welfare of the citizens of the State of
12 Washington. During testimony for the two rules cited above, the Board heard
13 considerable testimony expressing concerns that a pharmacy's refusal to timely
14 deliver a lawfully prescribed medication would inequitably impact health care
15 access for vulnerable populations, including patients who are low-income, have
16 limited transportation options, restricted mobility, reside in rural areas, and those
17 who have restricted insurance coverage. By heavily undermining the
18 Commission's duty to the public, the Final Rule presents a strong likelihood of
19 harming the health, safety and welfare of the citizens of the State of Washington.

20 15. It is also likely the Final Rule will require the Commission to engage
21 in rulemaking to modify or repeal the WACs. Having to engage in the rulemaking
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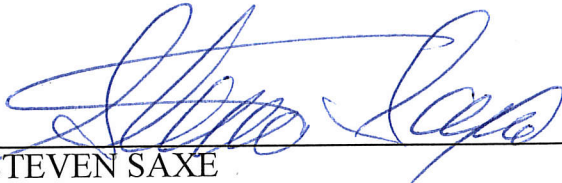
process would divert the Commission’s limited time and resources when a significant amount of these resources were already expended in the development of these WACs. Specifically, the Commission successfully defended, at significant financial cost, Wash. Admin. Code 246-869-010 in federal court after a complaint was filed in 2007 alleging, among other things, that the rules violated the Free Exercise Clause, the Due Process Clause, the Equal Protection Clause, and the Supremacy Clause of the United States Constitution. *Stormans, Inc. v. Wiesman*, 794 F.3d 1064, 1074 (9th Cir. 2015), *see also Stormans, Inc. v. Wiesman*, 136 S. Ct. 2433, 195 L. Ed. 2d 870 (2016).

16. Finally, it is likely the Final Rule will require the Commission to review an increased number of complaints filed by patients when a pharmacy refuses to fill the patient’s lawfully prescribed medication or device. An increased number of complaints could create a backlog of complaints to be investigated that would result in delays to the resolution of Commission complaints. Any delay to the resolution of a complaint puts the public health, safety and welfare at risk.

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I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 19th day of June, 2019, at Tumwater, Washington.



STEVEN SAXE

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court’s CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED this 24th day of June, 2019, at Seattle, Washington.

s/ Paul Crisalli

PAUL CRISALLI, WSBA #40681
Assistant Attorney General