No. 21-717

In The
Supreme Court of the United States

JANE DOES 1-6, et al.,

Petitioners,

v.

JANET T. MILLS, GOVERNOR OF THE STATE OF MAINE, et al.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether an expired, routine technical state agency rule that requires that employers in certain high-risk healthcare settings require their employees to be fully vaccinated against COVID-19, unless vaccination against COVID-19 would harm the employee's health, and that does not prohibit employees from seeking religious accommodations from their employers under Title VII of the Civil Rights Act of 1964, violates the Free Exercise Clause of the First Amendment.

2. Whether an expired, routine technical state agency rule that requires that employers in certain high-risk healthcare settings require their employees to be fully vaccinated against COVID-19, unless vaccination against COVID-19 would harm the employee's health, and that does not prohibit employees from seeking religious accommodations from their employers under Title VII of the Civil Rights Act of 1964, is preempted by Title VII, an issue not passed on by the courts below.

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STATUTES AND REGULATIONS INVOLVED

In addition to the Constitutional provisions and statutes listed in the Petition, *see* Pet. 1-2, pertinent state statutory and regulatory provisions are reproduced at Resp. App. 1a-28a.

INTRODUCTION

For more than 30 years, the State of Maine has mandated that healthcare facilities require their employees to be vaccinated against several highly communicable diseases. Under Maine's framework, the diseases that healthcare workers must be immunized against are designated in state regulations adopted by the Maine Department of Health and Human Services (Department) and the Maine Center for Disease Control and Prevention (Maine CDC). Immunization Requirements for Healthcare Workers, 10-144 Me. Code R. ch. 264. The exemptions to these vaccination requirements are provided in state statute. *See* Me. Rev. Stat. tit. 22, § 802(4-B) (2021) [hereinafter, "the Statute"].

In 2019, the Maine Legislature repealed all nonmedical vaccination exemptions (religious and philosophical) to required vaccinations for healthcare workers, daycare employees, schoolchildren, and college students. The legislation's purpose was to increase vaccination rates; prevent communicable, preventable diseases from spreading in schools, healthcare facilities, and daycare facilities; and protect persons

medically unable to be vaccinated. The only vaccination exemption currently allowed is a medical exemption. *Id.* § 802(4-B)(A).

The intervening COVID-19 pandemic requires little exposition except to emphasize that this case does *not* involve a fleeting gubernatorial executive order, subject to change at the stroke of a pen. The state authorities analyzed by the First Circuit and the District Court are a duly enacted state statute, *id.*, and a routine technical state agency rule, Resp. App. 2a-15a. These authorities establish some of Maine's procedures and requirements for the control and prevention of a variety of communicable diseases, including COVID-19. On August 12, 2021, the Department and Maine CDC adopted an emergency amendment to its healthcare worker vaccination rule by adding COVID-19 to the list of diseases against which healthcare workers in Designated Healthcare Facilities (DHCFs) must be vaccinated and requiring Dental Health Practices and Emergency Medical Services (EMS) Organizations to require their employees be vaccinated against COVID-19 (Rule).[1] Resp. App. 6a-7a.

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[1] The designation of the rule as "Emergency" is based on its categorization under Maine administrative law, not on the existence of a State of Civil Emergency. Maine state agencies have emergency rulemaking authority to adopt or amend rules without a traditional notice and comment period when "necessary to avoid an immediate threat to public health, safety or general welfare." Me. Rev. Stat. Ann. tit. 5, § 8054(1) (2013). Routine technical emergency rules are limited to 90 days in duration. *Id.* § 8054(3).

Because the Rule was statutorily limited to 90 days, the Department and Maine CDC adopted a permanent amendment requiring vaccination against COVID-19 (in addition to the other highly communicable diseases already included) (Final Rule) on November 10, 2021, thereby superseding the Rule. Resp. App. 16a-28a. The Final Rule is narrower than, but similar in many respects, to the Rule.

Contrary to the Petition, the Rule did not mandate that covered healthcare facilities terminate employees who were not fully vaccinated against COVID-19 or require employers to deny employees' requests for religious accommodations under Title VII. Pet. i. The Rule was silent on employment decisions, which remained within the purview of the employer healthcare facilities.

The Petition also misstates record facts, such as when and under what circumstances Maine repealed its nonmedical exemptions to its healthcare workers vaccination requirements, *compare* Pet. 8, *with* Pet. App. 14a-15a, 60a-62a, and makes the spurious claim that Maine officials have denied the supremacy of federal law or its applicability in the State of Maine, *compare* Pet. 4-5, 34-35, *with* Pet. App. 39a, 94a-95a. Federal law unquestionably applies within Maine's borders, and the State Respondents have never denied that. Where the parties have disagreed is whether federal law provides the relief Petitioners are seeking.

Framed properly, the Petition seeks interlocutory review of a decision of the First Circuit affirming the

District Court's denial of preliminary injunctive relief against a state agency rule that is no longer in effect. These circumstances do not warrant this Court's extraordinary review, and certainly not at this juncture of the case. Petitioners can continue to press their extant Free Exercise and Supremacy Clause challenges to the Rule (or Final Rule) to a final judgment in the District Court. But, based on the current posture and the reasons stated *infra*, *this* Petition should be denied.

STATEMENT OF THE CASE

A. History of Mandatory Immunizations in Maine

Maine has mandated that hospitals and other healthcare facilities require their employees to be vaccinated against several highly communicable diseases since 1989. Pet. App. 14a, 60a. Since 2002, the Department has identified the diseases against which healthcare workers must be vaccinated through routine regulations. Pet. App. 61a; *id.* 15a (noting, as of April 2021, vaccination against measles, mumps, rubella, chickenpox, Hepatitis B, and influenza required).

From 2001 to 2019, there were three statutory exemptions to the vaccine requirements for healthcare workers: when vaccination was (A) medically inadvisable, (B) contrary to a sincerely held religious belief, or (C) contrary to a sincere philosophical belief. Pet. App. 61a; *see also id.* (noting Maine provided the same exemptions to required vaccinations for school children).

The rationale for requiring immunization against vaccine-preventable diseases is the same in healthcare settings and schools: high vaccination rates are necessary to prevent the spread of communicable diseases through the population and among vulnerable populations, i.e., children and patients. D. Ct. Doc. 49-4 at 7. By 2018, vaccination rates for required vaccinations for healthcare workers and school children in Maine had fallen below the population-wide rates of vaccination necessary to prevent the spread of those communicable diseases. Pet. App. 14a; D. Ct. Docs. 48-2 to 48-5 & 49-7. The availability of nonmedical exemptions led to vaccination opt-out rates in Maine that were out of step with the rest of the country, and not evenly distributed across the State. Pet. App. 77a-78a (noting school vaccination opt out rates of 8% and 33% within a single county).

In 2019, a bill was introduced in the Maine Legislature to eliminate nonmedical exemptions from the State's mandatory vaccination programs in order to reverse the trajectory of Maine's falling vaccination rates; prevent communicable, preventable diseases from spreading in schools, healthcare facilities, and daycare facilities; and protect persons who are unable to be vaccinated for medical reasons. Pet. App. 15a; D. Ct. Doc. 48-2 (testimony of Maine Representative Ryan Tipping, sponsor of the legislation). As explained by then Acting Maine CDC Director Nancy Beardsley,

> [w]hen someone chooses not to vaccinate, that decision can jeopardize the health and safety of entire communities, especially the weakest

> and most vulnerable among us. Those who are unable to be vaccinated, such as young infants, pregnant mothers or children with cancer, face the most risk from disease complications. . . .
>
> . . . Evidence shows that states that have tighter exemption laws have higher immunization rates, and less disease.

D. Ct. Doc. 48-4 at 2. Maine Senator Heather Sanborn spoke of the bill's purpose: "I rise again today to urge this Body to follow science and to vote in favor of Enactment to protect those who cannot be immunized. Those include newborns. They include severely immune-compromised or medically weakened individuals and the very old may also be very susceptible to communicable diseases." D. Ct. Doc. 48-26 at 3.

After significant debate on the floor of the Maine House and Senate, in May of 2019, the Maine Legislature voted to eliminate nonmedical exemptions to vaccination requirements for healthcare workers and schoolchildren. Pet. App. 61a. The law was the subject of a statewide people's veto referendum on March 3, 3020; 72% of Maine voters approved the 2019 amendment to the Statute. Pet. App. 15a, 61a-62a. The law took effect in April of 2020. Pet. App. 13a. In order to comply with the statutory change, the Department removed nonmedical exemptions from the Rule in April 2021. Pet. App. 15a.

B. Vaccinations and COVID-19

The gold standard to prevent and stop the spread of communicable diseases, including COVID-19, is vaccination. Pet. App. 85a. Population-level immunity, or "herd immunity," is an epidemiological phenomenon whereby unvaccinated individuals are protected against a communicable disease by virtue of being in a community with sufficiently high rate of vaccination or immunity. Pet. App. 55a-56a. In particular, persons who cannot be vaccinated for medical reasons rely on the immunity of those around them for protection from those communicable diseases. D. Ct. Doc. 49-4 at 5, 7. When immunization rates fall below the necessary population-level rate of vaccination for a particular disease, both vaccinated and unvaccinated individuals are at increased risk of infection, especially the most vulnerable. Pet. App. 85a-86a. The rate of vaccination required to achieve population-level immunity varies with the contagiousness of the disease. Pet. App. 55a.

COVID-19 is a highly infectious respiratory illness caused by a virus (SARS-CoV-2) that spreads easily from person to person. As of December 13, 2021, there have been approximately 49.8 million confirmed cases of COVID-19 and 794,000 deaths from COVID-19 in the United States.[2] As of December 14, 2021, there

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[2] CDC Covid Data Tracker: United States at a Glance, United States Centers for Disease Control and Prevention (updated Dec. 13, 2021), https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

have been 131,380 total confirmed cases of COVID-19 in Maine, including 1,376 deaths from COVID-19.[3]

Several variants of SARS-CoV-2 have emerged over time, including the highly contagious Delta variant. Pet. App. 19a, 55a. The Delta variant is more than twice as contagious as previous variants and may cause more severe illness in unvaccinated people. Pet. App. 19a. An individual infected with the Delta variant can begin spreading it to others within 24 to 36 hours of exposure. Pet. App. 19a. In light of the emergence and current prevalence[4] 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. Pet. App. 20a.

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[3] *See* COVID-19: Maine Data, Maine Center for Disease Control & Prevention (updated Dec. 14, 2021), https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/data.shtml. This data reflects an alarming increase in COVID-19 cases and deaths in Maine since the State Respondents filed their opposition to the preliminary injunction motion on September 15, 2021. Pet. App. 55a. In the last three months, there have been 50,203 more cases of and 407 more deaths from COVID-19 in Maine, reflecting a 61% increase in the number of COVID-19 cases and a 42% increase in the number of COVID-19 deaths.

[4] As of August 27, 2021, the Delta variant accounted for 96.7% of all positive COVID-19 samples sequenced in Maine. Pet. App. 55a. The communicability of the most recent variant, Omicron, is under investigation and remains unknown, but preliminary data from South Africa suggests that "Omicron can infect three to six times as many people as Delta, over the same time period." Ellen Callaway & Heidi Ledford, *How bad is Omicron? What scientists know so far*, Nature (Dec. 2, 2021, corr. Dec. 7, 2021), https://www.nature.com/articles/d41586-021-03614-z.

Three COVID-19 vaccines are generally available. Pet. App. 56a. Studies show that the vaccines are both safe and highly effective, even against the Delta variant. Pet. App. 56a. Recent data from the United States Centers for Disease Control and Prevention (US CDC) shows that unvaccinated persons are 5.8 times more likely to contract COVID-19 and 14 times more likely to die of COVID-19 than fully vaccinated persons.[5]

The first COVID-19 vaccine doses in Maine were administered in December of 2020. Pet. App. 56a. In the interest of preserving Maine's health system capacity, Maine CDC prioritized eligibility for those first doses to frontline healthcare professionals and patient-facing staff in, among other places, hospitals, long-term care facilities, emergency medical services, physician practices, and dental practices. Pet. App. 16a-17a, 56a.

C. Maine CDC's Adoption of the Rule

Throughout the pandemic, Maine CDC has tracked statewide confirmed cases of COVID-19, including cases amongst healthcare workers, and investigated outbreaks of COVID-19, including in healthcare settings. Most healthcare facility outbreaks in Maine are the result of healthcare workers bringing COVID-19 into the facility. Pet. App. 57a-58a. On August 11, 2021,

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[5] CDC Covid Data Tracker: Rates of COVID-19 Cases and Deaths by Vaccination Status, United States Centers for Disease Control and Prevention (last visited Dec. 14, 2021), https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status.

4 of the 14 outbreaks then under investigation by Maine CDC were occurring in healthcare facilities. Pet. App. 20a. By September 3, 2021, 19 of the 33 COVID-19 outbreaks under investigation were occurring in healthcare facilities. Pet. App. 20a.

Maine CDC also tracked the rate of COVID-19 vaccination among the general population and among employees of DHCFs. Pet. App. 20a. For the monthly reporting period ending July 31, 2021, the rate of COVID-19 vaccination 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%

D. Ct. Doc. 49-4 at 10.[6] All facilities fell significantly below the minimum 90% threshold currently believed

[6] The figures cited above are averages of all facility types; some facilities had vaccination rates greater than the average, and some had vaccination rates lower than the average. For the monthly period that ended October 30, 2021, COVID-19 vaccination rates among healthcare workers in certain DHCFs were as follows, indicating the effectiveness of the amendment:

- Ambulatory Surgical Centers: 92.6%
- Assisted Housing Facilities: 96.8%
- Hospitals: 98.1%
- Intermediate Care Facilities for Individuals with Intellectual Disabilities: 95.6%
- Nursing Homes: 96.8%

Maine CDC, Maine Health Care Worker COVID-19 Vaccination Dashboard, https://www.maine.gov/dhhs/mecdc/infectious-disease/

to be needed to reduce the likelihood of facility-based outbreaks of the Delta variant of COVID-19. Pet. App. 20a.

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, patients, and Maine's healthcare system from the further spread of COVID-19. D. Ct. Doc. 49-4 at 10-12. Accordingly, the Department and Maine CDC amended the Rule on an emergency basis to require DHCFs, Dental Health Practices, and EMS Organizations to require their employees to be vaccinated against COVID-19. Resp. App. 6a-7a. Maine CDC determined that these types of facilities and settings were at a higher risk for the transmission of SARS-CoV-2 because of the patient populations served and the types of care provided. D. Ct. Doc. 49-4 at 10.

In reaching the decision to adopt the Rule, Maine CDC considered whether there were other measures that might be appropriate instead of a mandate. Pet. App. 20a-22a. Those options were considered, but Maine CDC determined that they would not have been as effective, or had been proven ineffective, at stopping the spread of COVID-19 in facilities covered by the Rule. Pet. App. 32a-34a. In particular, Maine CDC considered weekly and twice weekly testing, but the speed at which the Delta variant spreads (24 to 36 hours

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immunization/publications/health-care-worker-covid-vaccination-rates.shtml. Again, these figures are averages.

after exposure) made neither option efficacious. Pet. App. 21a. Daily testing was also considered, but rejected because it would have required the use of a less effective test method. Pet. App. 21a. And, existing protocols for personal protective equipment already had proven ineffective at stopping outbreaks of COVID-19. Pet. App. 21a.

The Rule was adopted on an emergency basis, effective August 12, 2021. Resp. App. 2a. The Rule originally required compliance by October 1, 2021, but the Department and Maine CDC later announced that they would not enforce the Rule against covered facilities until October 29, 2021. Resp. App. 10a; Pet. App. 23a. On November 10, 2021, the Department and Maine CDC adopted the Final Rule, which did not include Dental Health Practices and EMS Organizations. Resp. App. 16a-20a. The Final Rule also narrows the definition of "employee," so that remote employees and employees who otherwise do not work on the physical premises of a DHCF are not covered. Resp. App. 19a.

D. Proceedings Below

Petitioners are nine pseudonymous healthcare workers who allege that their "sincerely held religious beliefs compel them to abstain from obtaining or injecting any of [the available COVID-19 vaccines] into their bod[ies], regardless of perceived benefit or rationale." D. Ct. Doc. 1 at 20-21. Petitioners filed a five-count complaint on August 25, 2021, against Janet T. Mills,

Maine's Governor; Jeanne M. Lambrew, Department Commissioner; and Dr. Nirav D. Shah, Maine CDC Director (collectively, State Respondents), and several healthcare providers (Provider Respondents), along with a motion for temporary and preliminary injunctive relief from the Rule.[7] Pet. App. 52a-53a. As to State Respondents, and as relevant here, Petitioners claimed that the Rule violated their First Amendment rights to free religious exercise and the Supremacy Clause of the United States Constitution. Pet. App. 64a. Petitioners sought only injunctive and declarative relief against State Respondents, who have been sued only in their official capacities. Pet. App. 52a.

The District Court denied Petitioners' *ex parte* motion for a temporary restraining order on August 26, 2021. Pet. App. 53a. On October 13, 2021, the District Court denied the motion for preliminary injunction and motion for injunction pending appeal. Pet. App. 51a, 54a, 49a. Petitioners promptly appealed, seeking injunctive relief pending appeal from the First Circuit. The First Circuit denied that motion on October 15, 2021. Pet. App. 47a.

On October 19, 2021, the First Circuit affirmed the District Court decision. Pet. App. 12a, 14a. The First Circuit carefully examined the Rule, the Statute, and the measures State Respondents had taken to achieve its stated interests and concluded that Petitioners

[7] Seven Petitioners were employed by Provider Defendants; one of the Petitioners (John Doe 1) owned his own Dental Health Practice and employed the ninth Petitioner (Jane Doe 6). Pet. App. 58a; Pets.' Reply in Supp. of M. Expedite at 5.

were unlikely to succeed on the merits of their complaint. Pet. App. 24a-42a.

On October 29, 2021, this Court denied Petitioners' emergency application for writ of injunction pending a petition for writ of certiorari. Pet. App. 1a.

REASONS FOR DENYING THE PETITION

I. The Petition should be Denied Based on its Interlocutory Posture, Subsequent Federal Action, and the Adoption of the Final Rule.

Absent extraordinary circumstances, this Court "generally await[s] final judgment in the lower courts before exercising [its] certiorari jurisdiction." *Va. Military Inst. v. United States*, 508 U.S. 946, 946 (1993) (Scalia, J., concurring); *see also Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916) ("except in extraordinary cases, the writ is not issued until final decree"; the absence of a final judgment may "of itself alone furnish[ ] sufficient ground for the denial of the application"). Petitioners do not present any reason justifying a departure from this Court's usual practice of awaiting final judgment before taking a case.

The Court's reluctance to grant review of an interlocutory order reflects its sound policy against disposing of actions prematurely or unnecessarily. Awaiting a final judgment avoids the possibility of piecemeal or premature review and ensures that any legal issues

are evaluated on the basis of a complete record with the benefit of full consideration from the lower courts. *Cf. Cunningham v. Hamilton Cnty.*, 527 U.S. 198, 203-04 (1999). Those considerations are fully implicated here.

First, subsequent federal action purporting to preempt Maine's medical exemption from its COVID-19 vaccine requirement weighs strongly against granting this Petition. On November 5, 2021, the Centers for Medicare and Medicaid Services (CMS) published an Interim Final Rule with Comment Period (IFC or CMS Rule) entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination." 86 Fed. Reg. 61,555 (proposed Nov. 5, 2021) (to be codified at 42 C.F.R. pts. 416, 418, 441, 460, 482-86, 491 & 494). The CMS Rule, which covers many of the same healthcare entities as Maine's Rule and Final Rule, requires that those entities ensure that a broad swath of personnel within those facilities be vaccinated against COVID-19. CMS intends its Rule to preempt any inconsistent state and local laws, including the scope of any applicable COVID-19 vaccine exemption. *See*, *e.g.*, *id.* at 61,568 ("We intend . . . that this nationwide regulation preempts inconsistent State and local laws"); *id.* at 61,613 ("[T]his IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this IFC.").

The medical exemption in the CMS Rule mandate is narrower than Maine's medical exemption. Maine's

medical exemption provides: "A medical exemption is available to an employee who provides a written statement from a licensed physician, nurse 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." Me. Rev. Stat. Ann. tit. 22, § 802(4-B)(A).

In comparison, the CMS Rule provides an exemption from the requirement to obtain a COVID-19 vaccine for "confirm[ed] recognized clinical contraindications to COVID-19 vaccines," 86 Fed. Reg. 61,555, 61,616, based on guidance from US CDC, *id.* at 61,572.[8] US CDC recommends COVID-19 vaccination for all persons five and older, including pregnant women, nursing women, and persons with underlying medical conditions, and delayed vaccination for persons undergoing certain treatments or who are recovering from a COVID-19 infection.[9] Recognized contraindications to vaccination are limited to severe allergic reactions (anaphylaxis) to and cardiac conditions occurring after the administration of a prior dose of a COVID-19

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[8] An exemption may also be available in accordance with the Americans with Disabilities Act. 86 Fed. Reg. 61,555, 61,572.

[9] Centers for Disease Control & Prevention, Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (Nov. 5, 2021), *available at* https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf.

vaccine.[10] In other words, few healthcare workers will qualify for a medical exemption under the CMS Rule.

Here, Petitioners challenge the scope of Maine's exemption from the Rule's COVID-19 vaccine requirement, arguing its scope not only shows that the Rule is neither neutral nor generally applicable, but also is at odds with this Court's decision in *Tandon v. Newsom*, 141 S. Ct. 1294 (2021) (per curiam). Pet. 20, 31-34. Three members of this Court have criticized the scope of Maine's COVID-19 vaccine medical exemption as a system or mechanism of "individualized exemptions," Pet. App. 4a-5a, criticisms that may not apply if Maine's COVID-19 vaccine medical exemption is preempted by the medical exemption of the CMS Rule. The preemptive effect of the CMS Rule is currently being litigated and seems destined for this Court's review.[11]

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[10] *Id.* Research shows that the rate of anaphylaxis to Pfizer and Moderna vaccines is 2.5 to 11.1 per 1 million doses. Kimberly G. Blumenthal et al., *Acute Allergic Reactions to mRNA COVID-19 Vaccines*, 325 JAMA 1562, 1562 (2021).

[11] *Compare Florida v. Dep't of Health & Human Servs.*, No. 3:21-cv-2722-MCR-HTC, 2021 WL 5416122, at *1 (N.D. Fla. Nov. 20, 2021) (denying motion to preliminarily enjoin IFC), *inj. pending appeal denied*, ___ F. 4th ___, 2021 WL 5768796, at *1 (11th Cir. Dec. 6, 2021), *with Missouri v. Biden*, No. 4:21-CV-01329-MTS, 2021 WL 5564501, at *15 (E.D. Mo. Nov. 29, 2021) (granting preliminary injunction enjoining enforcement of IFC in Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming), *appeal docketed*, No. 21-3725 (8th Cir. Nov. 30, 2021), *and Louisiana v. Becerra*, No. 3:21-CV-03970, 2021 WL 5609846, at *17 (W.D. La. Nov. 30, 2021) (granting preliminary injunction enjoining enforcement of

To be sure, the Rule and Statute are constitutional "as is," so to speak, as neutral laws of general applicability. But the regulatory landscape has changed since the decisions below by the First Circuit and District Court, and a premature review does not lend itself to reliable analysis. *See Am. Constr. Co. v. Jacksonville, Tampa & Key W. Ry. Co.*, 148 U.S. 372, 384 (1893) ("[M]any orders made in the progress of a suit become quite unimportant by reason of the final result, or of intervening matters."). Petitioners may contend that the CMS Rule has no preemptive effect, or has a different preemptive effect. But those issues were not (and could not have been) addressed by the District Court or the First Circuit below and are now being litigated elsewhere. This unresolved preemption question weighs strongly against granting the petition. *Cf. Upper Skagit Indian Tribe v. Lundgren*, 138 S. Ct. 1649, 1654 (2018) (declining to address alternative argument for affirmance not raised until the merits stage and vacating and remanding).

Second, as noted, the Rule is no longer in effect; it is unnecessary for this Court to review whether the courts below correctly declined to enjoin an expired rule. The Final Rule is similar in many respects to the Rule, but narrower in scope in that it does not include Dental Health Practices or EMS Organizations. Petitioners have already admitted in their reply in support of their motion to expedite that two of their numbers (John Doe 1 and Jane Doe 6, i.e., a dentist and his

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IFC in the rest of the states, including Maine), *appeal docketed*, No. 21-30734 (5th Cir. Dec. 1, 2021).

employee) are not subject to the Final Rule; their claims are thus moot.

Petitioners will likely not concede mootness as to any Petitioner, but not all Petitioners present the same arguments. For example, in the first Question Presented, Petitioners seek certiorari on whether the Emergency Rule "violates the employers' and employees' rights under the Free Exercise Clause of the First Amendment." Pet. i-ii.[12] The only Petitioner that is also an employer is John Doe 1, a Petitioner whose claims are likely moot because he is not subject to the Final Rule. Granting the Petition now could therefore result in unnecessary briefing on an insufficiently definite issue.

Third, this is not a case where judicial review is unavailable to Petitioners. To the extent that Petitioners are subject to the Final Rule, they can move to amend their complaint and seek to challenge the new regulation. *See*, *e.g.*, *Diffenderfer v. Cent. Baptist Church of Miami*, *Fla., Inc.*, 404 U.S. 412, 415 (1972) (suggesting petitioners amend their complaint to challenge new statute after case was mooted by repeal of statute).

[12] Petitioners do not develop any argument that the Rule violates employers' sincerely held religious beliefs in their Petition.

II. The First Circuit's Correct Application of This Court's Decisions Does Not Warrant Review.

The First Amendment's Free Exercise Clause provides that "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). In evaluating Petitioners' claims, the First Circuit, like the District Court, correctly and faithfully applied this Court's Free Exercise decisions to deny preliminary injunctive relief to Petitioners. Pet. App. 25a-34a, 64a-90a.

On Petitioners' Free Exercise claim, the First Circuit concluded that the Rule and Statute are neutral laws of general applicability, subject to rational basis review. Pet. App. 27a. The Statute's medical exemption is a generalized, objective exception, unlike the systems of individualized exemptions at issue in *Sherbert v. Verner*, 374 U.S. 398 (1963), and *Fulton v. City of Philadelphia*, 141 S. Ct. 1868 (2021). Pet. App. 27a-28a. Both the Rule and the Statute are facially neutral; nothing in the text of either authority "refers to any religious practice." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 533 (1993). Unlike in *Lukumi*, neither the Rule nor the Statute is designed to infringe or restrict a particular religious practice; their purposes are neutral as to religion. *Id.* at 534-38; *see also Emp't Div., Dep't of Hum. Res. of Or. v. Smith*, 494 U.S. 872, 878 (1990). Pet. App. 27a.

Fulton explained that a policy "lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government's interests in a similar way." 141 S. Ct. at 1877. The First Circuit, consistent with *Fulton*, concluded that the medical exemption did not undermine Maine's stated interests in protecting workers and patients in covered facilities, Pet. App. 28a-31a, but actually furthered those goals.

The First Circuit reasoned that the medical exemption in the Statute was "meaningfully different" from other non-religious exceptions to other COVID-19 restrictions that this Court analyzed in *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63 (2020) (per curiam); *S. Bay United Pentecostal Church v. Newsom*, 141 S. Ct. 716 (2021) (mem.); and *Tandon*, 141 S. Ct. 1294. Pet. App. 29a-30a. Unlike the numerous gathering-limit exceptions addressed in those cases, Maine's sole medical exemption furthers its interests in protecting vulnerable populations, whereas a religious exemption does not. Pet. App. 30a. The First Circuit thus concluded that as neutral and generally appliable laws, the Rule and the Statute "easily satisf[y] rational basis review." Pet. App. 31a.

Petitioners contend that the First Circuit's decision is at odds with the gathering limit cases of *Roman Catholic Diocese*, *S. Bay*, and *Tandon*. Pet. 31-34. Petitioners claim that these three cases established a new "risk assessment mandate" that the First Circuit flouted by concluding Maine's medical exemption did not defeat the Rule's neutrality or general

applicability. Pet. 33. But Petitioners are forcing the facts of *Roman Catholic Diocese*, *S. Bay*, and *Tandon* onto this case, disregarding Maine's asserted interests in its statutory medical exemption.

Tandon explained: "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. at 1296 (second emphasis added). Petitioners rely on this sentence, Pet. 31-32, 33, while ignoring what follows: "[W]hether 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." *Id.* Here, Maine's asserted interests are not the same as the States' interests asserted in the gathering limit cases.

In the gathering-limit cases, each State assessed the risks posed by the different activities and settings and prohibited or limited religious gatherings while placing no restrictions (or fewer restrictions) on numerous, secular settings. For example, in *Roman Catholic Diocese*, the regulation at issue allowed houses of worship in a designated area to admit only ten persons, but "essential" businesses, such as "acupuncture facilities, camp grounds, garages, [and] plants manufacturing chemicals," could "admit as many people as they wish[ed]." 141 S. Ct. at 66; *see also Tandon*, 141 S. Ct. at 1297 (noting regulation permitted persons at "hair salons, retail stores, personal care services, movie theaters, private suites at sporting events" "to bring

together more than three households at a time" but did not allow the same for "at-home religious exercise"); *S. Bay*, 141 S. Ct. at 717 (statement of Gorsuch, J.) (criticizing California order that restricted worship but permitted larger groups to gather in "most retail" establishments and "other businesses"). In each case, the Court rejected the States' actual, asserted risk assessments because they singled out religious activity for harsher treatment than secular activity that posed equal risk.

In contrast, Maine's asserted interest in providing only a medical exemption in the Statute is not based on comparative assessments of risk between secular and religious activities. In 2018, Maine faced vaccination rates among healthcare workers and school children that had fallen below the rates of vaccination necessary to prevent the spread of those communicable diseases.[13] These vaccination rates were not sufficient to protect persons unable to be vaccinated for medical reasons. D. Ct. Doc. 49-4 at 5, 7. In eliminating nonmedical exemptions to vaccination requirements, the Maine Legislature sought to reverse the trajectory of falling vaccination rates in order to prevent communicable, preventable diseases from spreading in schools, healthcare facilities, and daycare facilities and protect persons who are unable to be vaccinated for medical

[13] When the Maine Legislature was debating the legislation eliminating nonmedical exemptions, a junior high student was diagnosed with measles, Maine's first measles case in two years. D. Ct. Doc. 48-26 at 3-4.

reasons.[14] Exempting persons who are medically able to be vaccinated would *not* serve any of Maine's goals, but providing a medical exemption to those for whom vaccination is medically advisable does serve the State's goals. As one religious liberty legal scholar and advocate has explained, "medical exceptions don't undermine the government's interest in saving lives, preventing serious illness or preserving hospital capacity. By avoiding medical complications, those exceptions actually serve the government's interests."[15] *See also Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944) ("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.").

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[14] Because the Maine Legislature eliminated nonmedical exemptions in 2019, the Court should look to the Legislature's asserted interests in 2019 for purposes of comparability—not the interests Maine asserted in 2021 in requiring vaccination against COVID-19. *See Fulton*, 141 S. Ct. at 1878-79 (rejecting City's post hoc rationalizations and reinterpretations of disputed contractual language). The year 2019 is the correct timeframe for another reason: neither the Department nor Maine CDC could have included a religious exemption in the text of the Rule in 2021. Executive agencies are creatures of statute and have only that authority provided to them by law. *See Valente v. Bd. of Env'tl Prot.*, 461 A.2d 716, 718 (Me. 1983). The Maine Legislature instructed the Department and Maine CDC to remove all religious and philosophical vaccine exemptions from their rules in 2019. 2019 Me. Laws ch. 154, § 11. The Department and Maine CDC have no authority to alter statutory language to create a religious exemption.

[15] Douglas Laycock, *What's the law on vaccine exemptions? A religious liberty expert explains*, The Conversation (Sept. 15, 2021), https://theconversation.com/whats-the-law-on-vaccine-exemptions-a-religious-liberty-expert-explains-166934.

The First Circuit correctly analyzed and applied the reasoning of *Roman Catholic Diocese*, *S. Bay*, and *Tandon* to Maine's vaccine framework:

> Maine's rule does not rest on assumptions about the public health impacts of various secular or religious activities. Instead, it requires all healthcare workers to be vaccinated as long as the vaccination is not medically contraindicated—that is as long as it furthers the state's health-based interests in requiring vaccination. Thus, the comparability concerns the Supreme Court flagged in the *Tandon* line of cases are not present here. *See Tandon*, 141 S. Ct. at 1296 ("Comparability [for free exercise purposes] is concerned with the risks various activities pose, not the reasons why people gather." (emphasis added)). By analogy, if Maine's emergency rule were an occupancy limit, it would apply to all indoor activities equally based on facility size, but it would exempt healthcare facilities. . . . Such a rule would not fall afoul of the Supreme Court's decisions. *See Tandon*, 141 S. Ct. at 1296.

Pet. App. 30a-31a. *See also Resurrection Sch. v. Hertel*, 11 F.4th 437, 458-59 (6th Cir. 2021) (concluding COVID-related mask mandate for secular and religious schools with exception for those medically unable to mask was neutral and generally applicable).

Petitioners also claim, without citing any record evidence, that Maine singles them out for especially harsh treatment and discriminates against their religious objections to vaccination solely "because of their

religious nature." *Fulton*, 141 S. Ct. at 1877; *Smith*, 494 U.S. at 877 (law not generally applicable if it "impose[s] special disabilities on the basis of" religious "acts or abstentions *only* when they are engaged in for religious reasons" (emphasis added)). *See* Pet. 21, 32. The First Circuit correctly rejected this argument based on the record. Maine's "[L]egislature removed both religious and philosophical exemptions from mandatory vaccination requirements, and thus did not single out religion alone." Pet. App. 27a.

Petitioners also contend, for the first time, that because the Rule applies to hospitals, nursing homes, and other residential care facilities, but not private physicians' offices or urgent care clinics, it is "the antithesis of a neutral, generally applicable law." Pet. 21. That new argument is at odds with *Fulton* and belied by the record. Again, a policy "lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the *government's interests* in a similar way." 141 S. Ct. at 1877 (emphasis added). Here, Maine required certain facilities to require their employees to be vaccinated against COVID-19 because Maine's interests were in protecting patients and staff and reducing the likelihood of COVID-19 outbreaks in those high-risk health care settings. D. Ct. Doc. 49-4 at 10. Declining to require COVID-19 vaccination for employees in lower-risk healthcare settings does not undermine Maine's interests.

Petitioners argue that certiorari should be granted to address what they contend is an important, unsettled question of federal law: whether a State that

allows for a medical exemption to an otherwise neutral law of general applicability must also allow a religious exemption. Pet. 18-21. This Court already addressed that circumstance in *Smith*. There, Oregon criminalized possession of certain controlled substances, "unless the substance had been prescribed by a medical practitioner." *Smith*, 494 U.S. at 874. The respondents in *Smith* were fired from their positions in a drug rehabilitation organization for ingesting peyote in a religious ceremony and then denied unemployment compensation because they were fired for "misconduct." *Id. Smith* upheld the State's statutes, which included a medical exemption, and denial of unemployment benefits to respondents' Free Exercise challenge. *See also Fulton*, 141 S. Ct. at 1877 (explaining a policy "lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government's interests in a similar way," but not adopting a per se rule).

Petitioners stress that the Rule must be subject to strict scrutiny and claim Maine is an "extreme outlier" in not providing a religious exemption to its vaccination requirements. Pet. 20-21. But, as Petitioners acknowledge, both New York and Rhode Island have adopted COVID-19 vaccine requirements that include medical exemptions, but not religious exemptions. *See* N.Y. Comp. Codes R. & Regs. tit. 10, § 2.61(d) (2021); 216-20-15 R.I. Code R. § 8.3(D) (2021). Further, in the school vaccination context, many States do not allow for religious exemptions to mandatory vaccination requirements, including California, Connecticut, Maine,

Mississippi, New York, and West Virginia.[16] Petitioners' claim that Maine is an extreme outlier is thus overstated. That other States have taken different approaches to vaccination requirements is a feature of federalism, and the application of strict scrutiny is not a lowest common denominator analysis. Moreover, what other States may choose to do does not answer the question of what is constitutionally required. *Cf. Walz v. Tax Comm'n of City of N.Y.*, 397 U.S. 664, 672-74 (1970) (explaining a state may, but need not, provide churches with an exemption from property tax).

Regardless, even if strict scrutiny were to apply, the Rule is narrowly tailored to achieve Maine's compelling interests. Narrow tailoring requires the government to show that its policy is the "least restrictive means among available, effective alternatives," *Ashcroft v. ACLU*, 542 U.S. 656, 666 (2004), and that it "seriously undertook to address the problem with less intrusive tools readily available to it," *McCullen v. Coakley*, 573 U.S. 464, 494 (2014).

Preventing the spread of communicable diseases is a compelling state interest, *S. Bay*, 141 S. Ct. at 718; *Roman Cath. Diocese*, 141 S. Ct. at 67, regardless of whether there is an ongoing pandemic, *Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. App'x 348, 353-54 (4th

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[16] *See* Cal. Health & Safety Code §§ 120370, 120372 (Westlaw 2021); Conn. Gen. Stat. Ann. § 10-204a(a) (Westlaw 2021); Me. Rev. Stat. Ann. tit. 20-A, §§ 6355, 6359 (Supp. 2021); Miss. Code Ann. § 41-23-37 (Westlaw 2021); N.Y. Public Health Law § 2164(8) (Westlaw 2021); W. Va. Code Ann. § 16-3-4(c) (Westlaw 2021).

Cir. 2011) (holding States have a clear, compelling interest in preventing the spread of communicable diseases even when there is no ongoing pandemic and when those diseases are not prevalent), *cert. denied*, 565 U.S. 1036 (2011).

State Respondents seriously "considered different methods" employed by other jurisdictions in order to achieve the State's goals. *McCullen*, 573 U.S. at 494. The record establishes that Maine considered and tried numerous methods of fighting COVID-19, including masking and testing (the exact tools Petitioners seek), before mandating vaccinations. Pet. 3. The record also shows that the measures Petitioners claim Maine must employ had not stopped outbreaks of COVID-19 in facilities covered by the Rule. Pet. App. 33a, 88a.

While Petitioners ignore these undisputed facts, Maine cannot—and the First Circuit did not. Pet. App. 31a-34a. The First Circuit correctly determined that even if the Rule and the Statute were subject to strict scrutiny, Petitioners still had no likelihood of success on the merits. The court examined the alternative measures the State had taken or considered in order to achieve its goals and concluded they were inadequate. Pet. App. 32a-34a. The court concluded: "In confronting the various risks to its own population and its own healthcare delivery system, Maine's rule does not violate the Constitution." Pet. App. 38a.

III. There is no Conflict Among the Circuits on Whether a State's Mandatory Vaccination Law Must Include a Religious Exemption.

Petitioners misconstrue the cases they cite to manufacture a conflict among the Courts of Appeals on whether a state's mandatory vaccination law must include a religious exemption. Pet. 22-29. No such conflict exists.

A. The Courts of Appeals have uniformly held that religious exemptions to mandatory vaccination laws are not required by the Free Exercise Clause.

The First Circuit's decision does not create a conflict among the Circuit Courts that requires this Court's resolution. On the contrary, numerous Courts of Appeals have held that religious exemptions to mandatory vaccination laws are *not* required by the Free Exercise Clause, even when medical exemptions to those laws were permitted. *See 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."), *cert. denied*, 138 S. Ct. 1999 (2018) (mem.); *Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir. 2015) ("mandatory vaccination as a condition for admission to school does not violate the Free Exercise Clause"), *cert. denied*, 577 U.S. 822 (2015); *Workman*, 419 F. App'x at 352-55 (concluding West Virginia's mandatory vaccination law that allowed for only medical exemptions withstood strict scrutiny review).

Most recently, the Second Circuit held that New York healthcare workers were not likely to succeed on the merits of their Free Exercise challenge to a mandatory COVID-19 vaccination regulation with only a medical exemption. *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 280-90 (2d Cir. 2021). And, within the last few weeks, the Ninth Circuit ruled that a 16-year-old high school student was not likely to succeed on the merits of her Free Exercise challenge to a mandatory COVID-19 vaccination requirement necessary for in-person school attendance and extra-curricular activities. *Doe v. San Diego Unified Sch. Dist.*, ___ F.4th ___, 2021 WL 5757397, at *2-5 (9th Cir. Dec. 4, 2021). There is no Court of Appeals decision that holds that the Free Exercise Clause requires a State to provide a religious exemption to a its mandatory vaccination laws.

B. The First Circuit's decision is not in conflict with the decisions of the Seventh, Sixth, and Third Circuits.

None of the cases cited by Petitioners hold that allowing a medical exemption but not a religious exemption is a per se violation of the Free Exercise Clause. *See* Pet. 22-31.

First, two of the cases relied on by Petitioners, *Klaassen* and *Dahl*, are factually distinct. Both cases addressed state university policies that mandated vaccination against COVID-19, but that also included both religious and medical exemptions. *Klaassen v. Trs. of Ind. Univ.*, 7 F.4th 592, 593-94 (7th Cir. 2021);

Dahl v. Bd. of Trs. of W. Mich. Univ., 15 F.4th 728, 730 (6th Cir. 2021).

Second, neither *Klaassen* nor *Dahl* ruled that a state university "must grant religious exemptions from a COVID-19 vaccine mandate." Pet. 25, 27-28. The Seventh Circuit in *Klaassen* denied a motion for injunction pending appeal brought by students challenging, on substantive due process grounds, the university's COVID-19 vaccine mandate. 7 F.4th at 593-94. The court declined to enjoin the mandate, but did not pass on whether a religious exemption was constitutionally required.

The Sixth Circuit denied a motion for stay pending appeal in a Free Exercise challenge to a state university's COVID-19 vaccine mandate for student athletes. *Dahl*, 15 F.4th at 728. There, the university retained full discretion to grant or deny its available medical and religious exemptions on an individualized, student-by-student basis. *Id.* at 733-34. The retention of that discretion, according to the court, meant the policy was neither neutral nor generally applicable and thus subject to strict scrutiny. *Id.*; *accord Fulton*, 141 S. Ct. at 1877 (criticizing retention of state authority to "grant exemptions based on the circumstances underlying each application"). The university was unlikely to prevail under strict scrutiny review, but *Dahl* did not rule that a religious exemption to the vaccine mandate was required.

Here, unlike in *Dahl*, the Statute's medical exemption is not a "mechanism for individualized

exemptions." *Fulton*, 141 S. Ct. at 1877 (quotation marks omitted). As the First Circuit recognized, the Statute vests authority regarding medical exemptions with healthcare providers, not State officials. Resp. App. 1a; Pet. App. 27a-28a. Those healthcare providers are to utilize their professional judgment in deciding whether to sign a written statement in support of a medical exemption. Resp. App. 1a. The State does not interrogate why the medical professional exercised her judgment, just as the State of Oregon did not evaluate why a doctor prescribed a controlled substance in *Smith*. 494 U.S. at 874.

Third, the last case relied on by Petitioners, *Fraternal Order of Police Newark Lodge No. 12 v. City of Newark*, 170 F.3d 359 (3d Cir. 1999), is not in conflict with the First Circuit. In *Fraternal Order*, police officers challenged the City of Newark's no-facial hair policy, that included several secular exemptions, including a medical exemption, but not a religious exemption. There, the constitutional defect identified by the court was not that the medical exemption was secular per se—the problem was that it undermined the City's stated goal in maintaining a uniform, easily identifiable appearance for its officers. *Id.* at 365-66. In the same decision, the court explained that a different secular exception—an exemption for undercover officers—was not problematic because those officers were not held out as members of the force. *Id.* at 366. Thus, exempting them from the no-facial-hair policy did not undermine the City's interest in a uniform appearance for its officers. *Id*. On the other hand, the City

could not explain why a "medical motivation" for a beard undermined its interest less than a religious motivation for a beard. *Id.* In other words, the undercover officer exception was acceptable because it was consistent with the City's goal; the medical exemption was not. *Cf. Smith*, 494 U.S. at 876-82 (categorical exemption for possession of controlled substance prescribed by a physician from criminal law otherwise prohibiting such conduct did not defeat neutrality or general applicability of state law).

Unlike the medical exemption in *Fraternal Order*, Maine's allowance for a medical exemption furthers Maine's interest in protecting the health of healthcare workers and patients. Pet. App. 30a; *see also* Pet. App. 34a-35a (distinguishing *Fraternal Order*). *See also We the Patriots*, 17 F.4th at 285 ("applying the vaccination requirement to individuals with medical contraindications and precautions would not effectively advance" New York's "asserted interest in protecting the health of covered personnel"); *cf. Fraternal Order*, 170 F.3d at 366 ("the Free Exercise Clause does not require the government to apply its laws to activities that it does not have an interest in preventing").

Because the First Circuit's decision is not in conflict with the cases relied on by Petitioners, there is no need to grant certiorari here.

IV. Petitioners' Second Question Presented was not Addressed by the First Circuit or the District Court.

The Supreme Court is a "court of review, not of first view." *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005). Therefore, this Court generally "does not decide questions not raised or resolved in the lower court." *Youakim v. Miller*, 425 U.S. 231, 234 (1976). "These principles help to maintain the integrity of the process of certiorari." *Taylor v. Freeland & Kronz*, 503 U.S. 638, 646 (1992).

Petitioners request that the Court grant certiorari as to whether the Rule "is preempted by the religious accommodation provisions of Title VII of the Civil Rights Act of 1964," Pet. ii, but that question was never addressed or resolved by the courts below. Both the District Court and the First Circuit correctly viewed Petitioners' "Supremacy Clause" claim as resting on their incorrect assertion that Respondents had somehow claimed that Title VII was inapplicable in Maine. Pet. App. 39a, 94a-95a. That assertion was incorrect and unsupported by the record. D. Ct. Doc. 43 at 1 (answering Petitioners' "simple question" of whether "federal law appl[ies] in Maine" as "obviously yes"); D. Ct. Doc. 49-5 at 10-11 (explaining how Rule did not prevent employers from providing accommodations for employees' sincerely held religious beliefs).

Neither the First Circuit nor the District Court engaged in the traditional preemption analysis that Petitioners seek from this Court. *See* Pet. 34-36; *Geier v.*

Am. Honda Motor Co., 529 U.S. 861 *passim* (2000) (analyzing express, field, and conflict preemption). That neither court below addressed this issue is unsurprising: Petitioners did not develop their preemption argument in their briefing in either court. Had they done so, the decisions below would, at a minimum, include a discussion of which theory of preemption Petitioners were asserting, analyze Congress's intent, interpret the text of Title VII's express preemptive provision, and address the presumption against federal preemption of a state's health and safety laws. *See N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995); *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715-16 (1985). The record addresses none of these issues. As a court of review, this Court should not consider issues that were not developed below and were neither addressed nor resolved by the District Court or First Circuit. *Cutter*, 544 U.S. at 718 n.7; *Glover v. United States*, 531 U.S. 198, 205 (2001).

CONCLUSION

Petitioners' petition for writ of certiorari should be denied.

Respectfully submitted,

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December 14, 2021

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Me. Rev. Stat. Ann. tit. 22 § 802
Authority of department
* * *

4-B. Exemptions to immunization. Employees are exempt from immunization otherwise required by this subchapter or by rules adopted by the department pursuant to this section under the following circumstances.

A. A medical exemption is available to an employee who provides a written statement from a licensed physician, nurse 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.

B. [Repealed.]

C. An exemption is available to an individual who declines hepatitis B vaccine, as provided for by the relevant law and regulations of the federal Department of Labor, Occupational Health and Safety Administration.

STATE OF MAINE

IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

10-144 CODE OF MAINE RULES CHAPTER 264

[SEAL]

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

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), multilevel 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)

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STATE OF MAINE

IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS

10-144 CODE OF MAINE RULES CHAPTER 264

[SEAL]

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

Date Amended: November 10, 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 establish procedures for the control and prevention of communicable diseases and to require immunization of the employees of Designated Healthcare Facilities as set forth in 22 MRS §802. The purpose of the immunization requirements set forth in this rule is to reduce the risk of exposure to and transmission of vaccine-preventable diseases among healthcare workers, patients, and other members of

the public in Designated Healthcare Facilities. Limiting transmission of vaccine-preventable diseases in Designated Healthcare Facilities also serves to reduce the risk of these diseases spreading throughout the general population. This rule prescribes the dosage for required immunizations; specifies the employees and certain contractors Designated Healthcare Facilities must exclude if the specified immunization requirements are not met; describes conditions under which unimmunized employees and certain contractors may be excluded by order of a Public Health Official, and defines recordkeeping responsibilities and reporting requirements for Designated Healthcare Facilities and their Chief Administrative Officers.

SECTION 1. DEFINTIONS [sic]

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.

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. **Department** means the Department of Health and Human Services.

E. **Designated Healthcare Facility** means a licensed nursing facility, residential care facility, Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), multilevel 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, for purposes of this rule, any person who performs any service for wages or other remuneration for a Designated Healthcare Facility, including independent contractors. Persons who provide ad hoc, non-health care services for a Designated Healthcare Facility and have no potential for direct contact (clinical, hands-on, or face-to-face interaction) with staff, patients, or visitors of a Designated Healthcare Facility are not included in this definition of employee. For illustrative purposes only, these may include, but are not limited to, landscapers, snow plow operators, and delivery persons.

H. **Exclusively work remotely** means to provide services while outside the physical premises of a Designated Healthcare Facility and have no direct contact (clinical, hands-on, or face-to-face interaction) with patients, visitors, and other employees.

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

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

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

L. **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).

M. **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

A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine must require for all employees who do not exclusively work remotely a Certificate of Immunization, or Proof of Immunity, subject to Section 4(B) of this rule, against:

1. Rubeola (measles);
2. Mumps;
3. Rubella (German measles);
4. Varicella (chicken pox);
5. Hepatitis B;
6. Influenza;
7. COVID-19.

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. No Chief Administrative Officer may permit any employee who does not exclusively work remotely to be in attendance at work without a Certificate of Immunization for each disease Proof of Immunity 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

An employee who does not provide a Certificate of Immunization or Proof of Immunity, 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), unless otherwise provided by law. 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 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 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 listed in Section 5(A)(1)-(5), the employee may present the hospital/facility Designated Healthcare Facility 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

A. The following schedule contains the minimally required number of doses for the

immunization(s) 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**: Fully completed series of either two or three doses of hepatitis B vaccine. If a two-dose series, then the second dose must be given one month after the first dose. If a three-dose series, the second dose must be given one month after the first dose and five months must separate the second and third doses.

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 labeling.

B. Any such 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

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. The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles) varicella (chickenpox), or COVID-19 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 that employee during the period of danger, unless otherwise ordered by the Public Health Official.

B. The following periods are defined as the minimum "period of danger: [sic]" 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.

SECTION 7. RECORD KEEPING, REPORTING, AND ENFORCEMENT

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, 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 provided services.

Where an exemption has been granted for a reason authorized by law, the documentation supporting the exemption (including any information regarding the anticipated duration of the exemption) must be on file with the employee health record. Where Proof of Immunity has been accepted, 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 for each disease of the employees who are not currently immunized and have not provided Proof of Immunity. 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**

The Chief Administrative Officer of each Designated Healthcare Facility is responsible for completing the Maine CDC's annual survey regarding the immunization status of all employees by December 15 of each calendar year. The survey will include the following information at a minimum:

1. Specific contact information identifying the facility;
2. The name of the Chief Administrative Officer;
3. The total number of employees; and
4. The number of employees identified by vaccine type as either being immunized, having demonstrated serological proof of immunity, having an exemption in accordance with law, having declined hepatitis B vaccine, or being out of compliance.

The 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.

E. **Record Sampling and Review**

The Department will conduct periodic reviews of annual survey results by selecting samples of employee health records to compare against information reported by the Designated Healthcare Facility and to assess for compliance with this rule. The Department will share the results of this review with the Chief Administrative Officer of the Designated Healthcare Facility and/or their designees(s) for the purpose of identifying problems with recordkeeping or other compliance issues.

F. **Compliance Rates**

Compliance rates may also be made available to the public at the Department's discretion in accordance with 22 MRS §824.

G. **Enforcement**

If a Designated Healthcare Facility fails to correct violations identified by the Department or otherwise fails to comply with the requirements of this rule, the Department may take enforcement action pursuant to 22 MRS §804 or as otherwise provided by law.

STATUTORY AUTHORITY:
22 MRS §802

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