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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MONTANA MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION, ET. AL.,	CV-21-108-M-DWM
PLAINTIFFS,	
AND Montana Nurses Association, Plaintiff-Intervenors,	DEFENDANTS' BRIEF IN SUPPORT OF MOTION FOR CLARIFICATION OF PRELIMINARY INJUNCTION
V.	
••	
Austin Knudsen, et al.,	
DEFENDANTS.	

INTRODUCTION

Defendants respectfully request that the Court clarify its March 18, 2022, Order, Doc. 53, granting in part and denying in part Plaintiffs' motion for preliminary injunction. Defendants seek clarification regarding COVID-19 "booster doses," the CMS Omnibus Covid-19 Health Care Staff Vaccination Interim Final Rule, 86 Fed. Reg. 61,568 ("CMS Rule"), and enforcement of MCA § 49-2-312. As discussed below, Defendants believe enforcement of MCA § 49-2-312 against health care facilities requiring employees to receive a COVID-19 booster dose is not prohibited by this Court's Order because the CMS Rule only requires staff to be "fully vaccinated," which is defined as "2 weeks or more since they completed a primary vaccination series for COVID-19." 86. Fed. Reg. at 61571. Defendants, however, in an abundance of caution and with due respect for the Court's March 18 Order, seek clarification prior to taking any further action.

DISCUSSION

On February 16, 2022, Plaintiffs and Plaintiffs-Intervenors filed a joint motion for preliminary injunction alleging that MCA § 49-2-312 and § 49-2-313 were (1) preempted by the CMS Rule and (2) unconstitutional

under the Equal Protection Clause of the Fourteenth Amendment. See Doc. 42 at 2; Doc. 43 at 10–11. On March 18, 2022, this Court granted the motion in part and denied it in part. Doc. 53. The Court granted the motion "in that enforcement of § 49-2-312 as it relates to the COVID-19 vaccine is enjoined from enforcement against all Montana health care facilities and individual practitioners and clinics subject to the Interim Final Rule for so long as the Interim Final Rule remains in effect." Doc. 53 at 24. The Court denied the motion in all other respect. *Id*.

Defendants seek clarification from this Court because they have been made aware that at least one healthcare provider in the State of Montana is presently requiring employees to receive COVID-19 booster doses by May 1, 2022 as a condition of employment. *See* Benefis Memo at 1. MCA § 49-2-312(1)(b) makes it unlawful for an employer "to refuse employment to a person, to bar a person from employment, or to discriminate against a person in compensation or in a term, condition, or privilege of employment based on the person's vaccination status." Vaccination status is defined by § 49-2-312(5)(b) as "an indication of whether a person has received one or more doses of a vaccine." Requiring booster doses, thus, plainly violates MCA § 49-2-312. On March 18, 2022, this Court issued an order granting in part and denying in part Plaintiffs' motion for preliminary injunction. Doc. 53. The only question is whether Defendants are enjoined from enforcing MCA § 49-2-312 under these circumstances by the Court's March 18 Order. Defendants believe they are not.

This Court found that MCA § 49-2-312 was preempted by the CMS Rule, which "requires most Medicare- and Medicaid-certified providers and suppliers to ensure that their staff are fully vaccinated for COVID-19." Doc. 53 at 5 (quoting 86 Fed. Reg. at 61,568). The Court concluded that Plaintiffs were likely to succeed on the merits of their claim that MCA § 49-2-312 was preempted by the CMS Rule because it would be impossible for private parties to comply with both Montana law and federal law. *See* Doc. 53 at 14–15. Defendants, therefore, believe this Court's injunction only bars enforcement of MCA § 49-2-312 so far as it is preempted by the CMS Rule.

The CMS Rule requires participating health care facilities to "develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19." 86 Fed. Reg. at 61616. The CMS Rule

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is clear throughout that "fully vaccinated" refers only to the primary COVID-19 vaccine—not booster doses:

For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

42 C.F.R. 482.42(g) (Hospitals); § 485.640(f) (Critical Access Hospitals), § 416.51(c) (Ambulatory Surgical Centers); *accord* 86 Fed. Reg. at 61563 ("Based on current CDC guidance, individuals are considered fully vaccinated for COVID-19 14 days after receipt of either a single-dose vaccine (Janssen/Johnson & Johnson) or the second dose of a two-dose primary vaccination series (Pfizer-BioNTech/Comirnaty or Moderna)").¹ The CMS Rule also says "a booster dose of vaccine is administered when the initial immune response to a primary vaccine series is likely to have

¹ The Preamble to the CMS Rule explains this as well: "In consideration of the different vaccines available for COVID-19, we require that providers and suppliers ensure that staff are fully vaccinated for COVID-19, which, for purposes of these requirements, is defined as being 2 weeks or more since completion of a primary vaccination series. This definition of 'fully vaccinated' is consistent with the CDC definition. Additionally, the completion of a primary vaccination series for COVID-19 is defined in the requirements as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine." 86 Fed. Reg. at 61571.

waned over time." 86. Fed. Reg. at 61562. It, thus, expressly differentiates between a "booster dose" and the primary COVID-19 vaccine that satisfies the CMS Rule's definition of "fully vaccinated." *See id.* at 61562– 61563.

This is all to say that the CMS Rule clearly does not require booster doses for staff at covered health care facilities. As such, the CMS Rule does not preempt MCA § 49-2-312 as it relates to any requirements that "fully vaccinated" individuals receive a COVID-19 booster dose. Thus, Defendants would not be in violation of the Court's Order for enforcing MCA § 49-2-312 against facilities subject to the CMS Rule that require booster doses for staff. *See* Doc. 53 at 24.

For the reasons set forth above, Defendants respectfully request clarification of this Court's March 18 Order.

DATED this 11th day of April, 2022.

Respectfully submitted.

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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 995 words, excluding tables of content and authority, certificate of service, certificate of compliance, and exhibit index.

> <u>/s/ Christian Corrigan</u> 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: April 11, 2022

<u>/s/ Christian Corrigan</u> Christian Corrigan