21-2566

United States Court of Appeals for the Second Circuit

DR. A., NURSE A., DR. C., NURSE D., DR. F., DR. G., THERAPIST I., DR. J., NURSE J., DR. M., NURSE N., DR. O., DR. P., TECHNOLOGIST P., DR. S., NURSE S., PHYSICIAN LIAISON X.,

Plaintiffs-Appellees,

v.

KATHY HOCHUL, Governor of the State of New York, in her official capacity, DR. HOWARD A. ZUCKER, Commissioner of the New York State Department of Health, in his official capacity, LETITIA JAMES, Attorney General of the State of New York, in her official capacity,

Defendants-Appellants.

On Appeal from the United States District Court for the Northern District of New York

BRIEF AND SPECIAL APPENDIX FOR APPELLANTS

BARBARA D. UNDERWOOD
Solicitor General
STEVEN C. WU
Deputy Solicitor General
MARK S. GRUBE
Assistant Solicitor General of Counsel

LETITIA JAMES
Attorney General
State of New York
Attorney for Appellants
28 Liberty Street
New York, New York 10005
(212) 416-8028

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TABLE OF CONTENTS

Page

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Cases **Page(s)**

Cases **Page(s)**

Cases **Page(s)**

Cases **Page(s)**

Laws

Federal

New York

Other States

Administrative Sources **Page(s)**

Miscellaneous Authorities

Miscellaneous Authorities **Page(s)**

Miscellaneous Authorities **Page(s)**

Miscellaneous Authorities **Page(s)**

PRELIMINARY STATEMENT

The COVID-19 pandemic has imposed a deadly toll on New York, which continues to this day with the spread of the highly contagious SARS-CoV-2 Delta variant. COVID-19's impact has been particularly devastating in the healthcare sector, where already-vulnerable patients and residents are at greater risk of severe harm from any infection, and where the spread of the virus among healthcare workers can lead to a vicious cycle of staff shortages and deterioration of patient care.

In light of these distinct concerns, the New York Department of Health (DOH) issued an emergency rule requiring COVID-19 vaccinations for certain healthcare workers: namely, any worker whose activities could potentially expose other personnel, patients, or residents to COVID-19 if he or she were infected. 10 N.Y.C.R.R. § 2.61 (Special Appendix (S.A.) 48-49.) Like preexisting vaccination requirements for measles and rubella that have long applied to healthcare workers, DOH's emergency COVID-19 rule contains only a narrow medical exemption.

The plaintiffs here—seventeen anonymous healthcare workers—moved for a preliminary injunction against enforcement of the rule based on the absence of a religious exemption. The U.S. District Court for the

Northern District of New York (Hurd, J.) granted their request for a preliminary injunction.

This Court should reverse. For several reasons, the district court erred in granting a statewide preliminary injunction against DOH's emergency COVID-19 rule.

First, plaintiffs fail to show a likelihood of success on the merits. Courts have upheld vaccination requirements for well over a century. And this Court has squarely recognized that religious exemptions are not required by the First Amendment. The presence of a limited medical exemption does not compel a different result under the Supreme Court's recent orders in cases like *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63 (2020) (per curiam). The Court's orders invalidated materially different schemes: ones that denied religious exemptions but broadly allowed comparable nonreligious exemptions that defeated the purpose of the underlying regulation at least as much as any religious exemption would have. Here, by contrast, DOH's emergency rule does not allow for broad nonreligious exemptions. And the *only* recognized exemption—to avoid medical harm—is not comparable to the nonreligious exemptions at issue in *Roman Catholic Diocese* and its

progeny because the medical exemption (1) serves rather than undermines the emergency rule's objective of protecting the health of healthcare workers, and (2) poses much more limited risks because it is tightly constrained in both scope and duration.

In addition, the emergency rule does not conflict with—and thus is not preempted by—Title VII of the Civil Rights Act of 1964. The rule itself does not dictate the actions that employers may take in response to unvaccinated employees; as a result, employers retain flexibility to provide an accommodation required by Title VII, including reassigning unvaccinated employees to activities where they will not expose others to COVID-19. On the other hand, Title VII does not require the accommodation that plaintiffs seek here, which is the continuation of their work with other personnel, patients, and residents despite being unvaccinated. Under well-established law, Title VII does not require religious accommodations that would impose more than a de minimis cost on employers; and here, the exemption that plaintiffs seek would risk serious harm to both healthcare workers and the vulnerable populations that they serve.

Second, the equities weigh heavily in favor of allowing DOH's emergency rule to go into effect while the district court considers the merits of plaintiffs' claims. Delaying the mandatory vaccination of New York's healthcare workers—including those who seek a religious exemption—poses the risk of infection, complications, and death to healthcare workers, patients, and residents. And the public at large risks receiving substandard medical care at facilities that have inadequate staffing following an outbreak among healthcare workers. By contrast, the adverse employment consequences that plaintiffs allege are not themselves compelled by the emergency rule; are unsupported by corroborating evidence; and are inadequate to justify the extraordinary remedy of a preliminary injunction in any event.

ISSUES PRESENTED

1. Whether plaintiffs have established a likelihood of success on the merits, where (a) courts have uniformly rejected First Amendment challenges to compulsory vaccination laws, including those without any religious exemption; and (b) the rule does not conflict with Title VII.

2. Whether the balance of the equities weighs against any preliminary injunction of DOH's emergency rule, when an injunction could

potentially lead to increased risk of transmission of a potentially fatal disease among healthcare workers and the vulnerable populations they serve, whereas plaintiffs have not demonstrated that the emergency rule would lead to imminent irreparable harm.

STATEMENT OF THE CASE

A. New York's Long and Successful History of Vaccination Requirements

New York has long been a national leader in mandating vaccinations to protect against the spread of communicable disease. The State required school-age children to be vaccinated against smallpox in the 1860s. *See* James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 Ky. L.J. 831, 851 (2002). The Legislature has regularly updated its compulsory school vaccination laws, and in 2019 eliminated any religious exemption from this requirement. *See* Public Health Law § 2164, *as amended by* Ch. 35, §§ 1, 2, 2019 McKinney's N.Y. Laws 153, 153-54.

New York has also regularly imposed vaccination requirements on healthcare workers. For example, DOH regulations require hospital employees who pose a risk of transmission to patients to be immunized

against measles and rubella; like the emergency rule at issue here, this requirement does not contain a religious exemption. *See* 10 N.Y.C.R.R. § 405.3(b)(10)(i)-(iii). Similar rules apply to healthcare workers in long-term care facilities and other institutions.[1] These regulations have been in place in similar form since 1980 for rubella and 1991 for measles.[2]

B. The COVID-19 Pandemic and New York's Response

1. The COVID-19 pandemic, the invention of safe and effective vaccines, and efforts to promote their use

COVID-19 is a highly infectious and potentially deadly respiratory illness that spreads easily from person to person. In the United States alone, COVID-19 has infected more than 43 million people and claimed

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[1] *See* 10 N.Y.C.R.R. §§ 415.26(c)(1)(v)(a)(2)-(4) (nursing home personnel), 751.6(d)(1)-(3) (employees of diagnostic and treatment centers), 763.13(c)(1)-(3) (personnel of home health agencies, long term home health care programs, and AIDS home care programs), 766.11(d)(1)-(3) (personnel of licensed home care services agencies), 794.3(d)(1)-(3) (hospice personnel), 1001.11(q)(1)-(3) (assisted living residences personnel).

[2] *See* Health and Immunization of Employees of Medical Facilities and Certified Home Health Agencies, 3 N.Y. Reg. 6, 6 (Jan. 14, 1981) (rubella); Immunization of Health Care Workers, 13 N.Y. Reg. 16, 16 (Dec. 24, 1991) (measles).

more than 700,000 lives,[3] including at least 550,000 infections and 1,750 deaths among healthcare workers, who have been disproportionately harmed by the disease.[4]

In light of the harms caused by the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) issued emergency use authorizations for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines in December 2020 and February 2021. On August 23, 2021, the FDA granted full regulatory approval for the Pfizer vaccine. (*See* Joint Appendix (J.A.) 221-222, 335-351, 358-362.)

Studies show that the vaccines are both safe and highly effective, particularly for preventing hospitalizations in vulnerable populations. For example, among adults 65 to 74 years old, one recent study showed the vaccines' efficacy for preventing hospitalizations ranged from 84% to 96%, and concluded that increasing vaccination coverage is "critical to

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[3] Centers for Disease Control & Prevention, *COVID Data Tracker: Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory* (internet). (For internet sources, URLs are provided in the Table of Authorities. All URLs were last visited on October 18, 2021.)

[4] Centers for Disease Control & Prevention, *COVID Data Tracker: Cases & Deaths Among Healthcare Personnel* (internet). (*See also* J.A. 227, 397-402.)

reducing the risk for COVID-19–related hospitalization, particularly in older adults."[5]

The COVID-19 vaccines do not contain aborted fetal cells. (J.A. 223, 371-376.) HEK-293 cells—which are currently grown in a laboratory and are thousands of generations removed from cells collected from a fetus in 1973—were used in testing during the research and development phase of the Pfizer and Moderna vaccines.[6] But the use of fetal cell lines for testing is common, including for the rubella vaccination, which New York's healthcare workers are already required to take. (J.A. 224, 383-392.)

In light of the success of the COVID-19 vaccines, a broad coalition of healthcare professional organizations has called for healthcare employers to require their employees to be vaccinated, including, among others, the American Medical Association, American Nurses Association, and American Academy of Pediatrics. As the president of the American

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[5] *See, e.g.*, Heidi L. Moline et al., *Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥ 65 Years – COVID-NET, 13 States, February-April 2021*, 70 Morbidity & Mortality Wkly. Rep. 1088, 1092 (2021).

[6] Los Angeles Cnty. Dep't of Pub. Health, *COVID-19 Vaccine and Fetal Cell Lines* 1-2 (Apr. 20, 2021) (internet).

Society of Clinical Oncology explained, "[p]atients with cancer need to know that their environment, including the people who care for them, is as safe as possible." (J.A. 228-229, 430-433 (quotation marks omitted).) Other organizations have noted that a vaccine requirement will prevent further harm to front line workers. (J.A. 229, 437-447.)

In addition to the medical consensus supporting the COVID-19 vaccine, a diverse range of religious leaders has also strongly encouraged adherents to receive a COVID-19 vaccination. For example, Pope Francis, the leader of the Roman Catholic Church (a church with which all but one of the seventeen plaintiffs are affiliated) has recognized that taking an approved COVID-19 vaccine is "an act of love" and "a simple yet profound way to care for one another, especially the most vulnerable."[7] The U.S. Conference of Catholic Bishops has explained that receiving the Pfizer and Moderna vaccines is consistent with the Catholic faith because the Pfizer and Moderna vaccines did not use fetal cell lines for their "design, development, or production," and the connection between those

[7] Devin Watkins, *Pope Francis Urges People to Get Vaccinated Against Covid-19*, Vatican News (Aug. 18, 2021) (internet) (quotation marks omitted).

vaccines and abortion "is very remote."[8] More broadly, a coalition of 145 global faith leaders, representing a variety of faiths, issued a statement that the "only way to end the pandemic" is to ensure that COVID-19 vaccines "are made available to all people as a global common good."[9]

2. New York's adoption of a COVID-19 vaccination requirement for certain healthcare workers

DOH is charged with protecting the public health and supervising and regulating "the sanitary aspects of . . . businesses and activities affecting public health." Public Health Law § 201(1)(m). Pursuant to this broad mandate, DOH has acted swiftly to respond to the risks posed by the Delta variant in New York's healthcare sector.

a. The August 18, 2021, Order for Summary Action

On August 18, 2021—prior to full FDA approval of the Pfizer vaccine—the DOH Commissioner issued an Order for Summary Action

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[8] Chairmen of the Comm. on Doctrine and the Comm. on Pro-Life Activities, *Moral Considerations Regarding the New COVID-19 Vaccines* 4-5, U.S. Conf. of Catholic Bishops (Dec. 11, 2020) (internet).

[9] Press Release, ReliefWeb, *World Religious Leaders Call for Massive Increases in Production of Covid Vaccines and End to Vaccine Nationalism* (Apr. 27, 2021) (internet).

under Public Health Law § 16, which allows him to "take certain action immediately" to remedy "a condition or activity which in his opinion constitutes danger to the health of the people," for a period not to exceed fifteen days. Public Health Law § 16. The Order required limited categories of healthcare entities to ensure that covered personnel were fully vaccinated against COVID-19. (S.A. 45.) The Order was narrow in scope, covering only hospitals and nursing homes. (S.A. 43.) It also included both a medical exemption and an exemption for individuals who "hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the employer." (S.A. 45-46.)

The Order was not intended to be a permanent solution, but rather served as an immediate "stop-gap measure pending action by the Public Health and Health Planning Council," a council within DOH that consists of the Commissioner and 24 other members drawn from the public health system, healthcare providers, and elsewhere.[10] As a result, the Order was superseded when, eight days later, the Council approved

[10] Decl. of Vanessa Murphy, J.D., M.P.H. ("Murphy Decl.") ¶ 6, *Does v. Hochul*, No. 21-cv-5067 (E.D.N.Y. Oct. 5, 2021), ECF No. 48.

the emergency rule that is at issue in this proceeding with the benefit of fuller consideration and input by its members.

b. The August 26, 2021, Emergency Rule

On August 26, 2021—three days after the FDA gave full approval to the Pfizer vaccine—the Council issued the emergency rule at issue here. Under New York law, an emergency rule may go into effect immediately and remain in effect for up to ninety days, at which point it must be renewed to remain in force. State Administrative Procedure Act § 202(6)(b).

The emergency rule requires covered healthcare entities to "continuously require" employees to be fully vaccinated against COVID-19 if they "engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease." 10 N.Y.C.R.R. § 2.61(a)(2), (c) (S.A. 48-49). In contrast to the Commissioner's Order for Summary Action, the emergency rule covers a broader range of healthcare entities—specifically, extending to certified home health agencies, long term home health care programs, AIDS home care programs, licensed home care service agencies, hospices, and adult care facilities. § 2.61(a)(1)(ii)-(iv). Also, unlike the Order, the emergency rule was formally published in the New York Register and

was accompanied by a full set of required documentation, including a Regulatory Impact Statement and findings to support the need for emergency action. (S.A. 37-40.)

The rule contains only a single exception to its requirements: a narrow medical exemption that is strictly limited in duration and scope. The rule exempts employees for whom a "COVID-19 vaccine [would be] detrimental to" their health "based upon a pre-existing health condition." § 2.61(d)(1). As to duration, the exemption applies "only until such immunization is found no longer to be detrimental to such personnel member's health," and that duration "must be stated in the personnel employment medical record." *Id.* As to scope, the exemption must be "in accordance with generally accepted medical standards," such as the "recommendations of the Advisory Committee on Immunization Practices" (ACIP), a committee that operates under the auspices of the CDC. *Id.*

DOH guidance on the emergency rule makes clear that the available grounds for a medical exemption are narrow and largely temporary. As explained by DOH's Frequently Asked Questions document

regarding the emergency rule,[11] the only "contraindications" recognized by the CDC as a ground for a medical exemption from COVID-19 vaccination are severe or immediate allergic reactions "after a previous dose" of the vaccine or "to a component of the COVID-19 vaccine."[12] Even then, the CDC advises that "the majority of contraindications are temporary," such that "vaccinations often can be administered later when the condition leading to a contraindication no longer exists."[13] The CDC also recognizes certain "precautions"—i.e., conditions that increase the risk of a serious reaction or that interfere with the effectiveness of a vaccine—that could warrant deferring administration of the COVID-19 vaccine (such as a recent acute illness), or administering a different version of

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[11] Department of Health, *Frequently Asked Questions (FAQs) Regarding the August 26, 2021 – Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation* 4 (internet) ("*FAQs*").

[12] Centers for Disease Control & Prevention, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* (last updated Sept. 27, 2021) (internet). (*See* J.A. 227-228, 426-429.)

[13] Centers for Disease Control & Prevention, *Vaccine Recommendations and Guidelines of the ACIP: Contraindications and Precautions* (internet).

the vaccine (such as a reaction to one of the three available vaccines).[14] By contrast, less serious conditions are not a basis for a medical exemption, including common side effects to the COVID-19 vaccine like fever, headache, or fatigue; allergic reactions to other substances; or immunosuppression due to a health condition or use of another medication.[15]

Consistent with the narrow criteria for medical exemptions under DOH's emergency rule, preliminary data as of October 4-5, 2021, indicate that only a small fraction of healthcare workers in New York have qualified. For hospitals, only 0.6% of staff have been found medically ineligible; and for nursing homes and adult care facilities, only 0.5% of staff. See *infra* at 20-22.

These figures are consistent with the findings of other public health experts, who have uniformly concurred that the number of individuals who are medically ineligible to receive a COVID-19 vaccine is very small.

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[14] *Id.* For example, the CDC notes that a small fraction—about seven per million—of women between eighteen and forty-nine years old experience thrombosis with thrombocytopenia syndrome after receiving the Janssen vaccine. (*See* J.A. 232, 468-470.) Any concerns about this unlikely risk, however, can be assuaged by receiving the Pfizer or Moderna vaccine.

[15] *FAQs*, *supra*, at 4-5.

Data show that the vaccines do not present "immediate health issues or side effects for most people with pre-existing medication conditions," and, apart from age, "there are no major exemptions that cover large groups of people." (J.A. 232-233, 513 (quotation marks omitted).) The vaccines are safe for immunocompromised people, pregnant women, and people with underlying conditions. The primary group of people who face serious medical risk from a COVID-19 vaccine are people who experience anaphylactic shock, but that "severe allergy is rare, and less than one in 1 million people experience it." (J.A. 232, 513.) A publication in the journal of the American Medical Association similarly estimated that the rate of anaphylaxis to the Pfizer and Moderna vaccines is extremely small: 2.5 to 11.1 per 1 million doses.[16]

The emergency rule does not contain a religious exemption. The availability of a medical but not religious exemption is also a feature of the requirement that healthcare workers be vaccinated against measles and rubella.[17] DOH has explained that the emergency rule is consistent

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[16] Kimberly G. Blumenthal et al., *Acute Allergic Reactions to mRNA COVID-19 Vaccines*, 325 JAMA 1562, 1562 (2021).

[17] See *supra* n.1.

with these preexisting obligations and that allowing a religious exemption for the COVID-19 vaccine, but not for measles and rubella, would undermine a consistent approach to preventing the transmission of these particularly infectious and harmful diseases in the healthcare sector. (J.A. 225-226.) The decision to omit a religious exemption is consistent with statements by the American Medical Association that "nonmedical exemptions, such as religious or philosophic objections to vaccinations, endanger the health of the unvaccinated individual and those whom the individual comes into contact with," and that healthcare workers in particular "have a fundamental obligation to patients [to get] vaccinated for preventable diseases, such as COVID-19." (J.A. 228, 213-232, 434, 464 (quotation marks omitted).)

In accompanying administrative materials, DOH further explained the basis for the emergency rule. It noted that the rule responded to the increasing circulation of the Delta variant, which has led to a tenfold increase in COVID-19 infections since early July 2021. DOH found that COVID-19 vaccines are safe and effective, and that the presence of unvaccinated personnel in healthcare settings poses "an unacceptably high risk" that employees may acquire COVID-19 and transmit the virus

both (a) to colleagues, thereby "exacerbating staffing shortages"; and (b) to "vulnerable patients or residents," thereby "causing [an] unacceptably high risk of complications." (S.A. 39.) DOH emphasized that, as compared with vaccinated individuals, unvaccinated individuals have *eleven times* the risk of being hospitalized with COVID-19.

The Council also conducted a public hearing on August 26, 2021, at which it provided further information concerning the need for the emergency rule and the scope of the obligations it imposed. DOH's Commissioner explained that the emergency rule was necessary because the State was at a crucial inflection point with the increasing prevalence of the Delta variant and the heightened risk for the spread of respiratory viruses (such as the flu) in the fall season.[18]

DOH counsel further explained that the scope of the emergency rule largely tracked preexisting vaccine requirements, including those for measles and rubella, in order to facilitate the rule's implementation and enforcement. For example, the definition of "covered personnel" aligns

[18] Video, Special Meeting of the N.Y. Pub. Health & Health Planning Council, Comm. on Codes, Reguls. & Legis., at 2:48-4:06 (Aug. 26, 2021) (internet) ("Comm. Meeting"). (*See* J.A. 231.)

with the scope of DOH's regulation requiring seasonal influenza vaccination or masking for certain healthcare workers.[19] *See* 10 N.Y.C.R.R. § 2.59(a)(1). Counsel similarly noted that the medical exemption is consistent with the existing standards governing immunizations for students.[20] *See id.* §§ 66-1.1(*l*), 66-1.3(c). DOH's Director of Epidemiology confirmed that the medical exemption in the emergency rule is consistent with medical exemptions in other regulations and is based on generally accepted medical standards such as the recommendations of CDC's ACIP.[21] And DOH counsel also explained that the lack of a religious exemption is consistent with a variety of regulatory provisions requiring measles and rubella vaccinations for certain healthcare workers.[22] See *supra* n.1.

DOH's findings about the immediate necessity for the emergency rule are supported by the CDC's conclusions that the Delta variant is more than twice as contagious as prior variants and may cause more

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[19] Comm. Meeting at 10:40-11:12.

[20] *Id.* at 30:42-31:00.

[21] *Id.* at 14:33-15:03.

[22] *Id.* at 37:20-37:38.

severe illness in unvaccinated people. Although vaccinated people may transmit the Delta variant to others, they do so at much lower rates than unvaccinated people. (J.A. 215-217, 267-269, 287-306.) The CDC has also recognized the importance of achieving high vaccination rates in settings where residents are at high risk of COVID-19-associated mortality, including long-term care facilities. Deaths at such facilities account for almost one third of COVID-19 related deaths in the United States, and the CDC has observed outbreaks that occurred in facilities where the "residents were highly vaccinated, but transmission occurred through unvaccinated staff members." (J.A. 230-231, 455.)

3. Early implementation of the COVID-19 vaccination requirement for healthcare workers

Although the emergency rule just went into effect on September 27, 2021—subject to limited temporary restraining orders (TROs) preventing DOH from interfering with employers' grants of religious exemptions (*see* S.A. 1-5)—some preliminary data have emerged concerning the rate of vaccinations and exemptions among New York's healthcare workforce.

As of October 4, 2021, 120,225 of 140,917 workers at nursing homes were fully vaccinated (85.3%), with an additional 17,084 having received

one dose of a two-dose vaccine (12.1%), according to self-reported data from facilities. Only 674 nursing-home workers were reported as currently medically ineligible for a COVID-19 vaccine (0.5%). Another 2,934 were reported as "other" exemptions (2.1%), which DOH understands to refer to the religious exemption currently still in place due to various TROs (*see* S.A. 1-5).[23]

As of the same date, 24,730 of 29,417 workers at adult care facilities were fully vaccinated (84.1%), with an additional 2,240 having received one dose of a two-dose vaccine (7.6%), according to self-reported data from facilities. Only 149 adult-care facility workers were reported as currently medically ineligible for a COVID-19 vaccine (0.5%). Another 399 were reported as "other" exemptions (1.36%), which DOH understands to encompass those who have claimed religious exemptions.[24]

As of October 5, 2021, 89% of hospital workers were fully vaccinated, according to self-reported data from facilities. Only 0.6% of hospital workers were medically ineligible for a COVID-19 vaccine at that

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[23] *See* Decl. of Valerie A. Deetz ¶ 3, *Does*, No. 21-cv-5067 (E.D.N.Y. Oct. 5, 2021), ECF No. 49.

[24] *Id.* ¶ 4.

time. Another 1.4% of staff were medically eligible to receive a vaccine, but were reported as "other" exemptions, which DOH understands to refer to the religious exemption currently still in place due to various TROs.[25]

These data are consistent with data from other jurisdictions, which have shown that the numbers of religious exemptions significantly exceed medical exemptions. For instance, a survey of San Diego's healthcare providers found that most of the requests for exemptions from COVID-19 vaccines cited religious reasons, with the largest providers indicating that approximately 3% of their workforce sought religious exemption, roughly seven times the number of people who sought medical exemptions.[26] In Kentucky, a hospital reported that religious exemptions were six times larger than medical exemptions.[27] And in New Jersey, a hospital reported

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[25] These figures come from an executed declaration prepared for, but not yet filed in, *Serafin v. New York State Department of Health*, Index No. 908296-21 (Sup. Ct. Albany County).

[26] *See* Paul Sisson, *Thousands of San Diego County Healthcare Workers Seek Vaccine Exemptions, Citing Religion*, San Diego Union-Tribune (Sept. 12, 2021) (internet).

[27] *See* Defs.' Response in Opp. to Pls.' Mot. for Restraining Order at 7, *Beckerich v. Saint Elizabeth Med. Ctr., Inc.*, No. 21-cv-105 (E.D. Ky. Sept. 14, 2021), ECF No. 15.

that 5% of its staff received a religious exemption, but only 1.2% percent received medical exemptions.[28]

C. Litigation Challenging COVID-19 Vaccine Requirements for Healthcare Workers

1. This lawsuit

On September 13, 2021, plaintiffs filed this lawsuit, challenging the omission of a religious exemption from DOH's emergency rule. The plaintiffs are seventeen anonymous healthcare workers allegedly subject to the emergency rule. (J.A. 12, 23-49.)

Plaintiffs, all but one of whom identify as Catholics,[29] allege that they have religious objections to receiving vaccines that use "aborted fetus cell lines in their testing, development, or production" (J.A. 12; *see* J.A. 20-23). Plaintiffs allege that if they do not take the vaccine they will face various employment consequences, risk disciplinary charges, or lose

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[28] *See* Elizabeth Llorente, *Will N.J. Hospitals Face a Nursing Shortage Under Vaccine Mandates? They Already Are*, NJ.com (Sept. 20, 2021) (internet).

[29] One plaintiff identifies as a Baptist. (J.A. 35.)

their licenses.[30] (*See, e.g.*, J.A. 24-29, 32, 36, 40, 45, 48-49.) Plaintiffs do not identify their employers. They claim that the DOH emergency rule violates their right to free exercise of religion and is preempted by Title VII. (*See* J.A. 49-57.) They seek declaratory and injunctive relief. (*See* J.A. 57.)

Plaintiffs moved for a TRO and a preliminary injunction that same day. Plaintiffs did not submit any evidence with that motion. Based on the verified allegations in the complaint, the district court granted plaintiffs' motion for a TRO without hearing from defendants. (S.A. 1-5.) On October 12, 2021, the district court granted plaintiffs' motion for a preliminary injunction. (*See* S.A. 10-36.) Defendants then filed this appeal. (J.A. 567.)

2. Other lawsuits

In addition to this proceeding, several other lawsuits sought similar relief against DOH's emergency rule. In one proceeding, a district court

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[30] Plaintiffs allege a diverse range of potential employment consequences. Some allege direct loss of employment. Others allege that they will be unable to continue their practices if their "hospital privileges [are] suspended." (*See* J.A. 29-31, 34, 41, 46.) Others allege that they were told that their employment would be at risk if they do not receive a COVID-19 vaccination. (*See* J.A. 37, 43.)

denied a preliminary injunction. *See* Order, *We The Patriots USA, Inc. v. Hochul*, No. 21-cv-4954 (E.D.N.Y. Sept. 12, 2021). Plaintiffs appealed and this Court granted a limited stay pending appeal barring defendants "from enforcing the mandate against persons claiming religious exemptions" in a manner that would violate the existing TRO in this matter. *See* Order, *We The Patriots USA, Inc. v. Hochul*, No. 21-2179 (2d Cir. Sept. 30, 2021), ECF No. 65. That appeal is now fully briefed and before this Court. In a separate proceeding, a district court denied a request for a TRO as moot in light of the TRO already in effect in this matter; a preliminary injunction motion remains pending. Mem. & Order at 1-3, *Does*, No. 21-cv-5067 (E.D.N.Y. Sept. 14, 2021), ECF No. 35. Another lawsuit, which does not raise a Free Exercise claim, remains pending in the Northern District. *See* Compl., *Andre-Rodney*, No. 21-cv-1053 (N.D.N.Y. Sept. 22, 2021), ECF No. 1.

Several state court lawsuits have also been filed. Although some state courts initially granted TROs, those TROs have now been dissolved after the state courts rejected Free Exercise (and other) claims similar to plaintiffs' claims here. *See, e.g.*, Decision & Order at 12, *Cattaraugus County v. New York State Dep't of Health*, Index No. 908382-21 (Sup. Ct.

Albany County Oct. 13, 2021), NYSCEF Doc. No. 95; Decision & Order at 16-17, *Serafin*, Index No. 908296-21 (Sup. Ct. Albany County Oct. 12, 2021), NYSCEF Doc. No. 41.

Finally, lawsuits are pending in two other jurisdictions that have similar vaccination requirements for healthcare workers. In Maine, a district court denied a motion for a preliminary injunction, rejecting both Free Exercise and Title VII claims. *See Does v. Mills*, No. 21-cv-242, 2021 WL 4783626, at *5-16 (D. Me. Oct. 13, 2021). And in Rhode Island, a district court denied a request for a TRO. *See Dr. T v. Alexander-Scott*, No. 21-cv-387, 2021 WL 4476784 (D.R.I. Sept. 30, 2021).

STANDARD OF REVIEW

A preliminary injunction is an "extraordinary and drastic remedy." *Moore v. Consolidated Edison Co. of N.Y., Inc.*, 409 F.3d 506, 510 (2d Cir. 2005) (quotation marks omitted). A party seeking preliminary injunctive relief must generally establish "(1) irreparable harm; (2) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; and (3) that a preliminary injunction is in the public interest." *New*

York ex rel. Schneiderman v. Actavis plc, 787 F.3d 638, 650 (2d Cir. 2015) (quotation marks omitted). But the "fair-ground-for-litigation" alternative is not available to "challenge governmental action taken in the public interest pursuant to a statutory or regulatory scheme." *Otoe-Missouria Tribe of Indians v. New York State Dep't of Fin. Servs.*, 769 F.3d 105, 110 (2d Cir. 2014) (quotation marks omitted).

While this Court reviews a "district court's decision to grant a preliminary injunction for an abuse of discretion," *Laureyssens v. Idea Grp., Inc.*, 964 F.2d 131, 136 (2d Cir. 1992), it reviews "*de novo* the district court's conclusions of law in connection with its issuance of the preliminary injunction," *Disabled Am. Veterans v. United States Dep't of Veterans Affairs*, 962 F.2d 136, 140 (2d Cir. 1992).

SUMMARY OF ARGUMENT

Plaintiffs have failed to show that they satisfy the prerequisites for the extraordinary relief of a preliminary injunction against a duly issued state regulation. This Court should accordingly reverse the order below.

I. Plaintiffs have failed to show a likelihood of success on the merits. Courts have long upheld mandatory vaccination requirements, including those without any religious exemption. And DOH's emergency

rule satisfies rational-basis review because it reasonably serves the objective of preventing COVID-19 spread among particularly vulnerable facilities and individuals—a point that plaintiffs do not contest.

Plaintiffs' claim that the emergency rule should be subject to heightened scrutiny under the First Amendment is meritless because the rule is a neutral, generally applicable requirement. The emergency rule is neutral because it does not expressly target religious activity for less favorable treatment and was not issued due to religious hostility. And the emergency rule is generally applicable because it extends to all covered personnel at healthcare facilities.

Contrary to the district court's conclusion, the presence of a narrow medical exemption does not preclude the emergency rule from being generally applicable for purposes of a Free Exercise claim. A policy's provision of a secular but not religious exemption triggers heightened scrutiny only (a) when the secular exemption would undermine the purpose of the underlying policy to at least the same degree as any religious exemption, or (b) when a government decisionmaker has broad discretion to extend an individualized exemption to claims of religious hardship but chooses not to.

Neither circumstance applies here. The medical exemption advances rather than undermines the emergency rule's objective of protecting healthcare workers and preventing them from becoming unavailable due to medical problems. The medical exemption is also not comparable to plaintiffs' requested religious exemption because the medical exemption is tightly constrained in both scope and duration in a manner that blunts its effect on COVID-19 transmission. And the medical exemption does not confer broad discretion on any decisionmaker to consider individual circumstances but is instead limited to a small number of federally recognized contraindications and precautions. The emergency rule's provision of a medical exemption thus does not compel DOH to grant plaintiffs' request for a religious exemption that would be very different in both scope and effect.

Finally, plaintiffs have failed to show a likelihood of success on their claim invoking Title VII. Plaintiffs cannot assert a Title VII claim directly against defendants, who are not their employers. And the emergency rule does not conflict with—and thus is not preempted by—Title VII. Because the rule itself does not dictate the actions that employers can take in response to unvaccinated employees, employers retain flexibility to

provide an accommodation required by Title VII, including reassigning employees with religious objections to activities where they will not expose others to COVID-19. On the other hand, Title VII does not require the accommodation that plaintiffs seek here, which is the continuation of their work with other personnel, patients, and residents despite being unvaccinated.

II. The equities also weigh heavily in favor of allowing DOH's emergency rule to go into effect. Delaying the mandatory vaccination of New York's healthcare workers—including those who seek a religious exemption—poses risks to the healthcare workers themselves, to their colleagues, and to the vulnerable populations that they serve, who are often at heightened risk of infection and death from COVID-19. The public at large also will suffer harm if COVID-19 outbreaks at healthcare facilities limit staffing or strain resources in a way that results in substandard medical care.

By contrast, the principal harm identified by plaintiffs is their conclusory assertion that they may face various employment consequences if they adhere to their religious objection to the vaccine. But the emergency rule does not compel such consequences. Plaintiffs' support

for their claims that they face such harm is absent or thin. And in any event, it is well settled that such economic harm is inadequate to justify the extraordinary remedy of a preliminary injunction.

ARGUMENT

POINT I

PLAINTIFFS HAVE NOT ESTABLISHED A LIKELIHOOD OF SUCCESS ON THE MERITS

A. Courts—Including This Court—Have Long Upheld Mandatory Vaccination Requirements, Including Those Without Religious Exemptions.

Courts have long held that mandatory vaccination laws constitute a valid exercise of the States' police powers, and such laws have withstood challenges on various constitutional grounds for more than a century. In 1905, for example, the Supreme Court held that mandatory vaccination laws do not offend "any right given or secured by the Constitution," and that the States' police powers allow imposition of "restraints to which every person is necessarily subject for the common good." *Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905); *see Zucht v. King*, 260 U.S. 174, 176 (1922).

Courts have specifically recognized that generally applicable vaccination requirements do not infringe on religious liberties. As the Supreme Court held over seventy years ago, "[t]he right to practice [one's] religion freely does not include liberty to expose the community . . . to communicable disease." *Prince v. Massachusetts*, 321 U.S. 158, 166-67 & n.12 (1944); *see also Wright v. DeWitt Sch. Dist. No. 1*, 238 Ark. 906, 913 (1965) (rejecting Free Exercise Clause challenge to school's smallpox vaccination requirement). More recently, the Court specifically identified "compulsory vaccination laws" as among the neutral, generally applicable laws that do not require religious exemptions under the First Amendment.[31] *Employment Div., Dep't of Human Res. of Ore. v. Smith*, 494 U.S. 872, 889 (1990).

As recently as 2015, this Court similarly explained that mandatory vaccination (in that case, for schoolchildren) "does not violate the Free Exercise Clause." *Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir.

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[31] The district court erred (S.A. 19 n.6) in questioning the applicability of *Jacobson* and its progeny. As Justice Gorsuch has noted, the Supreme Court in *Jacobson* did what this Court must do here: apply the appropriate tier of scrutiny. *Roman Catholic Diocese*, 141 S. Ct. at 70-71 (Gorsuch, J., concurring).

2015). This Court reasoned that "New York could constitutionally require that all children be vaccinated in order to attend public school" without any religious exemption at all, and that such an exemption "goes beyond what the Constitution requires." *Id.* In short, "it has been settled law for many years that claims of religious freedom must give way in the face of the compelling interest of society in fighting the spread of contagious diseases through mandatory inoculation programs." *Sherr v. Northport–E. Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 88 (E.D.N.Y. 1987); *see id.* at 83 (citing cases); *McCarthy v. Boozman*, 212 F. Supp. 2d 945, 948 (W.D. Ark. 2002).

The absence of a religious exemption in DOH's emergency rule is not an outlier. Comparable immunization laws also contain no such exemption. For example, New York's immunization requirement for schoolchildren no longer contains a religious exemption. *See* Public Health Law § 2164; *F.F. v. State*, 194 A.D.3d 80, 88 (3d Dep't) (rejecting Free Exercise challenge), *appeal dismissed & lv. denied*, 2021 N.Y. Slip Op. 72937 (N.Y. 2021). As discussed, New York's requirement that healthcare workers be vaccinated against measles and rubella does not allow for religious exemptions either. See *supra* at 5-6. And several other States

have similarly declined to permit religious exemptions from their immunization laws. *See* Cal. Health & Safety Code § 120325 et seq. (Westlaw 2021); Conn. Gen. Stat. Ann. § 10-204a (Westlaw 2021); Me. Rev. Stat. Ann. tit. 20-A, § 6355 (Westlaw 2021); Miss. Code Ann. § 41-23-37 (Westlaw 2021); W. Va. Code Ann. § 16-3-4 (Westlaw 2021). Indeed, the Fourth Circuit rejected a Free Exercise challenge to West Virginia's mandatory childhood vaccination statute, which, like DOH's emergency rule, recognized only medical but not religious exemptions. *See Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. App'x 348, 353-54 (4th Cir. 2011).

In light of this settled law upholding vaccination requirements, including those without religious exemptions, the district court erred in concluding that plaintiffs have shown a likelihood of success on the merits (*see* S.A. 21-32). Plaintiffs' Free Exercise claim fails because, as explained further below, DOH's emergency rule is a neutral law of general applicability that is subject to rational-basis review—a bar that it readily clears.[32] And plaintiffs' reliance on Title VII is misplaced because

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[32] Plaintiffs style Count III of their complaint as an Equal Protection claim. But the substance of that claim is duplicative of their Free Exercise claim: they allege that they are treated unequally due to their religious beliefs. (*See* J.A. 54-57.) Accordingly, defendants address that

(*continued on the next page*)

that statute does not override the authority of States to enact neutral and generally applicable measures to promote public health in the workplace. Plaintiffs are thus not entitled to a preliminary injunction.

B. DOH's Emergency Rule Comports with the Free Exercise Clause.

1. DOH's emergency rule is subject to rational-basis review because it is neutral and generally applicable.

It is well-established that the right to free exercise of religion does not relieve an individual of the obligation to comply with a "valid and neutral law of general applicability." *Smith*, 494 U.S. at 879 (quotation marks omitted). Rational-basis review is all that is required to uphold such laws—i.e., laws that do not target, disapprove of, or single out religious groups or practices, even if the law "proscribes (or prescribes) conduct that [one's] religion prescribes (or proscribes)." *Id.* at 889 (quotation marks omitted). Here, rational-basis review applies because DOH's emergency rule is both neutral and generally applicable. The district court thus erred in applying strict scrutiny (*see* S.A. 28-30).

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claim, which the district court did not consider (*see* S.A. 19 n.7), collectively with plaintiffs' Free Exercise claim.

a. DOH's emergency rule is neutral.

DOH's emergency rule is neutral because it does not target practices based on "their religious motivation." *See New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 162 (2d Cir. 2020) (quotation marks omitted). On its face, the rule does not mention religious activity at all—in contrast to the COVID-19 executive orders reviewed by the Supreme Court in *Roman Catholic Diocese*, which expressly "single[d] out houses of worship" for distinctive treatment. 141 S. Ct. at 66; *see also Agudath Israel of Am. v. Cuomo*, 980 F.3d 222, 229 (2d Cir. 2020) (Park, J., dissenting) (noting that orders' restrictions on "houses of worship" evidenced "disparate treatment of religious and secular institutions [that] is plainly not neutral").

Nor does the history or administration of DOH's emergency rule reveal any "subtle departures from neutrality" reflecting hostility or animus towards religion. *See Church of the Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 534 (1993) (quotation marks omitted); *see also Masterpiece Cakeshop, Ltd. v. Colorado Civil Rts. Comm'n*, 138 S. Ct. 1719, 1731 (2018). In assessing whether animus motivated a government action, courts look to "the historical background of the decision under

challenge, the specific series of events leading to the enactment or official policy in question, and the legislative or administrative history, including contemporaneous statements made by members of the decisionmaking body." *New Hope Fam. Servs.*, 966 F.3d at 163 (quotation marks omitted).

In *Roman Catholic Diocese*, for example, the Supreme Court was troubled by public statements by the Governor (who had issued the executive orders under review) that appeared to criticize the Orthodox Jewish community; the Court noted the observation by a judge of this Court that such statements could be "viewed as targeting" that community. 141 S. Ct. at 66 (quotation and alteration marks omitted) (citing *Agudath*, 980 F.3d at 229 (Park, J., dissenting)). Similarly, in *New Hope Family Services*, this Court held that plaintiffs had plausibly pleaded religious animus based in part on public statements by agency officials (who had rendered the administrative decision under review) suggesting that they "did not think [plaintiff's] religious beliefs about family and marriage could legitimately be carried into the public sphere." 966 F.3d at 168 (quotation marks omitted). This Court further found "a suspicion of religious animosity" based on the agency's departure from its statutory mandate and a history of agency inaction. *Id.* at 166.

This case does not present any similar circumstances that would plausibly suggest that religious animus motivated DOH's emergency rule. The district court did not identify any statements from DOH officials suggesting that they were "intolerant of religious beliefs." *See Fulton v. City of Philadelphia*, 141 S. Ct. 1868, 1877 (2021). And the district court erred in concluding (S.A. 28) that any religious animus can be inferred from the fact that the Commissioner's earlier August 18 Order for Summary Action contained a religious exemption.

As DOH has explained, the Commissioner issued the Order for Summary Action under his sole authority as an immediate, temporary "stop-gap measure"—limited by law to be in effect for only fifteen days, *see* Public Health Law § 16—that was narrower than the emergency rule at issue here in several respects. Murphy Decl. ¶ 6. And the Commissioner's Order was intended to be effective only "pending action by the Public Health and Health Planning Council," an expert body within DOH composed of two dozen healthcare professionals that considered and issued the more comprehensive and longer-term emergency rule at issue here. *Id.* Moreover, as DOH officials explained at the August 26 public hearing, the emergency rule decided and issued by the Council is silent

on a religious exemption in order to provide healthcare employers with standards consistent with the longstanding measles and rubella vaccination requirements. See *supra* at 18-19. Thus, the changes between the Order for Summary Action and the emergency rule do not reflect religious hostility, but rather the inherently temporary and limited nature of the Order; the Council's more extended consideration of a longer-term and more broadly applicable rule, based on input from its two dozen members; and the Council's attempt in the emergency rule to follow the model already established by preexisting vaccination requirements for similarly infectious and harmful diseases.

b. DOH's emergency rule is generally applicable.

As relevant here, courts have identified two circumstances under which a policy can fail to be generally applicable. *See generally Fulton*, 141 S. Ct. at 1877. The first is if the policy "is substantially underinclusive such that it regulates religious conduct while failing to regulate secular conduct that is *at least as harmful* to the legitimate government interests purportedly justifying it." *Central Rabbinical Cong. v. New York City Dep't of Health & Mental Hygiene*, 763 F.3d 183, 197 (2d Cir. 2014) (emphasis added). The second is if the policy "invites the government to

consider the particular reasons for a person's conduct by providing a mechanism for individualized exemptions." *Fulton*, 141 S. Ct. at 1877 (quotation and alteration marks omitted). The district court erred in concluding that the emergency rule is underinclusive (S.A. 29-30) and did not address whether it provides a mechanism for individualized exemptions. Neither circumstance applies here.

i. The rule is not substantially underinclusive.

On its face, DOH's emergency rule is generally applicable because it covers all healthcare workers at covered entities who "engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease." § 2.61(a)(2). The only exception to this requirement is a narrow medical exemption for workers who would currently suffer specific contraindications if they were to receive the COVID-19 vaccine or are otherwise subject to specific "precautions." *See* § 2.61(d)(1).

The district court mistakenly held (S.A. 29-30) that plaintiffs have shown a likelihood of success on their claim that this medical exemption precludes the emergency rule from being generally applicable and thus compels DOH to offer a religious exemption as well. Contrary to the

district court's reasoning, that result is supported neither by the Supreme Court's recent orders on COVID-19 assembly restrictions nor by settled case law on general applicability.

As this Court has explained, the availability of a nonreligious exemption does not necessarily require the availability of a religious exemption. Instead, the Free Exercise Clause subjects a policy to strict scrutiny only when it denies a religious exemption while at the same time offering a nonreligious exemption that is "at least as harmful" to the objectives of the underlying policy. *Central Rabbinical Cong.*, 763 F.3d at 197. In other words, what the Free Exercise Clause bars is "disparate treatment" of otherwise comparable exemption claims that differ only in their religious or nonreligious motivation. *Agudath*, 980 F.3d at 229 (Park, J., dissenting); *see also Tandon v. Newsom*, 141 S. Ct. 1294, 1296 (2021) (per curiam) (strict scrutiny applies only when a policy treats "*comparable* secular activity more favorably than religious exercise" (emphasis added)).

In *Roman Catholic Diocese*, for example, the Supreme Court found that COVID-19 executive orders were not generally applicable when, on the record before the Court, they appeared to impose more stringent

assembly restrictions on religious services than on a broad range of comparable secular businesses that "contributed to the spread of COVID-19" more than religious congregations would. 141 S. Ct. at 67. The Court reached the same conclusion in *Tandon*, holding that heightened scrutiny applied because, according to the record in that case, California appeared to treat a vast range of secular activities—including "hair salons, retail stores, personal care services, movie theaters, private suites at sporting events and concerts, and indoor restaurants"—more leniently than religious practices without any showing that the secular activities "pose[d] a lesser risk of [COVID-19] transmission than applicants' proposed religious exercise." 141 S. Ct. at 1297 (emphasis omitted).

Other appellate precedents similarly recognize that strict scrutiny applies only when a policy denies religious exemptions while granting nonreligious exemptions that are equally or more harmful to the claimed government interest. For example, in *Fraternal Order of Police Newark Lodge No. 12 v. City of Newark*, the Third Circuit applied strict scrutiny to a municipal policy allowing medical but not religious exemptions from a rule prohibiting police officers from wearing beards. 170 F.3d 359, 360, 365-66 (3d Cir. 1999) (Alito, J.). The court noted that the asserted

government interest was in maintaining a uniform appearance for law enforcement personnel and that the medical exemption directly undercut that interest in the same manner as any religious exemption would. Given that comparability, the availability of the medical exemption alone raised the concern that the municipality had "made a value judgment that secular (i.e., medical) motivations for wearing a beard are important enough to overcome its general interest in uniformity but that religious motivations are not." *Id.* at 366.

Similarly, in *Blackhawk v. Pennsylvania*, the Third Circuit applied strict scrutiny to a state law that forbade religious exemptions from restrictions on keeping wildlife in captivity while categorically exempting zoos and circuses from such restrictions. 381 F.3d 202, 210 (3d Cir. 2004) (Alito, J.). Noting that the purpose of the underlying state law was to raise revenue (from charging permit fees) and to "discourage the keeping of wild animals in captivity," *id.* at 211, the Third Circuit found that the nonreligious exemptions for zoos and circuses "undermine[d] the purpose of the law *to at least to the same degree* as the covered conduct that is religiously motivated," *id.* at 209 (emphasis added).

In sharp contrast, the medical exemption in DOH's emergency rule is not comparable to the religious exemption requested by plaintiffs, for at least two reasons. *First*, far from "undermin[ing] the interests served by" the emergency rule, *id.* at 211, the medical exemption *advances* the underlying rule's objective of protecting the health of healthcare workers and preventing them from becoming unavailable to work for medical reasons. Denying an exemption to workers for whom a "COVID-19 vaccine [would be] detrimental to" their health, § 2.61(d)(1), on the other hand, would exacerbate one of the very risks that DOH is attempting to address, and conflict with healthcare providers' ethical obligations to "do no harm." *See Jacobson*, 197 U.S. at 39.

The medical exemption is thus unlike the secular exemptions criticized by the Supreme Court in *Roman Catholic Diocese* and *Tandon*, and more similar to an exemption in the Oregon law that the Supreme Court nonetheless found to be generally applicable in *Smith*. The Oregon law prohibited possession of peyote "unless the substance has been prescribed by a medical practitioner." *Smith*, 494 U.S. at 874. But this "prescription exception" did not preclude the Oregon law from being generally applicable for purposes of a Free Exercise claim because it did

"not necessarily undermine Oregon's interest in curbing the unregulated use of dangerous drugs." *Fraternal Order*, 170 F.3d at 366. To the contrary, the prescription exception was consistent with the underlying drug law's objective of "protect[ing] public health and welfare" because "when a doctor prescribes a drug, the doctor presumably does so to serve the patient's health and in the belief that the overall public welfare will be served." *Blackhawk*, 381 F.3d at 211. The medical exemption here similarly serves rather than undercuts an important purpose of DOH's emergency rule.

Second, although the medical exemption may raise the risk of COVID-19 infection of and transmission from medically ineligible staff, its extremely narrow scope and limited duration means that the medical exemption does not risk such harm "to *at least the same degree* as would" plaintiffs' proffered religious exemption. *Id.* As explained above, the medical exemption is available only when a worker can demonstrate a small number of specific contraindications—essentially, a severe or immediate allergic reaction to the COVID-19 vaccine or one of its components—or certain "precautions" recognized by CDC and DOH guidance. See *supra* at 13-16. The number of medical exemptions will

thus necessarily be quite limited. And because the most significant contraindication is an adverse reaction to a prior dose of the COVID-19 vaccine, many of the workers who receive medical exemptions will already have received at least partial protection from further infection and transmission.[33] By contrast, our country's respect for diverse religious views, including individualized beliefs that may not reflect any institutionalized creed, make it both legally and practically difficult to limit the scope of any religious exemption in a similar manner. *See Gillette v. United States*, 401 U.S. 437, 457 (1971).

This practical reality is confirmed by preliminary data showing that as much as three to four times the number of healthcare workers have claimed religious exemptions as have claimed medical exemptions. See *supra* at 20-23. Reports from other jurisdictions implementing COVID-19 vaccine requirements for healthcare workers are in accord—for

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[33] Mark G. Thompson et al., *Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021*, 70 Morbidity & Mortality Wkly. Rep. 495, 495 (2021) (showing 80% effectiveness for partial immunization).

example, San Diego's largest healthcare providers received seven times the number of requests for religious exemptions compared to medical exemptions. See *supra* at 22-23. And a similar disparity existed when New York previously allowed religious exemptions from the vaccine requirements for public school children: in 2017 to 2018, for example, there were 4,571 medical exemptions but nearly six times as many religious exemptions (26,627).[34]

The medical exemption in DOH's emergency regulation is not only strictly limited in scope, but also in duration. It applies "only until [COVID-19] immunization is found no longer to be detrimental to such personnel member's health," and such duration "must be stated in the personnel employment medical record." § 2.61(d)(1). And CDC and DOH guidance note that the majority of contraindications and precautions will be temporary, meaning that most medical exemptions will simply defer the administration of the COVID-19 vaccine rather than permanently

[34] Aff. of Debra Blog ¶ 15, *F.F. v. State*, Index No. 04108/2019 (Sup. Ct. Albany County July 29, 2019).

excusing a worker from being vaccinated.[35] For example, individuals suffering from an acute illness may need to defer vaccination, but may receive a vaccination after recovering from the illness. See *supra* at 14-15. By contrast, plaintiffs have not suggested that any religious exemption would be limited in time or periodically reassessed, as the medical exemption must be under the emergency rule.

The strictly limited scope and duration of any medical exemption thus precludes the conclusion that the medical exemption will be "at least as harmful" to the underlying objectives of DOH's emergency rule as plaintiffs' requested religious exemption.[36] *See Central Rabbinical Cong.*, 763 F.3d 197. In sharp contrast, the Supreme Court found that the secular activities permitted by the exemptions in *Roman Catholic Diocese* and *Tandon* were *riskier* than religious congregation, in light of various churches' and synagogues' larger physical venues and "admirable safety

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[35] For example, while those who have experienced anaphylactic shock from taking a vaccine might qualify for an indefinite exemption, that "severe allergy is rare, and less than one in 1 million people experience it." (J.A. 232, 513.)

[36] The district court applied an erroneous standard in looking at whether the medical exemption accepts a risk "for a non-zero segment of healthcare workers." (S.A. 29.)

records." *Roman Catholic Diocese*, 141 S. Ct. at 67; *see also Tandon*, 141 S. Ct. at 1297 (noting that California had failed to "show that the religious exercise at issue is more dangerous"). And the Third Circuit similarly concluded in *Blackhawk* that the secular zoos-and-circuses exemption, which permitted large numbers of wild animals to be held in captivity, caused far greater harm than the plaintiff's religiously based request to keep just two black bears. 381 F.3d at 211.

Accordingly, because the medical exemption here advances rather than undermines the objectives of DOH's emergency rule, and because it poses significantly less of a risk than plaintiffs' requested religious exemption would, its presence here does not preclude the emergency rule from being generally applicable for purposes of a Free Exercise claim. Put simply, the medical exemption bears no similarity to the broad secular exemptions that the Supreme Court and other courts have found to raise concerns about discriminatory treatment against similarly situated religious concerns. Instead, the medical exemption is a singular and strictly limited exception that is not comparable in purpose or effect to any other exemption—religious or nonreligious alike.

ii. The rule does not provide for discretionary, individualized exemptions.

DOH's emergency rule is also generally applicable because it does not vest any government official or agency with broad discretion to grant individualized exemptions. A law that has such exemptions must satisfy strict scrutiny "because such a regime creates the opportunity for a facially neutral and generally applicable standard to be applied in practice in a way that discriminates against religiously motivated conduct." *Blackhawk*, 381 F.3d at 209.

The Supreme Court recently applied this principle to hold that Philadelphia's scheme for granting foster care contracts was not generally applicable because it allowed a state official to grant an exception "in his/her sole discretion" to particular applications of Philadelphia's prohibition on sexual-orientation discrimination. *Fulton,* 141 S. Ct. at 1878 (quotation marks omitted). Similarly, *Smith* explained that the unemployment-compensation scheme at issue in *Sherbert v. Verner*, 374 U.S. 398 (1963), was not generally applicable because it allowed exceptions for "good cause," an undefined standard. 494 U.S. at 884. "[W]here the State has in place a system of individual exemptions, it may

not refuse to extend that system to cases of 'religious hardship' without compelling reason." *Id.*

Here, by contrast, the emergency rule does not lay out any similarly broad discretionary scheme of individualized exemptions under which DOH could consider claims of religious hardship. Instead, the emergency rule contains only a single, limited exemption for employees for whom a "COVID-19 vaccine [would be] detrimental to" their health "based upon a pre-existing health condition." § 2.61(d)(1). The scope of the exemption is narrow and clearly defined: it must be "in accordance with generally accepted medical standards," and it specifically references the "recommendations of the Advisory Committee on Immunization Practices." *Id.* And healthcare providers lack discretion to grant exemptions outside of these federally recognized, health-based criteria. Thus, unlike the schemes at issue in *Fulton* and *Sherbert*, the medical exemption does not authorize consideration of religious concerns at all. And it tightly constrains healthcare providers even as to their application of medical criteria for excusing workers from receiving the COVID-19 vaccine. The medical exemption thus bears no similarity to the broad discretionary schemes that have triggered heightened scrutiny in other cases.

2. DOH's emergency rule has a rational basis and would survive heightened scrutiny in any event.

As a neutral law of general applicability, the DOH emergency rule easily satisfies rational-basis review because it demonstrates a "reasonable fit" between the State's purpose and "the means chosen to advance that purpose." *Leebaert v. Harrington*, 332 F.3d 134, 139 (2d Cir. 2003) (quotation marks omitted). New York seeks to protect public health and safety by reducing the incidence of COVID-19 in particularly vulnerable facilities that have borne the brunt of COVID-19 infections. The emergency rule reasonably serves this objective by vaccinating healthcare workers whose responsibilities require them to directly interact with patients, residents, and other personnel—thereby both protecting the workers themselves, and preventing them from being vectors of transmission to their colleagues and the vulnerable populations that they serve. These protections also prevent staffing shortages that could follow an outbreak among staff, and strains on limited healthcare resources that could follow an outbreak among patients or residents. (*See* S.A. 39.) *See Maniscalco v. New York City Dep't of Educ.*, No. 21-cv-5055, 2021 WL 4344267, at *3 (E.D.N.Y. Sept. 23, 2021) (holding COVID-19 vaccination requirement for teachers rational in light of CDC guidance

that vaccination is "the most critical strategy to help schools safely resume full operations" (quotation marks omitted)), *aff'd*, Summary Order, No. 21-2343 (2d Cir. Oct. 15, 2021), ECF No. 80. Indeed, the district court did not dispute the rationality of DOH's emergency rule.

Instead, the district court concluded that the emergency rule is likely to fail to satisfy heightened scrutiny. (*See* S.A. 30-32.) For the reasons given above, no heightened scrutiny applies here. But even if some form of heightened scrutiny did apply, DOH's emergency rule would satisfy it as well. As the Supreme Court has made clear, and the district court recognized (S.A. 30), promoting public health by preventing the spread of COVID-19 is "unquestionably a compelling interest." *Roman Catholic Diocese*, 141 S. Ct. at 67. And DOH's emergency rule is narrowly tailored to that end. *See id.*

First, there is "a very direct connection" between vaccination requirements and "the preservation of health and safety." *Garcia v. New York City Dep't of Health & Mental Hygiene*, 31 N.Y.3d 601, 612 (2018). DOH specifically noted that the COVID-19 vaccines are safe and effective, and that unvaccinated individuals have eleven times the risk of being hospitalized with COVID-19. (*See* S.A. 39.)

Second, the emergency rule focuses narrowly on specific workers in a discrete sector where COVID-19 transmission poses heightened and unacceptable risks: employees in healthcare settings who directly interact with patients and personnel in a way that would expose them to infection. Transmission of COVID-19 by healthcare workers in these facilities thus raises particular risks to (1) their own personal safety; (2) the safety of their colleagues; (3) the safety of the vulnerable populations they serve; and (4) the safety of the public at large, which could be threatened by staffing shortages or resource strains at healthcare facilities where there are COVID-19 outbreaks. (*See* S.A. 39.) The rule does not apply to individuals working outside of enumerated entities in the healthcare sector, and it does not apply to employees who pose no risk of exposing colleagues or patients to COVID-19. *See* § 2.61(a)(2). Like longstanding regulations governing measles and rubella vaccinations for healthcare workers, the emergency rule is thus narrowly drawn to address the particular concerns raised by specific vulnerable settings and populations.

Third, DOH considered but rejected alternative approaches to vaccination because they would not adequately achieve DOH's goal of promoting public health by preventing COVID-19 transmission in

healthcare settings. DOH concluded that a testing requirement, for example, would be impracticable due to its expense and the unreasonable burden of requiring near-daily testing for employees. DOH also noted that testing is limited in its effectiveness. Antigen tests have not proven as reliable for asymptomatic diagnosis. As for PCR tests, healthcare personnel could contract and spread COVID-19 between tests or while awaiting results because those test results cannot be obtained before the commencement of a shift. (S.A. 39.) Similarly, a masking requirement, while "helpful to reduce transmission . . . does not prevent transmission." (S.A. 39.) DOH thus reasonably concluded that masking should be required *in addition to* vaccination, not in place of it.[37]

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[37] The district court noted that a masking alternative is available to the influenza vaccination requirement and claimed without any citation to record evidence that influenza is "broadly similar to COVID-19." (S.A. 25 n.9.) In fact, the record evidence shows that COVID-19, and the Delta variant specifically, is uniquely transmissible and deadly. (J.A. 215-219, 397-402.) Moreover, the medical profession's long experience with the flu has resulted in a variety of treatments; by contrast, therapeutic options for COVID-19 remain experimental and are still being studied. *See* Jared S. Hopkins et al., *Merck Pill Intended to Treat Covid-19 Succeeds in Key Study*, Wall St. J. (Oct. 1, 2021) (internet). DOH's determination that stricter requirements are appropriate for COVID-19 is thus a rational determination within its expertise.

In addition, a policy allowing private healthcare employers to decide on their own whether to require vaccinations would be inadequate to address the harms that DOH has identified. For example, a recent study showed that vaccination rates among nursing home staff were lagging before DOH issued the emergency rule: only 60% were fully vaccinated as of July 2021.[38] DOH also has an interest in ensuring uniformity across New York's healthcare system to protect patients or residents who transfer between facilities.

Contrary to the district court's analysis (*see* S.A. 31-32), heightened scrutiny does not require defendants to show that the omission of a religious exemption in particular serves a compelling interest or is the least restrictive alternative. Applying that analysis here would improperly import the analysis required in the Religious Land Use and Institutionalized Persons Act, *see* 42 U.S.C. § 2000cc-1(a), and the Religious Freedom Restoration Act, *see id.* § 2000bb-1(b), which do not apply here to claims against the State outside the context of land use and prisons, *see City of*

[38] Brian E. McGarry et al., *Association of Nursing Home Characteristics with Staff and Resident COVID-19 Vaccination Coverage* 2, JAMA Internal Med. (Sept. 16, 2021) (internet).

Boerne v. Flores, 521 U.S. 507, 511 (1997). But even if that analysis did apply here, the emergency rule would still withstand scrutiny.

As explained above, a religious exemption would lead to significantly more unvaccinated healthcare workers for longer periods of time than are currently permitted by the emergency rule's narrow medical exemption. Heightened scrutiny would not preclude DOH from responding to the qualitatively higher risks posed by a religious exemption in the way that it chose. The "mere fact that a law contains some secular exceptions" is not in of itself sufficient to prove that "the government lacked a compelling interest in avoiding another exception to accommodate a claimant's religious exercise." *Yellowbear v. Lampert*, 741 F.3d 48, 61 (10th Cir. 2014) (Gorsuch, J.). Courts look for "a qualitative or quantitative difference between the particular religious exemption requested and other secular exceptions already tolerated." *Id.* Here, the significant differences between the narrow medical exemption and the religious exemption requested by plaintiffs justify DOH's decision to allow only tightly constrained medical exemptions to its emergency rule.

DOH's reasons for rejecting less restrictive alternatives than vaccination, such as masking and testing, also justify the absence of such

alternatives for workers claiming a religious exemption. Although testing and masking would reduce the risk of COVID-19 transmission and infection by unvaccinated workers, they are not as effective as vaccination. And these alternatives' reduced efficacy is particularly troubling in light of the Delta variant's markedly higher transmissibility and lethality. By contrast, the COVID-19 vaccines are not only highly effective at reducing infection and transmission, but are also safe, free, and easily available.

Accordingly, DOH's emergency rule would withstand heightened scrutiny even if such scrutiny were to apply.

C. DOH's Emergency Rule Is Not Preempted by Title VII.

The district court erred in concluding (S.A. 21-25) that plaintiffs were likely to succeed on the claim that Title VII preempts DOH's emergency rule.[39] Title VII prohibits an *employer* from discriminating

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[39] Plaintiffs styled their claim as a "Supremacy Clause" claim; as the district court correctly observed (S.A. 21), that clause does not provide an independent cause of action. *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324-25 (2015). The district court nonetheless assessed plaintiffs' claim as seeking injunctive relief under a preemption theory. As explained below, regardless of the legal framework used to assess this claim, plaintiffs fail to state a viable cause of action.

against an employee because of his or her religion, "unless an employer demonstrates that he is unable to reasonably accommodate" an employee's religious practice without "undue hardship." *See* 42 U.S.C. §§ 2000e(j), 2000e-2(a)(1); *Cosme v. Henderson*, 287 F.3d 152, 157 (2d Cir. 2002). Contrary to the district court's reasoning, several independent grounds explain why Title VII provides no basis to disturb DOH's authority here to enact neutral, generally applicable regulations governing "the sanitary aspects of . . . businesses and activities affecting public health," without providing a religious exemption. Public Health Law § 201(1)(m).

First, as an initial matter, Title VII imposes no direct obligations on DOH with respect to the plaintiffs, because DOH is not the employer of any of the plaintiffs in this case. The "existence of an employer-employee relationship is a primary element of Title VII claims." *Gulino v. New York State Educ. Dep't*, 460 F.3d 361, 370-71 (2d Cir. 2006). But the plaintiffs do not allege an employment relationship with DOH (or the other state defendants). And nothing in the emergency rule dictates termination or any other adverse employment actions for unvaccinated workers. At most, plaintiffs' complaint might be read to allege that DOH's

emergency rule interferes with their relationship with their unidentified employers. But this Court has already rejected that basis for Title VII liability, squarely holding that Title VII does not extend to "those who interfere with an individual's access to employment opportunities." *Id.* at 374. Plaintiffs have thus failed to establish a predicate element to invoking a Title VII claim against defendants here.

Second, not only have plaintiffs failed to name a proper Title VII defendant, but they have also failed to identify concrete Title VII injuries. Plaintiffs' assertions that they will actually suffer any cognizable injury under Title VII are unsupported or, at best, premature. They do not allege that they have *already* suffered an adverse employment action, such as termination. And their claim that they *will* suffer such consequences (*see, e.g.*, J.A. 24-26) is speculative. See *infra* at 68-69. As discussed immediately below, the emergency rule does not require that unvaccinated workers be terminated; employers could comply with the rule by reassigning such workers to activities where they would no longer expose others to COVID-19 infection. And Title VII provides for administrative remedies that could resolve any employment-related dispute before the need for litigation. *See* 42 U.S.C. § 2000e-5(f)(1); *Mills*,

2021 WL 4783626, at *15-16. Given the absence of any showing on this record that DOH's emergency rule will necessarily lead to cognizable Title VII injuries, there was no basis for the district court to rely on the mere possibility of such injuries to enjoin the emergency rule statewide—across all facilities and personnel, and under all circumstances. If Title VII violations are committed in the future by plaintiffs' unidentified private employers, plaintiffs can challenge those violations directly, in suits against their employers, after exhausting their administrative remedies.

Third, the district court erred in finding an irreconcilable conflict between Title VII and DOH's emergency rule. Beyond the ordinary presumption against preemption, *see Gregory v. Ashcroft*, 501 U.S. 452, 460-61 (1991), in enacting Title VII, Congress included two provisions explicitly disclaiming "any intent categorically to pre-empt state law"; those provisions "severely limit Title VII's pre-emptive effect." *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 281, 282 (1987) (op. of Marshall, J.). Congress provided that the Civil Rights Act as a whole should not be construed "as indicating an intent on the part of Congress to occupy the field" in which any title operates. 42 U.S.C. § 2000h-4. And

Title VII specifically does not "exempt or relieve any person from any liability, duty, penalty, or punishment provided by any present or future law of any State"—except in the limited circumstance where a state law "require[s] or permit[s] the doing of any act which would be an unlawful employment practice," and thus results in an actual conflict with Title VII. *Id.* § 2000e-7.

Plaintiffs have failed to show that the DOH emergency rule conflicts with federal law by necessarily "requir[ing] or permit[ting]" employers to violate Title VII. In fact, the emergency rule is silent about the employment-related actions that employers may choose to take when employees refuse to be vaccinated for religious reasons. Nothing in the emergency rule precludes employers from accommodating religious objectors by giving them to assignments—such as telemedicine—where they would not pose a risk of infection to other personnel, patients, or residents. Plaintiffs are thus mistaken in arguing that the emergency rule eliminates *any* opportunity for employees to secure a reasonable accommodation that is otherwise required by Title VII.[40] (*See* S.A. 22.)

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[40] Plaintiffs argued below that the emergency rule violates Title VII because it forbids employers from offering a religious exemption. *See*

(*continued on the next page*)

Absent such a showing, the district court should not have enjoined the enforcement of the emergency rule statewide, as though it were facially invalid due to Title VII preemption. Such broad relief is disfavored because, as here, it "often rest[s] on speculation" about a rule's effects and imposes broader restraints than are justified by the facts. *See Dickerson v. Napolitano*, 604 F.3d 732, 741 (2d Cir. 2010) (quotation marks omitted). Because compliance with Title VII and DOH's emergency rule is not "a physical impossibility" in all circumstances, there was no basis for the district court to enjoin the rule on preemption grounds. *California Fed. Sav.*, 479 U.S. at 281 (op. of Marshall, J.) (quotation marks omitted).

To be sure, the emergency rule precludes plaintiffs from receiving the accommodation that they would prefer—a blanket exemption allowing them to continue working with other staff, patients, and residents despite being unvaccinated. But an employer is not obligated

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Mem. of Law at 6 (Sept. 13, 2021), ECF No. 5-1. But a reasonable accommodation need not be an exemption from an existing policy; it can be a modification of the employee's tasks or working conditions that is consistent with existing policy. If an exemption were always required, "an employer whose formal policies attempt flexibly to anticipate the diverse needs of its employees will rarely be able to show that it has offered an 'accommodation.'" *Brown v. F.L. Roberts & Co.*, 419 F. Supp. 2d 7, 14 (D. Mass. 2006).

to offer "the accommodation the employee prefers"; rather, Title VII is satisfied "when any reasonable accommodation is provided" to address an employee's religious observance or practice. *Cosme*, 287 F.3d at 158; *see Shelton v. University of Med. & Dentistry of N.J.*, 223 F.3d 220 (3d Cir. 2000) (nurse transferred to different unit due to unwillingness to assist with emergency abortions).

Title VII is also satisfied if an employer is unable to accommodate an employee's religious practice without undue hardship. Title VII does not require employers to make any accommodation that imposes more than "a de minimis cost."[41] *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); *see, e.g.*, *Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 67 (1986); *Cosme*, 287 F.3d at 158. For example, the Supreme Court concluded in *Hardison* that Title VII did not prohibit the termination of an employee whose religious beliefs prohibited him from working on

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[41] Title VII's obligation to make a reasonable accommodation for religious practices thus differs significantly from the more stringent "obligation imposed by the Americans With Disabilities Act . . . to make reasonable accommodation of disabilities." *Kalsi v. New York City Tr. Auth.*, 62 F. Supp. 2d 745, 757 (E.D.N.Y. 1998), *aff'd*, 189 F.3d 461 (2d Cir. 1999). In comparison, "the obligation under Title VII is 'very slight.'" *Id.* (quoting Pamela S. Karlan et al., *Disabilities, Discrimination and Reasonable Accommodation*, 46 Duke L.J. 1, 7 (1996)).

Saturdays where the proposed scheduling accommodations would involve costs to the employer, such as "lost efficiency in other jobs or higher wages." 432 U.S. at 84.

In weighing the burdens of proffered accommodations on employers, courts give heavy weight to workplace safety. "Title VII does not require that safety be subordinated to the religious beliefs of an employee." *Draper v. United States Pipe & Foundry Co.*, 527 F.2d 515, 521 (6th Cir. 1975). Accordingly, where plaintiffs' proposed accommodation "threatens to compromise safety in the workplace," the burden of establishing that such an accommodation would constitute an undue burden "is light indeed." *Kalsi*, 62 F. Supp. 2d at 758. Applying that analysis, a court has found that an employer did not violate Title VII by terminating an employee who did not comply with an essential job requirement related to workplace safety for religious reasons. *See id.* at 757-60; *cf. Stevens v. Rite Aid Corp.*, 851 F.3d 224, 230-31 (2d Cir. 2017) (Americans with Disabilities Act did not preclude termination of pharmacist that suffered from "needle phobia" given that administering immunizations is essential function of position). Similarly, Title VII does not require state governments to provide accommodations that would

undermine important public policies, such as public health. *Cf. Knight v. Connecticut Dep't of Public Health*, 275 F.3d 156, 168 (2d Cir. 2001) (state agency not required to allow employees "to evangelize while providing services to clients" given that such an accommodation "would jeopardize the state's ability to provide services in a religion-neutral" manner).

Here, plaintiffs' requested religious accommodation would risk workplace safety and undermine DOH's policy of promoting public health. See *supra* at 52-28. Because these consequences impose far more than a de minimis cost, plaintiffs' proffered accommodation is not required under Title VII. DOH's rationales for requiring healthcare workers to be vaccinated, and its explanation (see *supra* at 54-55) of why alternative measures (such as masking and testing) would be less effective, easily satisfy the "light" burden applicable here. Accordingly, even if plaintiffs cannot be reassigned, Title VII does not obligate plaintiffs' employers to subordinate the health and safety of their workers and patients to plaintiffs' religious beliefs.

In sum, DOH's emergency rule thus does not conflict with Title VII because (a) the rule does not restrict employers' ability to offer accommodations that would be required by Title VII; and (b) plaintiffs'

requested religious accommodation is not required by Title VII. Accordingly, the rule does not "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in enacting Title VII. *California Fed. Sav.*, 479 U.S. at 281 (op. of Marshall, J.).

POINT II

THE BALANCE OF THE EQUITIES TIPS DECIDEDLY IN FAVOR OF DENYING A PRELIMINARY INJUNCTION HERE

Plaintiffs have failed to establish that they will suffer irreparable harm, "[p]erhaps the single most important prerequisite for the issuance of a preliminary injunction." *Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002) (quotation marks omitted). The principal harms asserted by plaintiffs are potential adverse employment actions that their employers (none of whom are identified or sued here) assertedly might take due to the DOH emergency rule. (*See, e.g.*, J.A. 24-26.) Plaintiffs also allege that they face the risk of "disciplinary charges" or "license suspension or revocation." (*See, e.g.*, J.A. 24-25 (¶ 44).) The district court did not endorse these claims of harm by plaintiffs. And in any event,

plaintiffs have failed to establish that any such harms are either imminent or irreparable.

First, plaintiffs' threadbare evidence fails to establish that they face any imminent threat of adverse employment actions, professional discipline, or loss of licensure. As an initial matter, plaintiffs' claims of harm mischaracterize the scope and effect of the emergency rule. Nothing in the emergency rule affects licensure, which is regulated by the State Education Department rather than DOH, *see, e.g.*, 8 N.Y.C.R.R. pts. 60, 63, 64; and plaintiffs have identified no relevant action by the State Education Department. Similarly, DOH's emergency rule does not require private employers to terminate or otherwise take adverse employment actions against unvaccinated healthcare workers. To comply with the emergency rule's requirement that certain healthcare workers be vaccinated, an employer could reassign such workers to activities where, if they were infected, they would not pose a risk of transmitting COVID-19 to patients, residents, or other workers. *See* § 2.61(a)(2).

Plaintiffs also fail to provide evidence to support their allegations that they face imminent harms to their employment or professional standing. Although some plaintiffs allege that they have received emails

threatening termination from their employers (*see, e.g.*, J.A. 25-26), none of them proffer any concrete corroboration of those allegations; indeed, plaintiffs do not even identify their employers. Moreover, several plaintiffs acknowledge that they have been told only that their employment would be "at risk" if they do not receive a COVID-19 vaccination. (*See, e.g.*, J.A. 44.) And plaintiffs fail to describe whether they have sought (or been denied) reassignment to activities that would place them outside the scope of the emergency rule.

Second, even if plaintiffs did face the imminent harms they allege, it is well-established that loss of employment, and the resulting financial loss, do not constitute "irreparable harm" because plaintiffs can be fully compensated by reinstatement or with money damages. *See Sampson v. Murray*, 415 U.S. 61, 90-92 (1974); *Hyde v. KLS Pro. Advisors Grp., LLC*, 500 F. App'x 24, 25 (2d Cir. 2012); *Savage v. Gorski*, 850 F.2d 64, 67 (2d Cir. 1988). This principle is independently fatal to plaintiffs' request for a preliminary injunction.

Plaintiffs also assert—and the district court appears to have credited (S.A. 20)—irreparable injury from an imminent deprivation of their First Amendment right to free exercise. *See Roman Catholic*

Diocese, 141 S. Ct. at 67. But plaintiffs do not allege—much less prove—that DOH's emergency rule will compel them to act in violation of their religious beliefs. They remain free to refuse a COVID-19 vaccine. At most, they allege that they will face employment consequences if they do so. But, as explained those harms can be fully compensated, and they may seek other employment not subject to the emergency rule. *See Mills*, 2021 WL 4783626, at *17; *see also Maniscalco*, 2021 WL 4344267, at *3 (refusal to comply with COVID-19 vaccine mandate may "render it more difficult for [plaintiff teachers] to pursue their calling, [but] plaintiffs are not absolutely being barred from doing so"). The purported harm here thus bears no resemblance to that alleged in *Roman Catholic Diocese*, where the Supreme Court found that the executive orders under review barred "the great majority of those who wish[ed] to attend Mass on Sunday or services in a synagogue on Shabbat" from doing so, thus directly inhibiting religious practice. 141 S. Ct. at 67-68.

In sharp contrast to plaintiffs' failure to show imminent irreparable harm, the public would suffer serious harms if DOH's emergency rule were stayed. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). As discussed above (see *supra* at 19-20), achieving high vaccina-

tion rates in particularly vulnerable settings is of the utmost importance. Those vulnerable populations include immunocompromised patients especially susceptible to viral infections and people who cannot receive the COVID-19 vaccine because they are too young or have contraindications. The COVID-19 vaccines are extremely safe and effective at protecting healthcare workers themselves and the populations they serve from suffering severe complications from COVID-19. And the vaccination requirement will also protect others who need emergency medical treatment—for example, individuals suffering heart attacks, strokes, or appendicitis—from the consequences of staffing shortages and overstrained emergency rooms that could follow a COVID-19 outbreak among healthcare workers.[42]

These concerns are especially urgent now in light of the uncertainty surrounding the scope of future COVID-19 outbreaks. The emergence and prevalence of the Delta variant have led experts to predict that there will be a fall surge in COVID-19 infections. And limited healthcare

[42] *See, e.g.*, Jenny Deam, *A Boy Went to a COVID-Swamped ER. He Waited for Hours. Then His Appendix Burst*, ProPublica (Sept. 15, 2021) (internet).

resources will soon face additional strains due to seasonal influenza and other diseases that accompany the onset of fall and winter. (J.A. 231.) Vaccination of healthcare workers will help to prevent additional burdens from being inflicted on the healthcare sector at the precise moment when it is already at threat of becoming overtaxed.

Accordingly, the balance of the equities tips decidedly in favor of defendants. This Court may reverse the district court's preliminary injunction on that ground alone.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's preliminary injunction.

Dated: New York, New York
October 18, 2021

Respectfully submitted,

LETITIA JAMES
Attorney General
State of New York
Attorney for Appellants

By: */s/ Mark S. Grube*
MARK S. GRUBE
Assistant Solicitor General

28 Liberty Street
New York, NY 10005
(212) 416-8028

BARBARA D. UNDERWOOD
Solicitor General
STEVEN C. WU
Deputy Solicitor General
MARK S. GRUBE
Assistant Solicitor General
of Counsel

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Kelly Cheung, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 13,890 words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7) and Local Rule 32.1.

/s/ *Kelly Cheung*

SPECIAL APPENDIX

TABLE OF CONTENTS

PAGE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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Dr. A, Nurse A., Dr. C., Nurse D., Dr. F., Dr. G., Therapist I., Dr. J., Nurse J., Dr. M., Nurse N., Dr. O., Dr. P., Technologist P., Dr. S., Nurse S., and Physician Liaison X.,

Plaintiffs,

-v- 1:21-CV-1009

KATHY HOCHUL, Governor of the State of New York, in her official capacity, DR. HOWARD A. ZUCKER, Commissioner of the New York State Department of Health, in his official capacity, and LETITIA JAMES, Attorney General of the State of New York, in her official capacity,

Defendants.

- -

DAVID N. HURD
United States District Judge

ORDER

On August 26, 2021, the New York State Department of Health ("DOH") promulgated a regulation that mandates COVID-19 vaccination of health care workers. This regulation requires personnel employed at general hospitals and nursing homes to receive their first dose of a COVID-19 vaccine

by September 27, 2021, and for personnel employed at other covered entities to receive a vaccine by October 7, 2021. Unlike a previously applicable Public Health Order, this new regulation excludes any religious exemption. The named plaintiffs are seventeen medical professionals employed in the State of New York who allege that their sincere religious beliefs compel them to refuse the COVID-19 vaccines that are currently available.

On September 13, 2021, plaintiffs filed this 42 U.S.C. § 1983 action alleging this "vaccination mandate" violates the First and Fourteenth Amendments, the Supremacy Clause, and the Equal Protection Clause of the U.S. Constitution. Plaintiffs sought to proceed pseudonymously. Plaintiffs also moved for a temporary restraining order ("TRO") and a preliminary injunction that would enjoin defendants from, *inter alia*, enforcing the vaccine mandate "to the extent it categorically requires health care employers to deny or revoke religious exemptions from COVID-19 vaccination mandates."

Upon review of plaintiffs' memorandum of law and supporting documentation, it is

ORDERED that

1. Plaintiffs' motion for a temporary restraining order is GRANTED;

2. Defendants, their officers, agents, employees, attorneys and successors in office, and all other persons in active concert or participation with them,

are temporarily ENJOINED from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the vaccine mandate such that:

(a) The vaccine mandate is suspended in operation to the extent that the DOH is barred from enforcing any requirement that employers deny religious exemptions from COVID-19 vaccination or that they revoke any exemptions employers already granted before the vaccine mandate issued;

(b) The DOH is barred from interfering in any way with the granting of religious exemptions from COVID-19 vaccination going forward, or with the operation of exemptions already granted;

(c) The DOH is barred from taking any action, disciplinary or otherwise, against the licensure, certification, residency, admitting privileges or other professional status or qualification of any of the plaintiffs on account of their seeking or having obtained a religious exemption from mandatory COVID-19 vaccination; and

(d) As noted *supra*, since the August 26, 2021 regulation does not require hospital and nursing home employees to receive a vaccine until September 27, 2021, the TRO does not, as a practical matter, go into effect until that date.

3. Plaintiffs shall serve defendants with (1) this Order; (2) the operative complaint and supporting exhibits; and (3) the motion for a temporary restraining order and preliminary injunction no later than Thursday, September 16, 2021 at 12:00 p.m.;

4. Defendants are to advise the Court if they oppose plaintiffs' request for a preliminary injunction pending an expedited resolution of the merits of the main issue for a permanent injunction;

5. If yes, defendants shall file and serve all submissions in opposition to the plaintiffs' motion for a preliminary injunction before Wednesday, September 22, 2021 at 5:00 p.m.;

6. No reply is permitted;

7. Defendants shall further advise the Court if they oppose plaintiffs' request to proceed pseudonymously;

8. If yes, defendants shall file and serve all submissions in opposition to the plaintiffs' request to proceed pseudonymously before Wednesday, September 22, 2021 at 5:00 p.m.;

9. No reply is permitted; and

10. If yes, defendants shall SHOW CAUSE at an in-person oral argument to be held at 10:00 a.m. on Tuesday, September 28, 2021 at the United States Courthouse in Utica, New York why the TRO should not be converted to a

preliminary injunction in accordance with Rule 65 of the Federal Rules of Civil Procedure.

IT IS SO ORDERED.

United States District Judge

Dated: September 14, 2021 at 10:00 a.m.
Utica, New York.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

- -

Dr. A, Nurse A., Dr. C., Nurse D., Dr. F., Dr. G., Therapist I., Dr. J., Nurse J., Dr. M., Nurse N., Dr. O., Dr. P., Technologist P., Dr. S., Nurse S., and Physician Liaison X.,

Plaintiffs,

-v- 1:21-CV-1009

KATHY HOCHUL, Governor of the State of New York, in her official capacity, DR. HOWARD A. ZUCKER, Commissioner of the New York State Department of Health, in his official capacity, and LETITIA JAMES, Attorney General of the State of New York, in her official capacity,

Defendants.

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United States District Judge

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On August 26, 2021, the New York State Department of Health ("DOH") promulgated a regulation that mandates COVID-19 vaccination of health care workers. This regulation requires personnel employed at general hospitals and nursing homes to receive their first dose of a COVID-19 vaccine

by September 27, 2021, and for personnel employed at other covered entities to receive their first dose of a COVID-19 vaccine by October 7, 2021. Unlike a previously applicable Public Health Order, the new regulation excludes any religious exemption. The named plaintiffs are seventeen medical professionals who allege that their sincere religious beliefs compel them to refuse the COVID-19 vaccines that are currently available.

On September 13, 2021, plaintiffs filed this 42 U.S.C. § 1983 action alleging New York's "vaccination mandate" violates the First and Fourteenth Amendments, the Supremacy Clause, and the Equal Protection Clause of the U.S. Constitution. Plaintiffs moved for a temporary restraining order ("TRO") and a preliminary injunction that would enjoin defendants from, *inter alia*, enforcing the vaccination mandate "to the extent it categorically requires health care employers to deny or revoke religious exemptions from COVID-19 vaccination mandates."

On September 14, 2021, the Court granted plaintiffs' request for a TRO and directed them to serve defendants with their pleading, the motion papers, and the Order granting temporary relief. Dkt. No. 7. The Order further directed defendants to advise the Court if they intended to oppose plaintiffs' request for a preliminary injunction pending a resolution of the merits of the dispute. *Id.* The Order tentatively scheduled an in-person oral argument for 10:00 a.m. on Tuesday, September 28, 2021. *Id.*

On September 17, 2021, defendants advised that they intended to oppose plaintiffs' request for preliminary injunctive relief. Dkt. No. 13.[1] As relevant here, defendants also requested that oral argument be rescheduled from September 28, 2021 to September 24, 2021. *Id.* Plaintiffs opposed any change in schedule. Dkt. No. 14.

Upon review, and with due consideration for the time-sensitive nature of this dispute, the security considerations necessary to ensure the safety of courthouse visitors and staff, and the health concerns posed by the ongoing COVID-19 pandemic, the Court concludes that oral argument is not necessary to promptly resolve the pending motion. *See* N.D.N.Y. L.R. 7.1(h).

Therefore, it is

ORDERED that

1. The in-person oral argument scheduled for 10:00 a.m. on Tuesday, September 28, 2021 is CANCELLED;

2. Plaintiffs' pending request to convert the TRO to a preliminary injunction will be heard on the submission of the papers with no appearances required or allowed;

3. Defendants' opposition remains due on or before Wednesday, September 22, 2021 at 5:00 p.m.;

[1] Defendants also indicated that they do not oppose plaintiffs' request to proceed pseudonymously. Dkt. No. 13.

4. Because of the likelihood of irreparable harm to plaintiffs and in light of the fact that the practical effect of the TRO will not begin to restrain the enforcement of the disputed regulation until September 27, 2021, the Court finds that good cause exists to extend the TRO a further fourteen days to October 12, 2021; and

5. A written decision on plaintiffs' request for a preliminary injunction will be issued on or before October 12, 2021.

IT IS SO ORDERED.

David N. Hurd
U.S. District Judge

Dated: September 20, 2021
Utica, New York.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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DR. A., NURSE A., DR. C., NURSE D., DR. F., DR. G., THERAPIST I., DR. J., NURSE J., DR. M., NURSE N., DR. O., DR. P., TECHNOLOGIST P., DR. S., NURSE S., and PHYSICIAN LIAISON X.,

Plaintiffs,

-v- 1:21-CV-1009

KATHY HOCHUL, Governor of the State of New York, in her official capacity, DR. HOWARD A. ZUCKER, Commissioner of the New York State Department of Health, in his official capacity, and LETITIA JAMES, Attorney General of the State of New York, in her official capacity,

Defendants.

- -

APPEARANCES: OF COUNSEL:

THOMAS MORE SOCIETY CHRISTOPHER FERRARA, ESQ.
Attorneys for Plaintiffs
148-29 Cross Island Parkway
Whitestone, NY 11357

THOMAS MORE SOCIETY
Attorneys for Plaintiffs
10506 Burt Circle, Suite 110
Omaha, NE 68114

MICHAEL MCHALE, ESQ.

HON. LETITIA JAMES
New York State Attorney General
Attorneys for Defendants
The Capitol
Albany, NY 12224

KASEY K. HILDONEN, ESQ.
RYAN W. HICKEY, ESQ.
Ass't Attorneys General

DAVID N. HURD
United States District Judge

MEMORANDUM-DECISION and ORDER

I. INTRODUCTION

On August 26, 2021, the New York State Department of Health adopted an emergency regulation that required most healthcare workers to be vaccinated against COVID-19 within the next thirty days. N.Y. COMP. CODES R. & REGS. tit. 10, § 2.61(c) (2021). As relevant here, § 2.61 eliminated a religious exemption included in the first iteration of this mandate.

On September 13, 2021, seventeen healthcare workers employed in New York State ("plaintiffs"), all of whom object to the existing COVID-19 vaccines on religious grounds, filed this official-capacity 42 U.S.C. § 1983 action against New York State Governor Kathy Hochul ("Hochul"), New York State Health Commissioner Howard A. Zucker ("Zucker"), and New York State Attorney General Letitia James ("James") (collectively "defendants").

Plaintiffs' three-count verified complaint alleges that § 2.61 violates their constitutional rights because it effectively forbids employers from considering workplace religious accommodations under processes guaranteed by federal law. Plaintiffs sought to enjoin defendants from, *inter alia*, enforcing § 2.61 "to the extent it categorically requires health care employers to deny or revoke religious exemptions from COVID-19 vaccination mandates."

On September 14, 2021, the Court issued a temporary restraining order ("TRO") to that effect, *Dr. A. v. Hochul*, 2021 WL 4189533 (N.D.N.Y.), and ordered briefing on whether the TRO should be converted to a preliminary injunction pending a resolution of the merits of plaintiffs' constitutional claims seeking a permanent injunction. The TRO was extended for good cause to this date, October 12, 2021. Dkt. No. 15. The motion has been fully briefed and will be decided on the basis of the submissions without oral argument.

II. BACKGROUND[1]

On June 25, 2021, then-Governor Andrew Cuomo rescinded the COVID-19 public health emergency declaration that had been in effect across New York

[1] The facts are taken from plaintiffs' verified complaint, Dkt. No. 1, which is tantamount to an affidavit, *see* 28 U.S.C. § 1746, and from the declaration of Elizabeth Rausch-Phung, M.D., M.P.H., Dkt. No. 16. A review of these submissions did not reveal any genuine disputes over the essential facts necessary to decide the motion. *See, e.g.*, *In re Defend H20 v. Town Bd. of Town of E. Hampton*, 147 F. Supp. 3d 80, 96–97 (E.D.N.Y. 2015) (discussing circumstances in which an evidentiary hearing on a preliminary injunction is unnecessary).

State for the previous eighteen months. Compl. ¶ 16; N.Y. Exec. Order 210 (June 24, 2021). As defendants explain, Cuomo's decision was based on "declining hospitalization and [rates of COVID-19] positivity statewide, as well as success in vaccination rates." Rausch-Phung Decl., Dkt. No. 16 ¶ 19.

However, the end of the emergency declaration did not bring an end to defendants' exercise of their emergency powers.[2] Compl. ¶ 17. On August 18, 2021, Health Commissioner Zucker issued an "Order for Summary Action" that required general hospitals and nursing homes to "continuously require all covered personnel to be fully vaccinated against COVID-19." Ex. B to Compl. at 95–101 (the "August 18 Order"). The August 18 Order included a medical exemption as well as an explicit religious exemption:

> Religious exemption. Covered entities shall grant a religious exemption for COVID-19 vaccination for covered personnel if they hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the employer.

Id.; *see also* Compl. ¶ 20.

Just five days later, on August 23, 2021, New York State's Public Health & Health Planning Council (the "Health Council"), acting on a summary basis pursuant to its statutory authority under the Public Health

[2] The New York legislature has curbed the executive's authority to issue new COVID-related orders. *See* N.Y. Sess. Laws ch. 71 § 4.

Law, published a proposed emergency regulation that would quickly be adopted as § 2.61.[3] *Id.* ¶¶ 4–5. This proposal expanded the vaccination requirement set forth in the August 18 Order to reach personnel in other healthcare settings. Rausch-Phung Decl. ¶ 5. This proposal also eliminated the religious exemption found in Zucker's August 18 Order. *See id.*

On August 26, 2021, three days after its publication, the Health Council adopted § 2.61, which superseded the August 18 Order and became effective immediately. Rausch-Phung Decl. ¶ 5. According to defendants, the Health Council's emergency action was a necessary measure to control the continued spread of Delta and other SARS-CoV-2 variants. *Id.* ¶¶ 8–21.

The seventeen plaintiffs are "practicing doctors, M.D.s fulfilling their residency requirement, nurses, a nuclear medicine technologist, a cognitive rehabilitation therapist and a physician's liaison." Compl. ¶ 36; *see also id.* ¶¶ 38, 47, 56, 66, 74, 84, 91, 98, 108, 117, 128, 140, 149, 161, 171, 181, 188. They are employed by hospitals, nursing homes, and other New York State entities that are subject to § 2.61. *See id.* ¶ 10.

Plaintiffs hold the sincere religious belief that they "cannot consent to be inoculated . . . with vaccines that were tested, developed or produced with fetal cell[ ] line[s] derived from procured abortions." Compl. ¶ 35; *see also*

[3] August 23 is also the date on which Cuomo resigned from office, Compl. ¶ 14, and when the Food & Drug Administration ("FDA") granted approval to the first COVID-19 vaccine for those age sixteen and older, Rausch-Phung Decl. ¶ 33. Hochul has since assumed the governorship.

id. ¶ 37 (detailing beliefs held in common by plaintiffs). According to plaintiffs, the COVID-19 vaccines that are currently available violate these sincere religious beliefs "because they all employ fetal cell lines derived from procured abortion in testing, development or production." *Id.* ¶¶ 9, 36; *see also* Rausch-Phung Decl. ¶¶ 35–45 (acknowledging that fetal cell lines are widely used in pharmaceutical development and were used in the testing and production of current COVID-19 vaccines).

The complaint alleges that each plaintiff has been denied a religious exemption, or had an existing religious exemption revoked, on the basis of their employers' application of § 2.61. Compl. ¶¶ 39–42, 49–51, 58–60, 67–68, 77–78, 85, 92–94, 102, 111–12, 118–23, 129–31, 142–43, 154–56, 162–63, 173–74, 183–85, 189. The complaint further alleges that each plaintiff has been threatened with professional discipline, loss of licensure, admitting privileges, reputational harm, and/or the imminent termination of their employment as a result of their refusal to comply with § 2.61. *Id.* ¶¶ 43–46, 52–55, 61–65, 69–73, 79–83, 86–90, 95–97, 103–07, 113–16, 124–27, 135–39, 144–48, 157–60, 164–65, 168–70, 176–80, 186–87, 190–91.

III. LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To win relief, the movant must ordinarily demonstrate: (1) a likelihood of irreparable

harm; (2) either a likelihood of success on the merits or sufficiently serious questions as to the merits plus a balance of hardships that tips decidedly in their favor; (3) that the balance of hardships tips in their favor regardless of the likelihood of success; and (4) that an injunction is in the public interest. *Page v. Cuomo*, 478 F. Supp. 3d 355, 362–63 (N.D.N.Y. 2020).

However, in cases like this one, where the movants seek to enjoin government action taken in the public interest pursuant to a statutory or regulatory scheme, the less rigorous "serious questions" component of this legal standard is unavailable. *Otoe-Missouria Tribe of Indians v. N.Y. State Dep't of Fin. Servs.*, 769 F.3d 105, 110 (2d Cir. 2014). As the Second Circuit has explained, "[t]his exception reflects the idea that governmental policies implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly." *Id.* (citation omitted).

Defendants' opposition memorandum invokes a second exception to the general rules governing preliminary injunctive relief. Defs.' Opp'n, Dkt. No. 16-50 at 4, 11.[4] As defendants correctly note, a heightened standard can also apply when the requested injunction (1) is "mandatory"; *i.e.*, it will alter the status quo by compelling some positive action; or (2) "will provide the movant

[4] Pagination corresponds to CM/ECF.

with substantially all of the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." *Page*, 478 F. Supp. 3d at 363. When either condition is met, the movant must make a "clear" or "substantial" showing of a likelihood of success on the merits, and must also make a "strong showing" of irreparable harm. *Id.*

Upon review, however, it is not clear why this heightened requirement should apply to plaintiffs' request for preliminary injunctive relief. "An injunction that enjoins a defendant from enforcing a regulation clearly prohibits, rather than compels, government action by enjoining the future enforcement." *Hund v. Cuomo*, 501 F. Supp. 3d 185, 207 (W.D.N.Y. 2020) (cleaned up). Nor have defendants articulated how this heightened standard has been triggered. *See generally* Defs.' Opp'n. Accordingly, the ordinary rules applicable to "prohibitory" injunctions will be applied. *See, e.g.*, *Hund*, 501 F. Supp. 3d at 207 (rejecting application of heightened standard where plaintiff sought to enjoin application of COVID-19 Executive Order).

IV. DISCUSSION[5]

Since its ratification in 1791, the First Amendment has protected religious practitioners from government action that "discriminates against some or all

[5] Although Eleventh Amendment immunity sometimes poses a bar to § 1983 relief against state officials, the doctrine of *Ex parte Young* permits an official-capacity claim for prospective injunctive relief to remedy an ongoing violation of federal constitutional law. *See, e.g.*, *Avitabile v. Beach*, 277 F. Supp. 3d 326, 332 (N.D.N.Y. 2017).

religious beliefs or regulates or prohibits conduct because it is undertaken for religious reasons." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 532 (1993). And since Congress amended the statute in 1972, Title VII of the Civil Rights Act of 1964 has explicitly required most employers to reasonably accommodate an employee's religious beliefs absent evidence that doing so would pose an undue hardship. 42 U.S.C. § 2000e(j).

Plaintiffs contend that § 2.61 conflicts with these longstanding federal protections. In plaintiffs' view, § 2.61 "flagrantly disallows the religious protections required by federal employment law and specifically deletes its own prior offering of religious exemptions for covered health care workers." Pls.' Mem., Dkt. No. 5-1 at 13. As plaintiffs explain, § 2.61 "forbids each of their employers from even considering requests for religious exemptions notwithstanding the contrary requirements of Title VII." *Id.* at 10 (emphases omitted). According to plaintiffs, "the specific events leading to [§ 2.61's] final version show that it effectively targets religious opposition to the available COVID-19 vaccines." *Id.* at 12.

A. Likelihood of Success & Irreparable Harm[6]

Plaintiffs have asserted § 1983 claims under the Free Exercise Clause, Compl. ¶¶ 192–209, the Supremacy Clause, *id.* ¶¶ 210–19, and the Equal Protection Clause, *id.* ¶¶ 220–37. To warrant preliminary injunctive relief, plaintiffs must show a likelihood of success on the merits of at least one of these constitutional claims. *See, e.g.*, *L.V.M. v. Lloyd*, 318 F. Supp. 3d 601, 618 (S.D.N.Y. 2018).[7]

As an initial matter, however, the parties dispute whether a presumption of irreparable harm should attach to these claims. Plaintiffs argue the Supreme Court has recognized that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Pls.' Mem. at 19 (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion)). Defendants respond that the Second Circuit has not "consistently presumed irreparable harm in cases involving allegations of the

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[6] Defendants' threshold invocation of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), *Zucht v. King*, 260 U.S. 174 (1922), and *Prince v. Massachusetts*, 321 U.S. 158 (1944) is misplaced. Defs.' Mem. at 12–13. The Second Circuit has previously relied on this line of precedent to reject a Free Exercise Clause challenge to vaccination requirements for schoolchildren. *Phillips v. City of N.Y.*, 775 F.3d 538 (2d Cir. 2015). And early in the COVID-19 pandemic a number of district courts, including this one, relied on *Jacobson* to reject constitutional challenges to various COVID-19 emergency restrictions. *See, e.g.*, *Page v. Cuomo*, 478 F. Supp. 3d 355 (N.D.N.Y. 2020). More recently, however, the Supreme Court and the Second Circuit have both cautioned that courts should not rely on *Jacobson* or its progeny to grant "special deference to the executive when the exercise of emergency powers infringes on constitutional rights." *Agudath Israel of Am. v. Cuomo*, 983 F.3d 620, 635 (2d Cir. 2020).

[7] Because plaintiffs are likely to succeed on the merits of their Free Exercise and Supremacy Clause claims, the Court declines to reach the merits of the Equal Protection Claim. *See* Defs.' Mem. at 18–19.

abridgement of First Amendment rights" unless the injury flows from "a rule or regulation that directly limits speech." Defs.' Opp'n at 25 (quoting *Bronx Household of Faith v. Bd. of Educ. of City of N.Y.*, 331 F.3d 342, 349 (2d Cir. 2003)).

To be sure, the existing precedent in this area of law is less than perfectly clear. The question seems to arise most frequently in free speech cases, but the Second Circuit has also applied the presumption in other constitutional contexts. *N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 486 (2d Cir. 2013) (identifying dispute over applicability of the presumption).

In short, as the Second Circuit explained in *Jolly v. Coughlin*, 76 F.3d 468 (2d Cir. 1996), the favorable presumption of irreparable harm arises only *after* a plaintiff has shown a likelihood of success on the merits of a constitutional claim. *Id.* at 482 (characterizing the presumption as one that "flows from a violation of constitutional rights").

"Thus, when a plaintiff seeks injunctive relief based on an alleged constitutional deprivation, 'the two prongs of the preliminary injunction threshold merge into one . . . in order to show irreparable injury, plaintiff must show a likelihood of success on the merits.'" *Page*, 478 F. Supp. 3d at 364 (quoting *Turley v. Guiliani*, 86 F. Supp. 2d 291, 295 (S.D.N.Y. 2000)).

1. The Supremacy Clause & Title VII

The Supremacy Clause declares that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. Art. VI, cl 2. Although it "is not the source of any federal rights and certainly does not create a cause of action," *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324–25 (2015) (cleaned up), the Supreme Court has long recognized that, "if an individual claims federal law immunizes him from state regulation, the court may issue an injunction upon finding the state regulatory actions preempted," *id.* at 326 (citing *Ex parte Young*, 209 U.S. 123, 155–56 (1908)).

Plaintiffs contend that § 2.61 runs afoul of the Supremacy Clause because it is preempted by Title VII, which prohibits discrimination in employment on the basis of "religion." 42 U.S.C. § 2000e-2(a)(1)–(2). Under Title VII, "[t]he term 'religion' includes all aspects of religious observance and practice, as well as belief, unless an employer demonstrates that he is unable to reasonably accommodate [ ] an employee's . . . religious observance or practice without undue hardship on the . . . employer's business." § 2000e(j).

This protection for religious belief means that "[a]n employer may not take an adverse employment action against an applicant or employee because of any aspect of that individual's religious observance or practice unless the employer demonstrates that it is unable to reasonably accommodate that

observance or practice without undue hardship." *Equal Emp. Opportunity Comm'n v. Abercrombie & Fitch Stores, Inc.*, 575 U.S. 768, 776 (2015) (Alito, J., concurring). Importantly, however, "Title VII does not demand mere neutrality with regard to religious practices . . . . [r]ather, it gives them favored treatment." *Id.* at 775 (majority opinion). Thus, under certain circumstances, Title VII "requires otherwise-neutral policies to give way to the need for an accommodation." *Id.*

Plaintiffs argue that § 2.61 conflicts[8] with Title VII's religious protections because it "conspicuously eliminates (and thereby forbids) any opportunity for covered employees to even attempt to secure a reasonable accommodation for their sincerely held religious objections to the currently available COVID-19 vaccines." Pl.'s Mem. at 7. Defendants respond that there is a distinction between a so-called "religious exemption" and a "reasonable accommodation." Defs.' Opp'n at 15 –16. According to defendants, "Title VII does not entitle employees to a religious exemption—it only requires employers to make reasonable accommodation so long as it can be provided by the employer without undue hardship." *Id.* at 16.

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[8] "In general, three types of preemption exist: (1) express preemption, where Congress has expressly preempted local law; (2) field preemption, where Congress has legislated so comprehensively that federal law occupies an entire field of regulation and leaves no room for state law; and (3) conflict preemption, where local law conflicts with federal law such that it is impossible for a party to comply with both or the local law is an obstacle to the achievement of federal objectives." *N.Y. SMS Ltd. P'ship v. Town of Clarkstown*, 612 F.3d 97, 104 (2d Cir. 2010) (cleaned up).

Upon review, plaintiffs have established at this early stage of the litigation that they are likely to succeed on the merits of this constitutional claim. Of course, defendants are correct that there is a substantial difference between a blanket "religious exemption" from a vaccination requirement and the "reasonable accommodation" for religious beliefs imposed on employers by Title VII. But defendants' assertion that § 2.61 "does not implicate Title VII at all" and "does not require covered entities to deny reasonable accommodation requests" fails to grapple with how the broad scope of the Health Council's mandate has allegedly impacted plaintiffs.

The plain terms of § 2.61 do not make room for "covered entities" to consider requests for reasonable religious accommodations. Instead, § 2.61 obligates all covered entities to "continuously require personnel to be fully vaccinated against COVID-19." And "personnel" is defined broadly, sweeping in "all persons employed or affiliated with a covered entity, whether paid or unpaid . . . who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease."

Plaintiffs allege that some of their employers have revoked existing religious exemptions and/or religious accommodations by pointing to the State's adoption of § 2.61. *See, e.g.*, Compl. ¶¶ 39–40, 77. Plaintiffs also allege that some of their employers have refused to consider exemption or

accommodation requests because of § 2.61. *See, e.g.*, *id.* ¶ 49. Although Title VII certainly does not require an employer in all cases to "accommodate" an employee by necessarily granting them an "exemption," the statute does require employers to entertain requests for religious accommodations and to "reasonably" accommodate those requests absent a showing of undue hardship. According to plaintiffs, their employers have refused to engage in that process because of § 2.61.

Defendants also argue that § 2.61's elimination of the religious exemption language found in the August 18 Order brings it more in line with healthcare workplace immunization requirements for measles and rubella. Although fetal cell lines were used in the development of the rubella vaccine, there is no religious exemption in the State regulations that require workers to be immunized against this pathogen. Rausch-Phung Decl. ¶¶ 44, 47–48.

However, this argument conflates the merits of plaintiffs' present constitutional claims with a hypothetical Title VII anti-discrimination claim for a religious accommodation. What matters here is not whether a religious practitioner would win or lose a future Title VII lawsuit. What matters is that plaintiffs' current showing establishes that § 2.61 has effectively foreclosed the pathway to seeking a religious accommodation that is guaranteed under Title VII.

In any event, plaintiffs have not alleged a religious objection to other workplace vaccination requirements. Nor have defendants explained why the State's approach to immunization against measles and rubella necessarily justifies an identical approach to SARS-CoV-2.[9] In sum, plaintiffs have established that § 2.61 stands "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 281 (1987). Accordingly, plaintiffs are likely to succeed on the merits of this claim.

2. The First Amendment & The Free Exercise Clause

The First Amendment provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." U.S. Const. amend. I. The "free exercise" component of this First Amendment guarantee has been incorporated against the States through the Fourteenth Amendment. *Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940).

"The free exercise of religion means, first and foremost, the right to believe and profess whatever religious doctrine one desires." *Emp. Div., Dep't of*

[9] The State's healthcare regulatory framework is not monolithic when it comes to workplace immunization requirements. Although it may not be an explicit "religious exemption," the relevant regulation for "influenza season" only requires covered entities to "ensure that all personnel not vaccinated against influenza for the current influenza season wear a surgical or procedure mask while in areas where patients or residents are typically present." N.Y. COMP. CODES R. & REGS. tit. 10, § 2.59(d) (2014). It may be true that a hypothetical healthcare worker who sought a Title VII religious accommodation from immunization against rubella would be rebuffed by their employer on the basis of "undue hardship." But the same hypothetical worker who objected on religious grounds to vaccination against influenza—a respiratory disease broadly similar to COVID-19—could be "reasonably accommodated" with a surgical mask.

Hum. Res. of Or. v. Smith, 494 U.S. 872, 877 (1990). Accordingly, "religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection." *Thomas*, 450 U.S. at 714.

To that end, the Free Exercise Clause "protect[s] religious observers against unequal treatment" and against "laws that impose special disabilities on the basis of religious status." *Espinoza v. Mont. Dep't of Revenue*, 140 S. Ct. 2246, 2254 (2020) (citation omitted). However, the Free Exercise Clause "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 religion prescribes (or proscribes)." *Smith*, 763 F.3d at 877 (citation omitted).

A neutral and generally applicable law is subject to rational basis review. *Agudath Israel of Am. v. Cuomo*, 983 F.3d 620, 631 (2d Cir. 2020). Under that standard, the law "is presumed to be valid and will be sustained if the [burden imposed] by the statute is rationally related to a legitimate state interest." *Cent. Rabbinical Cong. of U.S. & Can. v. N.Y. City Dep't of Health & Mental Hygiene*, 763 F.3d 183, 186 n.2 (2d Cir. 2014) (citation omitted). "A law burdening religious conduct that is *not* both neutral and generally applicable, however, is subject to strict scrutiny." *Id.* at 193. Under that standard, the government must establish that the law is "justified by a compelling interest" and "narrowly tailored to advance that

interest." *Id*. at 186 n.2 (citation omitted). "Neutrality and general applicability are interrelated, and . . . failure to satisfy one requirement is a likely indication that the other has not been satisfied." *City of Hialeah*, 508 U.S. at 531.

A law is not neutral if it is "specifically directed at [a] religious practice." *Cent. Rabbinical Cong.*, 763 F.3d at 193 (citation omitted). To determine whether a law is neutral, the court begins with the text, "for the minimum requirement of neutrality is that a law not discriminate on its face." *City of Hialeah*, 508 U.S. at 533. A law discriminates on its face "if it refers to a religious practice without a secular meaning discernable from the language or context." *Id*. Importantly, though, even a facially neutral law may trigger heightened scrutiny if it "targets religious conduct for distinctive treatment." *Id*. at 534. Likewise, "[t]he general applicability requirement prohibits the government from 'in a selective manner impos[ing] burdens only on conduct motivated by religious belief." *Cent. Rabbinical Cong.*, 763 F.3d at 196 (citation omitted). Although "[a]ll laws are selective to some extent, . . . categories of selection are of paramount concern when a law has the incidental effect of burdening religious practice." *Id*. at 197 (citation omitted).

Plaintiffs contend that § 2.61 "effectively targets religious opposition to the available COVID-19 vaccines." Pls.' Mem. at 12. In plaintiffs' view, the

vaccination requirement "flagrantly disallows the religious protections required by federal employment law and specifically deletes its own prior offering of religious exemptions for covered health care workers." *Id.* at 13. Defendants respond that § 2.61 is facially neutral because it "contains no reference to religion" and "applies to every employee of the covered entities." Defs.' Opp'n at 17. According to defendants, the "object" of the vaccination requirement "is to protect public health and safety by reducing the incidence of COVID-19." *Id.* at 18.

Upon review, plaintiffs have established at this early stage of the litigation that § 2.61 is not a neutral law. As the Supreme Court has explained, "the historical background of the decision under challenge, the specific series of events leading to the enactment or official policy in question, and the legislative or administrative history" are all relevant circumstantial evidence in detecting a lack of neutrality. *City of Hialeah*, 508 U.S. at 540.

Zucker's August 18 Order, which was imposed on a summary basis, included medical *and* religious exemptions to COVID-19 vaccination. The Health Council's adoption of § 2.61, which was imposed on a similar summary basis just eight days later, amended the vaccination mandate to eliminate the religious exemption. This intentional change in language is the kind of "religious gerrymander" that triggers heightened scrutiny.

Plaintiffs have also established at this early stage of the litigation that § 2.61 is not generally applicable. A law is "not generally applicable if it is substantially underinclusive such that it regulates religious conduct while failing to regulate secular conduct that is at least as harmful to the legitimate government interests purportedly justifying it." *Cent. Rabbinical Cong.*, 763 F.3d at 197; *see also Blackhawk v. Pennsylvania*, 381 F.3d 202, 209 (3d Cir. 2004) ("A law fails the general applicability requirement if it burdens a category of religiously motivated conduct but exempts or does not reach a substantial category of conduct that is not religiously motivated and that undermines the purposes of the law to at least the same degree as the covered conduct that is religiously motivated.").

Section 2.61's regulatory impact statement claims that "[u]nvaccinated personnel in [healthcare] settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications." Ex. A to Compl. at 78.

But as plaintiffs point out, the medical exemption that remains in the current iteration of the State's vaccine mandate expressly accepts this "unacceptable" risk for a non-zero segment of healthcare workers. Pls.' Mem. at 13. Although defendants claim that they expect the number of people in need of a medical exemption to be low, Rausch-Phung Decl. ¶¶ 65–66, the

Supreme Court has recently emphasized that "[c]omparability is concerned with the risks various activities pose," not the reasons for which they are undertaken. *Tandon v. Newsom*, 141 S. Ct. 1294, 1297 (2021). Thus, absent further factual development the Court cannot conclude that § 2.61 satisfies the requirement of "general applicability."

Finally, plaintiffs have established at this early stage of the litigation that § 2.61 is likely to fail strict scrutiny. To satisfy strict scrutiny, defendants must show that the challenged law advances "interests of the highest order" and is "narrowly tailored" to achieve those interests. *Fulton v. City of Phila., Pa.*, 141 S. Ct. 1868, 1881 (2021) (quoting *City of Hialeah*, 508 U.S. at 546). "Put another way, so long as the government can achieve its interests in a manner that does not burden religion, it must do so." *Id.*

Defendants have satisfied the first component of this analysis. *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) ("Stemming the spread of COVID-19 is unquestionably a compelling interest."). However, they have failed to establish that § 2.61—and in particular, its intentional omission of a religious exemption—is narrowly tailored to address that public health concern.

"Narrow tailoring requires the government to demonstrate that a policy is the 'least restrictive means' of achieving its objective." *Agudath Israel of Am.*, 983 F.3d at 633 (quoting *Thomas*, 450 U.S. at 718). The asserted justification

"must be genuine, not hypothesized or invented *post hoc* in response to litigation." *United States v. Virginia*, 518 U.S. 515, 533 (1996). "And the government must show that it 'seriously undertook to address the problem with less intrusive tools readily available to it.'" *Agudath Israel of Am.*, 983 F.3d at 633 (quoting *McCullen v. Coakley*, 573 U.S. 464, 494 (2014)).

Defendants have not made this showing. According to the "alternative approaches" component of § 2.61's regulatory impact statement, the Health Council considered two alternatives: (1) daily testing before each shift; and (2) wearing appropriately fitted N95 face masks at all times. Ex. A to Compl. at 81; *see also* Defs.' Opp'n at 21.

However, there is no adequate explanation from defendants about why the "reasonable accommodation" that must be extended to a medically exempt healthcare worker under § 2.61 could not similarly be extended to a healthcare worker with a sincere religious objection. *Fulton*, 141 S. Ct. at 1881 (cautioning courts to "scrutinize[ ] the asserted harm of granting specific exemptions to particular religious claimants").

Nor have defendants explained why they chose to depart from similar healthcare vaccination mandates issued in other jurisdictions that include the kind of religious exemption that was originally present in the August 18 Order. Pl.'s Mem. at 17 (citing Illinois and California COVID-19 regulations that include religious exemption language); *see also Roman Catholic Diocese*

of Brooklyn, 141 S. Ct. at 67 (finding tailoring requirement unsatisfied where, *inter alia*, the challenged restriction was "much tighter than those adopted by many other jurisdictions hard-hit by the pandemic"); *Mast v. Fillmore Cty., Minn.*, 141 S. Ct. 2430, 2433 (2021) (Gorsuch, J., concurring) ("It is the government's burden to show this alternative won't work; not the [challenger's] to show it will.").

In sum, "[t]o meet the requirement of narrow tailoring, the government must demonstrate that alternative measures imposing lesser burdens on religious liberty would fail to achieve the government's interests, not simply that the chosen route was easier." *Agudath Israel of Am.*, 983 F.3d at 633 (cleaned up). Defendants have not done so. Accordingly, plaintiffs are likely to succeed on the merits of this constitutional claim.

B. <u>The Balance of Hardships & The Public Interest</u>

Plaintiffs have also satisfied the remaining elements necessary to warrant preliminary injunctive relief. Where, as here, a governmental defendant is the party opposing relief, "balancing of the equities merges into [the court's] consideration of the public interest." *SAM Party of N.Y. v. Kosinski*, 987 F.3d 267, 278 (2d Cir. 2021).

<u>First</u>, the public interest lies with enforcing the guarantees enshrined in the Constitution and federal anti-discrimination law. *See, e.g.*, *Paykina ex rel. E.L. v. Lewin*, 387 F. Supp. 3d 225, 245 (N.D.N.Y. 2019) ("The public

interest generally supports granting a preliminary injunction where . . . a plaintiff has established a clear likelihood of success on the merits and made a showing of irreparable harm.").

Second, the balance of hardships clearly favors plaintiffs. Defendants argue that a preliminary injunction will hinder its "ongoing efforts to curb the spread" of SARS-CoV-2. Defs.' Opp'n at 26. According to defendants, the spread of SARS-CoV-2 among health care workers "imposes staffing burdens on already strained hospital and healthcare operations due to quarantining requirements and potential length of illness when healthcare workers become infected." *Id*. at 26–27.

However, defendants acknowledge that § 2.61 still includes a medical exemption that requires covered entities to make a "reasonable accommodation." As plaintiffs point out, defendants have not shown that granting the same benefit to religious practitioners that was originally included in the August 18 Order "would impose any more harm—especially when Plaintiffs have been on the front lines of stopping COVID for the past 18 months while donning PPE and exercising other proper protocols in effectively slowing the spread of the disease." Pls.' Mem. at 20.

V. CONCLUSION[10]

The question presented by this case is not whether plaintiffs and other individuals are entitled to a religious exemption from the State's workplace vaccination requirement. Instead, the question is whether the State's summary imposition of § 2.61 conflicts with plaintiffs' and other individuals' federally protected right to seek a religious accommodation from their individual employers.

The answer to this question is clearly yes. Plaintiffs have established that § 2.61 conflicts with longstanding federal protections for religious beliefs and that they and others will suffer irreparable harm in the absence of injunctive relief. *Tandon*, 141 S. Ct. at 1297 (finding irreparable harm from loss of free exercise rights for even minimal periods of time). Plaintiffs have also satisfied the remaining elements necessary to obtain preliminary relief.

To reiterate, these conclusions have nothing to do with how an individual employer should handle an individual employee's religious objection to a workplace vaccination requirement. But they have everything to do with the proper division of federal and state power. *Cf. Arizona v. United States*, 567 U.S. 387, 398 (2012) ("Federalism, central to the constitutional design, adopts

[10] The bond requirement is waived. *See* FED. R. CIV. P. 65(c).

the principle that both the National and State Governments have elements of sovereignty the other is bound to respect.").

In granting a preliminary injunction, the Court recognizes that it may not have the final word. Under 28 U.S.C. § 1292(a)(1), "Congress permits, as an exception to the general rule, an immediate appeal from an interlocutory order that either grants or denies a preliminary injunction." *N.Y. State Nat'l Org. for Women v. Terry*, 886 F.2d 1339, 1350 (2d Cir. 1989). Because the issues in dispute are of exceptional importance to the health and the religious freedoms of our citizens, an appeal may very well be appropriate.

Therefore, it is

ORDERED that

1. Plaintiffs' motion to proceed pseudonymously is GRANTED[11];

2. Plaintiffs' motion for a preliminary injunction is GRANTED;

3. Defendants, their officers, agents, employees, attorneys and successors in office, and all other persons in active concert or participation with them, are preliminarily ENJOINED from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with § 2.61 such that:

[11] Plaintiffs requested leave to proceed pseudonymously. Compl. ¶¶ 26–34. Defendants do not oppose. Defs.' Opp'n at 3 n.2.

(a) Section 2.61 is suspended in operation to the extent that the Department of Health is barred from enforcing any requirement that employers deny religious exemptions from COVID-19 vaccination or that they revoke any exemptions employers already granted before § 2.61 issued;

(b) The Department of Health is barred from interfering in any way with the granting of religious exemptions from COVID-19 vaccination going forward, or with the operation of exemptions already granted; and

(c) The Department of Health is barred from taking any action, disciplinary or otherwise, against the licensure, certification, residency, admitting privileges or other professional status or qualification of any of the plaintiffs on account of their seeking or having obtained a religious exemption from mandatory COVID-19 vaccination.

IT IS SO ORDERED.

Dated: October 12, 2021
Utica, New York.

David N. Hurd
U.S. District Judge

Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the United States Census estimated county populations for 2010:

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Reporting, recordkeeping, and other compliance requirements; and professional services:

As the proposed regulations largely clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected. With respect to mandating syndromic surveillance reporting during an outbreak of a highly infectious communicable disease, hospitals are already reporting syndromic surveillance data regularly and voluntarily. Additionally, the requirement for local health departments to continually report to the Department during an outbreak is historically a practice that already occurs. With respect to clinical laboratories, they must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102.

Compliance Costs:

As the proposed regulations largely clarify existing responsibility and duties among regulated entities and individuals, no initial or annual capital costs of compliance are expected above and beyond the cost of compliance for the requirements currently in Parts 2, 58 and 405.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

As the proposed regulations largely clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with local health departments to ensure they are aware of the new regulations and have the information necessary to comply.

Rural Area Participation:

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity provided comments during the notice and comment period.

Job Impact Statement

The Department of Health has determined that this regulatory change will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

EMERGENCY RULE MAKING

Prevention of COVID-19 Transmission by Covered Entities

I.D. No. HLT-37-21-00003-E
Filing No. 946
Filing Date: 2021-08-26
Effective Date: 2021-08-26

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of section 2.61; amendment of sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 and 1001.11 of Title 10 NYCRR; amendment of sections 487.9, 488.9 and 490.9 of Title 18 NYCRR.

Statutory authority: Public Health Law, sections 225, 2800, 2803, 3612, 4010; Social Services Law, sections 461 and 461-e

Finding of necessity for emergency rule: Preservation of public health and general welfare.

Specific reasons underlying the finding of necessity: The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen 10-fold, and 95 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 11 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19 in the identified regulated facilities or entities. As described above, current circumstances and the risk of spread to vulnerable resident and patient populations by unvaccinated personnel in these settings necessitate immediate action and, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Subject: Prevention of COVID-19 Transmission by Covered Entities.

Purpose: To require covered entities to ensure their personnel are fully vaccinated against COVID-19 subject to certain exemptions.

Text of emergency rule: Part 2 is amended to add a new section 2.61, as follows:

2.61. Prevention of COVID-19 transmission by covered entities.

(a) Definitions.

(1) "Covered entities" for the purposes of this section, shall include:

(i) any facility or institution included in the definition of "hospital" in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;

(ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies;

(iii) hospices as defined in section 4002 of the Public Health Law; and

(iv) adult care facility under the Department's regulatory authority, as set forth in Article 7 of the Social Services Law.

(2) "Personnel," for the purposes of this section, shall mean all persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.

(3) "Fully vaccinated," for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner's signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system; or

(iii) any other documentation determined acceptable by the Department.

(c) Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021 for general hospitals and nursing homes, and by October 7, 2021 for all other covered entities absent receipt of an exemption as allowed below. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in subdivision (d) of this section.

(d) Exemptions. Personnel shall be exempt from the COVID-19 vaccination requirements set forth in subdivision (c) of this section as follows:

(1) Medical exemption. If any licensed physician or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of member of a covered entity's personnel, based upon a pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be inapplicable only until such immunization is found no longer to be detrimental to such personnel member's health. The nature and duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record, and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services), and any reasonable accommodation may be granted and must likewise be documented in such record. Covered entities shall document medical exemptions in personnel records or other appropriate records in accordance with applicable privacy laws by: (i) September 27, 2021 for general hospitals and nursing homes; and (ii) October 7, 2021 for all other covered entities. For all covered entities, documentation must occur continuously, as needed, following the initial dates for compliance specified herein, including documentation of any reasonable accommodation therefor.

(e) Upon the request of the Department, covered entities must report and submit documentation, in a manner and format determined by the Department, for the following:

(1) the number and percentage of personnel that have been vaccinated against COVID-19;

(2) the number and percentage of personnel for which medical exemptions have been granted;

(3) the total number of covered personnel.

(f) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of this section and submit such documents to the Department upon request.

(g) The Department may require all personnel, whether vaccinated or unvaccinated, to wear an appropriate face covering for the setting in which such personnel are working in a covered entity. Covered entities shall supply face coverings required by this section at no cost to personnel.

Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(vi) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:

(5) collects documentation of COVID-19 or documentation of a valid medical exemption to such vaccination, for all personnel pursuant to section 2.61 of this title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 751.6 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (6) of subdivision (c) of Section 763.13 is added to read as follows:

(6) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation a ddressing such exemption.

Paragraph (7) of subdivision (d) of Section 766.11 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (8) of subdivision (d) of Section 794.3 is added to read as follows:

(8) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (q) of Section 1001.11 is added to read as follows:

(5) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is added to read as follows:

(18) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is added to read as follows:

(14) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is added to read as follows:

(15) Operator shall collect documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire November 23, 2021.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

Regulatory Impact Statement

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010 (4). PHL 225(5) authorizes the Public Health and Health Planning Council (PHHPC) to issue regulations in the State Sanitary Code pertaining to any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises.

PHL Article 28 (Hospitals), Section 2800 specifies that "hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article."

PHL Section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities. PHL Section

3612 authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Section 4010 (4) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

Social Service Law (SSL) Section 461 requires the Department to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF). SSL Section 461-e authorizes the Department to promulgate regulations to require adult care facilities to maintain certain records with respect to the facilities residents and the operation of the facility.

Legislative Objectives:

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen 10-fold, and 95 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 11 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, as well as any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Cost to State and Local Government:

The State operates several healthcare facilities subject to this regulation. Most county health departments are licensed under Article 28 or Article 36 of the PHL and are therefore also subject to regulation. Similarly, certain counties and the City of New York operate facilities licensed under Article 28. These State and local public facilities would be required to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. They must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant. State facilities should already be ensuring COVID-19 vaccination among their personnel, subject to State directives. Further, these entities are expected to realize savings as a result of the reduction in COVID-19 in personnel and the attendant loss of productivity and available staff.

Cost to the Department of Health:

There are no additional costs to the State or local government, except as noted above. Existing staff will be utilized to conduct surveillance of regulated parties and to monitor compliance with these provisions.

Local Government Mandates:

Covered entities operated by local governments will be subject to the same requirements as any other covered entity subject to this regulation.

Paperwork:

This measure will require covered entities to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Duplication:

This regulation will not conflict with any state or federal rules.

Alternative Approaches:

One alternative would be to require covered entities to test all personnel in their facility before each shift worked. This approach is limited in its effect because testing only provides a person's status at the time of the test and testing every person in a healthcare facility every day is impractical and would place an unreasonable resource and financial burden on covered entities if PCR tests couldn't be rapidly turned around before the commencement of the shift. Antigen tests have not proven as reliable for asymptomatic diagnosis to date.

Another alternative to requiring covered entities to mandate vaccination would be to require covered entities to mandate all personnel to wear a fit-tested N95 face covering at all times when in the facility, in order to prevent transmission of the virus. However, acceptable face coverings, which are not fit-tested N95 face coverings have been a long-standing requirement in these covered entities, and, while helpful to reduce transmission it does not prevent transmission and; therefore, masking in addition to vaccination will help reduce the numbers of infections in these settings even further.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

Compliance Schedule:

These emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed rule making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Regulatory Flexibility Analysis

Effect of Rule:

This regulation will not impact local governments or small businesses unless they operate a covered entity as defined in the emergency regulation. Currently, 5 general hospitals, 79 nursing homes, 75 certified home health agencies (CHHAs), 20 hospices and 1,055 licensed home care service agencies (LHCSAs), and 483 adult care facilities (ACFs) are small businesses (defined as 100 employees or less), independently owned and operated affected by this rule. Local governments operate 19 hospitals, 137 diagnostic and treatment facilities, 21 nursing homes, 12 CHHAs, at least 48 LHCSAs, 1 hospice, and 2 ACFs.

Compliance Requirements:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the

number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small businesses and local governments were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

While this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), "rural area" means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein."

The following 42 counties have an estimated population of less than 200,000 based upon 2019 United States Census projections:

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon 2019 United States Census population projections:

Albany County	Monroe County	Orange County
Niagara County	Saratoga County	Oneida County
Suffolk County	Erie County	Onondaga County

Reporting, recordkeeping, and other compliance requirements; and professional services:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Rural Area Participation:

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

Job Impact Statement

Nature of impact:

Covered entities may terminate personnel who are not fully vaccinated and do not have a valid medical exemption and are unable to otherwise ensure individuals are not engaged in patient/resident care or expose other covered personnel.

Categories and numbers affected:

This rule may impact any individual who falls within the definition of "personnel" who is not fully vaccinated against COVID-19 and does not have a valid medical exemption on file with the covered entity for which they work or are affiliated.

Regions of adverse impact:

The rule would apply uniformly throughout the State and the Department does not anticipate that there will be any regions of the state where the rule would have a disproportionate adverse impact on jobs or employment.

Minimizing adverse impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

STATE OF NEW YORK : DEPARTMENT OF HEALTH

IN THE MATTER

OF

COVERED ENTITIES IN THE PREVENTION AND CONTROL OF THE 2019 NOVEL CORONAVIRUS

ORDER FOR SUMMARY ACTION

WHEREAS the 2019 Novel Coronavirus ("COVID-19") is an infection associated with fever and signs and symptoms of pneumonia and other respiratory illness that is easily transmitted from person to person, predominantly through droplet transmission, and has significant public health consequences; and

WHEREAS COVID-19 is a global pandemic that, to date, has resulted in 2,195,903 documented cases and 43,277 deaths in New York State alone; and

WHEREAS the Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the Delta COVID-19 variant; and

WHEREAS the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorizations (EUA) for Pfizer -BioNTech, Moderna, and Janssen COVID-19 vaccines which have been shown to be safe and effective as determined by data from the manufacturers and findings from large clinical trials; and

WHEREAS while New York State has aggressively promoted vaccination since COVID-19 vaccines first became available in December 2020, current vaccination rates are not high enough to prevent the spread of the Delta variant, which is approximately twice as transmissible as the original SARS-CoV-2 strain; and

WHEREAS data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 as are vaccinated individuals; and

WHEREAS those who are unvaccinated have over 10 times the risk of being seriously ill and hospitalized with COVID-19; and

WHEREAS since early July, cases have risen 10-fold, and 95 percent of sequenced recent positives in New York State were the Delta variant; and

WHEREAS certain settings, such as healthcare facilities, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve; and

WHEREAS unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting such virus to colleagues and/or vulnerable patients or residents; and

WHEREAS based upon the foregoing, the Commissioner of Health of the State of New York is of the Opinion that all entities identified in this Order ("covered entities"), must immediately implement and comply with the requirements identified herein, and that failure to do so constitutes a danger to the health, safety, and welfare of the people of the State of New York; and

WHEREAS the Commissioner of Health of the State of New York has determined that requiring covered entities to immediately implement and comply with the requirements set forth herein and cannot be achieved through alternative means, including the adoption of the Public Health and Health Planning Council of emergency regulations, without delay, which would be prejudicial to health, safety, and welfare of the people of the State of New York; and

WHEREAS it therefore appears to be prejudicial to the interest of the people to delay action for fifteen (15) days until an opportunity for a hearing can be provided in accordance with the provisions of Public Health Law Section (PHL) 12-a.

NOW, THEREFORE, THE HEALTH COMMISSIONER HEREBY ORDERS THAT: Pursuant to PHL § 16:

(a) Definitions.

(1) Covered entity shall mean a general hospital or nursing home pursuant to section 2801 of the Public Health Law.

(2) Covered Personnel. All persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if

they were infected with COVID-19, they could potentially expose, patients, residents, or personnel working for such entity to the disease.

(3) Fully vaccinated. Covered personnel are considered fully vaccinated for COVID-19 ≥ 2 weeks after receiving either (1) the second dose in a 2-dose series (e.g., Pfizer-BioNTech or Moderna), or (2) a single-dose vaccine (e.g., Johnson & Johnson [J&J]/Janssen), authorized for emergency use or approved by the U.S. Food and Drug Administration, and holds an emergency use listing by the World Health Organization.

(4) Documentation of vaccination shall include:

(i) a record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner's signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system; or

(iii) any other documentation determined acceptable by the Department. Unless otherwise specified by the Department.

(iv) The following elements, unless otherwise specified by the Department: manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site.

(b) Covered entities shall continuously require all covered personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in section (c) of this order.

(c) Limited exemptions to vaccination:

1. Medical exemption. If any licensed physician or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to a specific member of a covered entity's personnel, based upon a specific pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be subject to a reasonable accommodation of such health condition only until such immunization is found no longer to be detrimental to the health of such member. The nature and duration of the medical exemption must be stated in the personnel employment medical record and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services). Covered entities shall document medical exemptions and any reasonable accommodation in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.
2. Religious exemption. Covered entities shall grant a religious exemption for COVID-19 vaccination for covered personnel if they hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the

employer. Covered entities shall document such exemptions and such reasonable accommodations in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.

(d) Upon the request of the Department, covered entities must report the number and percentage of covered personnel that have been vaccinated against COVID-19 and the number of personnel for which medical or religious exemptions have been granted by covered entities in a manner and format determined by the Department.

(e) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of Order.

(f) The Department may require all covered personnel, whether vaccinated or unvaccinated, to wear acceptable face coverings for the setting in which they work. Covered entities shall supply acceptable face coverings required by this section at no cost to covered personnel.

FURTHER, I DO HEREBY give notice that any entity that receives notice of and is subject to this Order is provided with an opportunity to be heard at 10:00 a.m. on September 2, 2021, via videoconference, to present any proof that failure to implement and comply with the requirements of this Order does not constitute a danger to the health of the people of the State of New York. If any such entity desires to participate in such a hearing, please inform the Department by written notification to **Vaccine.Order.Hearing@health.ny.gov**, New York State Department of Health, Corning Tower, Room 2438, Governor Nelson A. Rockefeller Empire

State Plaza, Albany, New York 12237, within five (5) days of their receipts of this Order. Please include in the notification the email addresses of all individuals who will be representing or testifying for the entity at the hearing so that an invitation to access the hearing remotely can be provided.

DATED: Albany, New York
August 18, 2021

NEW YORK STATE DEPARTMENT OF HEALTH

BY: Howard Zucker M.D.

HOWARD A. ZUCKER, M.D., J.D.
Commissioner of Health

10 N.Y.C.R.R. § 2.61

(a) Definitions.

(1) *Covered entities* for the purposes of this section, shall include:

(i) any facility or institution included in the definition of "hospital" in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;

(ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies;

(iii) hospices as defined in section 4002 of the Public Health Law; and

(iv) adult care facility under the Department's regulatory authority, as set forth in Article 7 of the Social Services Law.

(2) *Personnel*, for the purposes of this section, shall mean all persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.

(3) *Fully vaccinated*, for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner's signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system; or

(iii) any other documentation determined acceptable by the Department.

(c)[1] Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September

[1] So in original

27, 2021 for general hospitals and nursing homes, and by October 7, 2021 for all other covered entities absent receipt of an exemption as allowed below. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in subdivision (d) of this section.

(d) Exemptions. Personnel shall be exempt from the COVID-19 vaccination requirements set forth in subdivision (c) of this section as follows:

(1) Medical exemption. If any licensed physician or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of member of a covered entity's personnel, based upon a pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be inapplicable only until such immunization is found no longer to be detrimental to such personnel member's health. The nature and duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record, and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services), and any reasonable accommodation may be granted and must likewise be documented in such record. Covered entities shall document medical exemptions in personnel records or other appropriate records in accordance with applicable privacy laws by: (i) September 27, 2021 for general hospitals and nursing homes; and (ii) October 7, 2021 for all other covered entities. For all covered entities, documentation must occur continuously, as needed, following the initial dates for compliance specified herein, including documentation of any reasonable accommodation therefor.

(e) Upon the request of the Department, covered entities must report and submit documentation, in a manner and format determined by the Department, for the following:

(1) the number and percentage of personnel that have been vaccinated against COVID-19;

(2) the number and percentage of personnel for which medical exemptions have been granted;

(3) the total number of covered personnel.

(f) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of this section and submit such documents to the Department upon request.

(g) The Department may require all personnel, whether vaccinated or unvaccinated, to wear an appropriate face covering for the setting in which such personnel are working in a covered entity. Covered entities shall supply face coverings required by this section at no cost to personnel.