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MONTANA FOURTH JUDICIAL DISTRICT COURT,
MISSOULA COUNTY

CAROL BRIDGES, M.D., CARA HARROP, M.D., and TODD BERGLAND, M.D., Plaintiffs, v. The MONTANA BOARD OF MEDICAL EXAMINERS, TIM FOX, in his official capacity as the Montana Attorney General, and the STATE OF MONTANA, Defendants.	Cause No. ________________ Hon. ______________________ Dept. No. ________________ **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. This constitutional challenge seeks to vindicate the right of licensed Montana doctors to dispense safe, affordable medications directly to their patients. Plaintiffs Carol Bridges, M.D., Cara Harrop, M.D., and Todd Bergland, M.D., are family doctors based in Missoula, Polson, and Whitefish who regularly prescribe routine medications (e.g., antibiotics, antihistamines, antacids) for common health issues. Plaintiffs want to offer patients an easier way to obtain these medications, right when they prescribe them, at prices lower than those offered by pharmacies. Specifically, Plaintiffs want to dispense non-controlled medications directly to their patients at cost—a service that, in addition to saving patients time and money, will also reduce their risk of exposure to COVID-19 by eliminating unnecessary trips to the pharmacy.

2. Forty-four states and D.C. allow doctors to dispense in this manner. But Montana, unlike the vast majority of states, forbids doctors from dispensing unless an exception applies. Exceptions include dispensing when the doctor works over 10 miles from a pharmacy, dispensing samples, and dispensing "occasionally" or in an "emergency." These exceptions are too constraining for Plaintiffs, who want to offer patients access to their full prescriptions, whenever their professional judgment demands it, regardless of where the nearest pharmacy happens to be. The

"occasional" and "emergency" exceptions are also undefined, which means Plaintiffs would be forced to guess about when they can dispense on the margins.

3. Montana's ban is irrational. As 45 other jurisdictions have recognized, doctor dispensing is a safe and effective way to increase patients' access and adherence to their prescribed medications, which is good for patients, doctors, and the broader healthcare system. As licensed doctors, Plaintiffs are just as qualified as peers across the country to provide this beneficial service. Indeed, Montana already allows Plaintiffs to dispense sample, occasional, and emergency supplies of the medications they want to dispense regularly. And Montana already allows doctors who work over 10 miles from pharmacies to dispense full prescriptions and recover their costs. Yet Montana forbids Plaintiffs—who work within 10 miles of several pharmacies—from offering this service for their own patients.

4. Montana's ban has nothing to do with protecting the health or safety of real patients. But it does serve another purpose: protecting pharmacies from competition. Indeed, the practical effect of this regime is that doctors can dispense only at frequencies (occasionally), at prices (free samples), or in locations (far from pharmacies) that do not threaten pharmacies' profits. Pharmacies, by contrast, can dispense an unlimited supply of medications for profit anywhere in Montana—all while enjoying a 10-mile buffer from competition by the nearest doctor.

5. That is unconstitutional. Article II, Section 3 of the Montana Constitution forbids the legislature from imposing irrational and protectionist restrictions on Plaintiffs' fundamental right to pursue a chosen business. Article II, Section 4 forbids the legislature from drawing irrational and protectionist distinctions between Plaintiffs and doctors in other parts of Montana providing precisely the same service they want to provide. And Article II, Section 17 forbids the legislature from adopting vague laws. Because Montana's ban on doctor dispensing violates each provision, the Court should enjoin Defendants from enforcing it against Plaintiffs and all similarly situated doctors.

JURISDICTION AND VENUE

6. Plaintiffs seek declaratory and injunctive relief against enforcement of Montana's dispensing ban, Mont. Code Ann. § 37-2-104, which violates Plaintiffs' rights to economic liberty, equal protection, and due process of law.

7. Plaintiffs bring this lawsuit under Article II, Sections 3, 4, and 17 of the Montana Constitution and the Uniform Declaratory Judgments Act, Mont. Code Ann. § 27-8-201. Plaintiffs also have a cause of action for violation of their constitutional rights under Article II, Section 16 of the Montana Constitution.

8. This Court has jurisdiction and venue lies in this Court. *See* Mont. Code Ann. §§ 3-5-302(1), (5), 25-2-126.

PARTIES

9. Plaintiff Carol Bridges, M.D., is a Montana-licensed family doctor who practices in Missoula. Dr. Bridges would like to dispense non-controlled medications to her patients at cost, but Montana bans her from doing so.

10. Plaintiff Cara Harrop, M.D., is a Montana-licensed family doctor who practices in Polson. Dr. Harrop would like to dispense non-controlled medications to her patients at cost, but Montana bans her from doing so.

11. Plaintiff Todd Bergland, M.D., is a Montana-licensed family doctor who practices in Whitefish. Dr. Bergland would like to dispense non-controlled medications to his patients at cost, but Montana bans him from doing so.

12. Defendant the Montana Board of Medical Examiners (BME) is the state agency responsible for regulating the practice of medicine and for enforcing the dispensing ban against doctors.

13. Defendant Tim Fox is sued in his official capacity as the Montana Attorney General. The Attorney General can direct county attorneys to institute legal proceedings against licensed doctors who violate the dispensing ban.

14. Defendant the State of Montana is the entity ultimately responsible for enacting and enforcing the dispensing ban.

FACTS

Doctor Dispensing Is Mainstream

15. "Doctor dispensing" is the practice of licensed doctors supplying patients with the medications they have prescribed, at cost or more, directly in their offices.[1]

16. For many doctors, dispensing is a way to offer patients immediate access to the medications they need without the added cost and delay of a separate trip to the pharmacy.

17. There is no federal prohibition on doctor dispensing. *Cf.* 21 U.S.C. §§ 353(b)(1), 829.

18. This makes sense. Under federal law, certain medications are deemed unsafe for self-administration, yet safe when taken under the supervision of a licensed doctor. *See* 21 U.S.C. § 353(b)(1).

19. In other words, federal law recognizes that doctors are qualified, due to extensive training and knowledge of individual patients, to determine whether a medication would be appropriate and to supervise its administration in each case.

[1] As used in this complaint, the term refers solely to the act of furnishing a pre-manufactured drug product to a patient, and does not include the manufacture, preparation, or compounding of the medication itself.

20. Of course, a doctor who desires to dispense a medication is still required, under federal law, to ensure the medication is not "adulterated" or "misbranded." 21 U.S.C. § 331(a).

21. But a doctor can easily meet these requirements by purchasing the medication from a licensed wholesaler, *see* 21 U.S.C. §§ 360eee(23)(A), 360eee-1(c), 360eee-2, by storing it in accordance with federal best practices and under the conditions specified by the U.S. Pharmacopeia/National Formulary, *see* 21 C.F.R. §§ 205.50, 210.1(a), and by dispensing it with any labels or warnings required by the U.S. Food and Drug Administration, *see* 21 C.F.R. §§ 201, 208, 209.

22. The American Medical Association also approves of doctor dispensing if doctors "prescribe . . . based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug . . . for the particular patient" and "dispensing primarily benefits the patient." *Opinion 8.06—Prescribing and Dispensing Drugs and Devices*, 12 Am. Med. Ass'n J. of Ethics 925 (Dec. 2010).

23. Within these reasonable parameters, doctor-dispensed medications are at least as safe and effective as pharmacy-dispensed medications.

24. Within these reasonable parameters, doctor dispensing is a safe and effective way for doctors to offer patients more convenient and affordable access to the medications they need; to increase prescription-adherence rates; to reduce

the potential for avoidable medical complications and expenses; and to strengthen the doctor-patient relationship.

25. Given the benefits of doctor dispensing, the practice is widely embraced by both lawmakers and physicians nationwide. Forty-five jurisdictions allow doctors to dispense medications, at cost or more, directly to their patients, and a majority of American doctors now report dispensing on a daily basis.

Montana Effectively Bans Doctor Dispensing

26. Montana, unlike the vast majority of states, deems it "unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs." Mont. Code Ann. § 37-2-104(1).

27. Montana's ban is sweeping. It forbids routine dispensing services that doctors across the country provide on a daily basis. And it applies to all "drugs," even over-the-counter medications.

28. There are a few exceptions to the ban. *See* Mont. Code Ann. § 37-2-104(2). But they are narrow, often vague, and only allow doctors to dispense in ways that pose no threat to the financial interests of pharmacies.

29. For example, doctors can dispense "any drug in an emergency." Mont. Code Ann. § 37-2-104(2)(a). But this excludes everyday circumstances.

30. Doctors can dispense "occasionally, but not as a usual course of doing business." Mont. Code Ann. § 37-2-104(2)(d). But this excludes regular dispensing.

31. Doctors can dispense "whenever there is no community pharmacy available to the patient." Mont. Code Ann. § 37-2-104(2)(c). But this excludes doctors who work in urban areas, since "'[c]ommunity pharmacy,' when used in relation to a medical practitioner, means a pharmacy situated within 10 miles of any place at which the medical practitioner maintains an office for professional practice." Mont. Code Ann. § 37-2-101(1).

32. Doctors can dispense "a drug if the medical practitioner has prescribed the drug and verified that the drug is not otherwise available from a community pharmacy." Mont. Code Ann. § 37-2-104(2)(h). But this excludes doctors who want to dispense at prices lower than those offered by pharmacies.

33. Doctors can dispense "drug samples." But federal law limits this exception to free samples received by the grace of pharmaceutical companies. *See* 21 U.S.C. § 353(c)(1), (d)(2)(A).

34. Moreover, the terms "emergency," "occasionally," and "usual," as used in the dispensing ban, are not defined.

35. As a result, doctors are banned from dispensing as a regular part of their practices. And if they want to dispense under certain narrow exceptions to the ban, they are forced to guess about whether they are breaking the law.

36. Breaking the law is, of course, not an option. BME can fine doctors $1,000 per offense and revoke or suspend their medical licenses for violating the dispensing ban. Mont. Code Ann. § 37-1-312(1)(a), (b), (h). And the Attorney General can direct county attorneys to "institute appropriate proceedings," whether in court or in coordination with BME, against doctors who violate the ban. Mont. Code Ann. § 37-2-105.

Plaintiffs Want to Dispense Safe, Affordable Medication to Their Patients

37. Plaintiffs are three family doctors who want to dispense safe, affordable medications to patients in their offices.

38. Dr. Carol Bridges is a licensed physician and board-certified family doctor based in Missoula with over 20 years of experience practicing medicine.

39. In 2007, Dr. Bridges founded Cost Care, a family and emergency-care practice that has locations at 2819 Great Northern Loop and 3031 Russell Street in Missoula.

40. Dr. Cara Harrop is a licensed physician and board-certified family doctor based in Polson with over 20 years of experience practicing medicine.

41. In 2018, Dr. Harrop founded Pure Health DPC, a family practice located at 1105 1st Street E. in Polson.

42. Dr. Todd Bergland is a licensed physician and board-certified family doctor based in Whitefish with over 15 years of experience practicing medicine. Dr. Bergland practiced for seven years while on active duty in the U.S. Army and served as a tank battalion surgeon during Operation Iraqi Freedom.

43. In 2020, Dr. Bergland founded Fountainhead Family Med, a family practice located at 844 Baker Avenue in Whitefish.

44. Plaintiffs follow the "direct primary care" (DPC) practice model. DPC is an arrangement where patients pay a flat monthly fee in exchange for an agreed-upon list of medical services.

45. Two core tenets of the DPC model are that the doctor-patient relationship is sacred and that the delivery of routine primary care should be simplified to benefit the patient.

46. Thus, DPC arrangements do not involve insurance—they are agreements directly between doctors and patients.

47. DPC practices in 45 jurisdictions also offer patients the option of purchasing medications at the point of care. Indeed, the ability to purchase medications from their prescribing doctor is a major reason patients join DPC practices in the first place.

48. Plaintiffs were inspired to start DPC practices after speaking with DPC doctors across the country who consistently reported being able to provide higher-quality, lower-cost primary care for their patients.

49. As family doctors, Plaintiffs each offer a range of medical services—everything from routine checkups (e.g., annual exams, physicals, sick visits) to treatment for chronic conditions (e.g., diabetes, asthma, allergies) to care for acute conditions (e.g., influenza, sprains, lacerations).

50. As part of these services, Plaintiffs prescribe appropriate medications for patients as part of their overall treatment plans.

51. Most of the medications Plaintiffs prescribe are routine medications for common medical ailments that Plaintiffs have decades of experience treating.

52. If Plaintiffs were permitted to dispense these medications to patients at cost, they could save patients money, spare patients the hassle of an unnecessary trip to the pharmacy, and increase patients' likelihoods of taking their prescribed medications.

53. For example, Plaintiffs commonly prescribe Omeprazole to patients with acid reflux and Rosuvastatin to patients with high cholesterol. Omeprazole and Rosuvastatin are most often prescribed as oral tablets that, to effectively treat acid reflux and high cholesterol, must be taken over the course of days or weeks.

54. The average retail pharmacy prices of standard, 30-pill bottles of 20mg Omeprazole and 10mg Rosuvastatin are about $46 and $148, respectively. Yet Plaintiffs could purchase the same quantity from a licensed wholesaler and dispense them to patients for about 99 cents and $1.63, respectively.

55. Plaintiffs would like to dispense a limited number of non-controlled medications that, like Omeprazole and Rosuvastatin, can be safely dispensed in their offices at a fraction of the price charged by pharmacies.

56. In other words, Plaintiffs would like to provide the same services that Montana doctors who work over 10 miles from pharmacies are already allowed to provide. *See* Mont. Code Ann. §§ 37-2-104(2)(c), -101(1),

57. If Plaintiffs were allowed to dispense in this manner, they would comply with all federal and state laws regarding the purchase, storage, and sale of non-controlled medications, and with AMA Code of Medical Ethics Opinion 8.06.

Montana Bans Plaintiffs from Dispensing Safe, Affordable Medications to Their Patients

58. Plaintiffs are not allowed to dispense non-controlled medications in the safe, affordable manner described above. *See* Mont. Code Ann. § 37-2-104(1).

59. Plaintiffs are not banned from dispensing because it is difficult. To the contrary, dispensing involves simple tasks like storing medications, counting pills, labeling bottles, and keeping records. These are tasks that Plaintiffs, as licensed doctors who care for human lives every day, are more than qualified to perform.

60. Plaintiffs are not banned from dispensing because they would be unable to comply with relevant Montana Board of Pharmacy standards for the proper storage, labeling, and dispensing of medications. *See* ARM 24.174.814 (facility security), .817 (automated records), .818 (data security), .819 (sanitation and equipment), .832 (labeling), .833 (dispensing records). These are common-sense requirements that Plaintiffs, as licensed doctors with decades of experience, could easily meet.

61. Plaintiffs are not banned from dispensing because it falls outside their scope of practice. *See* Mont. Code Ann. § 37-7-103(1) (pharmacist-licensing law does not "prevent a person who is licensed to practice medicine from furnishing to a patient drugs, medicines, chemicals, or poisons that the person considers proper in the treatment of the patient").

62. Plaintiffs are not banned from dispensing because pharmacists are uniquely qualified to "promot[e] therapeutic appropriateness by identifying: (a) over-utilization and under-utilization; (b) therapeutic duplication; (c) drug-disease contraindications; (d) drug-drug interactions; (e) incorrect drug dosage or duration of drug treatment; (f) drug-allergy interactions; (g) clinical abuse/misuse." ARM 24.174.902(1). Rather, Plaintiffs are fully qualified to ensure "therapeutic appropriateness" by considering (at least) these factors before prescribing medications—as they have done for decades.

63. Moreover, to the extent failure to consider any factor listed in ARM 24.174.902(1) before dispensing would constitute "conduct likely to . . . harm the public," ARM 24.156.625(1)(c), or "conduct that does not meet the generally accepted standards of practice," Mont. Code Ann. § 37-1-316(18), BME could sanction Plaintiffs for "unprofessional conduct." BME has never sanctioned Plaintiffs for any conduct.

64. Plaintiffs are not banned from dispensing because they lack (or lack access to) any knowledge, technology, equipment, or other resources necessary to safely prescribe and dispense medications.

65. In truth, the only reason Plaintiffs are banned from dispensing non-controlled medications at cost is that Plaintiffs' offices are located within 10 miles of pharmacies. *See* Mont. Code Ann. §§ 37-2-104(1), (2)(c), -101(1).

Banning Plaintiffs from Dispensing Safe, Affordable Medications to Their Patients Serves No Compelling or Legitimate State Interest

66. Plaintiffs, just like their peers in 45 other jurisdictions and in certain parts of Montana, are qualified to safely and ethically dispense non-controlled medications to patients at cost.

67. Plaintiffs' proximity to pharmacies has no bearing on their ability to safely and ethically dispense non-controlled medications at cost.

68. If Plaintiffs were permitted to dispense in the same manner as doctors who work over 10 miles from pharmacies, Plaintiffs' patients would benefit from greater access to safe, affordable medications.

69. If Plaintiffs were permitted to dispense in the same manner as doctors who work over 10 miles from pharmacies, Plaintiffs' patients would be more likely to take their prescribed medications and less likely to suffer medical complications and expenses.

70. Montana's dispensing ban does not actually further any compelling or legitimate state interest, and Defendants can produce no evidence to the contrary.

71. The dispensing ban's actual purpose and effect is to protect pharmacies from economic competition, and that is not a compelling or legitimate state interest.

INJURY TO PLAINTIFFS

72. The dispensing ban prevents Plaintiffs from providing a service that would allow them to better care for the health and welfare of their patients.

73. The dispensing ban prevents Plaintiffs from dispensing non-controlled medications at prices lower than those available at most pharmacies.

74. The dispensing ban prevents Plaintiffs from operating their chosen business: a DPC practice that offers point-of-care medication dispensing.

75. The dispensing ban prevents Plaintiffs from offering a service that would make their practices more attractive to prospective patients.

76. The ban's exceptions for "emergency" and "occasional" dispensing, which are not defined, have deterred Plaintiffs from dispensing on the margins out of fear they might misinterpret the law and expose themselves to grave sanctions.

77. But for the dispensing ban, Plaintiffs would immediately begin dispensing non-controlled medications to their patients at cost and would do so in compliance with all relevant federal and state laws, and with AMA Code of Medical Ethics Opinion 8.06.

LEGAL CLAIMS

First Claim
(Mont. Const. art. II, § 3—Inalienable Rights)

78. Article II, Section 3 of the Montana Constitution provides: "All persons are born free and have certain inalienable rights. They include . . . the rights of pursuing life's basic necessities, enjoying and defending their lives and liberties, acquiring, possessing and protecting property, and seeking their safety, health and happiness in all lawful ways."

79. Article II, Section 3 protects the fundamental right to provide a useful service in the honest pursuit of one's livelihood.

80. Doctor dispensing is a useful service that Plaintiffs want to provide in the honest pursuit of their livelihoods.

81. Specifically, Plaintiffs want to dispense non-controlled medications at cost to expand their patients' access to safe, affordable medications, to attract more patients to their practices, and to run practices that fully embody the DPC model.

82. Montana's dispensing ban does not regulate doctor dispensing to protect the public health or safety; it simply forbids Plaintiffs from providing a useful service in their pursuit of life's basic necessities.

83. Banning Plaintiffs from dispensing non-controlled medications at cost does not serve any compelling (or even legitimate) state interest.

84. Worse, the actual purpose and effect of the ban is to protect pharmacies from competition, and protectionism is not a compelling (or even legitimate) state interest.

85. The dispensing ban violates Article II, Section 3, both on its face and as applied to Plaintiffs.

86. Unless Defendants are enjoined from enforcing the dispensing ban, Plaintiffs will suffer continuing and irreparable harm.

Second Claim
(Mont. Const. art. II, § 4—Equal Protection)

87. Article II, Section 4 of the Montana Constitution provides: "The dignity of the human being is inviolable. No person shall be denied the equal protection of the laws."

88. Article II, Section 4 protects the right to pursue a chosen business free from irrational and protectionist legislative classifications.

89. As licensed doctors who seek to provide better services for their patients and to expand their practices, Plaintiffs' chosen businesses would involve dispensing non-controlled medications at cost to patients who need them.

90. Montana's dispensing ban draws an irrational distinction between Plaintiffs (who are not permitted to dispense non-controlled medications at cost) and doctors who work over 10 miles from pharmacies (who are permitted to provide identical services) based solely on the locations of their offices.

91. The dispensing ban's distinction between Plaintiffs and doctors who work over 10 miles from pharmacies does not serve any legitimate state interest.

92. Worse, the actual purpose and effect of the ban is to protect pharmacies from competition, and protectionism is not a legitimate state interest.

93. The dispensing ban violates Article II, Section 4, both on its face and as applied to Plaintiffs.

94. Unless Defendants are enjoined from enforcing the dispensing ban, Plaintiffs will suffer continuing and irreparable harm.

<u>Third Claim</u>
(Mont. Const. art. II, § 17—Due Process)

95. Article II, Section 17 of the Montana Constitution provides: "No person shall be deprived of life, liberty, or property without due process of law."

96. Article II, Section 17 forbids the enactment of vague laws.

97. A law is vague if it fails to give people of ordinary intelligence fair notice whether their contemplated conduct is forbidden.

98. Montana's dispensing ban purports to allow dispensing "in an emergency" and "occasionally, but not as a usual course of doing business." Mont. Code Ann. § 37-2-104(2)(a), (d).

99. But the terms "emergency," "occasionally," and "usual" are not defined and do not give Plaintiffs fair warning about when they can dispense on the margins.

100. If Plaintiffs attempted to dispense under one of these exceptions, they would be forced to guess about whether they were violating the law.

101. The dispensing ban is vague and violates Article II, Section 17.

102. Unless Defendants are enjoined from enforcing the dispensing ban, Plaintiffs will suffer continuing and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

A. For a declaratory judgment that Montana's dispensing ban, Mont. Code Ann. § 37-2-104, violates Article II, Section 3 of the Montana Constitution, both on its face and as applied to Plaintiffs;

B. For a declaratory judgment that Montana's dispensing ban, Mont. Code Ann. § 37-2-104, violates Article II, Section 4 of the Montana Constitution, both on its face and as applied to Plaintiffs;

C. For a declaratory judgment that Montana's dispensing ban, Mont. Code Ann. § 37-2-104, violates Article II, Section 17 of the Montana Constitution, both on its face and as applied to Plaintiffs;

D. For an award of $1 in nominal damages;

E. For an award of attorneys' fees, court costs, and all other legal and equitable relief to which Plaintiffs may be entitled.

RESPECTFULLY SUBMITTED this 12th day of June, 2020.

By: *<u>/s/ Alexander L. Roots</u>*

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