

AUSTIN KNUDSEN
Montana Attorney General
KRISTIN HANSEN
Lieutenant General
DAVID M.S. DEWHIRST
Solicitor General
CHRISTIAN CORRIGAN
Assistant Solicitor General
BRENT MEAD
Assistant Solicitor General
ALWYN LANSING
Assistant Attorney General
215 North Sanders
P.O. Box 201401
Helena, MT 59620-1401
Phone: 406-444-2026
Fax: 406-444-3549
david.dewhirst@mt.gov
christian.corrigan@mt.gov.
brent.mead2@mt.gov
alwyn.lansing@mt.gov

EMILY JONES
Special Assistant Attorney General
115 N. Broadway, Suite 410
Billings, MT 59101
Phone: 406-384-7990
emily@joneslawmt.com

Attorneys for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION,
et. al.,

Plaintiffs,

and

MONTANA NURSES ASSOCIATION,

Plaintiff-Intervenors,

v.

AUSTIN KNUDSEN, et al.,

Defendants.

CV-21-108-M-DWM

**DEFENDANTS'
RESPONSE IN
OPPOSITION TO
PLAINTIFFS' MOTION
FOR PRELIMINARY
INJUNCTION**

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTRODUCTION 1

PRELIMINARY INJUNCTION STANDARD 2

ARGUMENT 4

I. Likelihood of Success on the Merits..... 4

 A. The CMS Rule..... 4

 B. Plaintiffs are not likely to succeed on their Equal
 Protection claim. 5

 1. Plaintiffs are not similarly situated..... 6

 2. HB 702 easily satisfies rational basis review..... 8

II. Plaintiffs have not demonstrated irreparable injury. 14

 A. Plaintiffs’ injuries are speculative. 15

 1. There’s no harm stemming from non-compliance with
 HB 702..... 16

 2. There’s no harm from the CMS Rule 19

CONCLUSION 31

CERTIFICATE OF COMPLIANCE 33

CERTIFICATE OF SERVICE..... 33

TABLE OF AUTHORITIES

CASES

<i>Ala. Dep’t of Revenue v. CSX Transp., Inc.</i> , 575 U.S. 21 (2015)	6
<i>Alliance For The Wild Rockies v. Cottrell</i> , 632 F.3d 1127 (9th Cir. 2011)	2
<i>Allied Concrete & Supply Co. v. Baker</i> , 904 F.3d 1053 (9th Cir. 2018)	9
<i>Anaheim & Riverside v. Fed. Energy Regulatory Com.</i> , 692 F.2d 773 (D.C. Cir. 1982)	18
<i>Angelotti Chiropractic v. Baker</i> , 791 F.3d 1075 (9th Cir. 2015)	2
<i>Ariz. Dream Act Coal. v. Brewer</i> , 855 F.3d 957 (9th Cir. 2017)	6
<i>Artichoke Joe’s Cal. Grand Casino v. Norton</i> , 353 F.3d 712 (9th Cir. 2003)	12
<i>Ayotte v. Planned Parenthood of N. New England</i> , 546 U.S. 320 (2006)	23
<i>Benisek v. Lamone</i> , 138 S. Ct. 1942 (2018)	2
<i>Biden v. Missouri</i> , 142 S. Ct. 647 (2022) (per curiam)	4, 5
<i>Boardman v. Pac. Seafood Grp.</i> , 822 F.3d 1011 (9th Cir. 2016)	15, 24
<i>Bresgal v. Brock</i> , 843 F.2d 1163 (9th Cir. 1987)	4

<i>Califano v. Yamasaki</i> , 442 U.S. 682 (1979)	3
<i>Caribbean Marine Servs. Co. v. Baldrige</i> , 844 F.2d 668 (9th Cir. 1988)	26
<i>City & Cty. of S.F. v. Trump</i> , 897 F.3d 1225 (9th Cir. 2018)	4, 23
<i>City & Cty. of S.F. v. United States Citizenship & Immigration Servs.</i> , 408 F. Supp. 3d 1057 (N.D. Cal. 2019)	22
<i>Clear Channel Outdoor, Inc. v. City of L.A.</i> , 340 F.3d 810 (9th Cir. 2003)	3
<i>Cottonwood Envtl. Law Ctr. v. United States Forest Serv.</i> , 789 F.3d 1075 (9th Cir. 2015)	19
<i>Culinary Studios, Inc. v. Newsom</i> , 517 F. Supp. 3d 1042 (E.D. Cal. 2021)	12
<i>Drakes Bay Oyster Co. v. Jewell</i> , 747 F.3d 1073 (9th Cir. 2014)	24
<i>E. Bay Sanctuary Covenant v. Barr</i> , 934 F.3d 1026 (9th Cir. 2019)	4
<i>FCC v. Beach Commc'ns</i> , 508 U.S. 307	13
<i>Fraihat v. United States Immigration & Customs Enft.</i> , 16 F.4th 613 (9th Cir. 2021)	2
<i>FTC v. Standard Oil Co.</i> , 449 U.S. 232 (1980)	18
<i>Gazelka v. St. Peter's Hosp.</i> , 420 P.3d 528 (Mont. 2018)	11
<i>Golden Gate Rest. Ass'n v. City of S.F.</i> , 512 F.3d 1112 (9th Cir. 2008)	24-25
<i>Harrison v. Kernan</i> , 971 F.3d 1069 (9th Cir. 2020)	6

<i>Heller v. Doe ex rel.</i> Doe, 509 U.S. 312 (1993)	11
<i>Hurley v. Irish-American Gay,</i> 515 U.S. 557 (1995)	14, 25
<i>Johnson v. Rancho Santiago Cmty. Coll. Dist.,</i> 623 F.3d 1011 (9th Cir. 2010)	13
<i>League of Wilderness Defs./Blue Mts. Biodiversity Project v. Connaughton,</i> 752 F.3d 755 (9th Cir. 2014)	21
<i>Louisiana, et v. Becerra,</i> 2021 U.S. Dist. LEXIS 229949 (W.D. La. Nov. 30, 2021)	4
<i>McGowan v. Maryland,</i> 366 U.S. 420 (1961)	13
<i>Montanans for Cmty. Dev.v. Motl,</i> 54 F. Supp. 3d 1153 (D. Mont. 2014)	19
<i>Nat’l Ass’n for the Advancement of Psychoanalysis v. Cal. Bd. of Psychology,</i> 228 F.3d 1043 (9th Cir. 2000)	11-12
<i>New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.,</i> 434 U.S. 1345 (1977)	25
<i>Paramount Land Co. Ltd. P’ship v. Cal. Pistachio Comm’n,</i> 491 F.3d 1003 (9th Cir. 2007)	3, 18-19
<i>Preminger v. Principi,</i> 422 F.3d 815 (9th Cir. 2005)	25
<i>Renegotiation Board v. Bannerkraft Clothing Co.,</i> 415 U.S. 1 (1974)	18
<i>Roberts v. United States Jaycees,</i> 468 U.S. 609 (1984)	13-14, 25
<i>Safeway Inc. v. City & Cnty. of S.F.,</i> 797 F. Supp. 2d 964 (N.D. Cal. 2011)	13

<i>Sagana v. Tenorio</i> , 384 F.3d 731 (9th Cir. 2004)	11
<i>SEC v. Banc de Binary, Ltd.</i> , 964 F. Supp. 2d 1229 (D. Nev. 2013)	3
<i>Slidewaters LLC v. Wash. State Dep’t of Labor & Indus.</i> , 4 F.4th 747 (9th Cir. 2021)	11
<i>SmithKline Beecham Corp. v. Abbott Labs.</i> , 740 F.3d 471 (9th Cir. 2014)	13
<i>State ex. rel. Bartmess v. Board of Trustees</i> , 223 Mont. 269, 726 P.2d 801 (1986) (Morrison, J. concurring)	13
<i>State v. Nelson</i> , 283 Mont. 231, 941 P.2d 441 (1997)	14, 25-26
<i>Stormans, Inc. v. Selecky</i> , 586 F.3d 1109 (9th Cir. 2009)	22, 23, 24
<i>Thornton v. City of St. Helens</i> , 425 F.3d 1158 (9th Cir. 2005)	6
<i>Tucson Woman’s Clinic v. Eden</i> , 379 F.3d 531 (9th Cir. 2004)	12
<i>United States v. Navarro</i> , 800 F.3d 1104 (9th Cir. 2015)	11
<i>United States v. Ruiz-Chairez</i> , 493 F.3d 1089 (9th Cir. 2007)	9
<i>Vance v. Bradley</i> , 440 U.S. 93 (1979)	11
<i>Vanguard Outdoor, Ltd. Liab. Co. v. City of L.A.</i> , 648 F.3d 737 (9th Cir. 2011)	5-6
<i>Vision Net, Inc. v. State</i> , 447 P.3d 1034 (Mt. 2019)	6
<i>Wadsworth v. Montana</i> , 275 Mont. 287, 911 P.2d 1165 (1996)	14

<i>Wadsworth v. Montana</i> , 911 P.2d 1165 (Mt. 1996)	26
<i>Weinberger v. Romero-Barcelo</i> , 456 U.S. 305 (1982)	24
<i>Whole Woman’s Health v. Jackson</i> , 142 S. Ct. 522 (2021)	16
<i>Winter v. NRDC, Inc.</i> , 555 U.S. 7 (2008)	14, 24

STATUTES

United States Code

16 U.S.C. § 1531	19
------------------------	----

Montana Code Annotated

§ 49-2-312	15
§ 49-2-312 and § 49-2-313	1
§ 49-2-501(1), (3)	17
§ 49-2-504(1)	17
§ 49-2-504(5)	17
§ 49-2-504(7)(a)	17
§ 49-2-504(7)(b)	17
§ 49-2-504(7)(c)	17
§ 49-2-505	17
§ 49-2-505(4)	18
§ 49-2-505(9)	18
§ 50-5-101(7), (26), (31), (37), (56)	8
§ 50-5-101(30), (37)	7
§ 50-5-225	9

OTHER

Federal Register

86 Fed. Reg. 26306, 26306 (May 13, 2021) 10
86 Fed. Reg. 61555 (Nov. 5, 2021) 1
86 Fed. Reg. 61559 27
86 Fed. Reg. at 61607 26, 27

Administrative Rules of Montana

Rules 37.106.4, 37.106.6, 37.106.28 8

Montana Constitution

Art II, § 3 26

Defendants Austin Knudsen and Laurie Esau (hereafter “the State”) submit this Response in Opposition to Plaintiffs’ Motion for Preliminary Injunction.

INTRODUCTION

Plaintiffs ask this Court to preliminarily enjoin MCA § 49-2-312 and § 49-2-313 (“HB 702”) primarily because it conflicts with the Interim Final Rule, Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccinations, 86 Fed. Reg. 61555 (Nov. 5, 2021), establishing the Centers for Medicare & Medicaid Services vaccine mandate (“CMS Rule”). An injunction is unwarranted and unnecessary. The parade of horrors offered by Plaintiffs is belied by the reality of the situation. So long as the CMS Rule remains in effect, it serves as an affirmative defense to liability under HB 702 for covered facilities. Plaintiffs may, thus, comply with the CMS Rule without fear of liability under Montana law and avoid their hypothetical harms altogether.

In the event the Court decides a preliminary injunction is appropriate, it must be narrowly tailored to the *specific* irreparable injuries found and limited to only those plaintiffs who would suffer them. An

injunction—particularly one that is overbroad—would harm the public interest of the people of Montana.

PRELIMINARY INJUNCTION STANDARD

“A preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion.” *Fraihat v. United States Immigration & Customs Enf’t*, 16 F.4th 613, 635 (9th Cir. 2021) (quotations omitted). “As a matter of equitable discretion, a preliminary injunction does not follow as a matter of course from a plaintiff’s showing of a likelihood of success on the merits.” *Benisek v. Lamone*, 138 S. Ct. 1942, 1943–44 (2018). “Rather, a court must also consider whether the movant has shown ‘that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.’” *Id.* at 1944.

Even under the sliding scale test from *Alliance For The Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011), Plaintiffs still must show a likelihood of irreparable injury and a hardship balance that tips sharply towards them. *Angelotti Chiropractic v. Baker*, 791 F.3d 1075, 1081 (9th Cir. 2015). Raising a serious constitutional question is not

enough to tip the hardship scales and enjoin a duly enacted law. *See Paramount Land Co. Ltd. P'ship v. Cal. Pistachio Comm'n*, 491 F.3d 1003, 1012 (9th Cir. 2007); *see also Clear Channel Outdoor, Inc. v. City of L.A.*, 340 F.3d 810, 816 (9th Cir. 2003) (vacating a preliminary injunction where plaintiffs were unlikely to succeed on the merits even though their First Amendment claims did raise the possibility of irreparable injury). This means there must be at least a reasonable probability of success on the merits. *See SEC v. Banc de Binary, Ltd.*, 964 F. Supp. 2d 1229, 1233 (D. Nev. 2013) (“The [*Alliance for the Wild Rockies*] court must have meant something like ‘reasonable probability,’ which appears to be the most lenient position on the sliding scale that can satisfy the requirement that success on the merits be ‘likely.’ If success on the merits is merely possible, but not at least reasonably probable, no set of circumstances with respect to the other prongs will justify preliminary relief.”).

Next, if a plaintiff establishes that a preliminary injunction should issue, the injunctive relief “should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.” *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). “Where relief can be structured on an individual basis, it must be narrowly tailored to remedy the specific

harm shown.” *Bresgal v. Brock*, 843 F.2d 1163, 1170 (9th Cir. 1987); *cf. E. Bay Sanctuary Covenant v. Barr*, 934 F.3d 1026, 1029 (9th Cir. 2019) (“all injunctions—even ones involving national policies—must be ‘narrowly tailored to remedy the specific harm shown’”). “This is so, in part, because broad injunctions may stymie novel legal challenges and robust debate.” *City & Cty. of S.F. v. Trump*, 897 F.3d 1225, 1244 (9th Cir. 2018).

ARGUMENT

I. Likelihood of Success on the Merits

A. The CMS Rule.

The State reserves argument on the preemption of HB 702 by the CMS Rule for purposes of this Motion. The State has asserted in other litigation that the CMS rule is invalid. *See* Doc. 51-1, Second Amended and Supplemental Complaint, *Louisiana v. Becerra*, No. 3:21-cv-03970 (W.D. La.). The U.S. Supreme Court did allow the CMS Rule to go into effect in *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam). But in staying the previously entered preliminary injunction, the Court didn’t address at least two independent constitutional grounds upon which the injunction was entered. *See Louisiana, et v. Becerra*, 2021 U.S. Dist. LEXIS 229949, at *37–46 (W.D. La. Nov. 30, 2021). And even for the

grounds the Supreme Court did address on the merits in *Biden v. Missouri*, it didn't adjudicate those claims on the merits. 142 S. Ct. at 655–56. Indeed, this Court reminded the parties during oral argument on the State's motion to dismiss that per curiam opinions at the stay stage may not be the final word on a particular legal question. That notwithstanding, Plaintiffs aren't entitled to a preliminary injunction because they haven't satisfied the other *Winter* factors.

B. Plaintiffs are not likely to succeed on their Equal Protection claim.

Plaintiffs allege HB 702 impermissibly exempts some “health care facilities,” but not others. *See* Doc. 43 at 10. Plaintiffs incorrectly assume all facilities providing any type of health care must be subject to the exact same regulations. That notion is belied by common sense, Equal Protection caselaw, and the State's broad power to engage in economic and health and safety regulation. Because Plaintiffs have failed to raise a serious Equal Protection question, this Court should not consider any harms stemming from an Equal Protection violation. *See Vanguard Outdoor, Ltd. Liab. Co. v. City of L.A.*, 648 F.3d 737, 740 (9th Cir. 2011) (“[A] preliminary injunction may be denied on the sole ground that the plaintiff has failed to raise even ‘serious questions’ going to the merits ... If the

Court so concludes, it need not address the other preliminary injunction factors.”) (cleaned up)).

1. Plaintiffs are not similarly situated.

“To prevail on an Equal Protection claim, plaintiffs must show ‘that a class that is similarly situated has been treated disparately.’” *Ariz. Dream Act Coal. v. Brewer*, 855 F.3d 957, 966 (9th Cir. 2017) (quotations omitted). “The groups must be comprised of similarly situated persons so that the factor motivating the alleged discrimination can be identified.” *Thornton v. City of St. Helens*, 425 F.3d 1158, 1167 (9th Cir. 2005); *accord Vision Net, Inc. v. State*, 447 P.3d 1034 (Mt. 2019).

Plaintiffs fail to identify similarly situated comparator classes. *See Ala. Dep’t of Revenue v. CSX Transp., Inc.*, 575 U.S. 21, 30 (2015) (“[P]icking a class is easy, but it is not easy to establish that the selected class is similarly situated ...”). They seemingly categorize any entity providing any type of medical care or accepting Medicare/Medicaid reimbursement as a “health care facility[y].” *See* Doc. 43 at 10.

The Ninth Circuit’s decision in *Harrison v. Kernan*, 971 F.3d 1069, 1075 (9th Cir. 2020), is instructive for identifying similarly situated classes. In *Harrison*, an inmate challenged a prison’s personal property

policy on the basis that it was applied differently to men’s and women’s populations. *Id.* at 1071. Under the policy, female inmates of the highest security classification and privilege groups had different property rights than male inmates of the same security classification and privilege groups. *Harrison* at 1076. Because prison officials used an identical methodology to determine security classifications of male and female inmates, the only relevant difference between the plaintiff male prisoner and imprisoned woman of the same security level and privilege group—when it came to allowable property under the Department-wide regulation—was sex. *Id.* at 1076. The inmates were, therefore, similarly situated in all relevant respects except for one factor that motivated the discriminatory treatment.

Plaintiffs here fail under that test. They don’t make any arguments to establish that clinics and hospitals are equivalent in “all similar respects” to nursing homes, long term care facilities, or assisted living facilities. *See* Doc. 43 at 11. Although hospitals and long-term care facilities are both technically “health care” facilities, they are distinct in many appreciable ways. *See* MCA § 50-5-101(30), (37). For one thing, the State uses distinct methodologies to regulate these different facilities. *See*

Harrison, 971 F.3d at 1075. They operate under different regulations and are licensed separately and differently. *See, e.g.*, MCA § 50-5-101(7), (26), (31), (37), (56) (defining assisted living facilities, long term care facilities, nursing homes, physician offices, and hospitals); *see also* Mont. Admin. R. 37.106.4, 37.106.6, 37.106.28 (setting distinct minimum standards for hospitals, nursing facilities, and assisted living facilities).

Plaintiffs flip the analysis and only point to the traits shared by the different types of healthcare facilities. *See* Doc. 43 at 11 (alleging “distinctions between different types of healthcare facilities that treat the same type of patients, utilizing the same types of health care providers”). But this is akin to claiming a hospital with a cafeteria must be regulated the same as a McDonalds because they both serve food. Plaintiffs fail to isolate and identify the one *dissimilar* trait that makes them the target of the discriminatory classification. *Harrison*, 971 F.3d at 1076. They, thus, cannot establish a likelihood of success on their Equal Protection claims.

2. HB 702 easily satisfies rational basis review.

This Court and Plaintiffs have recognized that Plaintiffs’ claims are subject to rational basis review. *See* Doc. 35 at 15, Doc. 43 at 11. So, even

if Plaintiffs are similarly situated to the exempted facilities, HB 702 must be upheld if there's a rational relationship between the disparity of treatment and some legitimate governmental purpose. *Allied Concrete & Supply Co. v. Baker*, 904 F.3d 1053, 1060 (9th Cir. 2018). "Further, because the classification is presumed constitutional, the burden is on the [party] attacking the legislative arrangement to negative every conceivable basis which might support it." *Id.* at 1060–61.

Plaintiffs make no substantive attempt to carry their burden, merely asserting the State has made "arbitrary distinctions between different types of healthcare facilities." Doc. 43 at 11. Simply calling something arbitrary doesn't make it so—and it certainly doesn't "disprove the rationality" of HB 702. *United States v. Ruiz-Chairez*, 493 F.3d 1089, 1091 (9th Cir. 2007). Hospitals and the exempted facilities under HB 702 are regulated separately because the core services provided are fundamentally different. *See, e.g.*, MCA § 50-5-225 (assisted living facilities may not hire certain persons, must provide personal services, and assistance with daily living, in recognition the population they care for triggers unique concerns). But this Court need not even rely on the State's reasoning. CMS itself said in May 2021 that vaccine policy may need to

be different for long-term care, assisted living, and nursing home facilities because their residents were more at risk with respect to communicable diseases and infections, including COVID-19. *See* Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs–IID) Residents, Clients, and Staff, 86 Fed. Reg. 26306, 26306 (May 13, 2021) (“ Individuals residing in congregate settings, regardless of health or medical conditions, are at greater risk of acquiring infections, and many residents and clients of long-term care (LTC) facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs–IID) face higher risk of severe illness due to age, disability, or underlying health conditions”). The Governor’s amendatory veto message on HB 702 expressly notes the exemptions were based on compliance with potential CMS requirements.¹ That should be the end of the inquiry.

¹ Letter from Governor Greg Gianforte to House Speaker Wylie Galt and Senate President Mark Blasdel at 2 (Apr. 28, 2021), <https://leg.mt.gov/bills/2021/AmdHtmH/HB0702GovAmd.pdf> (“Additionally, my amendment would ensure that provisions of HB 702 do not put licensed nursing homes, long-term care facilities, or assisted living facilities, in violation of regulations or guidance issued by the U.S. Centers for Medicare and Medicaid Services.”).

In any event, this Court’s rational-basis review is already “very narrow.” *Sagana v. Tenorio*, 384 F.3d 731, 743 (9th Cir. 2004). The State isn’t required to draw a perfect line in determining which entities are subject to HB 702 and which are not. *Slidewaters LLC v. Wash. State Dep’t of Labor & Indus.*, 4 F.4th 747,759–60 (9th Cir. 2021) (citing *Vance v. Bradley*, 440 U.S. 93, 108-09 (1979) (under rational-basis review, classifications that are under- or over-inclusive do not create constitutional violations)); *United States v. Navarro*, 800 F.3d 1104, 1114 (9th Cir. 2015) (“Under the rational-basis standard, we accept ‘generalizations even when there is an imperfect fit between means and ends. A classification does not fail rational-basis review because it is not made with mathematical nicety or because in practice it results in some inequality.’”) (quoting *Heller v. Doe ex rel. Doe*, 509 U.S. 312, 321 (1993); *Gazelka v. St. Peter’s Hosp.*, 420 P.3d 528, 535 (Mont. 2018) (A “statute does not violate the right to equal protection simply because it benefits a particular class”).

“The Supreme Court has held that a state legislature addressing health and safety reform ... may select one phase of one field and apply a remedy there, neglecting the others.” *Nat’l Ass’n for the Advancement*

of Psychoanalysis v. Cal. Bd. of Psychology, 228 F.3d 1043, 1052 (9th Cir. 2000) (upholding state’s psychology licensing scheme despite its licensing schemes for other, similar counseling professions being less stringent) (quotation marks omitted); *see also Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 547 (9th Cir. 2004) (statutory and regulatory scheme which required the licensing and regulation of medical facilities based on the number of abortions performed survived rational basis). In upholding California’s decision to restrict class III gaming operations to those conducted by Indian tribes on their own lands, the Ninth Circuit noted that “California could, of course, pursue [its interest in limiting the growth of class III gaming] even more effectively by banning class III gaming altogether. However ... rational-basis review does not require states to choose an all-or-nothing approach. It requires only that the means chosen are reasonable.” *Artichoke Joe's Cal. Grand Casino v. Norton*, 353 F.3d 712, 740 (9th Cir. 2003). The Montana Legislature’s decision to prevent vaccine discrimination in some facilities but not others enjoys the same deference. *See also Culinary Studios, Inc. v. Newsom*, 517 F. Supp. 3d 1042, 1073–74 (E.D. Cal. 2021) (State’s categorizations of essential vs. non-essential businesses during pandemic survived rational basis);

Safeway Inc. v. City & Cnty. of S.F., 797 F. Supp. 2d 964, 971–73 (N.D. Cal. 2011) (city ordinance prohibiting the sale of tobacco products in retail stores in which a pharmacy was located did not violate Equal Protection).

If that weren't enough, “a law must be upheld under rational basis review ‘if any state of facts reasonably may be conceived to justify’ the classifications imposed by the law.” *SmithKline Beecham Corp. v. Abbott Labs.*, 740 F.3d 471, 481 (9th Cir. 2014) (quoting *McGowan v. Maryland*, 366 U.S. 420, 426 (1961)); see also *Johnson v. Rancho Santiago Cmty. Coll. Dist.*, 623 F.3d 1011, 1031 (9th Cir. 2010) (“[A] state action need not actually further a legitimate interest; it is enough that the governing body could have rationally decided that the action would further that interest.”) (quotations omitted). It's the Plaintiffs' burden “to negative every conceivable basis which might support” statute's exemptions. *FCC v. Beach Commc'ns*, 508 U.S. 307, 315 (1993). They can't.

The State, meanwhile, possesses an unquestioned compelling interest in protecting the fundamental rights of its citizens. See *State ex. rel. Bartmess v. Board of Trustees*, 223 Mont. 269, 279, 726 P.2d 801, 807 (1986) (Morrison, J. concurring); *Roberts v. United States Jaycees*, 468

U.S. 609, 624 (1984); *Hurley v. Irish-American Gay*, 515 U.S. 557, 572 (1995) (“[Anti-discrimination provisions] are well within the State’s usual power to enact when a legislature has reason to believe that a given group is the target of discrimination, and they do not, as a general matter, violate the First or Fourteenth Amendments.”). This includes the right to pursue employment. *See Wadsworth v. Montana*, 275 Mont. 287, 911 P.2d 1165, 1176 (1996). The Montana Legislature also invoked its interest in protecting the individual right to privacy. *See* HB 702 (WHEREAS clause citing to *State v. Nelson*, 283 Mont. 231, 941 P.2d 441, 448 (1997) (“Medical records are quintessentially ‘private’ and deserve the utmost constitutional protection.”)).

The State has broad leeway to regulate healthcare facilities and protect the rights of its citizens. Plaintiffs don’t raise an Equal Protection question, much less a serious one. Thus, this court should reject their request for preliminary injunction on such claims.

II. Plaintiffs have not demonstrated irreparable injury.

Plaintiffs have failed to demonstrate they are “likely to suffer irreparable harm in the absence of preliminary relief.” *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). Plaintiffs’ purported injuries are not imminent

and rest on negative speculation about the interplay between MCA § 49-2-312 and the CMS Rule that current experience is not bearing out. Plaintiffs’ alleged irreparable injuries boil down to choosing between violating either MCA § 49-2-312 or the CMS Rule. *See* Doc. 43 at 11-14. But Plaintiffs present no evidence that any covered facilities are refusing to implement the CMS Rule, and any harm from violating HB 702 can be mended—completely—by reciting the Supremacy Clause as an affirmative defense to any administrative action taken due to HB 702.

A. Plaintiffs’ injuries are speculative.

“Speculative injury does not constitute irreparable injury sufficient to warrant granting a preliminary injunction. A plaintiff must do more than merely allege imminent harm sufficient to establish standing; a plaintiff must *demonstrate* immediate threatened injury as a prerequisite to preliminary injunctive relief.” *Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1022 (9th Cir. 2016) (emphasis in original) (quotations omitted).

1. There's no harm stemming from non-compliance with HB 702.

The alleged irreparable injuries associated with non-compliance with HB 702 are neither likely nor immediate.² Plaintiffs argue that the CMS Rule preempts HB 702. *See* Doc. 43 at 8-10. If that is correct, the CMS Rule acts as an affirmative defense to any action taken by the State pursuant to HB 702 – a defense that may be raised throughout the administrative process before subjecting Plaintiffs to liability. *Cf. Whole Woman's Health v. Jackson*, 142 S. Ct. 522, 530 n.1 (2021) (“But whatever a state statute may or may not say, applicable federal constitutional defenses always stand fully available when properly asserted.”).

As an initial matter, Plaintiffs offer virtually no evidence that they will be subject to irreparable harm through enforcement of HB 702. The depth of their evidence consists of PHS stating on February 15, 2022, that it has five pending claims with the Montana Human Rights Bureau (“MHRB”) alleging discrimination on the basis of vaccine status. *See* Doc.

² The State finds it noteworthy that *none* of the irreparable injuries asserted in Plaintiffs’ motion for preliminary injunction involve the alleged danger posed by unvaccinated individuals and COVID-19. *See* Doc. 43 at 11-14. After all, the amended complaints rely heavily on the alleged need to force workers to become vaccinated or terminate them due to fear of COVID-19. *See* Doc. 37 at ¶¶ 18, 21, 22, 24-26, 57-58, 72, 74; Doc. 38 at ¶¶ 16-20, 25-30, 35-37, 51-53, 59-62, 67, 69.

46 (Bodlovic Decl.) at ¶8. Plaintiffs do not provide the date on which these claims were filed—a fact that is relevant because the CMS Rule did not go into effect until February 14, 2022. *Id.* at ¶8. HB 702 has been in effect since May 7, 2021. Plaintiffs will have ample opportunity to use the Supremacy Clause as a shield against MHRB complaints. HB 702 is enforced by an aggrieved party filing a complaint with the Montana Department of Labor (“DOL”) within 180 days after the alleged discriminatory practice occurs. MCA § 49-2-501(1), (3). The respondent is notified of the complaint within 10 business days and then files and answer where the respondent may deny allegations and set forth affirmative defenses. MCA § 49-2-504(5). DOL then informally investigates the complaint to determine whether there is “reasonable cause to believe that the allegations are supported by a preponderance of the evidence.” MCA § 49-2-504(1). After informal investigation, DOL issues a finding on whether there is reasonable cause. MCA § 49-2-504(7)(a). If no reasonable cause exists, DOL dismisses the complaint. MCA § 49-2-504(7)(b). If DOL finds reasonable cause, DOL certifies the complaint for a contested case hearing. MCA § 49-2-504(7)(c); *see generally* MCA § 49-2-505 (contested case hearings). After a contested case hearing, a party may appeal the

decision of a hearings officer to the Montana Human Rights Commission. MCA § 49-2-505(4). After the Commission issues a final agency decision in writing, a party may petition a district court for judicial review. MCA § 49-2-505(9). Thus, where the CMS Rule preempts HB 702, Plaintiffs may rely on it as an affirmative defense to avoid liability.

Plaintiffs fret that they might have to participate in a costly and time-consuming civil administrative process during the pendency of this litigation. But that’s not an irreparable injury in the administrative context. The Supreme Court has said “[m]ere litigation expense, even substantial and unrecoupable cost, does not constitute irreparable injury.” *See FTC v. Standard Oil Co.*, 449 U.S. 232, 244 (1980) (quoting *Renegotiation Board v. Bannerkraft Clothing Co.*, 415 U.S. 1, 24 (1974)). And “the expense and annoyance of litigation is ‘part of the social burden of living under government.’” *Standard Oil Co.*, 449 U.S. at 244 (plaintiff was not irreparably harmed by FTC complaint not being immediately judicially reviewable); accord *Anaheim & Riverside v. Fed. Energy Regulatory Com.*, 692 F.2d 773, 779 (D.C. Cir. 1982). Even in the First Amendment context, where “bringing a colorable First Amendment claim ... certainly raises the specter of irreparable injury,” *Paramount Land Co. Ltd.*

P'ship v. Cal. Pistachio Comm'n, 491 F.3d 1003, 1012 (9th Cir. 2007), courts have found that subjecting an entity to a complaint and investigation is a “modest burden” compared to the State’s interest in enforcing its laws. *See Montanans for Cmty. Dev. v. Motl*, 54 F. Supp. 3d 1153, 1162 (D. Mont. 2014).

2. There’s no harm from the CMS Rule

Plaintiffs have not sufficiently shown that non-compliance with the CMS Rule will lead to irreparable injury.³ Plaintiffs allege consequences for non-compliance with CMS Rule such as “exclusion from CMS programs,” “monetary penalties,” “denial of payment for new admissions and other services,” and “termination of participation in Medicare and Medicaid.” Doc. 43 at 12. As a result of these measures, they speculate that there will be less health care available for Montanans. *See* Doc. 43 at 12–13. They assert no injuries related to immunocompromised individuals and COVID-19. *See id.* at 11–14.

³ Plaintiffs cite *Cottonwood Envtl. Law Ctr. v. United States Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015), for the proposition that demonstrating irreparable injury isn’t “an onerous task.” Doc. 43 at 12. It’s important to note that *Cottonwood*’s statement was made in the specific context of the Endangered Species Act. *Id.* (“In light of the stated purposes of the ESA in conserving endangered and threatened species and the ecosystems that support them, establishing irreparable injury should not be an onerous task for plaintiffs.”) (citing 16 U.S.C. § 1531 (Congressional findings and declaration of purposes and policy)).

First, Plaintiffs have failed to show that they, or any other facilities, are currently out of compliance with the CMS Rule or will be in the future. Without evidence, their concerns about non-compliance are pure conjecture and don't satisfy the burden to justify their request for an extraordinary and drastic remedy.

The State, moreover, proffers evidence that there are currently no facilities out of compliance with the CMS Rule. Pursuant to CMS Guidance, the task of verifying compliance with the CMS Rule falls to state surveyors, who regularly evaluate state-run and private healthcare facilities' compliance with Medicare and Medicaid requirements.⁴ In their first week of surveying, Montana's surveyors identified no vaccination deficiency with respect to all but one facility.⁵ Decl. Carter Anderson ¶ 12–13. The one facility that was deficient was not facing enforcement because it has a plan to achieve 100% compliance within 60 days. *Id.* ¶

⁴ See CMS, *Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Jan. 14, 2022) (“Jan. 14 Guidance”), <https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf>. Within thirty days, States must send surveyors out to ensure facilities have policies and procedures in place, that 100% of employees have received at least the first dose of the vaccine or have been granted an exemption; verify that facilities have plans to come into compliance if not already in compliance; and assess fines and penalties to be issued to noncompliant facilities. *Id.*

⁵ Another facility was cited for failure to include, in the required facility policy, the use of N-95 masks for vaccine exempt employees. *Id.* ¶13.

13. The State has also received no complaints about non-compliance with the CMS Rule at facilities in Montana. *Id.* ¶14.

Next, as discussed above, if this Court determines Plaintiffs are likely to succeed on the merits of the Supremacy Clause claim, Plaintiffs have an affirmative defense to liability under HB 702. With no threat of liability under HB 702, Plaintiffs are free to comply with their obligations under the CMS Rule. *See* Doc. 43 at 14. Without those harms on the table, there's no need for this Court to issue an injunction at all.

B The relief requested is too broad.

Even if this Court finds irreparable injury in some form, the preliminary relief granted must still be symmetrical to the demonstrated injury. *League of Wilderness Defs./Blue Mts. Biodiversity Project v. Connaughton*, 752 F.3d 755, 767 (9th Cir. 2014) (“Injunctive relief must be tailored to remedy the specific harm alleged, and an overbroad preliminary injunction is an abuse of discretion.”) (quotations omitted). If operative, the CMS Rule’s preemption of HB 702 is narrow, and any injunction must be tailored accordingly.

Plaintiffs ask this Court to “enjoin[] Defendants from enforcing [HB 702] against PH&S and all other Montana facilities covered by the CMS

rule during the pendency of this litigation.” Doc. 43 at 6. The requested relief is overbroad in both in the parties it applies to and in duration. This Court should limit any injunctive relief in two ways: (1) to only the plaintiff facilities subject to the CMS Rule and (2) for only so long as the CMS Rule is operative. *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1140 (9th Cir. 2009) (district court failed to tailor the injunction to remedy the specific harm alleged when it enjoined enforcement of anti-discrimination provisions as to all pharmacists and pharmacies in a state); *see also City & Cty. of S.F. v. United States Citizenship & Immigration Servs.*, 408 F. Supp. 3d 1057, 1129–30 (N.D. Cal. 2019) (district court declined to enjoin implementation of the “public charge” immigration rule nationwide—limiting it to the city and county plaintiffs who had shown that they would suffer irreparable harm from the loss of federal Medicaid funding).

It’s important to note that the irreparable injuries alleged for purposes of this motion are limited to *either* (1) liability for violating HB 702; *or* (2) consequences for non-compliance with CMS Rule such as “exclusion from CMS programs,” “monetary penalties,” denial of payment for new

admissions and other services,” and “termination of participation in Medicare and Medicaid.” *See* Doc. 43 at 11–12.

As discussed, Plaintiffs’ Equal Protection challenge is a nonstarter. Their only plausible avenue for an injunction, accordingly, is an as-applied challenge based on preemption. Thus, the only harms for the Court to prevent are those inflicted on providers in this litigation as a result of state law requirements that are subject to preemption by the CMS Rule. A broader injunction would “erroneously treat[] the as-applied challenge brought in this case as a facial challenge.” *Stormans*, 586 F.3d at 1140 (citing *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328-29 (2006) (“[g]enerally speaking, when confronting a constitutional flaw in a statute, we try to limit the solution to the problem. We ... enjoin only the unconstitutional applications of a statute while leaving other applications in force.”)); *City & Cty. of S.F. v. Trump*, 897 F.3d 1225, 1245 (9th Cir. 2018) (The record must sufficiently support the breadth of the injunction). Health care providers not subject to irreparable harm by CMS Rule are not entitled to an injunction.

Plaintiffs cannot mix and match causes of action, irreparable harms, and plaintiffs to build a complete case for a preliminary injunction.

III The balance of equities and the public interest favor HB 702.

The analyses of the public interest and balance of equities merge when the government is a party. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Plaintiffs must establish that “the balance of equities tips in [their] favor.” *Winter*, 129 S. Ct. at 374. Likewise, a district court should also consider whether a preliminary injunction would be in the public interest if “the impact of an injunction reaches beyond the parties, carrying with it a potential for public consequences.” *Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1023 (9th Cir. 2016). “In fact, ‘courts ... should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.’” *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1139 (9th Cir. 2009) (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)). An overbroad injunction can also implicate the public interest. *Stormans*, 586 F.3d 1139.

The fact that HB 702 is a duly enacted state statute weighs against granting an injunction. *Golden Gate Rest. Ass'n v. City of S.F.*, 512 F.3d

1112, 1126 (9th Cir. 2008) (“The public interest may be declared in the form of a statute.”); *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (A State “suffers a form of irreparable injury” any time it is prevented from “effectuating” laws “enacted by representatives of its people.”). The State—and the public at large—maintain strong interests in enforcing HB 702. *Preminger v. Principi*, 422 F.3d 815, 826 (9th Cir. 2005) (public interest did not favor injunction in First Amendment challenge because the government had a competing public interest in providing the best possible care, in a politically neutral environment). Pursuant to HB 702, Montanans now possess the autonomy to choose for themselves whether to receive the COVID-19 vaccine and others without fear of reprisal.

First, the State possesses a compelling interest in preventing discrimination. *See Hurley*, 515 U.S. at 572; *Roberts*, 468 U.S. at 624 (1984). The State “enjoys broad authority to create rights of public access on behalf of its citizens.” 468 U.S. at 625.

Second, the State has a compelling interest in protecting the individual right to privacy. *See* HB 702 (WHEREAS clause citing to *State v.*

Nelson, 941 P.2d at 448 (“Medical records are quintessentially private and deserve the utmost constitutional protection.”)).

Third, HB 702 protects Montanans’ fundamental right to pursue employment. *See Wadsworth v. Montana*, 911 P.2d 1165, 1176 (Mt. 1996) (The right “to pursue employment” is a fundamental right.) (citing MONT. CONST. art II, § 3). HB 702 protects Montana workers from coercion and fear of losing their jobs. *See* 86 Fed. Reg. at 61607 (“The most important inducement will be the fear of job loss, coupled with the examples set by fellow vaccine-hesitant workers who are accepting vaccination more or less simultaneously”).

Finally, it’s ironic that Plaintiffs bemoan (1) having to choose between compliance with state and federal law and (2) a fear a lack of health care options for Montanans—considering health care facilities already face a Hobson’s choice of terminating or being unable to hire much-needed unvaccinated staff, or falling below mandatory staffing requirements. But Plaintiffs would prefer this Court ignore the plain consequences of enjoining HB 702. *See Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 676 (9th Cir. 1988) (“failure to identify, evaluate, and weigh the potential harm alleged by the government is reversible

error”). In addition to protecting individual choice and privacy, it protects Montana healthcare facilities from worsening their already existing staffing problems.

Particularly interesting is Plaintiffs’ assertion that “a preliminary injunction will allow Plaintiffs to receive and provide quality healthcare in Montana.” Doc. 43 at 14. The paradigm of “mass disruption of healthcare services in Montana” if the law is not enjoined, *see* Doc. 43 at 19, is undermined by the fact CMS Rule itself is slated to cause many of the health care problems Plaintiffs lament. CMS estimated that the CMS Rule will force 2.4 million unvaccinated healthcare workers to either forfeit informed consent and bodily autonomy (by being forced to receive the vaccine) or their jobs. 86 Fed. Reg. at 61607. At the same time, it admits, “currently there are endemic staff shortages for almost all categories of employees at almost all kinds of healthcare providers and supplier[s].” *Id.* at 61607. One in five hospitals “report that they are currently experiencing a critical staffing shortage.” *Id.* at 61559. CMS even acknowledges that “these may be made worse” when unvaccinated workers leave as a result of the Rule. *Id.* at 61607.

Montana is no exception: Ten rural health care providers in Montana wrote to the State to express their concerns about the devastating impact of the CMS Rule. *See* Decl. Mary Stukalof, Ex. 1 (“MHN Letter”). Health care workers would rather leave employment at these facilities than receive the COVID vaccine. MHN Letter at 1. The alleged choice between HB 702 and the CMS Rule, they explain, isn’t the only one faced by health care facilities:

On the one hand, we cannot defy this mandate by continuing to employ those workers without punitive action being taken by CMS. On the other hand, if those workers persist in refusing to get the vaccine, we may need to close some of our departments due to severe staffing shortages. Either way, we, and the community, lose out. In some instances, a staffing shortage will be the lesser of the two evils by creating a hardship, but not causing us to close our doors. In other instances, the staffing shortage may cause the doors to close. Either scenario could cause a high percentage of long term care residents to be displaced or Medicare and Medicaid beneficiaries to lose local services.

MHN Letter at 2.

The CMS Rule exacerbates pre-existing labor shortages, which both CMS and Montana healthcare providers concede exposes patients to danger and lost access to care. So even without HB 702’s conflict with the CMS Rule, Montanans will lose access to healthcare.

Finally, the public interest heavily favors the State because Plaintiffs' case is now anachronistic, at best. The basis for the CMS Mandate and Plaintiffs' entire litigating position is that vaccinating health care workers will limit or stop transmission of COVID. That is now demonstrably false. The Delta variant effectively disappeared within weeks of the passage of the CMS Rule, replaced by the milder Omicron variant, which now accounts for 99.9% of all COVID cases in the United States.⁶ Omicron's transmission is largely undeterred by the vaccines.⁷ The CDC itself says "breakthrough infections in people who are vaccinated are likely to occur."⁸ Even Dr. Anthony Fauci warned that "Omicron, with its extraordinary, unprecedented degree of ... transmissibility, will ultimately find just about everybody" and that even those who have received

⁶ See CDC COVID Data Tracker, *Variant Proportions*, <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> (for the week ending Feb. 26, 2022) (last visited Mar. 2, 2022).

⁷ See Mark G. Thompson, et al. *Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance — VISION Network, 10 States, August 2021–January 2022*. CDC *MMWR Morb Mortal Wkly Rep* 2022; 71:139–145, (Jan. 21, 2022), <http://dx.doi.org/10.15585/mmwr.mm7104e3> (showing that vaccine efficacy is drastically reduced at preventing the transmission of the Omicron variant)

⁸ Centers for Disease Control & Prevention, *Omicron Variant: What You Need to Know* (Updated Feb. 2, 2022), <https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html> (last visited Mar. 2, 2022).

the initial vaccine and subsequent booster “will still get infected.”⁹ And even the CDC Director has acknowledged that the Omicron variant is far less severe than Delta.¹⁰ The science has apparently changed so much that the CDC has recognized staffing shortages by issuing new guidance that permits Covid *positive* employees to return to work, even if they are still testing positive, while the CMS Rule prohibits COVID-*negative* unvaccinated individuals from working in covered facilities at all, unless they obtain an exemption.¹¹

The CMS Rule’s days could be numbered—due to either judicial intervention or changing science. But meanwhile, Montana health care workers could still be forced to choose between their livelihoods and a COVID-19 vaccine that still has questions about its risks and side

⁹ Travis Caldwell, et al., *The highly contagious Omicron variant will ‘find just about everybody,’ Fauci says, but vaccinated people will still fare better*, CNN (Jan. 12, 2022), <https://www.cnn.com/2022/01/11/health/us-coronavirus-tuesday/index.html>.

¹⁰ *CDC’s Walensky cites study showing Omicron has 91% lower risk of death than Delta*, yahoo!news (Jan. 12, 2022), <https://news.yahoo.com/cdc-walensky>.

¹¹ CDC, Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 (Jan. 21, 2022), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>.

effects.¹² HB 702 protects their right to decide for themselves whether the vaccine is the right choice.

CONCLUSION

For the reasons set forth above, this Court should deny Plaintiffs' Motion for Preliminary Injunction.

DATED this 2nd day of March, 2022.

AUSTIN KNUDSEN
Montana Attorney General

KRISTIN HANSEN
Lieutenant General

DAVID M.S. DEWHIRST
Solicitor General

BRENT MEAD

¹² See, e.g., CDC, Omicron Variant: What You Need to Know (Dec. 20, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html>. And that comes amid increasing warnings about the risks and side effects posed by the vaccines. E.g., CDC, Selected Adverse Events Reported after COVID-19 Vaccination (Jan. 24, 2022), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html> ("CDC has also identified nine deaths that have been caused by or were directly attributed to [thrombosis with thrombocytopenia syndrome] following J&J/Janssen COVID-19 vaccination."); Matthew E. Oster et al., *Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021*, 327(4) J. AM. MED. ASS'N 331 (Jan. 25, 2022), <https://jamanetwork.com/journals/jama/fullarticle/2788346>; Jennifer Couzin-Frankel & Gretchen Vogel, *In rare cases, coronavirus vaccines may cause Long Covid-like symptoms*, 375 *SCIENCE* 6579 (JAN. 20 2022), <https://www.science.org/content/article/rare-cases-coronavirus-vaccines-may-cause-long-covid-symptoms>.

Assistant Solicitor General

ALWYN LANSING

Assistant Attorney General

EMILY JONES

Special Assistant Attorney General

/s/ Christian Corrigan

CHRISTIAN CORRIGAN

Assistant Solicitor General

215 North Sanders

P.O. Box 201401

Helena, MT 59620-1401

christian.corrigan@mt.gov

Attorneys for Defendant

CERTIFICATE OF COMPLIANCE

Pursuant to Rule Local Rule 7.1(d)(2), I certify that this brief is printed with a proportionately spaced Century Schoolbook text typeface of 14 points; is double-spaced except for footnotes and for quoted and indented material; and the word count calculated by Microsoft Word for Windows is 6,405 words, excluding tables of content and authority, certificate of service, certificate of compliance, and exhibit index.

/s/ Christian Corrigan
CHRISTIAN CORRIGAN

CERTIFICATE OF SERVICE

I certify that on this date, an accurate copy of the foregoing document was served electronically through the Court's CM/ECF system on registered counsel.

Dated: March 2, 2022

/s/ Christian Corrigan
CHRISTIAN CORRIGAN

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

MONTANA MEDICAL
ASSOCIATION, et al.,

Plaintiffs,

and

MONTANA NURSES ASSOCIATION,

Plaintiff-Intervenor

v.

AUSTIN KNUDSEN, et al.,

Defendants.

CV 21-108-M-DWM

**DECLARATION OF CARTER
ANDERSON**

DECLARATION OF CARTER ANDERSON

I, Carter Anderson, declare as follows:

1. I am the Inspector General of the Montana Department of Public Health and Human Services (DPHHS) and head of the Office of Inspector General (OIG) (formerly, the Quality Assurance Division of DPHHS). This declaration is based on my personal knowledge and experience, and I could competently testify to its contents if called to do so. .

2. I have been employed by the State of Montana for 3 1/2 years in my current position. DPHHS's OIG is responsible for, among other things,

licensing certain healthcare facilities and for conducting survey (inspection/investigation) and certification functions with respect to healthcare facilities that seek certification or recertification as Medicare or Medicaid providers or suppliers.

3. The Centers for Medicare & Medicaid Services (CMS) is responsible for oversight of, and compliance with the Medicare health and safety standards for, laboratories, acute and continuing care providers (including hospitals, nursing homes, home health agencies (HHAs), end-stage renal disease (ESRD) facilities, hospices, and other facilities serving Medicare and Medicaid beneficiaries), and makes available to beneficiaries, providers/suppliers, researchers and State surveyors information about these activities.

4. CMS contracts, under section 1864 of the Social Security Act, with State Survey Agencies to conduct surveys (inspections) for these oversight and compliance determinations.

5. DPHHS is the State Survey Agency for the State of Montana. Within DPHHS, that function has been assigned to the OIG's Certification Bureau. OIG has 22 surveyor positions, which includes the Life Safety and CLIA (Clinical Laboratory Improvements Act) programs, 3 supervisors, and a bureau chief.

6. Montana surveyors conduct a number of types of surveys, including

- Certification.
- Recertification.
- Complaint.
- Infection control.
- CLIA.
- Life Safety.

7. Surveyors operate under Social Security Act § 1864, 42 USC 1395aa, and 42 CFR §§ 488.11, 488.10, 488.9, and 489.13. CMS's Medicaid State Operations Manual Chapter 1, Program Background and Responsibilities details the expected activities of State Survey Agencies.

8. Surveys are unannounced. Surveyors will arrive on-site at a facility, conduct an entrance conference with the facility administrator and others, and inspect and investigate the facility based on pre-established survey protocols, depending on the type of survey. This includes inspection of a facility's relevant books and records, as well as interviews of staff and patients (or residents, in the case of nursing homes and other long-term care facilities). Surveys include, among other things,

- Observation of the manner in which healthcare services are delivered, or laboratory services are performed, in order to ascertain that the entity is operating in accordance with Federal requirements to protect health and safety.
- Scrutinizing the provider's/supplier's records to determine whether professional healthcare staff members have been properly noting and evaluating the progress of the care being provided or managing provider operations with continuing vigilance.

9. Regardless of whether the survey is conducted for Medicare or Medicaid purposes, the State Survey Agency surveys a healthcare entity in exactly the same way to ascertain and certify whether it meets the applicable Federal health and safety requirements for participation. Through the survey, the State Survey Agency determines, whether and how the applicable conditions, requirements, and standards are met.

10. The State Survey Agency certifies to CMS its findings. If the surveyors determine that a healthcare facility has not met, or is not in

substantial compliance with one or more of the applicable federal regulations, the Survey Agency will issue a "Statement of Deficiencies," on Form CMS-2567, to the facility, detailing its findings of noncompliance/deficiencies. The facility is given 10 calendar days in which to respond with a Plan of Correction (PoC) for each cited deficiency. If the facility has not come into compliance with all applicable requirements within the time period accepted as reasonable, the Survey Agency will certify noncompliance notwithstanding a PoC. CMS will determine the appropriate penalty(ies), if any, to impose on the facility, except with respect to Medicaid-only facilities, where the State Medicaid Agency must undertake either an action to terminate the non-complying facility's Medicaid, apply one or more of the statutory remedies (if a nursing facility), or both.

11. Montana State surveyors usually spend every other week in the field, engaging in unannounced surveys. The week of February 14, 2022 was the first week in which Montana health care facilities that are Medicare and Medicaid-certified providers or suppliers were required to be in compliance with Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (CMS Rule), pursuant to Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, QSO-22-09-ALL (QSO-22-09-ALL), issued January 14, 2022. During that week, Montana State surveyors conducted a total of seven (7) surveys, of which two were revisit surveys and five were recertification surveys. Six of the seven facilities surveyed that week were long term care facilities; the seventh facility was a home health agency.

12. In QSO-22-09-ALL, CMS indicated that, for the period between February 14, 2022 and March 15, 2022, a facility would be compliant under

the CMS Rule if it demonstrates (1) policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient/resident contact are vaccinated for COVID-19, and (2) 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted, a qualifying exemption, or have been identified as having a temporary delay, as recommended by CDC. If less than 100% of all staff meet such requirements, CMS directs that the facility is noncompliant with the CMS Rule and, if surveyed, would receive notice of its noncompliance with the 100% standard. However, a facility that is above 80% compliance and has a plan to achieve 100% compliance within 60 days would not be subject to additional enforcement action. QSO-22-09-ALL at 3.

13. With respect to the seven health care facilities surveyed during the week of February 14th, Montana State surveyors identified no vaccination deficiency with respect to five facilities (four long term care facilities and one home health agency) and deficiencies with respect to two long term care facilities. The comments noted with respect to one noncompliant long term care facility that its facility policy did not include the use of N-95 masks for vaccine exempt employees. With respect to the other noncompliant facility, the comments were that it had greater than 80% compliance at 99%--meeting the current federal standard to avoid additional enforcement action. There was, however, a COVID-19 outbreak in progress.

14. We generally receive complaints about facility infection control programs. However, to this point, we have not received any complaints that a Montana health care facility is in noncompliance with the CMS Rule. In fact, the majority of the complaints that we have received regarding the CMS Rule relate to denial of an exemption.

I DECLARE UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES AND THE STATE OF MONTANA THAT, TO THE BEST OF MY KNOWLEDGE, THE FOREGOING IS TRUE AND CORRECT.

A handwritten signature in black ink, appearing to read "C. Anderson", is written over a horizontal line.

Carter Anderson

Executed in Helena, Montana, this 2nd day of March, 2022.

AUSTIN KNUDSEN
Montana Attorney General

KRISTIN HANSEN
Lieutenant General

DAVID M.S. DEWHIRST
Solicitor General

CHRISTIAN CORRIGAN
Assistant Solicitor General

BRENT MEAD
Assistant Solicitor General

ALWYN LANSING
Assistant Attorney General

215 North Sanders

P.O. Box 201401

Helena, MT 59620-1401

Phone: 406-444-2026

Fax: 406-444-3549

david.dewhirst@mt.gov

christian.corrigan@mt.gov

brent.mead2@mt.gov

alwyn.lansing@mt.gov

EMILY JONES
Special Assistant Attorney General

115 N. Broadway, Suite 410

Billings, MT 59101

Phone: 406-384-7990

emily@joneslawmt.com

Attorneys for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION,
et. al.,

Plaintiffs,

and

MONTANA NURSES ASSOCIATION,

Plaintiff-Intervenors,

v.

AUSTIN KNUDSEN, et al.,

Defendants.

CV-21-108-M-DWM

**DECLARATION OF MARY
STUKALOFF**

I, Mary Stukaloff, declare:

1. I am employed as an administrative assistant at the Montana Attorney General's Office and am competent to testify to the matters set forth.
2. As part of my job duties, I receive, open, and file mail received by the Attorney General's Office.
3. On February 10, 2022, the Attorney General's Office received a letter from Montana Health Network.
4. I stamped and scanned said letter into the Attorney General's Office's mail logging system on February 10, 2022.

5. Attached here as Exhibit A is a true and correct copy of Montana Health Network's letter dated January 14, 2022, and received by the Attorney General's Office on February 10, 2022.

I hereby declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

DATED this 2nd day of March, 2022.


MARY STUKALOFF



MONTANA HEALTH NETWORK

MONTANA HEALTH NETWORK, INC. – FRONTIER FACILITIES WORKGROUP
RURAL HEALTH DEVELOPMENT, INC.
519 PLEASANT STREET
MILES CITY, MONTANA 59301
(406) 234-1420
FAX: (406) 234-1423

ATTORNEY GENERAL'S OFFICE
HELENA, MONTANA

FEB 10 2022

SCANNED

RECEIVED

FEB 10 2022

ATTORNEY GENERAL'S OFFICE
HELENA, MONTANA

January 14, 2022

Honorable Elected Official:

We, the undersigned, wish to collectively share information about the impact to our facilities and communities due to President Biden's September 2021 proclamation mandating covid-19 vaccination for all healthcare workers and the subsequent Interim Final Rule ("IFR") requiring all CMS providers to fully vaccinate staff and other covered individuals. We have grave concerns about the survivability of rural healthcare as a result of this mandate. The CMS rules will create havoc for all small rural hospitals and nursing homes nationwide over the coming weeks. We ask that your office consider these implications and support an injunction or legislation that would make this situation and any others like it illegal.

The crux of the problem is that they have made the mandate a "condition of participation" in the Medicare and Medicaid programs. CMS providers have a contract which lists the conditions under which the contract is valid. If a facility violates one or more of those conditions, they risk being decertified from the program. If they ignore the vaccine mandate and continue billing Medicare and Medicaid, they are committing fraud against the program, which could result in steep fines and jail terms for some of its employees.

On average, most small healthcare facilities in our remote, isolated Montana communities receive 60% or more of their gross billing from CMS. Without that revenue, we would not be able to pay our bills. We would not be able to provide long-term care for our long-term care residents, many of whom rely on Medicaid to pay for services. We would go insolvent quickly, as our meager financial reserves become depleted if we have any reserves at all. In any instance, we could not rely on commercial insurance or private payers to keep us afloat.

Further, by making it a "condition of participation", it makes it difficult if not impossible for Montana facilities to obtain or retain healthcare licenses even if they chose to decertify their CMS status. Currently, Montana's licensure and certification bureaus follow Federal standards closely when reviewing operations and care to either license or certify healthcare facilities. It is unclear despite inquiries to the state Licensure Bureau what regulations or "conditions of participation" healthcare facilities would follow if they don't receive Medicare or Medicaid.

With varying reasons, several healthcare workers refuse to receive the vaccine, indicating that they intend to terminate their employment if forced to do so. According to the mandate, all facilities had to produce a policy that requires all employees to be fully vaccinated in two stages

ending January 4, 2022 (new deadline of February 14, 2022), unless they have a medical exemption or religious exemption. Those employees who are not vaccinated by that date are violating the policy, which means that they are no longer employable by any facility that receives Medicare or Medicaid funding.

This puts our local healthcare facilities in difficult positions. On the one hand, we cannot defy the mandate by continuing to employ those workers without punitive action being taken by CMS. On the other hand, if those workers persist in refusing to receive the vaccine, we may need to close some of our departments due to severe staffing shortages. Either way, we, and the community, lose out. In some instances, a staffing shortage will be the lesser of the two evils by creating a hardship, but not causing us to close the doors. In other instances, the staffing shortage may cause the doors to close. Either scenario could cause a high percentage of long term care residents to be displaced or Medicare and Medicaid beneficiaries to lose local services. Whether our facilities lose significant percentages of staff or significant portions of funding, this would mean the end to significant local healthcare services to those who have paid into these benefits throughout their entire lifetimes.

Permanent and temporary staff have been difficult to find, and we can expect to pay the following agency rates for the following positions: at least \$150/hour for nurses and \$55/hour for CNAs. Some of our communities have to advertise \$140/hour for radiology techs, all with minimal response. Current staff are working overtime shifts at levels that could exacerbate workforce burnout in a profession that had significant shortages prior to the pandemic. The impact of this mandate on all of our healthcare organizations will be to decrease or stop local access to healthcare for thousands of Montana's residents and millions of Americans.

The impact will hit especially hard in rural and frontier communities where distances to a healthcare facility could exceed 100 miles one way. People who choose the rural and frontier lifestyles won't have the option of going to another facility down the block or a mile or two away. Because of this, many will forego care because of the inconvenience or impossibility of travel and added costs associated with it. The loss of access to critical and life-saving hospital and clinic services as well as long term care will cost lives and diminish the overall health of our communities. Dozens of long term care residents could be displaced from their homes, and thousands of Medicare and Medicaid beneficiaries could lose access to healthcare completely. These individuals cannot even expect to get access in other locations because even the larger healthcare facilities in larger communities are struggling to staff their facilities and serve their communities much less the displaced patients from our communities.

Small healthcare organizations are the top one or two employers in rural communities across America that offer higher paying jobs and usually higher-than-minimum wage jobs for unlicensed employees. Closure of hospitals and clinics will have a high, undetermined negative economic impact on communities of any size. It will also make it difficult for other community businesses to recruit employees to a community without access to basic healthcare. Our communities function with all employers, businesses, and organizations being interdependent upon each other for long term survival and the survivability of the community as a whole. There is a far-reaching negative impact that could create "ghost towns" throughout rural America due to people leaving for lack of jobs, lack of healthcare, lack of education, and lack of a livelihood.

There is no doubt that we need to be prudent and protect our communities and patients much the way we have since the start of the pandemic. However, this mandate will rob healthcare workers who exercise their right to choose to not be vaccinated of their livelihood, will cause economic strife in community businesses where healthcare workers do business, and sharply decrease access to healthcare through decreased services and closures. It will potentially decimate our frontier communities and displace thousands of patients in rural America.

Our facilities follow the CDC healthcare worker recommendations to the tee, which so far have greatly limited nosocomial infections for both staff and patients and have resulted in minimal infections within our facilities despite potential for community spread. We feel that we can manage the risk, but if we lose any of our workers, we aren't as certain that we will be able to continue to operate and retain the safety and health in our facilities and communities. Current mitigating actions have been successful, and additional mandates most likely won't improve infection rates or negative patient outcomes. As representatives of constituents in Montana who will be drastically affected by this mandate, it is imperative that you take the steps necessary to implement an injunction on this mandate or require CMS to rescind it. It is time to reign in and tighten congressional oversight on CMS's power and rulemaking authority.

SIGNATURE	NAME	TITLE	FACILITY	CITY
<i>David Espeland</i>	David Espeland	CEO	Fallon Medical Complex	Baker, MT
<i>Audrey Stromberg</i>	Audrey Stromberg	Administrator	Roosevelt Medical Center	Culbertson MT
<i>N. Rosaaen</i>	Nancy Rosaaen	CEO	McCone County Health Center	Circle
<i>B. Keltner</i>	Burt J Keltner	CEO	Prairie Community Hospital	Terry, MT
<i>Sean Hill</i>	Sean Hill	Ceo	Powder river manor	Broadus, mt
<i>Mindy Price</i>	Mindy Price	CEO	Rosebud Health Care Center	Forsyth
<i>Earline Lawrence</i>	Earline Lawrence	COO	Garfield County Health Center	Jordan
<i>Ryan Tooke</i>	Ryan Tooke	CEO	Dahl Memorial	Ekalaka
<i>Andrew Riggan</i>	Andrew Riggan	CEO	Phillips County Hospital	Malta
<i>Kody Brinton</i>	Kody Brinton	CEO	Daniels Memorial Healthcare Center	Scobey

citrix | RightSignature

SIGNATURE CERTIFICATE**REFERENCE NUMBER**

5739AAB6-1FFE-4E17-BA73-049E0BA2FA51

TRANSACTION DETAILS**Reference Number**

5739AAB6-1FFE-4E17-BA73-049E0BA2FA51

Transaction Type

Signature Request

Sent At

01/26/2022 13:49 MST

Executed At

02/01/2022 16:43 MST

Identity Method

email

Distribution Method

email

Signed Checksum

3ee3bbefba042494e73893bc1e7cc315cbb7df0a18dfbc1d829827f552ded055

Signer Sequencing

Disabled

Document Passcode

Disabled

DOCUMENT DETAILS**Document Name**

Legislative Letter On Mandates Final

Filename

legislative_letter_on_mandates_final.docx

Pages

3 pages

Content Type

application/vnd.openxmlformats-officedocument.wordprocessingml.document

File Size

43.2 KB

Original Checksum

f62818114af6221f8ee24f359c326fca731ed64259bc84a880e56bd56f8ae6d7

SIGNERS**SIGNER****Name**

Earline Lawrence

Email

elawrence@gchealth.net

Components

5

E-SIGNATURE**Status**

signed

Multi-factor Digital Fingerprint Checksum

d0dd79acfee25ca560be04aa50ea1d9fda5752be3a3ea63209b2711ce3290829

IP Address

216.228.61.22

Device

Chrome via Windows

Drawn Signature**Signature Reference ID**

B5F2D6C0

Signature Biometric Count

790

EVENTS**Viewed At**

02/01/2022 16:40 MST

Identity Authenticated At

02/01/2022 16:43 MST

Signed At

02/01/2022 16:43 MST

Name

Ryan Tooke

Email

rtooke@dmhainc.com

Components

5

Status

signed

Multi-factor Digital Fingerprint Checksum

efa9d0eaa81465ebe2a569a532ec915b1d2f62a9fd70b7098ff74212d34dcca2

IP Address

72.250.130.36

Device

Chrome via Windows

Drawn Signature**Signature Reference ID**

3528D294

Signature Biometric Count

719

Viewed At

01/31/2022 09:05 MST

Identity Authenticated At

01/31/2022 09:06 MST

Signed At

01/31/2022 09:06 MST

298

Name
Mindy Price
Email
mprice@rosebudhealthcare.com
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
19b805e98c503cb24eec131b90ece47e6856acecac1bcfb3d3607842903e050c
IP Address
72.36.14.12
Device
Chrome via Windows
Typed Signature

Viewed At
01/26/2022 13:58 MST
Identity Authenticated At
01/26/2022 13:58 MST
Signed At
01/26/2022 13:58 MST

Mindy Price

Signature Reference ID
D2121859

Name
Burt Keltner
Email
bkeltner@pchc-mt.com
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
6851cfcf56a79ad84efdcdf83f38eee4d60942b40dcda094e632b4a40be6
IP Address
108.59.121.114
Device
Chrome via Windows
Drawn Signature

Viewed At
01/26/2022 13:55 MST
Identity Authenticated At
01/26/2022 13:56 MST
Signed At
01/26/2022 13:56 MST

B. Keltner

Signature Reference ID
37997C79
Signature Biometric Count
328

Name
Audrey Stromberg
Email
astromberg@roosmem.org
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
c4f8f88607f1ba5fbd4c4dbdbf267fec8d6425f36b9c07adfcbe7593a3a4dba9
IP Address
199.190.61.87
Device
Chrome via Windows
Typed Signature

Viewed At
01/26/2022 13:51 MST
Identity Authenticated At
01/26/2022 13:52 MST
Signed At
01/26/2022 13:52 MST

Audrey Stromberg

Signature Reference ID
22DC2D83

Name
Nancy Rosaaen
Email
nrosaaen@mcconehealth.org
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
99b1110e6be6af536dce5ee6a805d200f6f5577b5eb38f635e3b4adbca7b5599
IP Address
216.228.45.220
Device
Chrome via Windows
Typed Signature

Viewed At
01/26/2022 13:50 MST
Identity Authenticated At
01/26/2022 13:51 MST
Signed At
01/26/2022 13:51 MST

N. Rosaaen

Signature Reference ID
2F168983

Name
Sean Hill
Email
sean.hill@powderriverhealth.org
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
7e111f5ca441d8b2a4b78d8b3955b8e425249b0a9544d5dba4e1255be2b1ac46
IP Address
76.75.33.193
Device
Mobile Safari via iOS
Drawn Signature

Viewed At
01/28/2022 10:10 MST
Identity Authenticated At
01/28/2022 10:13 MST
Signed At
01/28/2022 10:13 MST



Signature Reference ID
F1C215C9
Signature Biometric Count
82

Name
Andrew Riggin
Email
ariggin@pchospital.us
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
fe71fee1d92ea32095058b7bed8311b857ae653d82a161b60ac21681225ebbe7
IP Address
64.187.197.141
Device
Chrome via Windows
Typed Signature

Viewed At
01/27/2022 10:13 MST
Identity Authenticated At
01/27/2022 10:13 MST
Signed At
01/27/2022 10:13 MST

Andrew Riggin

Signature Reference ID
96AD472A

Name
David Espeland
Email
deespela@fallonmedical.org
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
715a0b6b48ad77f97b1cae2e6c35765cd648555f91b449198287fe23454b6174
IP Address
216.228.60.59
Device
Firefox via Windows
Typed Signature

Viewed At
01/26/2022 16:09 MST
Identity Authenticated At
01/26/2022 16:10 MST
Signed At
01/26/2022 16:10 MST

David Espeland

Signature Reference ID
490C90AD

Name
Kody Brinton
Email
kbrinton@billingsclinic.org
Components
5

Status
signed
Multi-factor Digital Fingerprint Checksum
3d79b98f840bd86af7ac2165c7b46f232752af7149f0a2491cb56bb94f98dcb2
IP Address
76.75.23.20
Device
Mobile Safari via iOS
Drawn Signature

Viewed At
01/26/2022 14:22 MST
Identity Authenticated At
01/26/2022 14:29 MST
Signed At
01/26/2022 14:29 MST



Signature Reference ID
022D5BA5
Signature Biometric Count