UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

JANE DOES 1-6, et al., Plaintiffs, v. JANET T. MILLS, Governor of the State of Maine, et al. Defendants.	Civil Action No. 1:21-cv-00242-JDL

OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION OF STATE DEFENDANTS WITH INCORPORATED MEMORANDUM OF LAW

Defendants Janet T. Mills, Governor of the State of Maine, Jeanne M. Lambrew, Commissioner of the Maine Department of Health and Human Services (Department), and Dr. Nirav D. Shah, Director of the Maine Center for Disease Control (Maine CDC), (collectively, "State Defendants") hereby oppose Plaintiffs' Motion for Preliminary Injunction (ECF 3). Plaintiffs are unlikely to succeed on the merits of their Verified Complaint (ECF 1) and likewise have not demonstrated that the remaining factors weigh in their favor. State Defendants request that Plaintiffs' motion be denied.

STATUTORY BACKGROUND ON MANDATORY IMMUNIZATIONS

Since 1989, Maine has mandated that hospitals and other healthcare facilities require their employees to be vaccinated against several highly communicable diseases. *See* P.L. 1989, ch. 487, § 11 (eff. Sept. 30, 1989) (requiring employees of hospitals to be vaccinated against measles, mumps, and rubella). These requirements were enacted in the wake of the HIV/AIDS epidemic as part of comprehensive legislation designed to identify, report, prevent, and control communicable diseases that threaten the health of the people of Maine.

In 2001, the Maine Legislature moved the mandatory vaccinations requirements from statute to rules adopted by the Department. P.L. 2001, ch. 185, §§ 1-2 (eff. Sept. 21, 2001).[1] In response, the Department and the Maine CDC promulgated "Immunization Requirements for Healthcare Workers" (CDC Rule), which required that designated healthcare facilities (DHCF) mandate immunizations against several diseases for their employees.[2] (Declaration of Donald Wismer [hereinafter, "Wismer Decl."] Ex. 1.) Up until 2019, Maine law provided medical, religious, and philosophical exemptions from these vaccination requirements and from those required for school children.[3] 22 M.R.S.A. § 802(4-B)(B) (2019); 20-A M.R.S.A. § 6359(3)(B) (2008). The rationale for requiring immunization against vaccine-preventable diseases is the same in school and healthcare settings: high vaccination rates are necessary to prevent the spread of communicable diseases through the population and among vulnerable populations, i.e., children and patients. (Declaration of Nirav D. Shah [hereinafter, "Shah Decl."] ¶ 37.)

By 2018, vaccination rates for required vaccinations for school children and healthcare workers in Maine had fallen below the population-wide rates of vaccination necessary to prevent the spread of those communicable diseases. (Declaration of Sara Gagné-Holmes [hereinafter, "SGH Decl."] Ex. 2; Declaration of Kimberly Patwardhan [hereinafter, "Patw. Decl."] Exhs. 2-5.) Legislation thus was introduced in 2019 to eliminate nonmedical exemptions from these vaccination requirements in order to protect public health.[4] L.D. 798 (129th Legis. 2019).

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[1] Rulemaking provided a nimbler, more efficient process than legislation to address the rapid development of vaccines and vaccine recommendations. *See* L.D. 1401, Statement of Fact (120th Legis. 2001).

[2] Those diseases were rubeola (measles), mumps, rubella (German measles), Hepatitis B, and varicella (chickenpox). (Wismer Decl. Exh 1, § 2(A).)

[3] A statutory exemption for sincere philosophical beliefs was added in 2001. *See* P.L. 2001, ch. 185, § 2 (eff. Sept. 21, 2001) (enacting 22 M.R.S. § 802(4-B)(B)). (*See also* Wismer Decl. Ex. 1, § 3(B).)

[4] Hundreds of Mainers testified in support of, in opposition to, or neither for nor against the bill. (Patw. Decl. ¶ 4; *see also* Patw. Decl. Exs. 2-18.). Maine CDC and the Department offered testimony in support of L.D. 798, and that support was based in part on the then existing insufficient rates of vaccination for healthcare workers. (SGH Decl. ¶ 32 & Ex. 2; Patw. Decl. Ex. 4.) The bill, as amended, was also the topic of significant debate and discussion on the floors of both the Maine House and Senate. (Patw. Decl. Exs. 20-26.)

Ultimately, effective September 19, 2019, the Maine Legislature eliminated nonmedical exemptions to vaccination requirements for healthcare workers and likewise mandated the removal of nonmedical exemptions from all Department vaccination requirements.[5] P.L. 2019, ch. 154, §§ 9, 11 (effective Sept. 19, 2019) (repealing 22 M.R.S. § 802(4-B)(B)). The law was the subject of a statewide people's veto referendum on March 3, 3020; 72.8% of Maine voters elected to keep the law in place.[6] In order to comply with the statutory change, the Department removed nonmedical exemptions from the CDC Rule in April of 2021. (SGH Decl. Ex. 1.)

FACTUAL BACKGROUND

For the last 18 months, the world has contended with the worldwide COVID-19 pandemic. COVID-19 is a respiratory illness caused by a virus (SARS-CoV-2) that spreads when an infected person exhales droplets and very small particles that contain the virus. (Shah Decl. ¶¶ 11, 17.) All variants of the COVID-19 virus exhibit asymptomatic transmission, meaning an infected person can spread the virus without noticing any symptoms. (Shah Decl. ¶¶ 18-19, 26.)

To date, there have been approximately 219 million confirmed cases of COVID-19 worldwide, including approximately 41 million in the United States. (Shah Decl. ¶ 13.) There have been approximately 4.55 million deaths from COVID-19 worldwide; approximately 660,000 of those deaths were in the United States. (Shah Decl. ¶ 13.) As of September 14, 2021, there have been 81,177 total confirmed cases of COVID-19 in Maine, including 969 deaths from COVID-19. (Shah Decl. ¶ 14.)

The Court is well aware of the various measures Maine officials took in response to the COVID-19 pandemic in order to prevent the spread of COVID-19. *See, e.g.*, *Calvary Chapel of*

[5] At the same time, the Legislature also eliminated nonmedical exemptions for school children and employees of daycare facilities. P.L. 2019, ch. 154, §§ 1-2, 12 (effective Sept. 1, 2021).

[6] Full results of the March 3, 2020, election are available on the website of the Maine Secretary of State: https://www.maine.gov/sos/cec/elec/results/index.html.

Bangor v. Mills, 459 F. Supp. 3d 273, 284 (D. Me. 2020) (addressing COVID-related gathering limits in houses of worship), *appeal dismissed*, 984 F.3d 21 (1st Cir. 2020); *Bayley's Campground Inc. v. Mills*, 463 F. Supp. 3d 22 (D. Me. 2020) (evaluating COVID-related self-quarantine requirements for interstate travelers), *aff'd*, 985 F.3d 153 (1st Cir. 2021); *Savage v. Mills*, 478 F. Supp. 3d 16 (D. Me. 2020) (reviewing several COVID-related restrictions on businesses).

Fortunately, there are now three COVID-19 vaccines that have been authorized for use by the Food and Drug Administration (FDA) and that are highly effective at preventing infection with COVID-19.[7] (Shah Decl. ¶¶ 40-43.) The first COVID-19 vaccine doses in Maine were administered on December 14, 2020. (SGH Decl. ¶ 15.) In the interest of preserving health system capacity, Maine CDC prioritized eligibility for those first doses to frontline healthcare professionals and patient facing staff in, among others, hospitals, long-term care facilities, emergency medical services, physician practices, and dental practices. (SGH Decl. ¶¶ 15-18.)

Nevertheless, given the length of the pandemic, several variants of SARS-CoV-2 have emerged over time, including the highly contagious Delta variant. (Shah Decl. ¶ 22.) The Delta variant is more than twice as contagious as previous variants and may cause more severe illness than previous variants in unvaccinated people. (Shah Decl. ¶ 22.) Individuals infected with the Delta variant carry a much higher viral load, making the virus far more contagious and allowing it to spread and multiply in a shorter time period; an individual infected with the Delta variant can begin spreading it to others within 24 to 36 hours of exposure. (Shah Decl. ¶¶ 24-25.)

The gold standard to prevent and stop the spread of communicable diseases, including COVID-19, is vaccination. (Shah Decl. ¶ 34.) When immunization rates fall below the necessary

[7] Months before the COVID-19 vaccines were available, the Department and Maine CDC worked with hospitals, healthcare providers, health centers, and many others to develop a plan to facilitate distribution and administration of any COVID-19 vaccine that received authorization or approval from FDA. (SGH Decl. ¶ 6.) The Department and Maine CDC also hosted weekly COVID-19 vaccine information sessions on, among other topics, the science of vaccines; methods for addressing vaccine hesitancy; and patient conversations. (SGH Decl. ¶¶ 8, 13.)

population-level rate of vaccination for a particular disease, both vaccinated and unvaccinated individuals are at risk of infection. (Shah Decl. ¶ 38.) In light of the Delta variant, epidemiological models suggest that at least 90% of the population would need to be vaccinated against COVID-19 in order to achieve population-level immunity.[8] (Shah Decl. ¶ 29.)

The Delta variant was first identified in Maine via genomic sequencing on May 11, 2021. (Shah Decl. ¶ 49.) As of August 27, 2021, the Delta variant accounted for 96.7% of all positive COVID-19 samples sequenced in Maine, and the Delta variant is now the predominant variant within the United States. (Shah Decl. ¶ 50.)

Throughout the pandemic, Maine CDC has tracked statewide confirmed cases of COVID-19, including the number of healthcare workers who have contracted COVID-19, and investigated outbreaks of COVID-19, including in healthcare settings. After vaccines became available, Maine CDC also started tracking the rate of COVID-19 vaccination among the general population and among employees of DHCFs. (SGH Decl. ¶ 30.)

Most healthcare facility outbreaks are the result of healthcare workers who bring COVID-19 into the facility. (Shah Decl. ¶ 48.) As of September 9, 2021, 5,723 self-identified healthcare workers in Maine have contracted COVID-19. (Shah Decl. ¶ 45.) Of those, approximately 1,900 (or more than one third) have occurred since January 18, 2021 (i.e., the first date that any person could be considered fully vaccinated against COVID-19). (Shah Decl. ¶ 45.) On August 11, 2021, four of the fourteen outbreaks then under investigation by Maine CDC were occurring in healthcare facilities. (Shah Decl. ¶ 47.) By September 3, 2021, nineteen of the thirty-three COVID-19 outbreaks under investigation by Maine CDC were occurring in healthcare facilities. (Shah Decl. ¶ 46.)

[8] Under prior models formulated based on prior variants, only around 70% of the population would have needed to be vaccinated to achieve population-level immunity. (Shah Decl. ¶ 29.)

For the monthly reporting period ending July 31, 2021, the rate of COVID-19 vaccines among healthcare workers in certain DHCFs was as follows:

- Ambulatory Surgical Centers: 85.9%
- Assisted Housing Facilities: 74.7%
- Hospitals: 80.3%
- Intermediate Care Facilities for Individuals with Intellectual Disabilities: 68.2%
- Nursing Homes: 73.0%

(Shah. Decl. ¶ 53.) All facilities fell significantly below the minimum 90% threshold believed to be needed to reduce the likelihood of facility-based outbreaks of COVID-19. (Shah Decl. ¶ 54.)

Based on these and other facts, Maine CDC determined that requiring COVID-19 vaccinations for healthcare workers in certain high-risk settings was necessary to protect public health, healthcare workers, and Maine's healthcare system from the further spread of COVID-19. (Shah Decl. ¶ 55.) Accordingly, the Department and Maine CDC amended the CDC Rule on an emergency basis [hereinafter, "Emergency CDC Rule"] to required DHCFs, Dental Health Practices, and Emergency Medical Services (EMS) Organizations to ensure their employees were vaccinated against COVID-19. (Shah Decl. ¶ 55.) Maine CDC determined that these types of facilities and settings posed a higher risk for the transmission of the virus that causes COVID-19 because of the patient populations served and type of care provided.[9] (Shah Decl. ¶ 55; *see also* Shah Decl. ¶¶ 56-58 (describing public health reasons for issuance of Emergency CDC Rule).)

In reaching the decision to adopt the Emergency CDC Rule, Maine CDC considered whether there were other, less restrictive measures that might be appropriate instead of the Emergency CDC Rule. As discussed *infra*, those options were considered, but would not have been as effective at stopping the spread of COVID-19 in the covered facilities. (Shah Decl. ¶¶ 59-67.)

[9] The facilities outbreaks described above were occurring in facilities that are now covered by the Emergency CDC Rule. (Shah Decl. ¶¶ 46-47.)

ARGUMENT

In determining whether to issue a preliminary injunction, the court considers four factors.

> Those factors are: (1) the likelihood of success on the merits; (2) the potential for irreparable harm to the movant if the injunction is denied; (3) the balance of relevant impositions, i.e., the hardship to the nonmovant if enjoined as contrasted with the hardship to the movant if no injunction issues; and (4) the effect (if any) of the court's ruling on the public interest.

Douglas v. Lalumiere, No. 2:20-CV-00227-JDL, 2021 WL 641370, at *2 (D. Me. Feb. 18, 2021) (cleaned up). Plaintiffs have not met their burden.

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS OF THEIR COMPLAINT

Of the four relevant factors, "the movant's likelihood of success is the touchstone of the preliminary injunction inquiry. If the moving party cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity." *Id.* (cleaned up).

A. THE EMERGENCY CDC RULE AND SECTION 802(4-B) DO NOT VIOLATE PLAINTIFFS' FIRST AMENDMENT RIGHTS TO FREE RELIGIOUS EXERCISE.

In Count I, Plaintiffs assert a violation of their right to free religious exercise by the so-called "Governor's COVID-19 Vaccine Mandate." (ECF 1 ¶¶ 122-39.) The First Amendment's Free Exercise Clause provides in pertinent part: "Congress shall make no law . . . prohibiting the free exercise" of religion. U.S. Const. amend. I; *Cantwell v. Connecticut*, 310 U.S. 296, 303-04 (1940) (incorporating Free Exercise Clause against the States via the Fourteenth Amendment).

Plaintiffs' arguments on their Free Exercise claim are a hodgepodge of constitutional and statutory claims, and they fail to grapple with or even properly identify the two laws whose effects they challenge. As described above, Plaintiffs' claims involve two different State legal authorities: 1) the Emergency CDC Rule, which requires covered entities to ensure their employees are vaccinated against COVID-19; and 2) 22 M.R.S.A. § 802(4-B), which provides only medical

exemptions to mandatory vaccination requirements. Regardless of the standard of review, neither the statute nor the rule violates Plaintiffs' First Amendment rights to free religious exercise.

1. Mandatory vaccination laws with only medical exemptions are constitutional under *Jacobson* and its progeny.

The Supreme Court has long upheld states' mandatory vaccination laws to constitutional challenges. In *Jacobson v. Massachusetts*, the City of Cambridge had an outbreak of smallpox, and it enacted a regulation requiring that, under threat of criminal penalties, all inhabitants, adults and children alike, be vaccinated. 197 U.S. 11, 12-13 (1905). The ordinance included an exception for children "who present[ed] a certificate, signed by a registered physician, that they are unfit subjects for vaccination." *Id.* at 12; *cf.* 22 M.R.S.A. § 802(4-B)(A) (including similar medical exemption for healthcare workers). Mr. Jacobson refused to be vaccinated based on his personal beliefs, was convicted of violating the regulation, and then challenged the law on Fourteenth Amendment grounds. 197 U.S. at 13-14. The Supreme Court rejected the challenge, stating that

> There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy.

Id. at 26 (emphasis added); *accord Emp't Div., Dep't of Hum. Res. of Or. v. Smith*, 494 U.S. 872, 890 (1990) (rejecting system of religious accommodation "in which each conscience is a law unto itself"). The Court held that a regulation intended to protect against "an epidemic of disease which threatens the safety of its members" would be struck down only if it has "no real or substantial relation" to its goal of protecting the public health or is "beyond all question, a plain, palpable invasion of rights secured by the fundamental law." *Jacobson*, 197 U.S. at 27, 31; *cf. Compagnie Francaise de Navigation a Vapeur v. Bd. of Health of State of La.*, 186 U.S. 380, 387 (1902) ("state quarantine laws and state laws for the purpose of preventing, eradicating, or controlling the spread of contagious or infectious diseases, are not repugnant to the Constitution of the United States").

Applying this test, the Court upheld the compulsory vaccination law because the means chosen to "stamp out the disease of smallpox"—mandatory vaccination—had "a real and substantial relation to the protection of the public and the public safety." *Jacobson*, 197 U.S. at 31.

Relying in part on *Jacobson*, the Supreme Court likewise has upheld a state's compulsory school vaccination laws against a Fourteenth Amendment challenge brought by a parent whose child was denied enrollment in both public and private schools. *See Zucht v. King*, 260 U.S. 174, 176 (1922) (explaining *Jacobson* "settled that it is within the police power of a state to provide for compulsory vaccination"). Later, when confronted with First Amendment challenges to laws regulating the conduct of children, the Supreme Court wrote:

> The rights of children to exercise their religion, and of parents to give them religious training and to encourage them in the practice of religious belief, as against preponderant sentiment and assertion of state power voicing it, have had recognition here . . . .
>
> But the family itself is not beyond regulation in the public interest, as against a claim of religious liberty. And neither rights of religion nor rights of parenthood are beyond limitation. [A parent] cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.

Prince v. Massachusetts, 321 U.S. 158, 165–67 (1944) (citations omitted) (emphasis added); *see also In re Z.S.*, 2015 ME 110, ¶¶ 7-10 121 A.3d 1286 (affirming trial court decision to approve vaccination of child in Department custody over mother's non-medical objections to vaccination).

Numerous courts subsequently have affirmed the principle that mandatory vaccination laws do not violate free exercise rights. *See, e.g.*, *Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017) ("[Nikolao] has not been denied any legal right on the basis of her religion. Constitutionally, Nikolao has no right to a[vaccine] exemption."); *Phillips v. City of New York*, 775 F.3d 538, 543-44 (2d Cir. 2015) ("mandatory vaccination as a condition for admission to school does not violate the Free Exercise Clause"); *Workman v. Mingo Cnty. Bd. of Educ.*, 419 Fed. App'x 348, 352-54

(4th Cir. 2011) (concluding West Virginia's mandatory vaccination law that allowed for only medical exemptions withstood strict scrutiny review); *Harris v. Univ. of Mass., Lowell*, No. 21-CV-11244-DJC, 2021 WL 3848012, at *7 (D. Mass. Aug. 27, 2021) ("UMass is under no constitutional obligation to offer a religious exemption to its Vaccine Requirement."); *W.D. v. Rockland Cnty.*, No. 19-Civ.-2066 (JCM), 2021 WL 707065, at *22-31 (S.D.N.Y. Feb. 22, 2021) (upholding emergency exclusion order during measles outbreak that applied to all unvaccinated persons except those with medical exemptions in free exercise challenge); *Boone v. Boozman*, 217 F. Supp. 2d 938, 954 (E.D. Ark. 2002) (upholding compulsory vaccination law with medical exemption but no religious exemption against free exercise challenge), *appeal dismissed as moot*, 359 F.3d 1029 (8th Cir. 2004); *Brown v. Smith*, 235 Cal. Rptr. 3d 218, 224-25 (Cal. Ct. App. 2018) (holding mandatory school vaccination law with only medical exemptions did not violate free exercise clause under California Constitution); *F.F. v. New York*, 143 N.Y.S.3d 734 *passim* (N.Y. App. Div. 2021) (upholding repeal of religious exemptions from mandatory school vaccination law against free exercise challenge).

2. The Emergency CDC Rule and section 802(4-B) are neutral laws of general applicability that are rationally related to achieve the State's legitimate goal of stemming the spread of COVID-19.

The Free Exercise Clause protects "the right to believe and profess whatever religious doctrine one desires," *Smith*, 494 U.S. at 877, but it "does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his [or her] religion prescribes (or proscribes),'" *id.* at 879 (quoting *United States v. Lee*, 455 U.S. 252, 263 n.3 (1982) (Stevens, J., concurring in judgment)). "Under *Smith*, a neutral law of general applicability is constitutional if it is supported by a rational basis," even when applied to religious practices. *See Illinois Bible Colleges Ass'n v. Anderson*, 870 F.3d 631, 639 (7th Cir. 2017); *Parker v. Hurley*, 514 F.3d 87, 96 (1st Cir. 2008) (describing

Smith as "mere rationality standard"); *Commack Self-Serv. Kosher Meats, Inc. v. Hooker*, 680 F.3d 194, 212 (2d Cir. 2012) (neutral and generally applicable laws subject to rational basis review in Free Exercise analysis).

Neutrality. The neutrality inquiry begins with the text of the law in question. *See Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 533 (1993). "A law lacks facial neutrality if it refers to a religious practice without a secular meaning discernable from the language or context." *Id.* Neither the text of the Emergency CDC Rule nor the text of section 802(4-B) refers to religious practice, conduct, belief, or motivation. Plaintiffs have not identified any such facially discriminatory language or even engaged with the facial neutrality analysis. Thus, the rule and statute are facially neutral.

The laws are also neutral because their object or purpose is not to infringe or restrict any particular religious practice and are not "specifically directed at religious practice." *Smith*, 494 U.S. at 878. As the record demonstrates, the object of the Emergency CDC Rule is to prevent the spread of COVID-19 among healthcare workers in high risk settings, protect patients and individuals from disease and death, and protect Maine's healthcare system. (Shah Decl. ¶¶ 56-58.) Similarly, the Legislature's elimination of all nonmedical exemptions was intended to increase the overall rate of vaccination and protect individuals who are unable to be vaccinated for medical reasons.[10] Neither the rule nor the statute can be said to be directed at religious practice.

Plaintiffs take particular umbrage with the existence of a medical exemption from vaccination requirements. (ECF 3 at 7, 14-15.) As of September 1, 2021, "[a] medical exemption is available to an employee who provides a written statement from a licensed physician, nurse

[10] (*See, e.g.* Patw. Decl. Ex. 2 (testimony of Rep. Tipping); Patw. Decl. Ex. 18; Patw. Decl. Ex. 20 at H-397 (remarks of Rep. Ingwersen); Patw. Decl. Ex. 21 at S-556 to -557 & S-563 (remarks of Sen. Millett) & S-561 to -562 (remarks of Sen. Chenette); Patw. Decl. Ex. 22 at H-492 (remarks of Rep. Fecteau); Patw. Decl. Ex. 23 at S-653 to -654 (remarks of Sen. Carson); Patw. Decl. Ex. 24 at H-595 to -596 (remarks of Rep. McDonald); Patw Decl. Ex. 25 at S-754 (remarks of Sen. H. Sanborn) & S-755 (remarks of Sen. L. Sanborn).)

practitioner or physician assistant that, in the physician's, nurse practitioner's or physician assistant's professional judgment, immunization against one or more diseases may be medically inadvisable." 22 M.R.S.A. § 802(4-B)(A) (Supp. 2021). They claim the existence of this medical exemption necessarily means that Maine's laws are not neutral, relying on *Tandon v. Newsom*, where the Court stated: "government regulations are not neutral and generally applicable, and therefore trigger strict scrutiny under the Free Exercise Clause, whenever they treat *any* comparable secular activity more favorably than religious exercise." 141 S. Ct. 1294, 1296 (2021) (second emphasis added). Plaintiffs claim that medical exemptions are secular, and that Maine law thus treats secular activity more favorably than religious exercise.[11] (ECF 3 at 7-8.)

But Plaintiffs ignore the next step of the analysis. The Supreme Court went on to explain in *Tandon* that "whether two activities are comparable for purposes of the Free Exercise Clause must be judged against the asserted government interest that justifies the regulation at issue." 141 S. Ct. at 1296. Plaintiffs simply assume that medical exemptions are comparable to religious exemptions without any analysis. That assumption ignores the Supreme Court's instruction.

As noted, the Legislature's goal in eliminating of nonmedical exemptions was to increase the overall rate of vaccination and protect the health of individuals who are unable to be vaccinated for medical reasons. (*See* Shah Decl. ¶ 39 (explaining circumstances when vaccination may be medically inadvisable).) Requiring vaccination of persons whose health may be harmed by vaccination would not serve the State's interest in protecting those same individuals from the spread of communicable diseases and death. Medical exemptions are thus not "comparable" to religious exemptions under *Tandon*. *See Resurrection Sch. v. Hertel*, No. 20-2256, 2021 WL

[11] Plaintiffs allege, without any elaboration or developed argument, that Maine law "provides for individualized medical exemptions but not religious." (ECF 3 at 7; ECF 1 ¶ 132.) State Defendants disagree with this characterization. Section 802(4-B)(A) vests authority regarding medical exemptions with healthcare providers, not State officials. Those healthcare providers are to utilize their professional judgment in deciding whether to sign a written statement in support a medical exemption. 22 M.R.S.A. § 802(4-B)(A).

3721475, at *13 (6th Cir. Aug. 23, 2021) (concluding COVID-related mask mandate for secular and religious schools with exception for those medically unable to mask was neutral and generally applicable). Moreover, *Jacobson* strongly suggests that requiring individuals with health issues to be vaccinated would be unconstitutional. 197 U.S. at 38-39; *see also Rockland Cnty.*, 2021 WL 707065, at *29 ("the medical exemption furthered Defendants' public health purpose by encouraging community-wide vaccination on the one hand, and protecting the lives and safety of those who could not be vaccinated, on the other").

Further, despite Plaintiffs' conclusory statements to the contrary, they have failed to show how either law is targeted to regulate their religious abstention, such that only they are affected by the laws, and there are no restrictions on secular abstention. *Cf. Lukumi*, 508 U.S. at 535-36 (explaining how ban on ritual animal sacrifice without banning other animal slaughter targeted specific practice of Santeria faith).

General applicability. The general applicability requirement prohibits the government from "in a selective manner impos[ing] burdens only on conduct motivated by religious belief." *Lukumi*, 508 U.S. at 543 (emphasis added). It "protect[s] religious observers against unequal treatment, and inequality [that] results when a legislature decides that the governmental interests it seeks to advance are worthy of being pursued only against conduct with a religious motivation." *Id.* at 542–43 (emphasis added).

Here, the Emergency CDC Rule applies equally to all covered entities: DHCFs, Dental Health Practices, and EMS Organizations. (SGH Decl. Ex. 3.) Those organizations must require their employees to show proof of vaccination against COVID-19, unless the employee is medically exempt. (SGH Decl. Ex. 3, §§ 2(A)(7), (B), (E).) Section 802(4-B) only permits employees to assert medical exemptions to mandatory vaccination requirements; exemptions based on any other reason, religious or otherwise, are not permitted. An individual's personal, philosophical, or

religious beliefs simply do not come into play under section 802(4-B); thus, the laws in question are generally applicable.[12]

Rational basis review. Because the Emergency CDC Rule and Section 802(4-B) are neutral and generally applicable, the applicable standard of constitutional review is rational basis. Because "[s]temming the spread of COVID–19 is unquestionably a compelling interest," *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) (per curiam), the State's goal of stopping the spread of COVID-19 in certain facilities and protecting those unable to be vaccinated are unquestionably legitimate state interests. And requiring vaccination, the most effective method of stopping the spread of communicable diseases (Shah Decl. ¶¶ 34, 67), is rationally related to achieving that goal. *Accord Jacobson*, 197 U.S. at 31 (upholding municipality's mandatory vaccination law based on its "real and substantial relation" to protecting public health).

3. The Emergency CDC Rule and Section 802(4-B) are narrowly tailored to achieve the State's compelling interest of stemming the spread of COVID-19 among healthcare workers.

As shown above, both Maine laws in question are neutral and generally applicable and "need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice." *Lukumi*, 508 U.S. at 531. But if strict scrutiny were to apply, then both laws would still stand up against Plaintiffs' free exercise challenge.

As noted, "[s]temming the spread of COVID–19 is unquestionably a compelling interest," *Roman Cath. Diocese*, 141 S. Ct. at 67, and Plaintiffs do not seriously contend otherwise. (ECF 3 at 8.) Plaintiffs contend instead that the laws are not narrowly tailored. Narrow tailoring requires the government to show that its policy is the "least restrictive means" of achieving its objective, *Thomas v. Rev. Bd. of Ind. Emp. Sec. Div.*, 450 U.S. 707, 718 (1981), and that it "seriously

[12] Any individual who may have nonmedical reasons to object to vaccinations could still qualify for a medical exemption: Maine law distinguishes not by belief, but by medical condition.

undertook to address the problem with less intrusive tools readily available to it," *McCullen v. Coakley*, 573 U.S. 464, 494 (2014). To evaluate the requirement of narrow tailoring, "the court should ask whether the challenged regulation is the least restrictive means among available, effective alternatives." *Ashcroft v. ACLU*, 542 U.S. 656, 666 (2004).

Plaintiffs propose two alternatives that they assert are less restrictive: 1) continuing to comply with existing "face covering" and other "reasonable health and safety requirements" or 2) "submit[ting] to reasonable testing and reporting requirements." (ECF 1 ¶¶ 76, 80; ECF 3 at 9-10.) Plaintiffs assert that these measures were good enough for the last 18 months and they should continue to be good enough now. (ECF 3 at 9-10.) But these options would not be effective at achieving the State's goals, and some measures that Plaintiffs propose have not been effective.

Plaintiffs, as employees of the Provider Defendants, were required to comply with applicable law for infection control practices, including those pertaining to COVID-19.[13] Notwithstanding these existing health and safety protocols, there have been numerous outbreaks of COVID-19 at healthcare facilities during the last 18 months. (Shah Decl. ¶ 65.) As of September 3, 2021, 19 of the 33 outbreaks that Maine CDC was investigating occurred at healthcare facilities that are now covered by the Emergency CDC Rule. (Shah Decl. ¶ 46.) Continuing under current conditions would not achieve the State's goals of stopping the spread of COVID-19 in high risk facilities. Moreover, there is no equivalency between measures taken before and after vaccines became available; when more effective measures to achieve the State's goals become available, the State should not be required to continue using less effective measures.

Plaintiffs also propose regular testing. Maine CDC considered, but rejected, regular testing as an alternative to protect against the Delta variant. (Shah Decl. ¶ 61.) Given the speed with

[13] (*See* Declaration of Judy West ¶ 6; Declaration of Gail Cohen ¶ 6; Declaration of April Nichols ¶ 6; Declaration of Paul Bolin ¶ 6.)

which the Delta variant is transmitted, weekly or twice weekly testing would be wholly ineffective as a tool for preventing transmission. (Shah Decl. ¶ 61.) An employee who tests negative on a Monday morning could be exposed that afternoon and, within 36 hours, could be spreading the virus to others over the course of the several days until the next test. (Shah Decl. ¶ 61.)

Daily testing was also considered, but rejected. The most effective test utilized for the detection of the virus that causes COVID-19 is a polymerase chain reaction (PCR) test; a PCR test requires a minimum of 24 hours before results are available, and sometimes results are not available for up to 72 hours. (Shah Decl. ¶ 62.) Because of this delay, PCR testing on a daily basis would be insufficient for the same reasons that occasional testing is insufficient. (Shah Decl. ¶ 62.) Daily testing likely would require the use of the less-effective rapid antigen test, which provides results in fifteen minutes, but is more likely to provide false negative result; research shows that these tests correctly identify only about 50% of positive COVID-19 cases. (Shah Decl. ¶ 62.) Moreover, the nation is currently experiencing a shortage of rapid antigen tests, which is not expected to end in the next two months. (Shah Decl. ¶ 62.) Daily testing would not be effective at stopping the spread of COVID-19 in covered facilities, particularly in light of the Delta variant. (Shah Decl. ¶ 62.)

Plaintiffs also contend that State Defendants "tried nothing else" before resorting to adopting the Emergency CDC Rule. (ECF 3 at 9.) But the record shows that the Department and Maine CDC have engaged in extensive educational outreach to clinicians across the State, discussing the efficacy and safety of the three available COVID-19 vaccinations. (SGH Decl. ¶¶ 13-14.) Employees of the facilities covered by the Emergency CDC Rule were some of the first (if not the first) Maine residents eligible for vaccination. (SGH Decl. ¶¶ 16-17.) The State engaged in numerous programs to distribute vaccines across the State and to encourage vaccination statewide. (SGH Decl. ¶¶ 20-29.) And Plaintiffs' employers also encouraged vaccination by

making vaccines available onsite and making time spent getting vaccinated compensable.[14] Nevertheless, as of July 31, 2021, the average employee rate of COVID-19 vaccination at ambulatory surgical centers, hospitals, and nursing homes was 85.9%, 80.3%, and 73.0%, respectively—below the minimum 90% vaccination rate now believed to be needed for population-level immunity. (SGH Decl. ¶ 33; Shah Decl. ¶¶ 53-54.)

In sum, there were no less restrictive alternatives that would have been effective at achieving the State's goals. *Ashcroft*, 542 U.S. at 666.

4. Plaintiffs' other arguments are meritless.

In support of its Free Exercise claim, Plaintiffs argue that John Doe 1 has sincerely held religious beliefs that are substantially burdened by the Emergency CDC Rule and Section 802(4-B). (ECF 18 at 5-7.) In support, they rely on *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). *Burwell* is inapplicable to this case because its analysis rested on the Religious Freedom Restoration Act (RFRA), 42 U.S.C.A. §§ 2000bb to 2000bb-4 (Westlaw, through Publ. L. 103-141). Congress enacted RFRA in response to *Smith* in order to provide increased protection to religious exercise. *Burwell*, 573 U.S. at 693-95. But RFRA categorically does not apply to State and municipal actors. *See City of Boerne v. Flores*, 521 U.S. 507, 529-36 (1997).

B. IT IS UNDISPUTED THAT FEDERAL LAW APPLIES WITHIN THE STATE OF MAINE.

Count II of Plaintiffs' Complaint is puzzling and, ultimately, largely duplicative of the rest of their claims. (ECF 1 ¶¶ 140-51.) Plaintiffs demand that Defendants acknowledge the supremacy of federal law over state law and its applicability in the State. (ECF 3 at 2.) State Defendants have already done so. (*See* ECF 43 at 1.) In any event, to the extent that this count is

[14] (*See* Declaration of Judy West ¶ 5; Declaration of Gail Cohen ¶ 5; Declaration of April Nichols ¶ 5; Declaration of Paul Bolin ¶ 5.)

directed at State Defendants, or even states a valid cause of action, Plaintiffs have provided no evidence of how State Defendants have denied the supremacy of federal law or the inapplicability of Title VII. (ECF 1 ¶ 144 (alleging State Defendants "tacitly stated" Title VII is inapplicable in Maine).) The opposite is true.

As between the Emergency CDC Rule and Title VII, Maine CDC has already published guidance stating that the Emergency CDC Rule does not prohibit employers from providing accommodations for employees' religious beliefs where applicable.[15] (SGH Decl. ¶ 36.) And even if Plaintiffs could be said to be making a preemption claim in Count II—a claim they do not articulate or analyze under any traditional preemption analysis—they only, as to State Defendants, assert "preemption" of Maine law by the First Amendment. (ECF 3 at 5.) Those claims are addressed fully in Count I above.

C. THE EMERGENCY CDC RULE AND SECTION 802(4-B) DO NOT DENY PLAINTIFFS EQUAL PROTECTION OF THE LAW UNDER THE FOURTEENTH AMENDMENT.

In Count III of their Complaint, Plaintiffs allege that their right to equal protection of the laws has been violated by the lack of a religious exemption in the Emergency Rule and section 802(4-B). "Where a plaintiff's First Amendment Free Exercise claim has failed, the Supreme Court has applied only rational basis scrutiny in its subsequent review of an equal protection fundamental right to religious free exercise claim based on the same facts." *Wirzburger v. Galvin*, 412 F.3d 271, 282 (1st Cir. 2005) (citing *Locke v. Davey*, 540 U.S. 712, 720 n.3 (2004)).

As shown above, the State's goals of stopping the spread of COVID-19 in certain facilities and protecting those unable to be vaccinated are legitimate state interests. Requiring vaccination,

[15] Moreover, Title VII does not require employers to make accommodations that compromise workplace safety. *See, e.g., Robinson v. Children's Hospital Boston*, No. 14-10263-DJC, 2016 WL 1337255, at **9-10 (D. Mass. Apr. 5, 2016) (concluding hospital did not violate Title VII when it terminated an employee who refused the flu vaccine based on her religious beliefs pursuant to a hospital vaccination policy that only allowed for medical exemptions).

the most effective method of stopping the spread of communicable diseases (Shah Decl. ¶¶ 34, 67), is rationally related to achieve those goals.

Plaintiffs argue that *Romer v. Evans*, 517 U.S. 620, 635 (1996), dictates the result in this case. (ECF 3 at 14-15.) But *Romer* involved an amendment to the Colorado state constitution that targeted, with express language, persons of homosexual, lesbian, or bisexual orientation, *Romer*, 517 U.S. at 624; the two state laws at issue do no such thing. Further, the Supreme Court applied a rational basis review to the law in question in *Romer*, and State Defendants have already demonstrated how the laws at issue are rationally related to a legitimate state interest.

D. PLAINTIFFS' CIVIL CONSPIRACY CLAIM IS WITHOUT MERIT.

Finally, in Count V, Plaintiffs allege that State Defendants and Plaintiffs' employers have engaged in a civil conspiracy to deprive them of equal protection under the law by prohibiting any religious exemption or accommodation.[16] (ECF 1 ¶¶ 180-97.) *See Alston v. Spiegel*, 988 F.3d 564, 577 (1st Cir. 2021) (describing elements of civil conspiracy claim under 42 U.S.C. § 1985(3)). Plaintiffs are unlikely to succeed on the merits of this claim because, as demonstrated above, their constitutional rights have not been violated and because, even at this early stage, they have failed to plausibly allege any conspiracy between and among the Defendants or discriminatory animus.

Most notably, Plaintiffs presume and allege it was State Defendants who eliminated religious exemptions from vaccination requirements. (ECF 1 ¶¶ 183-84.) But, as shown above, the Maine Legislature eliminated all nonmedical exemptions in 2019. P.L. 2019, ch. 154, §§ 9, 11. Thus, the alleged "overt acts" are in fact allegations that State Defendants are complying with Maine law. (ECF 3 at 12-13.) Further, a mere alignment of interests among the Defendants to

[16] While the Supreme Court and the First Circuit have speculated that Section 1985 might apply to other class-based invidiously discriminatory animus, they have never applied Section 1985 to anything other than race. *Griffin v. Breckenridge*, 403 U.S. 88, 102 & n.9 (1971); *Soto–Padró v. Pub. Bldgs. Auth.*, 675 F.3d 1, 4 (1st Cir.2012).

protect the health of patients and staff through vaccination of healthcare workers against COVID-19 is insufficient as a matter of law to establish an agreement or meeting of the minds. *See Morpurgo v. Inc. Vill. of Sag Harbor*, 697 F. Supp. 2d 309, 337 (E.D.N.Y. 2010), *aff'd*, 417 F. App'x 96 (2d Cir. 2011). Plaintiffs' claim rests on the independent actions of the alleged wrongdoers, not the concerted action necessary for a conspiracy claim. *Alston*, 988 F.3d at 578.

III. EVEN IF PLAINTIFFS HAD ESTABLISHED A LIKELIHOOD OF SUCCESS, THE REMAINING FACTORS SUPPORT DENYING AN INJUNCTION.

Plaintiffs have not established irreparable harm, that the balance of hardships tips in their favor, or that the public interest warrants an injunction.

As to irreparable harm, Plaintiffs claim that even minimal infringements of their First Amendment rights constitute irreparable injury, relying on the Supreme Court's decision in *Roman Catholic Diocese*, 141 S. Ct. at 67. But as the Court has already pointed out, the restrictions at issue in that case directly "prevented certain religious gatherings but did not prevent secular gatherings involving the same number of people," thereby preventing religious practices. (ECF 44 at 3.) "Here, in contrast, the Emergency Rule does not prevent the nine Plaintiffs from adhering to their sincerely held religious beliefs that compel them to decline to receive any of the three currently available vaccines." (ECF 44 at 3; *see also* ECF 1 ¶ 68.) And the other Defendants, Plaintiffs' employers, have explained fully how there are remedies available to Plaintiffs.

With respect to the balance of harms, State Defendants are seeking to protect the health and lives of healthcare workers and patients across the State, and that far outweighs the harm, if any, that Plaintiffs may suffer. Similarly, the public interest weighs heavily in State Defendants favor. Plaintiffs should not be permitted to interfere with the careful, medically based approach taken by State Defendants and the Legislature.

CONCLUSION

For the reasons set forth above, State Defendants request that Plaintiffs' motion be denied.

DATED: September 15, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2021, I electronically filed this document and its attachments with the Clerk of the Court using the CM/ECF system and that the same will be sent electronically to registered participants as identified in the CM/ECF electronic filing system for this matter.

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UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

JANE DOES 1-6, et al.,

Plaintiffs,

v.

JANET T. MILLS, Governor of the State of Maine, et al.,

Defendants.

Civil Action No. 1:21-cv-00242-JDL

DECLARATION OF DONALD WISMER

1. My name is **Donald Wismer**. I am the Administrative Procedure Act Coordinator in the office of the Maine Secretary of State.

2. The statements made in this declaration are based upon my personal knowledge and records available to me.

3. The Maine Secretary of State's Office maintains records of prior versions of rules adopted by Maine state agencies.

4. Attached hereto as Exhibit 1 is a true and accurate copy of Chapter 264 of the rules of the Department of Human Services, "Immunization Requirements for Healthcare Workers," as originally adopted and effective as of April 16, 2002.

5. Attached hereto as Exhibit 2 is a true and accurate copy of Chapter 264 of the rules of the Department of Health and Human Services, "Immunization Requirements for Healthcare Workers," effective as of December 8, 2009.

I DECLARE, PURSUANT TO 28 U.S.C. §1746, UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Dated: September 13, 2021

Donald Wismer

10-144 DEARTMENT OF HUMAN SERVICES

BUREAU OF HEALTH

Chapter 264: IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

SUMMARY: Healthcare workers are at risk for exposure to and possible transmission of vaccine preventable diseases due to their contact with patients, or infectious material from patients. The health and safety of the health-care workers and the patients they care for is an essential area of concern.

This rule is issued pursuant to the statutory authority of the Department of Human Services to require immunization of the employees of designated health care facilities as set forth in 22 M.R.S.A.§802, as amended by P.L. 2001, Ch. 185. It prescribes the dosage for required immunizations and defines responsibilities, exclusion periods, record keeping and reporting requirements for officials of hospitals and healthcare facilities.

---

1. Definitions

A. "Certificate of Immunization" means a written statement from a physician, nurse or health official who has administered an immunization agent to an employee, specifying the vaccine administered and the date it was administered. Secondary school or collegiate health records, having been compiled and maintained as an official document based on certificates of immunization, which provide at a minimum the month and year that the immunization was administered and/or which contain copies of laboratory evidence of immunity, may also be accepted as proof of immunization.

B. "Chief administrative officer" means the person designated as the president, chief executive officer, administrator, director or otherwise the senior official of a designated health facility.

C. "Declination" means a formal process where an individual makes an informed choice declining Hepatitis B vaccination, following standards and procedures established by the federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910.1030(f)(2)(iv) (effective July 6, 1992).

D. "Designated Healthcare Facility" means a licensed nursing facility, residential care facility, Intermediate Care Facility for the Mentally Retarded (ICF/MR), multi-level health care facility, hospital, or home health agency.

E. "Disease" means the following conditions which may be preventable by immunization agent:

(1) Rubeola (measles)

(2) Rubella (German measles)

(3) Hepatitis B

(4) Influenza

(5) Mumps

(6) Varicella (chickenpox).

F. "Employee" means a person who performs a service for wages or other remuneration for a designated health facility.

G. "Exemption" means a formal procedure to procure discharge from requirement to vaccinate.

H. "Immunization agent" means a vaccine, antitoxin, or other substances used to increase an individual's immunity to disease.

I. "Public Health Official" means a local health officer, the Director of the Maine Bureau of Health, or a designated employee or agent of the Maine Department of Human Services.

2. Immunizations Required

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine shall require for all employees proof of immunization or documented immunity against:

(1) Rubeola (measles)

(2) Mumps

(3) Rubella (German measles)

(4) Varicella (chicken pox)

(5) Hepatitis B

B. In accordance with 29 CFR 1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities shall make available the Hepatitis B vaccine to all health care workers with a risk of occupational exposure, at no cost to the employee.

C. All Designated Healthcare Facilities shall adopt a policy that recommends and offers annual immunizations against influenza to all personnel who provide direct care to residents of the facility.

D. No chief administrative officer may permit any employee to be in attendance at work without a certificate of immunization for each disease or other acceptable evidence of immunity to each disease, or documentation of exemption or declination.

3. Exceptions and Declinations

An employee who does not meet the immunization/immunity requirement may be permitted to attend work under the following conditions:

A. The employee presents to the designated healthcare facility a physician's written statement that immunization against one or more of these diseases is medically inadvisable. If the statement does not include all diseases, the employee must meet the immunization/immunity requirements for any diseases not covered by the statement.

B. The employee states in writing an opposition to immunization because of a sincere religious belief or for philosophical reasons.

C. Declination for Hepatitis B pursuant to OSHA Regulations: An exemption is available to an employee who declines Hepatitis B vaccination in accordance with the applicable regulations established by the Occupational Safety and Health Administration.

4. Certification of Immunization and Proof of Immunity

A. Certificate of Immunization

To demonstrate proper immunization against each disease, an employee shall present the designated healthcare facility with a Certificate of Immunization from a physician, nurse or health official who has administered the immunizing agent(s) to the employee. Physicians within their own practice may authorize their own employees to issue a certificate of immunization on behalf of the physician. The certificate shall specify the immunizing agent, and the date(s), including month and year, on which it was administered. Physicians, having reviewed

official patient records created by another practitioner which indicate that a particular patient has received an immunization on a specified date, demonstrating at a minimum the month and year the immunization was given, may certify that the immunization was given. Adequately prepared secondary and/or collegiate school health records will also be considered acceptable for the purpose of meeting this requirement.

B. Proof of Immunity

To demonstrate that an employee is immune to any of the diseases, the employee shall present the hospital/facility with laboratory evidence demonstrating immunity, or other acceptable evidence of immunity. (See 7-B Individual Health Records.)

5. Immunization Dosage

A. The following schedule contains the minimally required number of doses for the immunizing agents addressed under these rules:

(1) Rubeola (Measles): Two (2) doses of live measles vaccine given after the first birthday, with a minimum of four weeks separating the 2 doses.

(2) Mumps: One (1) dose of live mumps vaccine given after the first birthday.

(3) Rubella (German Measles): One (1) dose of live rubella vaccine given after the first birthday.

(4) Varicella (Chickenpox): Two (2) doses of live varicella vaccine given after the first birthday, with a minimum of four weeks separating the 2 doses.

(5) Hepatitis B: Three (3) doses of hepatitis B vaccine, the first two given one month apart and the third given five months after the second.

(6) Influenza: Annual dose of inactivated influenza vaccine.

B. Any such immunizing agent must meet the standards for biological products which are approved by the United States Public Health Service.

6. Exclusions from the Workplace

A. Exclusion by order of Public Health Official

An employee not immunized or otherwise immune from a disease shall be excluded from the worksite, when in the opinion of a public health official, the employee's continued presence at work poses a clear danger to the health of others. The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles) or varicella (chickenpox) in a designated healthcare facility or amongst its employees may be interpreted as a clear danger to the health of others.

The chief administrative officer shall exclude the employee during the period of danger or for one incubation period following immunization of the employee, when one or more cases of disease are present.

B. The following periods are defined as the "period of danger":

(1) Measles: 15 days from the onset of symptoms from the last identified case

(2) Mumps: 18 days from the onset of symptoms from the last identified case

(3) Rubella: 23 days from the onset of symptoms from the last identified case

(4) Varicella: 16 days from the onset of symptoms from the last identified case

C. Except as otherwise provided for by law, contract or collective bargaining Agreement, an employer will not be responsible for maintaining an employee in pay status as a result of this rule.

D. When a public health official determines there are reasonable grounds to believe a public health threat exists, an exempted employee may be immunized or tested for serologic evidence of immunity. Employees without serologic evidence of immunity and those who become immunized against the disease in question at the time of a documented case or cases of disease must be excluded from the work site during one incubation period.

7. Records and Record Keeping

A. Designated Record Keeping

The chief administrative officer in each designated healthcare facility shall be responsible for the maintenance of employee immunization records. The chief

administrative officer may designate a person to be responsible for record keeping.

B. Individual Health Records

Each designated healthcare facility shall adopt a uniform, permanent health record for maintaining information regarding the health status of each employee. The immunization status of each employee with regard to each disease shall be noted on the employee's health record. The health record of each employee shall include at a minimum the month and year that each immunizing agent was administered.

Where an exception has been granted for medical or religious reason, the written request for exemption must be on file with the employee health record. Where laboratory or other acceptable evidence of immunity has been submitted, a copy of the documentation must also be on file.

C. List of Non-Immunized Employees

The chief administrative officer or his/her designee in each designated healthcare facility shall keep a listing of the names of all employees within the facility who are not currently immunized or do not have documented serological immunity against each disease. This list shall include the names of all employees with authorized exemptions from immunization as well as any who are otherwise not known to be immune and shall state the reason that the employee is not immune. The purpose of the list is to provide an efficient means to rapidly contact non-immunized employees in the event of disease outbreaks and exclude them from the workplace as necessary.

D. Required Reports

The chief administrative officer of each designated healthcare facility is responsible for submitting a summary report on the immunization status of all employees by December 15 of each calendar year, on a form prescribed by the Department, to the Director of the Bureau of Health of the Department of Human Services. The summary report will include the following information at a minimum: Specific information identifying the facility; the chief administrative officer; the total number of employees; the number of employees born on or after January 1, 1957; and the number of employees identified by vaccine type as either immunized, serological proof of immunity, exempt, having declined hepatitis B vaccine, or out of compliance. The summary report may be constructed so as to reflect meaningful data by groupings within the facility (e.g., pediatric unit). Each report shall be signed by the hospital/facility's chief administrative officer as a certification that the information is accurate.

The Bureau of Health will, from time to time, select a sample of employee health records for the purpose of comparing reported results against the criteria

delineated in these rules. The results of this sample survey will be shared with chief administrative officer of the designated healthcare facility for the purpose of identifying problem areas that may be occurring in the maintenance of their employee health records. Any published or unpublished reports of such sampling of employee health records shall not identify individual employees and/or designated healthcare facilities, directly or indirectly.

8. Effective Date

Designated healthcare facilities under this section shall be allowed up to one year from the effective date of this rule to ensure that all employees are in compliance with the requirements herein.

STATUTORY AUTHORITY: 22 M.R.S.A.§802

EFFECTIVE DATE:
April 16, 2002

10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

Chapter 264: IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

SUMMARY: Healthcare workers are at risk for exposure to and possible transmission of vaccine preventable diseases due to their contact with patients, or infectious material from patients. The health and safety of the health care workers and the patients they care for is an essential area of concern.

This rule is issued pursuant to the statutory authority of the Department of Human Services to require immunization of the employees of designated health care facilities as set forth in 22 M.R.S.A.§802, as amended by P.L. 2001, Ch. 185. It prescribes the dosage for required immunizations and defines responsibilities, exclusion periods, record keeping and reporting requirements for officials of hospitals and healthcare facilities.

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B. "Chief administrative officer" means the person designated as the president, chief executive officer, administrator, director or otherwise the senior official of a designated health facility.

C. "Declination" means a formal process where an individual makes an informed choice declining Hepatitis B vaccination, following standards and procedures established by the federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910.1030(f)(2)(iv) (effective July 6, 1992).

D. "Designated Healthcare Facility" means a licensed nursing facility, residential care facility, Intermediate Care Facility for the Mentally Retarded (ICF/MR), multi-level health care facility, hospital, or home health agency.

E. "Disease" means the following conditions which may be preventable by immunization agent:

(1) Rubeola (measles)

(2) Rubella (German measles)

(3) Hepatitis B

(4) Seasonal Influenza

(5) Mumps

(6) Varicella (chickenpox)

(7) 2009 Novel H1N1 Influenza.

F. "Employee" means a person who performs a service for wages or other remuneration for a designated health facility.

G. "Exemption" means a formal procedure to procure discharge from requirement to vaccinate.

H. "Immunization agent" means a vaccine, antitoxin, or other substances used to increase an individual's immunity to disease.

I. "Public Health Official" means a local health officer, the Director of the Maine Center for Disease Control and Prevention, or a designated employee or agent of the Maine Department of Health and Human Services.

2. Immunizations Required

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine shall require for all employees proof of immunization or documented immunity against:

(1) Rubeola (measles)

(2) Mumps

(3) Rubella (German measles)

(4) Varicella (chicken pox)

(5) Hepatitis B.

B. In accordance with 29 CFR 1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities shall make available the Hepatitis B vaccine to all health care workers with a risk of occupational exposure, at no cost to the employee.

C. All Designated Healthcare Facilities shall adopt and implement a policy that recommends and offers annual immunizations against seasonal influenza to all personnel who provide direct care to residents of the facility.

D. All Designated Healthcare Facilities shall adopt and implement a policy that recommends and offers immunization against 2009 Novel H1N1 Influenza to all personnel who provide direct care to residents of the facility.

E. No chief administrative officer may permit any employee to be in attendance at work without a certificate of immunization for each disease or other acceptable evidence of immunity to each disease, or documentation of exemption or declination.

3. Exceptions and Declinations

An employee who does not meet the immunization/immunity requirement may be permitted to attend work under the following conditions:

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(6) **Influenza**: Annual dose of inactivated influenza vaccine or live attenuated influenza vaccine.

(7) **2009 Novel H1N1 Influenza**: one dose of inactivated influenza vaccine or live attenuated influenza vaccine against 2009 novel H1N1 influenza.

B. Any such immunizing agent must meet the standards for biological products which are approved by the United States Public Health Service.

6. Exclusions from the Workplace

A. **Exclusion by order of Public Health Official**

An employee not immunized or otherwise immune from a disease shall be excluded from the worksite, when in the opinion of a public health official, the employee's continued presence at work poses a clear danger to the health of others. The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles) or varicella (chickenpox) in a designated healthcare facility or amongst its employees may be interpreted as a clear danger to the health of others.

The chief administrative officer shall exclude the employee during the period of danger or for one incubation period following immunization of the employee, when one or more cases of disease are present.

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D. Required Reports

1. Routine Reporting

The chief administrative officer of each designated healthcare facility is responsible for submitting a summary report on the immunization status of all employees by December 15 of each calendar year, on a form prescribed by the Department, to the Director of the Maine CDC of the Department of Health and Human Services. The summary report will include the following information at a minimum: Specific information identifying the facility; the chief administrative officer; the total number of employees; the number of employees born on or after January 1, 1957; and the number of employees identified by vaccine type as either immunized, serological proof of immunity, exempt, having declined hepatitis B vaccine, or out of compliance. The summary report may be constructed so as to reflect meaningful data by groupings within the facility (e.g., pediatric unit). Each report shall be signed by the hospital/facility's chief administrative officer as a certification that the information is accurate.

2. Reporting on 2009 Novel H1N1 Influenza A and Influenza

The chief administrative officer of each designated healthcare facility is responsible for submitting a summary report on a form prescribed by the Department, to the Director of the Maine CDC by December 15, 2009, March 15, 2010, and June 15, 2010 on the number of employees who are vaccinated and the total number of employees who are offered the vaccine for 2009 Novel H1N1 Influenza.

3. Maine CDC Sample Survey

The Maine CDC will, from time to time, select a sample of employee health records for the purpose of comparing reported results against the criteria delineated in these rules. The results of this sample survey will be shared with the chief administrative officer of the designated healthcare facility for the purpose of identifying problem areas that may be occurring in the maintenance of their employee health records. Any published or unpublished reports of such sampling of employee health records shall not identify individual employees and/or designated healthcare facilities, directly or indirectly.

STATUTORY AUTHORITY: 22 M.R.S.A.§802

EFFECTIVE DATE:
April 16, 2002

NON-SUBSTANTIVE CORRECTIONS:
May 13, 2002 - corrected the spelling of DEPARTMENT in header, page 1
May 10, 2004 - spacing, capitalization and punctuation only

EFFECTIVE DATE:
October 6, 2009 to January 4, 2010: filing 2009-531 (EMERGENCY)
December 8, 2009 – filing 2009-644

Proofed
4/29/02

10-144 DEARTMENT OF HUMAN SERVICES

BUREAU OF HEALTH

Chapter 264: IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

SUMMARY: Healthcare workers are at risk for exposure to and possible transmission of vaccine preventable diseases due to their contact with patients, or infectious material from patients. The health and safety of the health-care workers and the patients they care for is an essential area of concern.

This rule is issued pursuant to the statutory authority of the Department of Human Services to require immunization of the employees of designated health care facilities as set forth in 22 M.R.S.A.§802, as amended by P.L. 2001, Ch. 185. It prescribes the dosage for required immunizations and defines responsibilities, exclusion periods, record keeping and reporting requirements for officials of hospitals and healthcare facilities.

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1. Definitions

A. "Certificate of Immunization" means a written statement from a physician, nurse or health official who has administered an immunization agent to an employee, specifying the vaccine administered and the date it was administered. Secondary school or collegiate health records, having been compiled and maintained as an official document based on certificates of immunization, which provide at a minimum the month and year that the immunization was administered and/or which contain copies of laboratory evidence of immunity, may also be accepted as proof of immunization.

B. "Chief administrative officer" means the person designated as the president, chief executive officer, administrator, director or otherwise the senior official of a designated health facility.

C. "Declination" means a formal process where an individual makes an informed choice declining Hepatitis B vaccination, following standards and procedures established by the federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910.1030(f)(2)(iv) (effective July 6, 1992).

D. "Designated Healthcare Facility" means a licensed nursing facility, residential care facility, Intermediate Care Facility for the Mentally Retarded (ICF/MR), multi-level health care facility, hospital, or home health agency.

E. "Disease" means the following conditions which may be preventable by immunization agent:

(1) Rubeola (measles)

(2) Rubella (German measles)

(3) Hepatitis B

(4) Influenza

(5) Mumps

(6) Varicella (chickenpox).

F. "Employee" means a person who performs a service for wages or other remuneration for a designated health facility.

G. "Exemption" means a formal procedure to procure discharge from requirement to vaccinate.

H. "Immunization agent" means a vaccine, antitoxin, or other substances used to increase an individual's immunity to disease.

I. "Public Health Official" means a local health officer, the Director of the Maine Bureau of Health, or a designated employee or agent of the Maine Department of Human Services.

2. Immunizations Required

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine shall require for all employees proof of immunization or documented immunity against:

(1) Rubeola (measles)

(2) Mumps

(3) Rubella (German measles)

(4) Varicella (chicken pox)

(5) Hepatitis B

B. In accordance with 29 CFR 1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities shall make available the Hepatitis B vaccine to all health care workers with a risk of occupational exposure, at no cost to the employee.

C. All Designated Healthcare Facilities shall adopt a policy that recommends and offers annual immunizations against influenza to all personnel who provide direct care to residents of the facility.

D. No chief administrative officer may permit any employee to be in attendance at work without a certificate of immunization for each disease or other acceptable evidence of immunity to each disease, or documentation of exemption or declination.

3. Exceptions and Declinations

An employee who does not meet the immunization/immunity requirement may be permitted to attend work under the following conditions:

A. The employee presents to the designated healthcare facility a physician's written statement that immunization against one or more of these diseases is medically inadvisable. If the statement does not include all diseases, the employee must meet the immunization/immunity requirements for any diseases not covered by the statement.

B. The employee states in writing an opposition to immunization because of a sincere religious belief or for philosophical reasons.

C. Declination for Hepatitis B pursuant to OSHA Regulations: An exemption is available to an employee who declines Hepatitis B vaccination in accordance with the applicable regulations established by the Occupational Safety and Health Administration.

4. Certification of Immunization and Proof of Immunity

A. Certificate of Immunization

To demonstrate proper immunization against each disease, an employee shall present the designated healthcare facility with a Certificate of Immunization from a physician, nurse or health official who has administered the immunizing agent(s) to the employee. Physicians within their own practice may authorize their own employees to issue a certificate of immunization on behalf of the physician. The certificate shall specify the immunizing agent, and the date(s), including month and year, on which it was administered. Physicians, having reviewed

official patient records created by another practitioner which indicate that a particular patient has received an immunization on a specified date, demonstrating at a minimum the month and year the immunization was given, may certify that the immunization was given. Adequately prepared secondary and/or collegiate school health records will also be considered acceptable for the purpose of meeting this requirement.

B. Proof of Immunity

To demonstrate that an employee is immune to any of the diseases, the employee shall present the hospital/facility with laboratory evidence demonstrating immunity, or other acceptable evidence of immunity. (See 7-B Individual Health Records.)

5. Immunization Dosage

A. The following schedule contains the minimally required number of doses for the immunizing agents addressed under these rules:

(1) Rubeola (Measles): Two (2) doses of live measles vaccine given after the first birthday, with a minimum of four weeks separating the 2 doses.

(2) Mumps: One (1) dose of live mumps vaccine given after the first birthday.

(3) Rubella (German Measles): One (1) dose of live rubella vaccine given after the first birthday.

(4) Varicella (Chickenpox): Two (2) doses of live varicella vaccine given after the first birthday, with a minimum of four weeks separating the 2 doses.

(5) Hepatitis B: Three (3) doses of hepatitis B vaccine, the first two given one month apart and the third given five months after the second.

(6) Influenza: Annual dose of inactivated influenza vaccine.

B. Any such immunizing agent must meet the standards for biological products which are approved by the United States Public Health Service.

6. Exclusions from the Workplace

A. Exclusion by order of Public Health Official

An employee not immunized or otherwise immune from a disease shall be excluded from the worksite, when in the opinion of a public health official, the employee's continued presence at work poses a clear danger to the health of others. The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles) or varicella (chickenpox) in a designated healthcare facility or amongst its employees may be interpreted as a clear danger to the health of others.

The chief administrative officer shall exclude the employee during the period of danger or for one incubation period following immunization of the employee, when one or more cases of disease are present.

B. The following periods are defined as the "period of danger":

(1) Measles: 15 days from the onset of symptoms from the last identified case

(2) Mumps: 18 days from the onset of symptoms from the last identified case

(3) Rubella: 23 days from the onset of symptoms from the last identified case

(4) Varicella: 16 days from the onset of symptoms from the last identified case

C. Except as otherwise provided for by law, contract or collective bargaining Agreement, an employer will not be responsible for maintaining an employee in pay status as a result of this rule.

D. When a public health official determines there are reasonable grounds to believe a public health threat exists, an exempted employee may be immunized or tested for serologic evidence of immunity. Employees without serologic evidence of immunity and those who become immunized against the disease in question at the time of a documented case or cases of disease must be excluded from the work site during one incubation period.

7. Records and Record Keeping

A. Designated Record Keeping

The chief administrative officer in each designated healthcare facility shall be responsible for the maintenance of employee immunization records. The chief

administrative officer may designate a person to be responsible for record keeping.

B. Individual Health Records

Each designated healthcare facility shall adopt a uniform, permanent health record for maintaining information regarding the health status of each employee. The immunization status of each employee with regard to each disease shall be noted on the employee's health record. The health record of each employee shall include at a minimum the month and year that each immunizing agent was administered.

Where an exception has been granted for medical or religious reason, the written request for exemption must be on file with the employee health record. Where laboratory or other acceptable evidence of immunity has been submitted, a copy of the documentation must also be on file.

C. List of Non-Immunized Employees

The chief administrative officer or his/her designee in each designated healthcare facility shall keep a listing of the names of all employees within the facility who are not currently immunized or do not have documented serological immunity against each disease. This list shall include the names of all employees with authorized exemptions from immunization as well as any who are otherwise not known to be immune and shall state the reason that the employee is not immune. The purpose of the list is to provide an efficient means to rapidly contact non-immunized employees in the event of disease outbreaks and exclude them from the workplace as necessary.

D. Required Reports

The chief administrative officer of each designated healthcare facility is responsible for submitting a summary report on the immunization status of all employees by December 15 of each calendar year, on a form prescribed by the Department, to the Director of the Bureau of Health of the Department of Human Services. The summary report will include the following information at a minimum: Specific information identifying the facility; the chief administrative officer; the total number of employees; the number of employees born on or after January 1, 1957; and the number of employees identified by vaccine type as either immunized, serological proof of immunity, exempt, having declined hepatitis B vaccine, or out of compliance. The summary report may be constructed so as to reflect meaningful data by groupings within the facility (e.g., pediatric unit). Each report shall be signed by the hospital/facility's chief administrative officer as a certification that the information is accurate.

The Bureau of Health will, from time to time, select a sample of employee health records for the purpose of comparing reported results against the criteria

delineated in these rules. The results of this sample survey will be shared with chief administrative officer of the designated healthcare facility for the purpose of identifying problem areas that may be occurring in the maintenance of their employee health records. Any published or unpublished reports of such sampling of employee health records shall not identify individual employees and/or designated healthcare facilities, directly or indirectly.

8. Effective Date

Designated healthcare facilities under this section shall be allowed up to one year from the effective date of this rule to ensure that all employees are in compliance with the requirements herein.

STATUTORY AUTHORITY: 22 M.R.S.A.§802

EFFECTIVE DATE:
April 16, 2002

10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

Chapter 264: IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

SUMMARY: Healthcare workers are at risk for exposure to and possible transmission of vaccine preventable diseases due to their contact with patients, or infectious material from patients. The health and safety of the health care workers and the patients they care for is an essential area of concern.

This rule is issued pursuant to the statutory authority of the Department of Human Services to require immunization of the employees of designated health care facilities as set forth in 22 M.R.S.A.§802, as amended by P.L. 2001, Ch. 185. It prescribes the dosage for required immunizations and defines responsibilities, exclusion periods, record keeping and reporting requirements for officials of hospitals and healthcare facilities.

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D. "Designated Healthcare Facility" means a licensed nursing facility, residential care facility, Intermediate Care Facility for the Mentally Retarded (ICF/MR), multi-level health care facility, hospital, or home health agency.

E. "Disease" means the following conditions which may be preventable by immunization agent:

(1) Rubeola (measles)

(2) Rubella (German measles)

(3) Hepatitis B

(4) Seasonal Influenza

(5) Mumps

(6) Varicella (chickenpox)

(7) 2009 Novel H1N1 Influenza.

F. "Employee" means a person who performs a service for wages or other remuneration for a designated health facility.

G. "Exemption" means a formal procedure to procure discharge from requirement to vaccinate.

H. "Immunization agent" means a vaccine, antitoxin, or other substances used to increase an individual's immunity to disease.

I. "Public Health Official" means a local health officer, the Director of the Maine Center for Disease Control and Prevention, or a designated employee or agent of the Maine Department of Health and Human Services.

2. Immunizations Required

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine shall require for all employees proof of immunization or documented immunity against:

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(3) Rubella (German measles)

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(5) Hepatitis B.

B. In accordance with 29 CFR 1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities shall make available the Hepatitis B vaccine to all health care workers with a risk of occupational exposure, at no cost to the employee.

C. All Designated Healthcare Facilities shall adopt and implement a policy that recommends and offers annual immunizations against seasonal influenza to all personnel who provide direct care to residents of the facility.

D. All Designated Healthcare Facilities shall adopt and implement a policy that recommends and offers immunization against 2009 Novel H1N1 Influenza to all personnel who provide direct care to residents of the facility.

E. No chief administrative officer may permit any employee to be in attendance at work without a certificate of immunization for each disease or other acceptable evidence of immunity to each disease, or documentation of exemption or declination.

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(7) **2009 Novel H1N1 Influenza**: one dose of inactivated influenza vaccine or live attenuated influenza vaccine against 2009 novel H1N1 influenza.

B. Any such immunizing agent must meet the standards for biological products which are approved by the United States Public Health Service.

6. Exclusions from the Workplace

A. **Exclusion by order of Public Health Official**

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(1) **Measles**: 15 days from the onset of symptoms from the last identified case

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D. Required Reports

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3. Maine CDC Sample Survey

The Maine CDC will, from time to time, select a sample of employee health records for the purpose of comparing reported results against the criteria delineated in these rules. The results of this sample survey will be shared with the chief administrative officer of the designated healthcare facility for the purpose of identifying problem areas that may be occurring in the maintenance of their employee health records. Any published or unpublished reports of such sampling of employee health records shall not identify individual employees and/or designated healthcare facilities, directly or indirectly.

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EFFECTIVE DATE:
October 6, 2009 to January 4, 2010: filing 2009-531 (EMERGENCY)
December 8, 2009 – filing 2009-644

UNITED STATES DISTRICT COURT
FOR THEDISTRICT OF MAINE

JANE DOES 1-6, et al.,

Plaintiffs,

v.

JANET T. MILLS, in her official capacity as the Governor of the State of Maine, et al.,

Defendants.

Civil Action No. 1:21-cv-00242-JDL

DECLARATION OF NIRAV DINESH SHAH, M.D., J.D.

I, Nirav Dinesh Shah, hereby declare as follows:

1. My name is Nirav Dinesh Shah. I am the Director of the Maine Center for Disease Control and Prevention ("Maine CDC"), a bureau within the Maine Department of Health and Human Services (Department).

2. I hold a medical degree (MD) and a law degree (JD), both from The University of Chicago.

3. I previously served as the Director of the Illinois Department of Public Health from January 2015-February 2019.

4. I have served as Director of the Maine CDC since June 2019.

5. My professional experience includes having worked on the public health response to large, multi-country outbreaks.

6. I previously worked for the National Institute for Public Health of the Ministry of Health for the country of Cambodia. There, I was part of a large team that managed the country

of Cambodia's response to the outbreak of Severe Acute Respiratory Syndrome (SARS) in 2002.

7. I have also been part of epidemiological investigation teams that have responded to outbreaks of dengue fever, falciparum-resistant malaria, multi-drug-resistant tuberculosis, and HIV, among others.

8. During my time as Director of the Illinois Department of Public Health, I led the State of Illinois's response to large international outbreaks such as Zika virus, among others. I have also taught classes in mathematical epidemiology and public health at The University of Chicago Pritzker School of Medicine.

9. As the Director of the Maine CDC, I have been responsible for coordinating the public health aspects of the State of Maine's response to the COVID-19 pandemic. On a daily basis, I review emerging data and research from the Maine CDC, the United State Centers for Disease Control and Prevention (USCDC), the United States Food and Drug Administration (FDA), the World Health Organization (WHO), and academic researchers around the world, among other sources.

10. The information in this declaration is based upon my personal knowledge, scientific expertise, and information that is required to be reported to the Maine CDC.

11. The 2019 Novel Coronavirus (COVID-19) is a respiratory illness caused by a coronavirus, known as SARS-CoV-2. COVID-19 was first identified in December 2019 in Wuhan City, China, and has since spread around the world.

12. On January 31, 2020, the United States Department of Health and Human Services determined that as of January 27, 2020, the COVID-19 virus constituted a nationwide

public health emergency. On March 11, 2020, the World Health Organization declared the COVID-19 virus to be a global pandemic.

13. As of September 12, 2021, there have been approximately 219 million cases of COVID-19 worldwide, including approximately 41 million in the United States alone. There have been approximately 4.55 million deaths from COVID-19 worldwide; approximately 660,000 of those deaths were in the United States.

14. As of 12:00 p.m. on September 14, 2021, there have been 81,177 total cases of COVID-19 in Maine, including 969 deaths from COVID-19.

15. As of September 14, 2021, based on daily reporting to CDC's Public Health Emergency Preparedness (PHEP) team, there are 192 people hospitalized with COVID-19 in Maine. Of those, 66 are in an intensive care unit, and 39 are on a ventilator. Of the 332 ICU beds available in the state, 61 are available.

16. As of September 9, 2021, 67% of individuals hospitalized with COIVD-19 in Maine were not fully vaccinated. That number has fluctuated and was, at one time, as high as 94%. At certain times in some hospitals in Maine, 100% of all patients in the ICU were not fully vaccinated.

17. COVID-19 spreads when an infected person exhales droplets and/or very small aerosol particles that contain the virus. These droplets and/or aerosols can be inhaled by other people or land on their eyes, noses, or mouth. People who are closer than 6 feet from the infected person for more than 15 cumulative minutes are most likely to get infected. COVID-19 is spread in three main ways:

    a. Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus.

b. Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze.

c. Touching eyes, nose, or mouth with hands that have the virus on them.

18. The COVID-19 virus variants that circulated at the beginning of the pandemic had an incubation period of up to 14 days. A person could be infected and spread the virus during that entire time period, sometimes without experiencing any symptoms during that time.

19. This phenomenon, known as "asymptomatic transmission," makes control of COVID-19 especially challenging because individuals can transmit the disease before knowing they may have it. An analysis by the USCDC concluded that approximately 40% of all COVID-19 transmission of the early variants could occur while individuals were asymptomatic and approximately 35% of all COVID-19 patients did not have symptoms at all.

20. Given the length of the pandemic, several variants of SARS-CoV-2 have emerged over time.

21. All variants of the COVID-19 virus spread easily between people at a rate faster than influenza spreads.

22. An even more contagious variant of the novel coronavirus, known as the Delta variant, emerged in 2021. According to the USCDC, the Delta variant is more than twice as contagious as previous variants and may cause more severe illness than previous variants in unvaccinated people.

23. According to recent nationwide data published by the USCDC, unvaccinated individuals are at least 10 times more likely to be hospitalized with COVID-19 than those who have been vaccinated. The same data showed that unvaccinated individuals are 11 times more likely to die of the virus as compared with vaccinated individuals.

24. The higher contagiousness and potentially greater severity occur because individuals infected with the Delta variant exhibit a much higher viral load. This higher viral load makes the virus far more contagious and allows it to spread and multiply in a shorter time period.

25. It is possible for an individual infected with the Delta variant to begin spreading it to others within 24 to 36 hours of exposure.

26. The Delta variant also exhibits asymptomatic transmission.

27. Population-level immunity, colloquially referred to as "herd immunity," is an epidemiological phenomenon whereby even unvaccinated individuals are protected against an infectious disease by virtue of being in an environment with sufficiently high vaccination levels. When population-level immunity is achieved, an individual who is not able to be vaccinated can enjoy the benefits of being vaccinated because others around them are vaccinated and can block the virus from spreading from person to person.

28. The level of vaccination required to achieve population-level immunity varies with the contagiousness of the infectious disease at issue. The higher the contagiousness, the higher the vaccination rate required to achieve population-level immunity.

29. In light of the Delta variant, epidemiological models suggest that at least 90% of a population would need to be vaccinated against COVID-19 in order to achieve population-level immunity. Under models formulated based on earlier COVID-19 variants, only around 70% of the population would have needed to be vaccinated to achieve population-level immunity.

30. The treatment of patients with COVID-19 remains a clinical challenge. Though there are some medical treatments available to physicians, treatment of COVID-19 infection

consists primarily of supportive care, including supplemental oxygen and ventilator support when needed.

31. One drug efficacious in the treatment of COVID-19, remdesivir, received full FDA approval on October 22, 2020. It is unclear whether or to what extent remdesivir can reduce mortality in a statistically significant manner. It reduces the length of hospitalization for severely ill patients by approximately 4 days. Remdesivir does not prevent COVID-19.

32. Another category of pharmaceutical treatments, monoclonal antibodies, can reduce the likelihood that a patient infected with COVID-19 will require hospitalization. As with remdesivir, it is unclear whether or to what extent monoclonal antibodies may reduce mortality associated with COVID-19. In addition, administration of monoclonal antibodies is a challenge, requiring either a multi-hour infusion or multiple injections.

33. There are also therapies like the drug dexamethasone, mainly used for patients who are hospitalized. While this drug does not treat the underlying virus itself, it can reduce lung inflammation that is thought to be caused by the SARS-CoV-2 virus.

34. The gold standard to prevent and stop the spread of communicable diseases, including COVID-19, is vaccination. The elimination of communicable diseases through vaccination is one of the greatest achievements of public health in the 20th century.

35. Today, most people receive vaccinations against measles, mumps, rubella, and varicella (chicken pox) in childhood. Childhood vaccinations ensure long-term population-level immunity from communicable diseases. For instance, the following population-level vaccination rates are necessary to protect against each of the following diseases:

    a. Measles: 95%

    b. Mumps: 92%

c. Chickenpox: 90%

d. Rubella: 85%

36. Keeping the number of unvaccinated individuals in school settings as low as possible is necessary to achieve these population-level immunity thresholds and prevent outbreaks of these infectious diseases in school settings and in the general population.

37. The same is true for healthcare settings. The rationale for requiring immunization in healthcare settings is the same as that against vaccine-preventable childhood diseases: high vaccination rates prevent the spread of disease through the population and amongst vulnerable population, namely children and patients. Just as there is close contact amongst children in a classroom, healthcare settings require close contact between health care professionals and patients.

38. When vaccination rates fall below the population-level immunity rates above, the health and safety of both vaccinated and unvaccinated individuals is at risk, especially the most vulnerable. In particular, the health of individuals with weakened immune systems, infants too young to be vaccinated, and persons unable to be vaccinated are put in jeopardy.

39. In general, there are also situations when certain vaccinations may not be advisable, such as women during pregnancy, individuals undergoing treatment for serious diseases, and individuals who have a demonstrated allergy to one of the vaccine components. In these circumstances, vaccination could have adverse health consequences for the patient.

40. There are three COVID-19 vaccines that are generally available to the public.

a. On December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the use of the Pfizer-BioNTech COVID-19 Vaccine ("Pfizer vaccine"). The Pfizer vaccine EUA authorized the administration of two doses of the Pfizer

vaccine, spaced three weeks apart. On August 23, 2021, the FDA gave full approval to the Pfizer vaccine.

b. On December 18, 2020, the FDA issued an EUA for the use of the Moderna COVID-19 Vaccine ("Moderna vaccine"). The Moderna vaccine EUA authorized the administration of two doses of the Moderna vaccine, spaced four weeks apart.

c. On February 27, 2021 the FDA issued an EUA for the use of the Janssen COVID-19 Vaccine ("J&J vaccine"). The J&J vaccine EUA authorized administration of a single dose of the J&J vaccine.

d. None of these vaccines is authorized or approved for administration to children under the age of 12.

41. After receiving the final dose of one the three COVID-19 vaccines, an individual is considered "fully vaccinated" two weeks later, when the vaccine has had time to take effect.

42. The Pfizer vaccine prevented 95% of individuals in clinical trials from becoming infected with COVID-19. The Moderna vaccine prevented infection in 94.1% of cases. The Johnson & Johnson vaccine prevented 66.1% of infections globally; in the United States, it was 72% effective against infection and 86% effective in preventing severe disease.

43. Even in the face of the more-contagious Delta variant, the three available COVID-19 vaccines remain effective, particularly with respect to conferring protection against hospitalization and death.

44. The first vaccine doses in Maine were administered on December 14, 2020.

45. In Maine, as of September 9, 20201, 5,723 self-identified health care workers have contracted COVID-19. Of those, at least 1,900 (or more than one third) have occurred

since January 18, 2021. The January 18, 2021, date is important because that is the first date that any person could be considered fully vaccinated against COVID-19.

46. As of September 3, 2021, of the thirty-three COVID-19 outbreaks under investigation by Maine CDC, nineteen were occurring in health care facilities that would be covered by the recent Emergency Rule.

47. On August 11, 2021, of the fourteen open COVID-19 outbreaks under investigation by Maine CDC, four were occurring in health care facilities that would have been covered by the recent Emergency Rule, had it been in effect. These outbreaks were occurring in facilities such as long-term care facilities and hospitals. The hospitals where these outbreaks were occurring have strong infection control programs.

48. Most health care facility outbreaks are the result of health care workers who bring COVID-19 into the facility.

49. The Delta variant was first identified in Maine via genomic sequencing May 11, 2021.

50. As of August 27, 2021, the Delta variant accounted for 96.7% of all positive COVID-19 samples sequenced in Maine. According to the USCDC's variant tracker, the Delta variant is now the predominant variant within the United States.

51. In Maine, since September 1, 2021, the rate of infection in the population of individuals aged 12 and older is 8 times higher among the unvaccinated.

52. In Maine, the rate of COVID-19 hospitalization in the 12 and older population is 7.1 times higher among the unvaccinated, as compared with those who are fully vaccinated. The USCDC reported on July 25, 2021, that COVID-19 infection and hospitalization rates among unvaccinated individuals were 4.9 and 29.2 times, respectively, those in fully vaccinated individuals.

53. For the monthly reporting period ending July 31, 2021, the rate of COVID-19 vaccines among healthcare workers was as follows:

a. Ambulatory Surgical Centers: 85.9%

b. Assisted Housing Facilities: 74.7%

c. Hospitals: 80.3%

d. Intermediate Care Facilities for Individuals with Intellectual Disabilities: 68.2%

e. Nursing Homes: 73.0%

54. All facilities fell significantly below the minimum 90% threshold needed to reduce the likelihood of facility-based outbreaks.

55. In light of all of the above, Maine CDC determined that requiring COVID-19 vaccinations for healthcare workers in certain high-risk settings was necessary to protect public health, healthcare workers, and Maine's health care system from the further spread of COVID-19. Accordingly, the Department and Maine CDC issued an emergency rule (Emergency CDC Rule) that required Designated Health Care Facilities, Dental Health Practices, and Emergency Services Organizations to ensure their employees were vaccinated against COVID-19. Maine CDC determined that these types of facilities and settings posed a higher risk for transmission of COVID-19 because of the patient populations served and type of care provided.

56. There are at least four public health reasons for the issuance of the Emergency CDC Rule:

a. **Protection of individual patients.** Many patients receiving care in the settings covered by the Emergency CDC Rule are particularly vulnerable to developing serious illness as a result of COVID-19, including the elderly and those with underlying health problems.

b. **Protection of individual workers.** Workers in these high-risk healthcare settings are likely to interact with many patients in any given day, increasing the risk that they will be exposed to an individual with COVID-19. Because employees interact with not just their patients, but each other, they are also at risk of transmitting disease amongst themselves.

c. **Protection of the State's healthcare infrastructure, including the workforce.** In some areas of Maine, an outbreak among healthcare workers requiring them to quarantine, or to be absent for a longer period as a result of illness caused by COVID-19, could cripple the facility's ability to provide care. Combined with increasing infection rates in the community, this could lead to an insufficient workforce to respond to the state's healthcare needs. Even before the onset of COVID-19, Maine's healthcare system was fragile due to understaffing. An outbreak of COVID-19 amongst ICU nurses in a rural hospital could incapacitate the hospital's entire ability to care for seriously ill patients.

d. **Reducing the likelihood of facility outbreaks.** As noted above, most COVID-19 outbreaks in facilities are caused by an infected healthcare worker bringing the virus into the facility. Reducing the number of unvaccinated health care workers statewide lowers the likelihood of health care facility outbreaks. Limiting the number of outbreaks in high-risk facilities is essential to slowing the spread of COVID-19 across the state.

57. In addition to the general reasons stated above, requiring vaccination for employees of Dental Health Practices is particularly important given the nature of the care they provide. A patient receiving dental services does not have the option to wear a mask or to physically

distance; instead, they may spend an hour or more with their mouth open while in close contact with one or more providers. Under these conditions, it is essential that every available precaution be taken to prevent transmission of COVID-19, particularly against the highly transmissible Delta variant.

58. Requiring vaccination for employees of EMS organizations is essential for a number of reasons. In many cases, their patients do not have the option of controlling the environment in which they receive services. Also, their patients in many cases are in acute distress, increasing the likelihood that they will be unmasked when EMS personnel treat them. The provision of the emergency services they provide most often cannot be provided while maintaining the recommended distance; it is likely to require direct physical contact. EMS workers may spend extended periods of time riding in ambulances, putting them in close contact with both their colleagues and patients for extended periods. Transport services carry personnel and patients from one facility to another, and EMS clinicians may interact with staff at multiple nursing homes, long-term care facilities, and/or hospitals on any given day. For these reasons, taking every measure to reduce the likelihood of transmission of COVID-19, and the Delta variant in particular, is essential to protecting public health.

59. In reaching the decision to adopt this Emergency Rule, Maine CDC considered whether there were other, less restrictive measures that might be appropriate. Ultimately, we concluded that there were none.

60. Prior to the widespread availability of testing, symptom monitoring for COVID-19 prior to the start of each shift was important for infection control. Symptom monitoring remains important, though is not the sole strategy to identify individuals who have COVID-19

because of the large percentage of transmission that occurs while individuals are asymptomatic.

61. We considered the possibility of testing covered health care workers on a periodic basis. But regular testing for the presence of the virus in employees is insufficient to protect against the Delta variant. Given the speed with which the Delta variant is transmitted, weekly or twice weekly testing would be ineffective to preventing transmission. This is because the Delta variant can cause illness and spread to another person as soon as 48 hours after exposure, rendering occasional testing ineffective. An employee who tests negative on a Monday morning could be exposed that afternoon, and, within 36 hours, could be spreading the virus to others over the course of the several days until the next test.

62. Daily testing was also considered and was rejected. The most effective test utilized for the detection of the virus that causes COVID-19 is a polymerase chain reaction (PCR) test. A PCR test requires a minimum of 24 hours before results are available. Because test results are not available for at least 24 hours, and sometimes up to 72 hours, daily PCR testing is insufficient for the same reasons that occasional PCR testing is insufficient. Daily testing likely would require the use of the less-effective rapid antigen test, which provides results in fifteen minutes, but is more likely to provide false negative results. This means that an individual could test negative but, in fact, truly be carrying the virus that causes COVID-19. Moreover, the nation is currently experiencing a shortage of these rapid antigen tests, which is not expected to be alleviated in the next two months. Daily testing simply would not be effective at stopping the spread of COVID-19 in covered facilities, particularly in light of the Delta variant.

63. There continues to be significant scientific uncertainty about whether and to what extent individuals who have previously been infected with COVID-19 develop sufficient immunity to prevent them from transmitting the virus. For that reason, Maine CDC did not include a provision within our Emergency Rule providing an exemption from the vaccination requirement for health care workers who previously had COVID-19.

64. Although the use of personal protective equipment (PPE) is effective in reducing transmission, it does not eliminate the possibility of spreading COVID-19, especially in healthcare settings. As noted, 19 of the 33 COVID-19 outbreaks under investigation as of September 3, 2021, were in health care facilities that are covered by the Emergency CDC Rule. Sole reliance on PPE, even when fitted and worn correctly, is insufficient to entirely stop the spread of COVID-19 in healthcare settings in Maine.

65. Health care facilities in Maine have continued to use a mixture of these practices—symptom monitoring, testing, PPE, etc.—throughout the pandemic to reduce the likelihood of health care workers bringing COVID-19 into a facility and causing an outbreak. But despite the use of these health and safety protocols, there have been numerous COVID-19 outbreaks at health care facilities in Maine during the past 18 months.

66. Further, compared with other states, the size of Maine's healthcare workforce is limited, such that the impact of any outbreaks among personnel is far greater than it would be in a state with more extensive healthcare delivery systems. Considering the unique circumstances of the state of Maine, it is necessary to take every available precaution to limit the spread of COVID-19 both in healthcare facilities and among their workers.

67. The three COVID-19 vaccines remain the most effective method to prevent COVID-19 infection and protecting health care workers and the patients they serve.

I DECLARE, PURSUANT TO 28 U.S.C. § 1746, UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Dated: September 15, 2021

/s/ Nirav D. Shah
Nirav Dinesh Shah, M.D., J.D.

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

JANE DOES 1-6, JOHN DOES-1-3, JACK DOES 1-1000, and JOAN DOES 1-1000,

Plaintiffs,

v.

JANET T. MILLS, Governor of the State of Maine, JEANNE M. LAMBREW, Commissioner of the Maine Department of Health and Human Services, NIRAV D. SHAH, Director of the Maine Center for Disease Control, MAINEHEALTH, GENESIS HEALTHCARE OF MAINE, LLC, GENESIS HEALTHCARE, LLC, NORTHERN LIGHT FOUNDATION, and MAINEGENERAL HEALTH,

Defendants.

Civil Action No. 1:21-cv-00242-JDL

DECLARATION OF SARA GAGNÉ-HOLMES

I, Sara Gagné-Holmes, hereby declare as follows:

1. I am Sara Gagné-Holmes, an attorney authorized to practice law in Maine since 2001. I am currently a Deputy Commissioner of the Maine Department of Health and Human Services (Department). The Department includes several divisions, including the Maine Center for Disease Control and Prevention (Maine CDC). Since March of 2020, I have been involved in many aspects of the COVID-19 response including, the creation and implementation of social supports needed for those who must quarantine or isolate, policy development regarding testing, vaccine accessibility, vaccine incentives, and outreach to communities and providers.

2. The following declaration is based upon my personal knowledge and information and documents that are available to me.

3. The Maine CDC is the lead state agency guiding the State's public health-based responses to the ongoing COVID-19 pandemic.

4. The primary goal of Maine CDC's management of the COVID-19 pandemic has been to a) prevent and stop the spread of the virus that causes COVID-19 (SARS-CoV-2) in order to protect the people of Maine from acute sickness and death, and b) protect Maine's health care delivery system from being overwhelmed by an unrestrained pandemic.

5. Prior to the availability of COVID-19 vaccinations, the United States Center for Disease Control and Prevention (USCDC) and Maine CDC advised that the most effective way to limit the spread of the virus was to wear face coverings and distance members of society from one another by limiting their in-person contact.

6. Although vaccines were not available until December of 2020, Maine began planning for vaccine distribution in the spring of 2020. The Department and Maine CDC worked with hospitals, health care providers, health centers, and many others to develop a plan to facilitate distribution and administration of any COVID-19 vaccine that received authorization or approval from the Food and Drug Administration (FDA).

7. In April of 2020, the Department and Maine CDC began holding weekly remote (Zoom /telephonic) information session regarding COVID-19. The 60-minute sessions were open to the medical directors, clinicians, and staff at long term care facilities. The sessions were held weekly until approximately May of 2021, when they went to bimonthly, and then monthly in July of 2021. As of September, the sessions reverted back to bimonthly.

8. Additionally, beginning in September 2020, Maine CDC staff held weekly Vaccine Planning Group webinars that provided clinical and administrative updates both clinicians and health care administrators enrolled in the Maine Immunization Program on issues related to vaccine planning, distribution, administration, and monitoring. Those sessions were held weekly through June 2021, and were also recorded and posted to the ME CDC website.

9. Once vaccinations became available, the Department and Maine CDC undertook a series of steps to acquire and distribute those vaccines to Maine Immunization Program providers to administer to members of the public.

10. There are three COVID-19 vaccines that have been authorized for use by the FDA:

    a. On December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the use of the Pfizer-BioNTech COVID-19 Vaccine ("Pfizer vaccine"). The Pfizer vaccine EUA authorized the administration of two doses of the Pfizer vaccine, spaced three weeks apart. On August 23, 2021, the FDA gave final approval to the Pfizer vaccine.

    b. On December 18, 2020, the FDA issued an EUA for the use of the Moderna COVID-19 Vaccine ("Moderna vaccine"). The Moderna vaccine EUA authorized the administration of two doses of the Moderna vaccine, spaced four weeks apart.

    c. On February 27, 2021 the FDA issued an EUA for the use of the Janssen COVID-19 Vaccine ("J&J vaccine"). The J&J vaccine EUA authorized administration of a single dose of the J&J vaccine.

11. After receiving the final dose of one the three COVID-19 vaccines, an individual is considered "fully vaccinated" two weeks later, when the vaccine has had time to take effect.

12. Maine placed its first order for the COVID-19 vaccine from USCDC on December 4, 2020. The first allocation was 12,675 doses of Pfizer, allowing 12,675 people to receive a first dose of the Pfizer vaccine.

13. Beginning in December of 2020, the Department and Maine CDC started holding twice weekly telephonic information session regarding COVID-19 vaccines. The 30-minute sessions were open to any clinician in the State and approximately 30 to 100 clinicians attended each session. During the sessions, the Department and Maine CDC provided information on the science of vaccines; vaccine development and approval process; the mechanism and make up of initial vaccines; vaccine distribution planning; methods for addressing vaccine hesitancy and patient conversations; vaccine storage, handling and administration; and reporting and tracking adverse events. Beginning in April of 2021, the sessions were held biweekly, and then monthly starting in July of 2021.

14. In December of 2020, the Department and Maine CDC began convening on a monthly basis (30 minutes) a workgroup consisting of 12 clinicians from across the state representing different provider types, focused on getting input on the best way to offer education to clinicians on the COVID-19 vaccine.

15. First doses of COVID-19 vaccines were Pfizer vaccines administered on December 14, 2020. The first date that any person could be fully vaccinated was January 18, 2020.

16. Maine CDC prioritized eligibility for the first allocation of Pfizer vaccine, as well as the subsequent weeks' allotments of Pfizer and Moderna, to frontline health care professionals and patient facing staff in the interest of preserving health system capacity. This included, but was not limited to, hospitals, long-term care facilities, outpatient clinics, physician practices, home health care, pharmacies, emergency medical services, public health

settings, dental practices, and school nurses and school health clinics throughout Maine. Residents of long-term care facilities were also prioritized for eligibility in that first month. This prioritization was consistent with guidelines issues by USCDC.

17. Given limited vaccine supply in the first several weeks of distribution, hospitals received doses of the Pfizer and Moderna vaccine and then administered them to their staff, as well as other health care providers not on their staff but eligible under Maine guidelines. As supply expanded, so did the types of health care providers receiving vaccine to provide to eligible health care workers and long-term care residents.

18. By December 31, 2020, 27,122 healthcare workers and long-term care residents had received their first dose of the COVID-19 vaccine.

19. As Maine received further allocations of vaccines, additional members of the public became eligible for COVID-19 vaccination.

    a. The week of January 11, 2021, COVID-19 vaccines became available to firefighters, police, law enforcement personnel, and critical COVID-19 response personnel.

    b. On January 18, 2021, Maine residents age 70 and older became eligible to receive a COVID-19 vaccine.

    c. On March 3, 2021, Maine residents age 60 and older became eligible to receive a COVID-19 vaccine.

    d. On April 1, 2021, Maine residents age 50 and older became eligible to receive a COVID-19 vaccine.

    e. On April 7, 2021, all Maine residents age 16 and older became eligible to receive a COVID-19 vaccine.

f. On May 12, 2021, all Maine children ages 12 and older became eligible to receive a COVID-19 vaccine.

20. In order to facilitate the administration of COVID-19 vaccinations to members of the public, the Department and Maine CDC partnered with hospital systems to stand up and operate large throughput vaccination sites across the State. The Department and Maine CDC formed these partnerships with MaineHealth, Northern Light, Central Maine Medical Center, and MaineGeneral Health (collectively, "Hospital Systems").

21. The Department and Maine CDC provided the COVID-19 vaccines and offered the use of its newly created call centers for scheduling of vaccinations. The State also allowed for Maine Responds volunteers to be utilized at the sites.

22. Maine Responds is a program is a partnership that integrates local, regional, and statewide volunteer resources to assist our public health and healthcare systems. It is part of a national initiative to train, coordinate, and mobilize volunteers during an emergency. Maine Responds coordinates verified, pre-credentialed public health, healthcare and emergency response volunteers into a single database that can coordinate the need for volunteers across county, regional, and state lines if needed.

23. The Hospital Systems managed and operated the large throughput vaccination sites and provided staff to administers vaccines to members of the public. Maine Responds volunteers filled in as necessary to assist in the operation of the sites and administration of vaccines.

a. MaineHealth operated large throughput vaccination sites at 2 Scarborough Downs Rd, Scarborough and at 1364 Main St., Sanford.

b. Northern Light operated the large throughput vaccination site at Cross Insurance Center, 515 Main St, Bangor.

c. MaineGeneral operated the large throughput vaccination site at the Augusta Civic Center, 76 Community Dr., Augusta.

d. Central Maine Health Center operated the large throughput vaccination site at the Auburn Mall, 550 Center St., Auburn.

24. There were also vaccination sites at numerous designated health care facilities, EMS organizations, and pharmacies across the State where health care workers and members of the public could be vaccinated.

25. On March 9, 2021, the Department began providing free transportation to COVID-19 appointments to Maine residents unable to drive or travel or otherwise without reliable transportation.

26. On March 25, 2021, the Maine Legislature passed L.D. 1, "An Act To Establish the COVID-19 Patient Bill of Rights and To Amend the Governor's Emergency Powers," on an emergency basis. P.L. 2021, ch. 28 (effective Mar. 25, 2021). Two parts of that law increased the number of persons in the State who could be authorized to administer COVID-19 vaccines.

a. Part B-2 of that law permitted licensed pharmacists in the State to administer COVID-19 vaccines licensed or authorized under an EUA to persons 3 years or older.

b. Part D of that law allowed individual clinicians authorized to administer vaccines, under designated circumstances, to delegate their authority to other qualified persons.

27. On April 12, 2021, the Department and Maine CDC, in coordination with the Federal Emergency Management Agency, began operating a mobile vaccination unit to provide COVID-19 vaccinations to people in rural and under-served communities across Maine. The mobile vaccination unit was in use until June 18, 2021.

28. On May 11, 2021, the Department initiated a public-private partnership to encourage vaccination against COVID-19. Between May 11, 2021, and May 31, 2021, any person who got their first dose of a COVID-19 vaccine could receive a complimentary fishing license, a complimentary hunting license, Maine Wildlife Park Pass, a $20 L.L. Bean gift card, a ticket to a Portland Sea Dogs game, or an Oxford Plains Speedway Pass.

29. On June 16, 2021, the State announced a sweepstakes to vaccinated Mainers. The winner would receive $1 per every person vaccinated in Maine by the Fourth of July weekend.

30. Maine CDC keeps records of the number of persons that have been vaccinated against COVID-19.

    a. On January 31, 2021, 10.07% of eligible Mainers had received one dose, and 3.41% of eligible Mainers were fully vaccinated against COVID-19.

    b. On February 28, 2021, 19.90% of eligible Mainers had received one dose, and 10.85% of eligible Mainers were fully vaccinated against COVID-19.

    c. On March 31, 2021, 37.65% of eligible Mainers had received one dose, and 24.19% of eligible Mainers were fully vaccinated against COVID-19.

    d. On April 30, 2021, 55.02% of eligible Mainers had received one dose, and 45.39% of eligible Mainers were fully vaccinated against COVID-19.

    e. On May 31, 2021, 61.48% of eligible Mainers had received one dose, and 60.58% of eligible Mainers were fully vaccinated against COVID-19.

f. On June 30, 2021, 63.40% of eligible Mainers had received one dose, and 67.00% of eligible Mainers were fully vaccinated against COVID-19.

g. On July 31, 2021, 65.01% of eligible Mainers had received one dose, and 68.68% of eligible Mainers were fully vaccinated against COVID-19.

h. On August 31, 2021, 67.80% of eligible Mainers had received one dose, and 70.65% of eligible Mainers were fully vaccinated against COVID-19.

31. On April 14, 2021, the Department and Maine CDC issued an amendment to chapter 264 of their rules, "Immunization Requirements for Healthcare Workers" (CDC Rule). A true and accurate copy of that amendment is attached hereto as Exhibit 1.

32. Maine CDC periodically conducts immunization assessments of State of Maine Healthcare Workers. Attached hereto as Exhibit 2 is a true and accurate copy of the 2018 Healthcare Worker Immunization Assessment Report.

a. Maine CDC and the Department testified in favor of *An Act To Protect Maine Children and Students from Preventable Diseases by Repealing Certain Exemptions from the Laws Governing Immunization Requirements*, L.D. 798 (129th Legis. 2019).

b. The support of Maine CDC and the Department for L.D. 798 was at least in part influenced by the 2018 Healthcare Worker Immunization Assessment Report.

33. In May of 2021, Maine CDC began requiring that designated health care facilities report the rate of COVID-19 vaccination for their employees.

a. As of May 31, 2021, the employee rate of COVID-19 vaccination at ambulatory surgical centers, hospitals, and nursing homes was 80.6%, 73.5%, and 67.8%, respectively.

b. As of June 30, 2021, the employee rate of COVID-19 vaccination at ambulatory surgical centers, hospitals, and nursing homes was 85.7%, 78.7%, and 70.8%, respectively.

c. As of July 31, 2021, the employee rate of COVID-19 vaccination at ambulatory surgical centers, hospitals, and nursing homes was 85.9%, 80.3%, and 73.0%, respectively.

34. On August 12, 2021, the Department and Maine CDC issued a further amendment to the CDC Rule on an emergency basis ("Emergency CDC Rule").

a. A true and accurate copy of the Emergency CDC Rule is attached hereto as Exhibit 3.

b. A true and accurate copy of the basis statement for the Emergency CDC Rule is attached here as Exhibit 4.

c. The Emergency CDC Rule is only effective through November 10, 2021.

35. On August 17, the Department and Maine CDC issued interpretive guidance on the Emergency CDC Rule through answers to frequently asked questions (FAQs). The Emergency CDC Rule FAQs explained the definition of employees under the rule: "Employees are defined as 'any person who performs any services for wages or other remuneration for a Designated Health Care Facility, EMS Organization and Dental Practice.' For the purposes of this rule, DHHS interprets employee to mean those physically present at a Designated Health Care Facility EMS Organization or Dental Practice."

36. On August 27, 2021, the Department and Maine CDC updated the Emergency CDC Rule FAQs to include the following questions and answers:

> Does this rule prohibit Designated Health Care Facilities, Dental Health Practices, or Emergency Medical Services Organizations from making accommodations for unvaccinated employees who object to receiving the COVID-19 vaccine because of sincerely held religious beliefs, as may be required by the Maine Human Rights Act and/or Title VII of the Civil Rights Act?
>
> This rule does not prohibit employers from providing accommodations for employees' sincerely held religious beliefs or practices that may otherwise be required by law. For example, this rule does not prohibit employers from allowing employees to work remotely or reassigning employees to positions outside of a Designated Health Care Facility, Dental Health Practice, or Emergency Medical Services Organization. However, if accommodations provided by a Designated Health Care Facility, Dental Health Practice, or Emergency Medical Services Organization are not in compliance with this rule, then the Designated Health Care Facility, Dental Health Practice, or Emergency Medical Services Organization may be subject to enforcement action.
>
> If an employee of an organization is not vaccinated and doesn't plan on getting the vaccine, should they be dismissed from the organization covered by the rule on September 17 or can the employee continue to work until October 1?
>
> Organizations subject to this rule may make their own specific enforcement policies within the framework of the rule.

37. On September 2, 2021, the Department and Maine CDC announced that although the Emergency CDC Rule was not being amended, the Department and Maine CDC would not begin enforcing its provisions before October 29, 2021, thereby allowing more time for entities covered by the rule to come into compliance.

38. On September 8, 2021, the Department and Maine CDC proposed further amendment to the CDC Rule (Proposed CDC Rule), which rule is subject to a notice and comment period. A true and accurate copy of the Proposed CDC Rule is attached hereto as Exhibit 5.

I DECLARE, PURSUANT TO 28 U.S.C. § 1746, UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Dated: September 11, 2021

/s/ Sara Gagné-Holmes
Sara Gagné-Holmes, Deputy Commissioner
Maine Department of Health & Human Services

STATE OF MAINE

IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

10-144 CODE OF MAINE RULES
CHAPTER 264

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
Augusta, Maine 04333-0011

Date Amended: April 14, 2021

10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

Chapter 264: IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

Purpose: This rule is issued pursuant to the statutory authority of the Department of Health and Human Services to require immunization of the employees of designated healthcare facilities as set forth in 22 MRS §802 to reduce the risk for exposure to, and possible transmission of, vaccine-preventable diseases due to healthcare workers' contact with patients, or infectious material from patients. It prescribes the dosage for required immunizations and defines responsibilities, exclusion periods, record keeping and reporting requirements for officials of hospitals and healthcare facilities.

1. Definitions

A. **Certificate of Immunization** means a written statement from a physician, nurse, physician assistant or health official who has administered an immunization agent to an employee, specifying the vaccine administered and the date it was administered. Secondary school or collegiate health records, having been compiled and maintained as an official document based on certificates of immunization, which provide at a minimum the month and year that the immunization was administered and/or which contain copies of laboratory evidence of immunity, may also be accepted as proof of immunization.

B. **Chief Administrative Officer** means the person designated as the president, chief executive officer, administrator, director or otherwise the senior official of a Designated Healthcare Facility.

C. **Declination** means a formal process where an individual makes an informed choice declining Hepatitis B vaccination, following standards and procedures established by the federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR §1910.1030(f)(2)(iv) (effective July 6, 1992).

D. **Designated Healthcare Facility** means a licensed nursing facility, residential care facility, Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), multi-level healthcare facility, hospital, or home health agency subject to licensure by the State of Maine, Department of Health and Human Services Division of Licensing and Certification.

E. **Disease** means the following conditions which may be preventable by immunization agent:

1. Rubeola (measles);

2. Mumps;

3. Rubella (German measles);

4. Varicella (chicken pox);

5. Hepatitis B.; and

6. Influenza.

F. **Employee** means a person who performs a service for wages or other remuneration for a Designated Healthcare Facility.

G. **Exemption** means a formal procedure to procure discharge from requirement to vaccinate.

H. **Extreme Public Health Emergency** means a state of emergency declared by the Governor of the State of Maine pursuant to 22 MRS §802(2-A) and 37-B MRS §742 based upon an occurrence or imminent threat of widespread exposure to a highly infectious or toxic agent that poses an imminent threat of substantial harm to the population of the State.

I. **Immunization agent** means a vaccine, antitoxin, or other substances used to increase an individual's immunity to disease.

J. **Public Health Emergency** means a declaration by the Department, arising from an actual or threatened epidemic or public health threat for which the Department may adopt emergency rules for the protection of the public health, pursuant to 22 MRS §802(2).

K. **Public Health Official** means a local health officer, the Director of the Maine Center for Disease Control and Prevention (Maine CDC), or a designated employee or agent of the Maine Department of Health and Human Services (Department).

L. **Public Health Threat** means a condition or behavior that can reasonably be expected to place others at significant risk of exposure to a toxic agent or environmental hazard or infection with a notifiable disease or condition, as defined in 22 MRS §801.

2. Immunizations Required

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine must require for all employees proof of immunization or documented immunity against:

1. Rubeola (measles);

2. Mumps;

3. Rubella (German measles);

4. Varicella (chicken pox);

5. Hepatitis B; and

6. Influenza.

B. In accordance with 29 CFR §1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities must make available the Hepatitis B vaccine to all healthcare workers with a risk of occupational exposure, provided at no cost to the employee and at a reasonable time and place.

C. In the event of a Public Health Emergency or Extreme Public Health Emergency declared by the Governor, the Department may impose control measures, including, but not limited to, mass vaccinations and exclusions from the workplace, and may require immunization or documented immunity to protect public health and minimize the impact from the specific communicable disease.

D. No Chief Administrative Officer may permit any employee to be in attendance at work without a certificate of immunization for each disease or other acceptable evidence of immunity to each disease, or documentation of authorized exemption or declination in accordance with 22 MRS §802(4-B).

3. Exceptions and Declinations

An employee who does not provide proof of immunization or immunity for a vaccine required under this rule may be permitted to attend work if that employee is exempt in accordance with 22 MRS §802 (4-B). Documentation for an employee's immunization exemption must be maintained in the permanent health record for that employee for a minimum of six years after termination.

4. Certification of Immunization and Proof of Immunity

A. Certificate of Immunization

To demonstrate proper immunization against each disease, an employee must present the Designated Healthcare Facility with a Certificate of Immunization from a physician, nurse or health official who has administered the immunizing agent(s) to the employee. Physicians within their own practice may authorize their own employees to issue a certificate of immunization on behalf of the physician. The certificate must specify the immunizing agent, and the date(s), including month and year, on which it was administered. Physicians, having reviewed official patient records created by another practitioner which indicate that a particular patient has received an immunization on a specified date, demonstrating at a minimum the month and year the immunization was given, may certify that the immunization was given. Adequately prepared secondary and/or collegiate school health records will also be considered acceptable for the purpose of meeting this requirement.

B. **Proof of Immunity**

To demonstrate that an employee is immune to any of the diseases, the employee must present the hospital/facility with laboratory evidence demonstrating immunity, or other acceptable evidence of immunity. (See Section 7-B Individual Health Records.)

5. Immunization Dosage

A. The following schedule contains the minimally required number of doses for the immunizing agents addressed under this rule:

1. **Rubeola (Measles)**: Two doses of live measles vaccine given after the first birthday, with a minimum of four weeks separating the two doses.

2. **Mumps**: Two doses of live mumps vaccine given after the first birthday.

3. **Rubella (German Measles)**: Two doses of live rubella vaccine given after the first birthday.

4. **Varicella (Chickenpox)**: Two doses of live varicella vaccine given after the first birthday, with a minimum of four weeks separating the two doses.

5. **Hepatitis B**: Three doses of hepatitis B vaccine, the first two given one month apart and the third given five months after the second.

6. **Influenza**: Annual dose of inactivated influenza vaccine or live attenuated influenza vaccine.

In the event of a Public Health Emergency or Extreme Public Health Emergency declared by the Governor, the Maine CDC will specify the recommended dose for any vaccination imposed as a control measure to protect public health.

B. Any such immunizing agent must meet the standards for biological products which are approved by the United States Public Health Service.

6. Exclusions from the Workplace

A. **Exclusion by order of Public Health Official**

An employee not immunized or otherwise immune from a disease must be excluded from the worksite, when in the opinion of a public health official, the employee's continued presence at work poses a clear danger to the health of others. The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles) or varicella (chickenpox) in a Designated Healthcare Facility or amongst its employees may be interpreted as a clear danger to the health of others.

The Chief Administrative Officer must exclude the employee during the period of danger or for one incubation period following immunization of the employee, when one or more cases of disease are present.

B. The following periods are defined as the "period of danger:"

1 **Measles**: 15 days from the onset of symptoms from the last identified case

2. **Mumps**: 18 days from the onset of symptoms from the last identified case

3. **Rubella**: 23 days from the onset of symptoms from the last identified case

4. **Varicella**: 16 days from the onset of symptoms from the last identified case.

C. Except as otherwise provided for by law, contract or collective bargaining agreement, an employer will not be responsible for maintaining an employee in pay status as a result of this rule.

D. When a public health official determines there are reasonable grounds to believe a Public Health Threat exists, an exempted employee may be immunized or tested for serologic evidence of immunity. Employees without serologic evidence of immunity and those who become immunized against the disease in question at the time of a documented case or cases of disease must be excluded from the work site during one incubation period.

7. Records and Record Keeping

A. Designated Record Keeping

The Chief Administrative Officer in each Designated Healthcare Facility must be responsible for the maintenance of employee immunization records. The Chief Administrative Officer may designate a person to be responsible for record keeping.

B. Individual Health Records

Each Designated Healthcare Facility must adopt a uniform, permanent health record for maintaining information regarding the health status of each employee. The immunization status of each employee with regard to each disease must be noted on the employee's health record. The health record of each employee must include at a minimum the month and year that each immunizing agent was administered. Health records are to be retained a minimum of six years after the date the employee is no longer employed.

Where an exception has been granted for a reason authorized by law, the written request for exemption must be on file with the employee health record. Where laboratory or other acceptable evidence of immunity has been submitted, a copy of the documentation must also be on file.

C. List of Non-Immunized Employees

The Chief Administrative Officer or his/her designee in each Designated Healthcare Facility must keep a listing of the names of all employees within the facility who are not currently immunized or do not have documented serological immunity against each disease. This list must include the names of all employees with authorized exemptions from immunization as well as any who are otherwise not known to be immune and must state the reason that the employee is not immune. The purpose of the list is to provide an efficient means to rapidly contact non-immunized employees in the event of disease outbreaks and exclude them from the workplace as necessary.

D. **Required Reports**

1. **Routine Reporting**

The Chief Administrative Officer of each Designated Healthcare Facility is responsible for submitting a summary report on the immunization status of all employees by December 15 of each calendar year, on a form prescribed by the Maine CDC. The summary report will include the following information at a minimum: specific contact information identifying the facility; the name of the Chief Administrative Officer; the total number of employees; the number of employees born on or after January 1, 1957; and the number of employees identified by vaccine type as either immunized, serological proof of immunity, exempt in accordance to law, having declined hepatitis B vaccine, or out of compliance. The summary report may be constructed so as to reflect meaningful data by groupings within the facility (e.g., pediatric unit). Each report must be signed by the Chief Administrative Officer as a certification that the information is accurate.

2. **Maine CDC Sample Survey**

The Maine CDC will conduct periodic reviews by selecting a sample of employee health records for the purpose of comparing reported results against the criteria delineated in these rules. The results of this sample survey will be shared with the Chief Administrative Officer of the Designated Healthcare Facility for the purpose of identifying problem areas that may be occurring in the maintenance of their employee health records. Any published or unpublished reports of such sampling of employee health records must not identify individual employees and/or Designated Healthcare Facilities, directly or indirectly.

STATUTORY AUTHORITY:
22 MRS §802(3)

EFFECTIVE DATE:
April 16, 2002

NON-SUBSTANTIVE CORRECTIONS:
May 13, 2002 - corrected the spelling of DEPARTMENT in header, page 1
May 10, 2004 - spacing, capitalization and punctuation only

EFFECTIVE DATE:
October 6, 2009 to January 4, 2010 - filing 2009-531 (EMERGENCY)
December 8, 2009 – filing 2009-644
April 14, 2021 – filing 2021-068 (ROUTINE TECHNICAL)

Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
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2018 Healthcare Worker Immunization Assessment Report

The Maine Immunization Program conducts an annual immunization assessment of State of Maine Healthcare Workers. Rules pursuant to 22 M.R.S. § 802 requires each designated healthcare facility in the State of Maine to require from all employees proof of immunization or documented immunity against Measles, Mumps, Rubella, Varicella, and also Hepatitis B for all at-risk employees. The healthcare facility should also adopt a uniform, permanent health record for maintaining information regarding the health status of each employee and submit a summary of the immunization status of all employees to the Maine CDC annually.

The 2018 Healthcare Worker Immunization Survey was conducted online from October to December 31, 2018. The vaccination data reported by all facility types was analyzed and a summary table was generated (Table 1). Hospital specific data was analyzed separately and graphical representations of these results by vaccine type can be found on the following pages (Figures 1-5).

Immunization is the most effective and efficient way to ensure that healthcare workers, their family members, and patients, particularly those who are immunocompromised, are protected against these vaccine preventable diseases. This is perhaps one of the most important reasons why it would be advantageous for facilities to meet all requirements of the Maine Immunization Healthcare Workers law and to help reach the goal of the Maine Immunization Program to bring the State vaccine coverage rate average for each of these vaccines to 100%.

Table 1: Immunization Rates by Facility Type

2018 Healthcare Worker Immunization Rates by Facility Type, Statewide							
Vaccine	Home Health	Hospital	Intermediate Care/MR	Licensed Nursing	Multi-Level Healthcare	Residential Care	All Reporting Facilities
# Facilities Assessed	**13**	**33**	**9**	**33**	**15**	**113**	**216**
Hepatitis B	79.3%	91.8%	70.4%	73.5%	75.5%	47.9%	84.5%
Measles	88.6%	97.6%	91.5%	86.3%	89.8%	62.6%	93.1%
Mumps	87.8%	97.4%	90.4%	86.1%	89.7%	62.6%	92.9%
Rubella	89.8%	97.9%	91.5%	86.3%	90.0%	62.5%	93.4%
Varicella	95.4%	98.1%	91.1%	85.0%	88.3%	61.8%	93.7%

Figure 1: Hepatitis B Immunization Rates

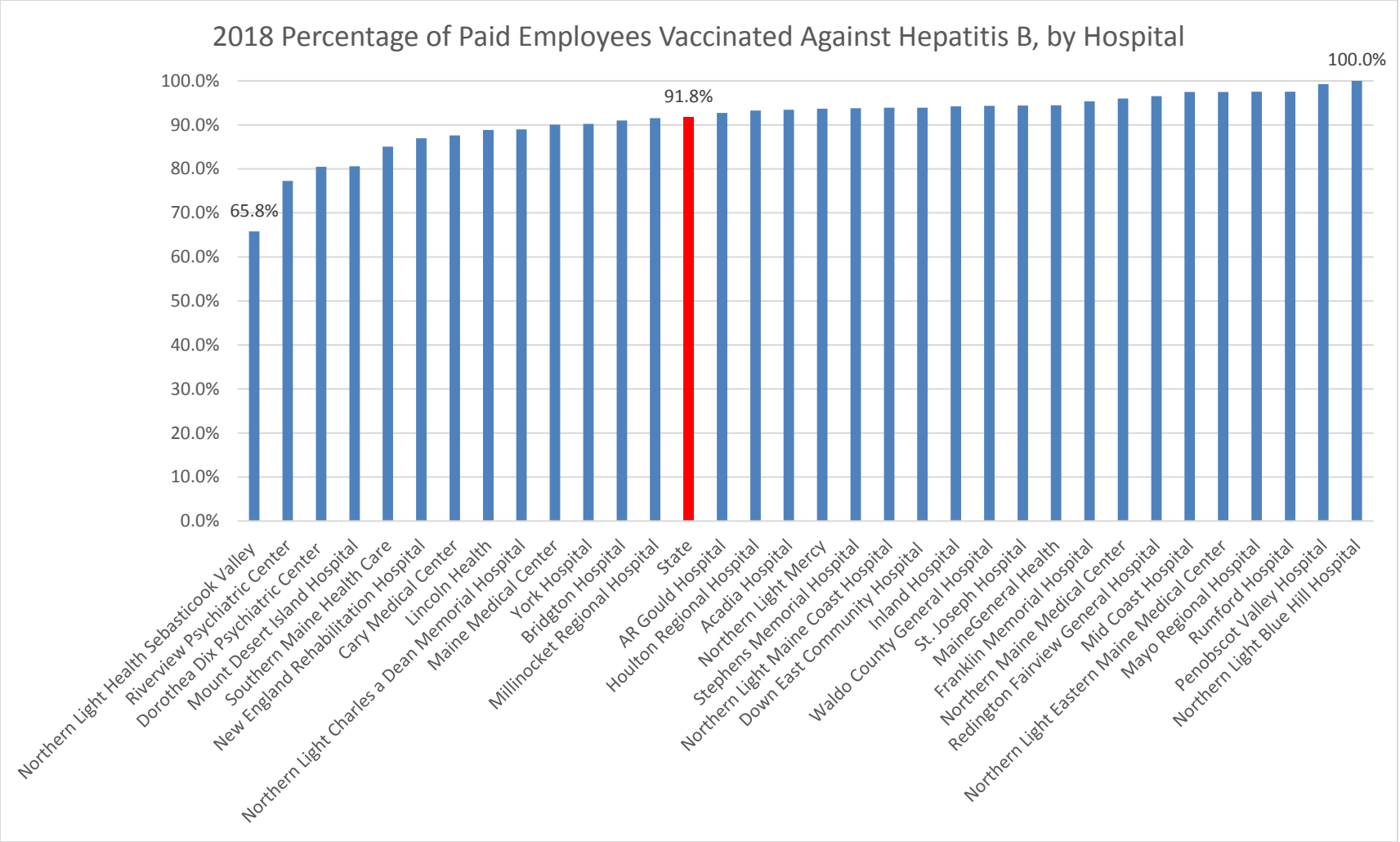

Figure 1: The bars in the graph above represent the percent of healthcare workers who are immune to hepatitis B by vaccination or have laboratory evidence of immunity.

EXHIBIT 2

Figure 2: Measles Immunization Rates

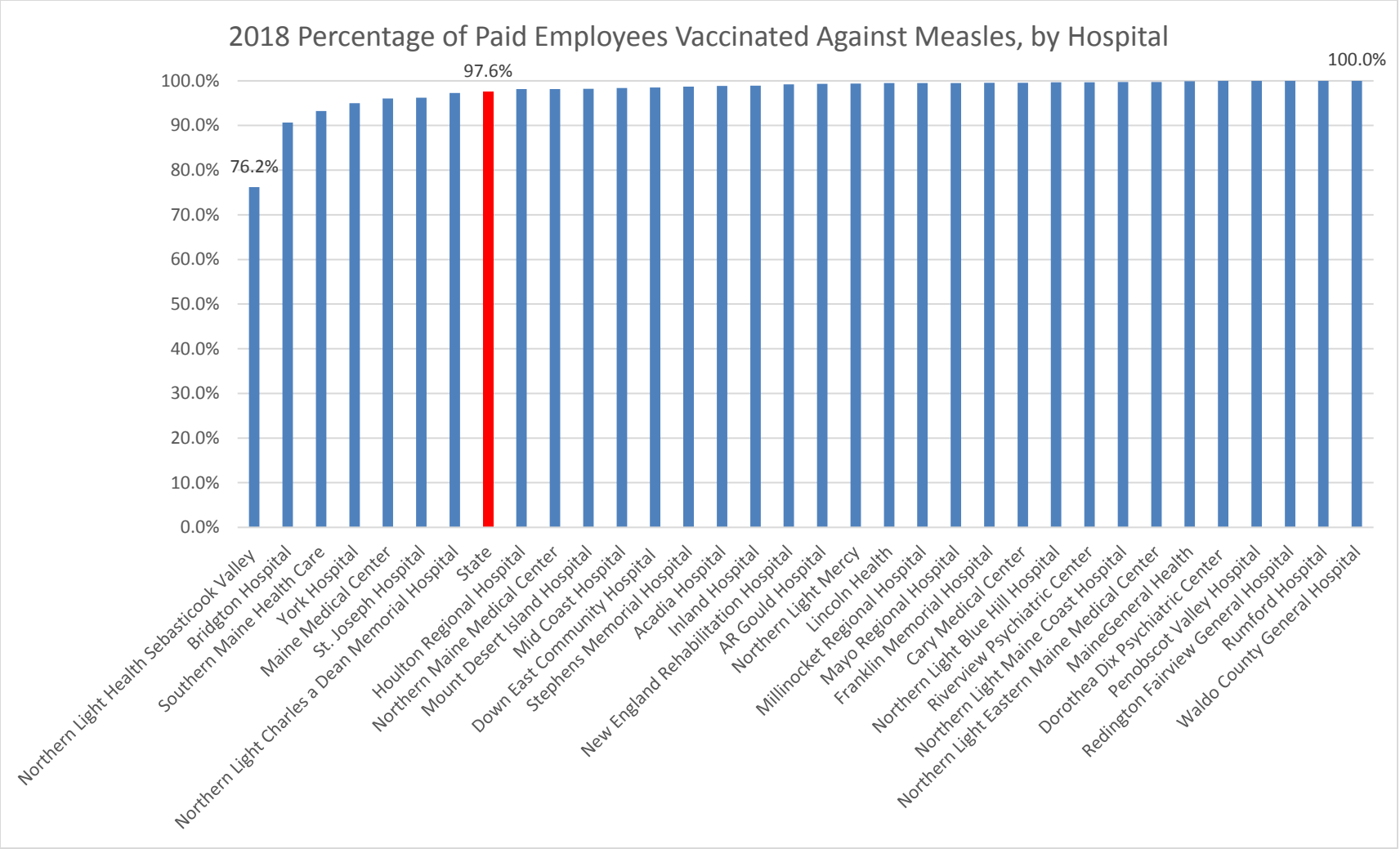

Figure 2: The bars in the graph above represent the percent of healthcare workers who are immune to measles by vaccination or have laboratory evidence of immunity.

Figure 3: Mumps Immunization Rates

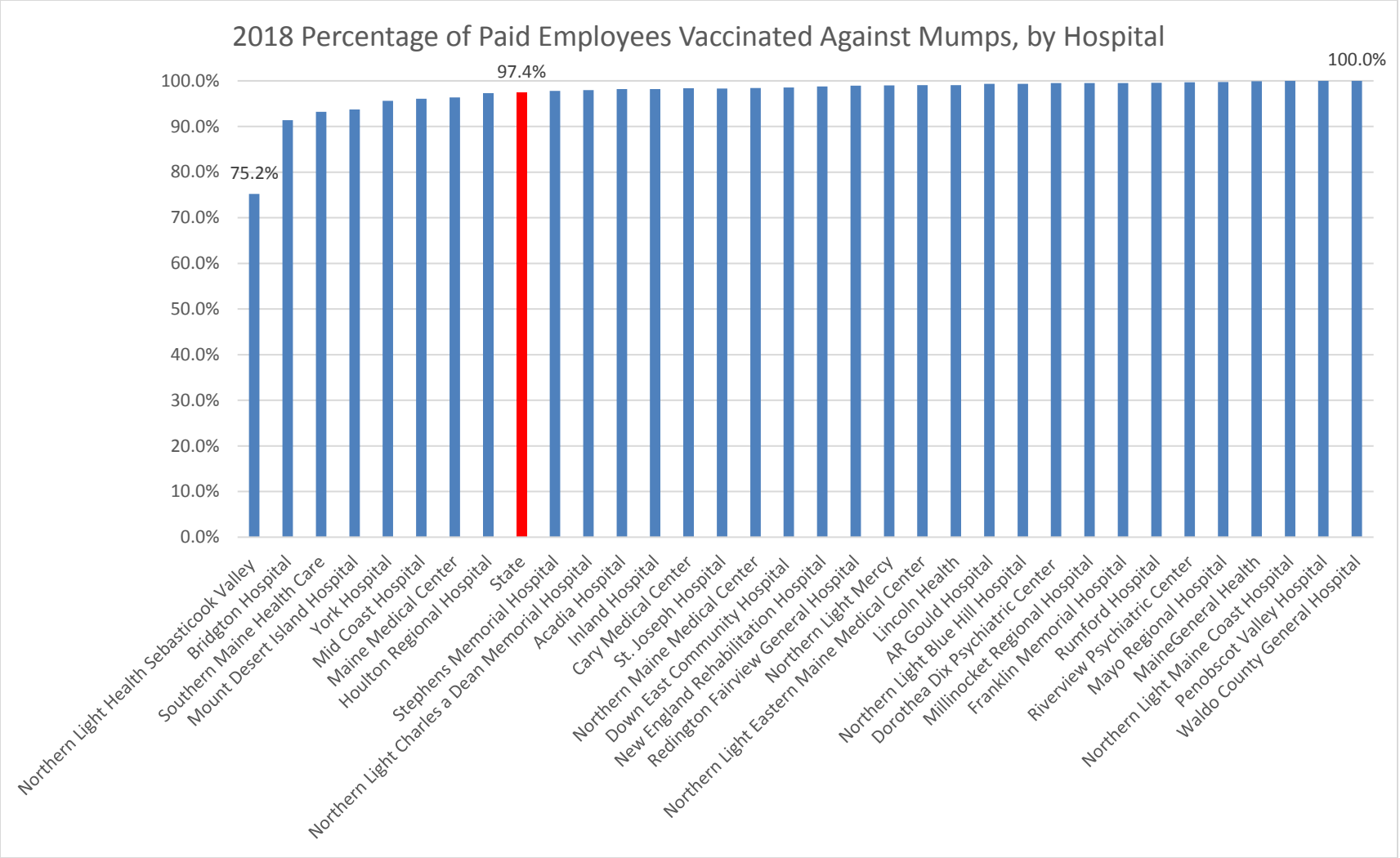

Figure 3: The bars in the graph above represent the percent of healthcare workers who are immune to mumps by vaccination or have laboratory evidence of immunity.

Figure 4: Rubella Immunization Rates

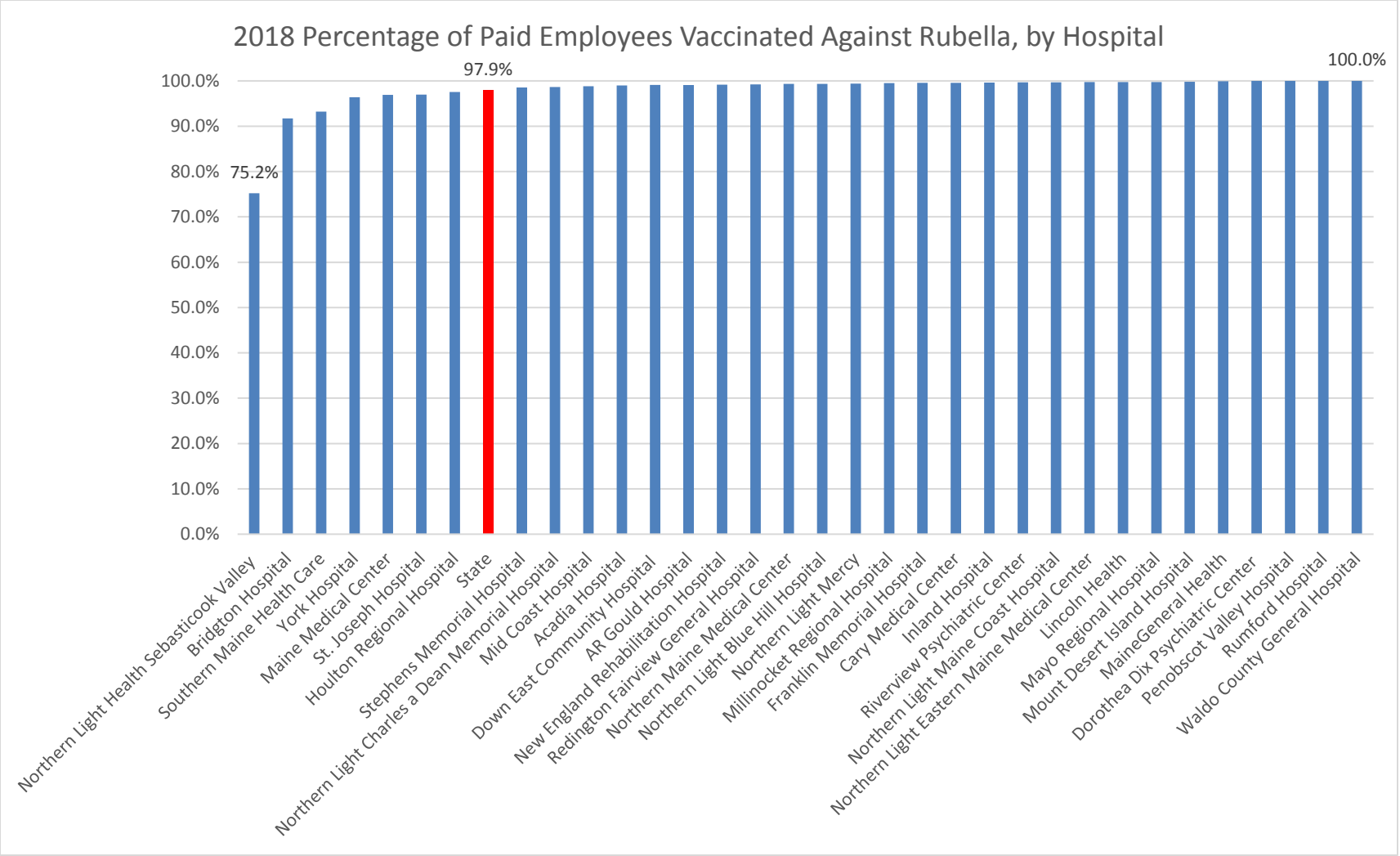

Figure 4: The bars in the graph above represent the percent of healthcare workers who are immune to rubella by vaccination or have laboratory evidence of immunity.

Figure 5: Varicella Immunization Rates

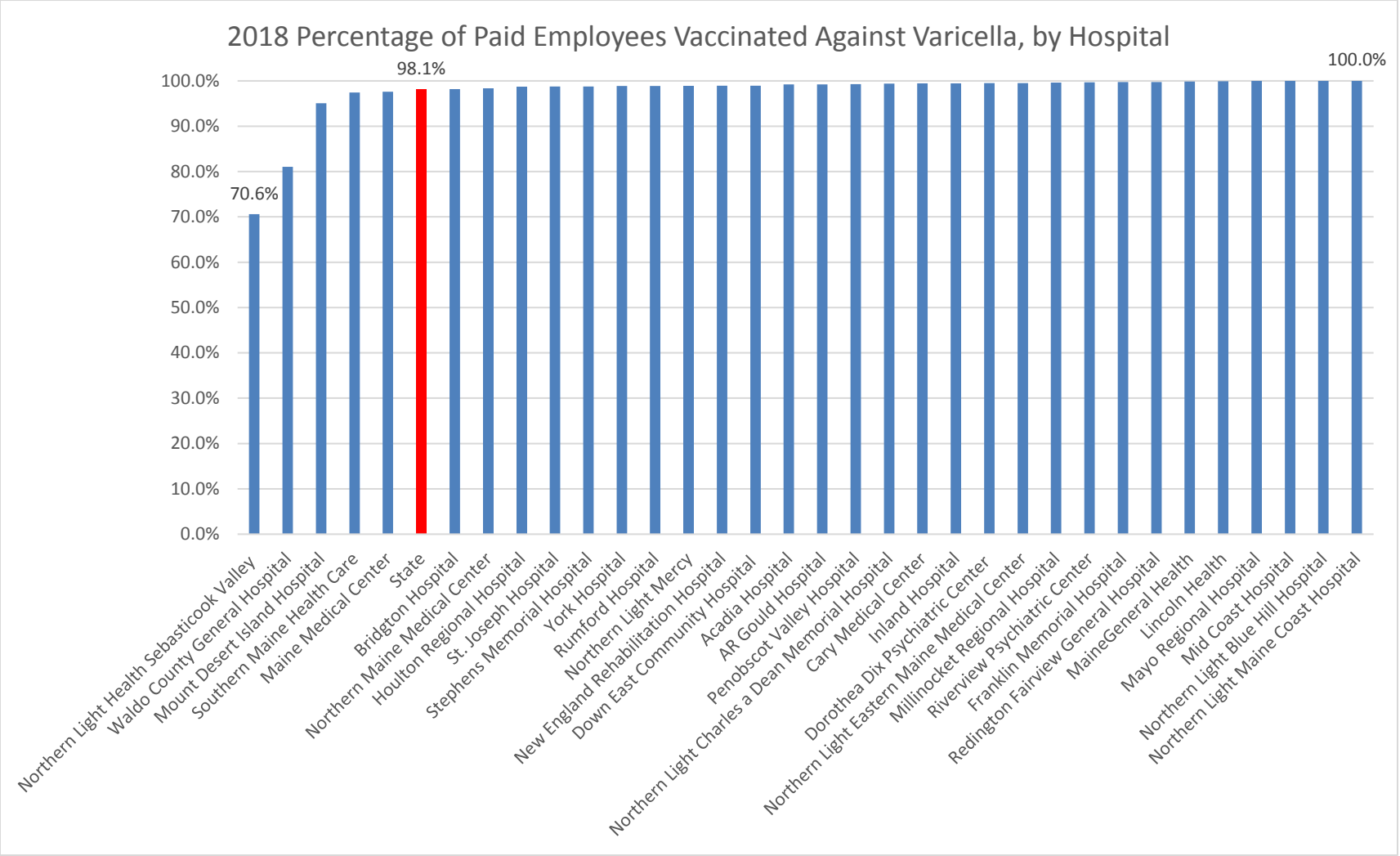

Figure 5: The bars in the graph above represent the percent of healthcare workers who are immune to varicella by vaccination or have laboratory evidence of immunity.

EXHIBIT 2

STATE OF MAINE

IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

10-144 CODE OF MAINE RULES
CHAPTER 264

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
Augusta, Maine 04333-0011

EMERGENCY ROUTINE TECHNICAL RULE
Effective August 12, 2021

EXHIBIT 3

10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

Chapter 264: IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

Purpose: This rule is issued pursuant to the statutory authority of the Department of Health and Human Services to establish procedures for the control and prevention of communicable diseases as set forth in 22 MRS § 802(1)(D) in addition to its authority to require immunization of the employees of designated healthcare facilities as set forth in 22 MRS §802. This rule requires employees of Designated Health Facilities to reduce the risk for exposure to, and possible transmission of, vaccine-preventable diseases resulting from contact with patients, or infectious material from patients. It prescribes the dosage for required immunizations and defines responsibilities, exclusion periods, record keeping and reporting requirements for officials of hospitals and healthcare facilities. This rule also requires employees of Designated Health Care Facilities, Dental Health Practices, and EMS Organizations to become immunized to COVID-19.

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1. Definitions

A. **Certificate of Immunization** means a written statement from a physician, nurse, physician assistant, or health official who has administered an immunization to an employee, specifying the vaccine administered and the date it was administered. Secondary school or collegiate health records, having been compiled and maintained as an official document based on certificates of immunization, which provide at a minimum the month and year that the immunization was administered and/or which contain copies of laboratory evidence of immunity, may also be accepted as proof of immunization.

B. **Chief Administrative Officer** means the person designated as the president, chief executive officer, administrator, director or otherwise the senior official of a Designated Healthcare Facility, Dental Health Practice, or EMS Organization.

C. **Declination** means a formal process where an individual makes an informed choice declining Hepatitis B vaccination, following standards and procedures established by the federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR § 1910.1030(f)(2)(iv) (effective July 6, 1992).

D. **Dental Health Practice** means, for the purpose of this rule, any practice where dentists (whose scope of practice is defined in 32 MRS §18371) and dental hygienists (defined in 32 MRS §18374) provide oral health care to patients in the State of Maine.

E. **Designated Healthcare Facility** means a licensed nursing facility, residential care facility, Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), multi-level healthcare facility, hospital, or home health agency subject to licensure by the State of Maine, Department of Health and Human Services Division of Licensing and Certification.

F. **Disease** means the following conditions which may be preventable by immunization:

1. Rubeola (measles);

2. Mumps;

3. Rubella (German measles);

4. Varicella (chicken pox);

5. Hepatitis B.;

6. Influenza; and

7. COVID-19.

G. **Employee** means any person who performs any service for wages or other remuneration for a Designated Healthcare Facility, EMS Organization or Dental Health Practice. For purposes of this rule, independent contractors for any of the listed facilities in this definition are considered employees.

H. **Emergency Medical Services (EMS) Organization** means an EMS ground ambulance service, non-transporting EMS service, air ambulance service, EMS training center, and/or emergency medical dispatch center, as defined in the Maine Emergency Services System Rules at 16-163 CMR Chapter 2.

I. **Exemption** means a formal procedure to procure discharge from requirement to vaccinate.

J. **Extreme Public Health Emergency** means a state of emergency declared by the Governor of the State of Maine pursuant to 22 MRS §802(2-A) and 37-B MRS §742 based upon an occurrence or imminent threat of widespread exposure to a highly infectious or toxic agent that poses an imminent threat of substantial harm to the population of the State.

K. **Immunization** means a vaccine, antitoxin, or other substances used to increase an individual's immunity to disease.

L. **Public Health Emergency** means a declaration by the Department, arising from an actual or threatened epidemic or public health threat for which the Department may adopt emergency rules for the protection of the public health, pursuant to 22 MRS § 802(2).

M. **Public Health Official** means a local health officer, the Director of the Maine Center for Disease Control and Prevention (Maine CDC), or a designated employee or agent of the Maine Department of Health and Human Services (Department).

N. **Public Health Threat** means a condition or behavior that can reasonably be expected to place others at significant risk of exposure to a toxic agent or environmental hazard or infection with a notifiable disease or condition, as defined in 22 MRS §801.

2. Immunizations Required

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine must require for all employees proof of immunization or documented immunity against:

1. Rubeola (measles);

2. Mumps;

3. Rubella (German measles);

4. Varicella (chicken pox);

5. Hepatitis B;

6. Influenza; and

7. COVID-19.

B. Each EMS organization and Dental Health Practice must require for all employees a Certificate of Immunization against COVID-19.

C. In accordance with 29 CFR §1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities must make available the Hepatitis B vaccine to all healthcare workers with a risk of occupational exposure, provided at no cost to the employee and at a reasonable time and place.

D. In the event of a Public Health Emergency or Extreme Public Health Emergency declared by the Governor, the Department may impose control measures, including, but not limited to, mass vaccinations and exclusions from the workplace, and may require immunization or documented immunity to protect public health and minimize the impact from the specific communicable disease.

E. No Chief Administrative Officer may permit any employee to be in attendance at work without a certificate of immunization for each disease or other acceptable evidence of immunity to each disease (if applicable), or documentation of authorized exemption or declination in accordance with 22 MRS §802(4-B).

3. Exceptions and Declinations

An employee who does not provide proof of immunization or immunity for a vaccine required under this rule may be permitted to attend work if that employee is exempt in accordance with 22 MRS §802 (4-B). Documentation for an employee's immunization exemption must be maintained in the permanent health record for that employee for a minimum of six years after termination.

4. Certification of Immunization and Proof of Immunity

A. **Certificate of Immunization**

To demonstrate proper immunization against each disease, an employee must present the Designated Healthcare Facility, EMS Organization, or Dental Health Practice with a Certificate of Immunization from a physician, nurse or health official who has administered the immunization(s) to the employee. Physicians within their own practice may authorize their own employees to issue a certificate of immunization on behalf of the physician. The certificate must specify the immunization(s), and the date(s), including month and year, on which it was administered. Physicians, having reviewed official patient records created by another practitioner which indicate that a particular patient has received an immunization on a specified date, demonstrating at a minimum the month and year the immunization was given, may certify that the immunization was given. Adequately prepared secondary and/or collegiate school health records will also be considered acceptable for the purpose of meeting this requirement.

B. **Proof of Immunity**

To demonstrate that an employee is immune to any of the diseases, the employee must present the hospital/facility with laboratory evidence demonstrating immunity, or other acceptable evidence of immunity. (See Section 7-B Individual Health Records.)

5. Immunization Dosage

A. The following schedule contains the minimally required number of doses for the immunization(s) addressed under this rule:

1. **Rubeola (Measles)**: Two doses of live measles vaccine given after the first birthday, with a minimum of four weeks separating the two doses.

2. **Mumps**: Two doses of live mumps vaccine given after the first birthday.

3. **Rubella (German Measles)**: Two doses of live rubella vaccine given after the first birthday.

4. **Varicella (Chickenpox)**: Two doses of live varicella vaccine given after the first birthday, with a minimum of four weeks separating the two doses.

5. **Hepatitis B**: Three doses of hepatitis B vaccine, the first two given one month apart and the third given five months after the second.

6. **Influenza**: Annual dose of inactivated influenza vaccine or live attenuated influenza vaccine.

7. **COVID-19:** The number of recommended doses shall be in accordance with the COVID-19 immunization manufacturer's Emergency Use Authorization or labelling. All employees of Designated Healthcare Facilities, EMS Organizations, and Dental Health Practices must have received their final dose by September 17, 2021.

In the event of a Public Health Emergency or Extreme Public Health Emergency declared by the Governor, the Maine CDC will specify the recommended dose for any vaccination imposed as a control measure to protect public health.

B. Any such immunization must meet the standards for biological products which are approved by the United States Public Health Service.

6. Exclusions from the Workplace

A. **Exclusion by order of Public Health Official**

An employee not immunized or otherwise immune from a disease must be excluded from the worksite, when in the opinion of a public health official, the employee's continued presence at work poses a clear danger to the health of others. The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles) or varicella (chickenpox) in a Designated Healthcare Facility or amongst its employees may be interpreted as a clear danger to the health of others.

The Chief Administrative Officer must exclude the employee during the period of danger or for one incubation period following immunization of the employee, when one or more cases of disease are present.

B. The following periods are defined as the "period of danger:"

1 **Measles**: 15 days from the onset of symptoms from the last identified case;

2. **Mumps**: 18 days from the onset of symptoms from the last identified case;

3. **Rubella**: 23 days from the onset of symptoms from the last identified case;

4. **Varicella**: 16 days from the onset of symptoms from the last identified case; and

5. **COVID-19:** The duration of the Department’s declared public health emergency, effective as of July 1, 2021.

C. Except as otherwise provided for by law, contract or collective bargaining agreement, an employer will not be responsible for maintaining an employee in pay status as a result of this rule.

D. When a public health official determines there are reasonable grounds to believe a Public Health Threat exists, an exempted employee may be immunized or tested for serologic evidence of immunity. Employees without serologic evidence of immunity and those who become immunized against the disease in question at the time of a documented case or cases of disease must be excluded from the work site during one incubation period.

7. Records and Record Keeping

A. **Designated Record Keeping**

The Chief Administrative Officer in each Designated Healthcare Facility, EMS Organization, or Dental Health Practice must be responsible for the maintenance of

employee immunization records. The Chief Administrative Officer may designate a person to be responsible for record keeping.

B. **Individual Health Records**

Each Designated Healthcare Facility, EMS Organization, or Dental Health Practice must adopt a uniform, permanent health record for maintaining information regarding the health status of each employee. The immunization status of each employee with regard to each disease must be noted on the employee's health record. The health record of each employee must include, at a minimum, the month and year that each immunization was administered. Health records are to be retained a minimum of six years after the date the employee is no longer employed.

Where an exception has been granted for a reason authorized by law, the written request for exemption must be on file with the employee health record. Where laboratory or other acceptable evidence of immunity has been submitted, a copy of the documentation must also be on file.

C. **List of Non-Immunized Employees**

The Chief Administrative Officer or his/her designee in each Designated Healthcare Facility, EMS Organization, or Dental Health Practice, must keep a listing of the names of all employees within the facility who are not currently immunized or do not have documented serological immunity against each disease. This list must include the names of all employees with authorized exemptions from immunization as well as any who are otherwise not known to be immune and must state the reason that the employee is not immune. The purpose of the list is to provide an efficient means to rapidly contact non-immunized employees in the event of disease outbreaks and exclude them from the workplace as necessary.

D. **Required Reports**

1. **Routine Reporting**

The Chief Administrative Officer of each Designated Healthcare Facility, EMS Organization, or Dental Health Practice is responsible for submitting a summary report on the immunization status of all employees by December 15 of each calendar year, on a form prescribed by the Maine CDC. The summary report will include the following information at a minimum: specific contact information identifying the facility; the name of the Chief Administrative Officer; the total number of employees; the number of employees born on or after January 1, 1957; and the number of employees identified by vaccine type as either immunized, serological proof of immunity, exempt in accordance to law, having declined hepatitis B vaccine, or out of compliance. The summary report may be constructed so as to reflect meaningful data by groupings within the facility (*e.g.*, pediatric unit). Each report must be signed by the Chief Administrative Officer as a certification that the information is accurate.

2. **Maine CDC Sample Survey**

The Maine CDC will conduct periodic reviews by selecting a sample of employee health records for the purpose of comparing reported results against the criteria delineated in these rules. The results of this sample survey will be shared with the Chief Administrative Officer of the Designated Healthcare Facility, EMS Organization, or Dental Health Practice, for the purpose of identifying problem areas that may be occurring in the maintenance of their employee health records. Any published or unpublished reports of such sampling of employee health records must not identify individual employees and/or Designated Healthcare Facilities, EMS Organization, or Dental Health Practices directly or indirectly.

STATUTORY AUTHORITY:
22 MRS §§ 802(1), (3)

EFFECTIVE DATE:
April 16, 2002

NON-SUBSTANTIVE CORRECTIONS:
May 13, 2002 - corrected the spelling of DEPARTMENT in header, page 1
May 10, 2004 - spacing, capitalization and punctuation only

EFFECTIVE DATE:
October 6, 2009 to January 4, 2010: filing 2009-531 (EMERGENCY)
December 8, 2009 – filing 2009-644
April 14, 2021 – filing 2021-068 (ROUTINE TECHNICAL)
August 12, 2021 – filing 2021-166 (EMERGENCY ROUTINE TECHNICAL)

BASIS STATEMENT
EMERGENCY ROUTINE TECHNICAL RULE

IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

10-144 CMR CH 264

In accordance with 5 MRS § 8054, the Department is amending 10-144 CMR chapter 264, *Immunization Requirements For Healthcare Workers* on an emergency basis to immediately add COVID-19 to the list of vaccine-preventable diseases for which employees of a licensed nursing facility, residential care facility, Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), multi-level healthcare facility, hospital, or home health agency subject to licensure by the State of Maine, Department of Health and Human Services Division of Licensing and Certification must be immunized. In addition, the Department is also requiring Emergency Medical Services Organizations and Dental Health Practices to require all employees to provide proof of immunization against COVID-19. Employees who do not provide proof of immunization must be excluded from the workplace for the duration of the Department's declared public health emergency, which began on July 1, 2021 and is currently in effect.

Findings of Emergency

Cases of COVID-19 have increased over 300% nationally between June 19, 2021 and July 23, 2021. This increase has been driven by the highly transmissible B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19. The Delta variant is now believed to be the predominant variant of the virus in the country. Like the rest of the nation, Maine is experiencing a rapid increase in the number of COVID-19 infections as a result of the Delta variant, which is significantly more contagious than previous versions of the virus and more likely to cause serious illness, hospitalization, and death. The Delta variant represented more than 86% of positive COVID-19 samples sequenced in Maine in July 2021. Across the United States, only a very small amount of transmission can be traced to individuals who have been fully vaccinated against COVID-19. Virtually all hospitalizations and deaths caused by COVID-19 are occurring among the unvaccinated. In Maine, less than 2% of all confirmed cases since January 18, 2021 have been among fully vaccinated individuals; less than 4% of COVID-related hospitalizations and less than 6% of COVID-related deaths have been among fully vaccinated people. Since July 21, 2021, Maine has opened outbreak investigations associated with two hospitals and three long-term care facilities. As of August 11, 2021, outbreak investigations associated with hospitals and long-term care facilities account for just more than one third of all open outbreak investigations in Maine.

The Department finds that getting vaccinated against COVID-19 prevents severe illness, hospitalization, and death, and that it helps to reduce the spread of the virus, including the Delta variant, in communities. The presence of the highly contagious Delta variant in Maine constitutes an imminent threat to public health, safety, and welfare. The Department finds that immediate adoption of this rule is necessary to avoid further spread of COVID-19 in those healthcare settings within this rule in order to prevent infection, illness, hospitalization, and death. The Department further finds that immediate adoption of this rule on an emergency basis is necessary to prevent further strain on the state's healthcare system as a result of increased COVID-19-related hospitalizations, as well as reduced capacity caused by illnesses among members of the workforce.

STATUTORY AUTHORITY: 22 MRS §§ 802(1), 802(3)

EFFECTIVE DATE: August 12, 2021

STATE OF MAINE

IMMUNIZATION REQUIREMENTS FOR EMPLOYEES IN CERTAIN HEALTHCARE ~~WORKERS~~SETTINGS

10-144 CODE OF MAINE RULES
CHAPTER 264

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
Augusta, Maine 04333-0011

Date Amended: ~~April 14,~~ 2021

EXHIBIT 5

10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

Chapter 264: IMMUNIZATION REQUIREMENTS FOR EMPLOYEES IN CERTAIN HEALTHCARE ~~WORKERS~~ SETTINGS

Purpose: This rule is issued pursuant to the statutory authority of the Department of Health and Human Services ~~to require immunization of the employees of designated healthcare facilities~~ as set forth in 22 MRS §802. This rule requires employees of certain Healthcare Settings, which include Designated Healthcare Facilities, EMS Organizations, and Dental Health Practices to become immunized for the diseases listed in this rule, to reduce the risk for exposure to, and possible transmission of, vaccine-preventable diseases ~~due to healthcare workers'~~resulting from contact with patients, or infectious material from patients. It prescribes the dosage for required immunizations and defines responsibilities, conditions for exclusion ~~periods~~, record keeping and reporting requirements for officials of ~~hospitals and~~ Designated H~~h~~ealthcare F~~f~~acilities, EMS Organizations, and Dental Health Practices.

SECTION 1. DEFINITIONS~~Definitions~~

A. **Certificate of Immunization** means a written statement from a physician, nurse, physician assistant, or health official who has administered an immunization ~~agent~~ to an employee, specifying the vaccine administered and the date it was administered. Secondary school or collegiate health records, having been compiled and maintained as an official document based on certificates of immunization, which provide at a minimum the month and year that the immunization was administered and/or which contain copies of laboratory evidence of immunity, may also be accepted as proof of immunization.

B. **Chief Administrative Officer** means the person designated as the president, chief executive officer, administrator, director or otherwise the senior official of a Designated Healthcare Facility or Dental Health Practice.

C. **Declination** means a formal process where an individual makes an informed choice declining Hepatitis B vaccination, following standards and procedures established by the federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR § 1910.1030(f)(2)(iv) (effective July 6, 1992).

D. **Dental Health Practice** means, for the purpose of this rule, any practice where dentists (whose scope of practice is defined in 32 MRS §18371) and dental hygienists (defined in 32 MRS §18374) provide oral health care to patients in the State of Maine.

E~~D~~. **Designated Healthcare Facility** means a licensed nursing facility, residential care facility, Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), multi-level healthcare facility, hospital, or home health agency subject to licensure by the State of Maine, Department of Health and Human Services Division of Licensing and Certification.

F~~E~~. **Disease** means the following conditions which may be preventable by immunization ~~agent~~:

1. Rubeola (measles);

2. Mumps;

3. Rubella (German measles);

4. Varicella (chicken pox);

5. Hepatitis B.; ~~and~~

6. Influenza~~.~~; and

7. COVID-19.

G~~F~~. **Employee** means, for the purposes of this rule, any person who performs any service for wages or other remuneration ~~for a~~ who~~that~~ is physically present at a Designated Healthcare Facility, EMS Organization, or Dental Health Practice. For purposes of this rule, "employee" includes independent contractors, and any of their employees, who provide services while physically present at a Designated Healthcare Facility, EMS Organization, or Dental Health Practice. "Employee" does not include any individual who exclusively works remotely (while not physically present at a Designated Healthcare Facility, EMS Organization or Dental Health Practice).

H.~~G.~~ **Emergency Medical Services (EMS) Organization** means an EMS ground ambulance service, non-transporting EMS service, air ambulance service, or EMS training center, within the Maine Emergency Services System Rules at 16-163 CMR Chapters 1-19.

I. **Exemption** means a formal procedure to procure discharge from requirement to vaccinate.

~~H. **Extreme Public Health Emergency** means a state of emergency declared by the Governor of the State of Maine pursuant to 22 MRS §802(2-A) and 37-B MRS §742 based upon an occurrence or imminent threat of widespread exposure to a highly infectious or toxic agent that poses an imminent threat of substantial harm to the population of the State.~~

J. **Health Official** means, for the purposes of this rule, any person who is authorized to administer immunization to the employees within this rule.

K. **Healthcare Setting** means, for the purpose of this rule, a Designated Healthcare Facility, EMS Organization, or a Dental Health Practice.

L.~~I.~~ **Immunization ~~agent~~** means a vaccine, antitoxin, or other substance~~s~~ used to increase an individual's immunity to disease.

~~J. **Public Health Emergency** means a declaration by the Department, arising from an actual or threatened epidemic or public health threat for which the Department may adopt emergency rules for the protection of the public health, pursuant to 22 MRS § 802(2)~~.

MJK. **Public Health Official** means a local health officer, the Director of the Maine Center for Disease Control and Prevention (Maine CDC), or a designated employee or agent of the Maine Department of Health and Human Services (Department).

NIL. **Public Health Threat** means a condition or behavior that can reasonably be expected to place others at significant risk of exposure to a toxic agent or environmental hazard or infection with a notifiable disease or condition, as defined in 22 MRS §801.

SECTION 2. IMMUNIZATIONS REQUIRED~~Immunizations Required~~

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine must require for all employees a Certificate of Immunization, or Proof of Immunity, subject to Section 4(B) of this rule, ~~proof of immunization or documented immunity~~ against:

1. Rubeola (measles);

2. Mumps;

3. Rubella (German measles);

4. Varicella (chicken pox);

5. Hepatitis B; ~~and~~

6. Influenza; ~~and~~

7. COVID-19.

B. Except as otherwise provided by law, each EMS Organization and Dental Health Practice in Maine must require for all employees a Certificate of Immunization against COVID-19, or documentation of an applicable exemption.

~~B~~C. In accordance with 29 CFR §1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities must make available the Hepatitis B vaccine to all healthcare workers with a risk of occupational exposure, provided at no cost to the employee and at a reasonable time and place.

~~C. In the event of a Public Health Emergency or Extreme Public Health Emergency declared by the Governor, the Department may impose control measures, including, but not limited to, mass vaccinations and exclusions from the workplace, and may require immunization or documented immunity to protect public health and minimize the impact from the specific communicable disease.~~

D. No Chief Administrative Officer may permit any employee to be in attendance at work without a Ceertificate of Iimmunization for each disease, ~~or other acceptable~~ Proof of Immunity ~~evidence of immunity to each disease~~ as described in Section 4(B) of this rule, or documentation of an authorized exemption or declination in accordance with 22 MRS § 802(4-B).

SECTION 3. EXEMPTIONS ~~Exceptions and Declinations~~

An employee who does not provide ~~proof of immunization~~a Certificate of Immunization or Proof of I~~i~~mmunity, as described in Section 4(B) for a vaccine required under this rule, may be permitted to attend work if that employee is exempt in accordance with 22 MRS § 802 (4-B). Documentation for an employee's immunization exemption must be maintained in the permanent health record for that employee for a minimum of six years after termination.

SECTION 4. CERTIFICATE ~~Certification~~ of IMMUNIZATION~~Immunization~~ and PROOF OF IMMUNITY~~Proof of Immunity~~

A. **Certificate of Immunization**

To demonstrate proper immunization against each disease, an employee must present the ~~Designated Healthcare Facility~~Healthcare Setting with a Certificate of Immunization from a physician, nurse or health official who has administered the ~~immunizing agent~~immunization(s) to the employee. Physicians within their own practice may authorize their own employees to issue a certificate of immunization on behalf of the physician. The certificate must specify the ~~immunizing agent~~immunization(s), and the date(s), including month and year, on which it was administered. Physicians, having reviewed official patient records created by another practitioner which indicate that a particular patient has received an immunization on a specified date, demonstrating at a minimum the month and year the immunization was given, may certify that the immunization was given. Adequately prepared secondary and/or collegiate school health records will also be considered acceptable for the purpose of meeting this requirement.

B. **Proof of Immunity**

To demonstrate that an employee is immune to any of the diseases listed in Section 5(A)(1)-(5), the employee must present the ~~hospital/facility~~Healthcare Setting with laboratory evidence demonstrating immunity, or other acceptable evidence of immunity. (See Section 7(-B) Individual Health Records.) No Proof of Immunity is available for COVID-19 or Influenza.

SECTION 5. IMMUNIZATION DOSAGE~~Immunization Dosage~~

A. The following schedule contains the minimally required number of doses for the ~~immunizing agents~~ immunization(s) ~~addressed under~~listed in Section 2(A) of this rule:

1. **Rubeola (Measles)**: Two doses of live measles vaccine given after the first birthday, with a minimum of four weeks separating the two doses.

2. **Mumps**: Two doses of live mumps vaccine given after the first birthday.

3. **Rubella (German Measles)**: Two doses of live rubella vaccine given after the first birthday.

4. **Varicella (Chickenpox)**: Two doses of live varicella vaccine given after the first birthday, with a minimum of four weeks separating the two doses.

5. **Hepatitis B**: Three doses of hepatitis B vaccine, the first two given one month apart and the third given five months after the second.

6. **Influenza**: Annual dose of inactivated influenza vaccine or live attenuated influenza vaccine.

7. **COVID-19:** The number of recommended doses must be in accordance with the COVID-19 immunization manufacturer's Emergency Use Authorization or labelling.

~~In the event of a Public Health Emergency or Extreme Public Health Emergency declared by the GGovernor, the Maine CDC will specify the recommended dose for any vaccination imposed as a control measure to protect public health.~~

B. Any such ~~immunizing agent~~ immunization must meet the standards for biological products which are approved by the United States Public Health Service.

SECTION 6. EXCLUSIONS FROM THE HEALTHCARE SETTING
~~Exclusions from the Workplace~~

A. **Exclusion by order of Public Health Official**

A Public Health Official may order a Chief Administrative Officer to exclude from the worksite an employee who has not been immunized when the employee's continued presence poses a clear danger to the health of others. ~~An employee not immunized or otherwise immune from a disease must be excluded from the worksite, when in the opinion of a public health official, the employee's continued presence at work poses a clear danger to the health of others.~~ The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles), ~~or~~ varicella (chickenpox), (or COVID-19 in an EMS Organization, Dental Health Practice, or Designated Healthcare Facility) or amongst its employees may be interpreted as a clear danger to the health of others.

The Chief Administrative Officer must exclude ~~the~~ that employee during the period of danger ~~or for one incubation period following immunization of the employee, when one or more cases of disease are present.~~, unless otherwise ordered by the Public Health Official.

B. The following periods are defined as the minimum "period of danger~~:~~" for each disease listed below:

1 **Measles**: 15 days from the onset of symptoms from the last identified case;

2. **Mumps**: 18 days from the onset of symptoms from the last identified case;

3. **Rubella**: 23 days from the onset of symptoms from the last identified case;

4. **Varicella**: 16 days from the onset of symptoms from the last identified case;~~.~~

C. There is no defined minimum period of danger for influenza, Hepatitis B, or COVID-19. ~~Except as otherwise provided for by law, contract or collective bargaining agreement, an~~

~~employer will not be responsible for maintaining an employee in pay status as a result of this rule.~~

~~D.~~ ~~When a public health official determines there are reasonable grounds to believe a Public Health Threat exists, an exempted employee may be immunized or tested for serologic evidence of immunity. Employees without serologic evidence of immunity and those who become immunized against the disease in question at the time of a documented case or cases of disease must be excluded from the work site during one incubation period.~~

SECTION 7. RECORDS AND RECORD KEEPING~~Records and Record Keeping~~

A. Designated Record Keeping

The Chief Administrative Officer in each Healthcare Setting~~Designated Healthcare Facility~~ must be responsible for the maintenance of employee immunization records. The Chief Administrative Officer may designate a person to be responsible for record keeping.

B. Individual Health Records

Each Healthcare Setting~~Designated Healthcare Facility~~ must adopt a uniform, permanent health record for maintaining information regarding the health status of each employee. The immunization status of each employee with regard to each disease must be noted on the employee's health record. The health record of each employee must include, at a minimum, the month and year that each ~~immunizing agent~~immunization was administered. Health records are to be retained a minimum of six years after the date the employee is no longer employed.

Where an ~~exception~~ exemption has been granted for a reason authorized by law, the ~~written request for exemption~~documentation supporting the exemption must be on file with the employee health record. Where ~~laboratory or other acceptable evidence of immunity~~Proof of Immunity has been submitted, a copy of the documentation must also be on file.

C. List of Non-Immunized Employees

The Chief Administrative Officer or his/her designee in each Healthcare Setting ~~Designated Healthcare Facility,~~ must keep a listing for each disease ~~of the names of all~~ employees ~~within the facility~~ who are not currently immunized ~~or~~ and have not provided Proof of Immunity.~~do not have documented serological immunity against each disease.~~ This list must include the names of all employees with authorized exemptions from immunization, as well as any who are otherwise not known to be immune and must state the reason that the employee is not immune. The purpose of the list is to provide an efficient means to rapidly contact non-immunized employees in the event of disease outbreaks and exclude them from the workplace as necessary.

D. Required Reports

1. Routine Reporting

The Chief Administrative Officer of each Healthcare Setting~~Designated Healthcare Facility~~ is responsible for completing the Maine CDC's annual

survey regarding ~~submitting a summary report on~~ the immunization status of all employees by December 15 of each calendar year~~, on a form prescribed by the Maine CDC~~. The survey results~~summary report~~ will include the following information at a minimum:

a. S~~s~~pecific contact information identifying the facility;

b. T~~t~~he name of the Chief Administrative Officer;

c. T~~t~~he total number of employees; and

~~the number of employees born on or after January 1, 1957; and~~

d. T~~t~~he number of employees identified by vaccine type as either being immunized, having demonstrated serological proof of immunity, having an exemption in accordance ~~to~~ with law, having declined hepatitis B vaccine~~,~~ or being out of compliance.

The ~~summary report~~survey results may be constructed so as to reflect meaningful data by groupings within the facility (*e.g.*, pediatric unit). Each report must be signed by the Chief Administrative Officer as a certification that the information is accurate.

2. **~~Maine CDC Sample Survey~~Enforcement of Immunization Requirements**

The Maine CDC will conduct periodic reviews of annual survey results, by selecting a sample of employee health records for the purpose of comparing reported results against the criteria delineated in th~~e~~is~~e~~ rule~~s~~. The results of this review~~sample survey~~ will be shared with the Chief Administrative Officer of the Healthcare Setting~~Designated Healthcare Facility~~, for the purpose of identifying problem areas that may be occurring in the maintenance of their employee health records. Any ~~published or unpublished~~ reports of such sampling of employee health records must not identify individual employees. ~~and/or Designated Healthcare Facilities, directly or indirectly.~~ Compliance rates may be made public, in accordance with 22 MRS §824.

STATUTORY AUTHORITY: 22 MRS §802

EFFECTIVE DATE:
April 16, 2002

NON-SUBSTANTIVE CORRECTIONS:
May 13, 2002 - corrected the spelling of DEPARTMENT in header, page 1
May 10, 2004 - spacing, capitalization and punctuation only

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October 6, 2009 to January 4, 2010: filing 2009-531 (EMERGENCY)
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April 14, 2021 – filing 2021-068 (ROUTINE TECHNICAL)
August 12, 2021 – filing 2021-166 (EMERGENCY ROUTINE TECHNICAL)
, 2021 – filing 2021- (ROUTINE TECHNICAL)