

IN THE UNITED STATES DISTRICT COURT FOR THE
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.

KATHY HOCHUL, Governor of the State of New York, in
her official capacity; HOWARD ZUCKER, M.D.,
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.

DECLARATION

21 CV 1009 (DNH)(ML)

**DECLARATION OF
EMILY LUTTERLOH
MD, MPH**

EMILY LUTTERLOH MD, MPH, declares under penalty of perjury, pursuant to 28 U.S.C. §
1746, that the following is true:

1) I am the Director of the Division of Epidemiology at the New York State
Department of Health (“DOH” or the “Department”). Before assuming my current position in
July 2021, I was the Director of the Bureau of Healthcare Associated Infections, a position I held
since 2011. I have been employed by the Department since 2010. In my position, I coordinate
the Department’s efforts to investigate, reduce, and prevent outbreaks and transmission of
infectious diseases.

2) In 1998, I received my MD degree from Indiana University School of Medicine.
In 2010, I received my Master of Public Health (“MPH”) degree from Johns Hopkins University.
Before joining the Department in 2010, I served as an attending physician in pediatric infectious

disease, and then as a Lieutenant Commander and Epidemic Intelligence Service Officer in the United States Public Health Service. I have been licensed to practice medicine in New York State since 2010, and I am Board Certified in Infectious Disease and Pediatric Infectious Disease.

3) My responsibilities as they relate to COVID-19 include oversight of Department epidemiologists who advise local health departments, healthcare facilities, and other internal and external partners about the pandemic response. Additionally, my responsibilities include writing guidance related to epidemiology and the pandemic response and advising other groups within the Department and other State agencies about issues related to epidemiology.

COVID-19 Continues to Present a Threat to Health and Safety

4) Despite the gains that New York has made, the pandemic is not over. COVID-19 variants create a continued risk for increased transmission. As expected, the surges of these variants over the winter holiday season caused COVID-19 case numbers and hospitalizations to rise.

5) The CDC conducts surveillance on SARS-CoV-2 strains to create a library of the various specimens and sequences to better assist in the public health response.¹

6) The first surge of COVID-19 in New York was March-April-May 2020, and a resurgence of the COVID-19 pandemic swept through New York in November-December-January 2020-2021, with previous variants. Now we are recovering from another resurgence, first with the late 2021 surge of the Delta variant, coupled with the emergence of the highly transmissible

¹ On May 31, 2021, The World Health Organization (“WHO”) announced new naming labels for the variants of interest and concern. See *Tracking SARS-CoV-2 Variants*, World Health Organization, found at <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/> (last viewed January 3, 2022).

Omicron variant.

7) According to the CDC, the Delta variant is considered more than two times more contagious than previous variants and caused severe illness than previous variants in unvaccinated people. A copy of the CDC's *Delta Variant: What We Know About the Science* is attached hereto as **Exhibit A**.

8) A new variant, Omicron, which was first detected in South Africa in November 2021, has rapidly spread around the world. A Copy of the CDC's *Omicron Variant: What You Need to Know* is attached hereto as **Exhibit B**. It was first discovered in the United States on December 1, 2021. Id.

9) According to the CDC, data as of the week ending February 5, 2022, suggest that Omicron is the predominant variant in the United States, accounting for essentially 100% of COVID-19 cases.^{2,3} Omicron is also likely the predominant variant in the New Jersey, New York, Puerto Rico and the Virgin Islands Region, accounting for essentially 100% of cases.⁴

10) The CDC notes that current vaccines are expected to protect against severe illness, hospitalizations, and deaths due to Omicron-related infection and vaccination remains the best public health measure to protect individuals from COVID-19. **Exhibit B**.

11) The existence of this new variant, which is reported to be more contagious than the Delta variant, has made implementation of the layered mitigation strategies, such as vaccination,

² See CDC, *COVID Data Tracker*, at <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> (last visited February 10, 2022).

³ These estimates use Nowcast, a model that estimates more recent proportions of circulating variants and enables timely public health action. Variant proportion estimates lag because it often takes weeks after an infection to complete the sequencing and reporting.

⁴ These estimates use Nowcast, a model that estimates more recent proportions of circulating variants and enables timely public health action. Variant proportion estimates lag because it often takes weeks after an infection to complete the sequencing and reporting.

masking, and testing, even more important. Id., see also the Cleveland Clinic's *What to Know about the Omicron Variant* attached hereto as **Exhibit C**.

12) The holiday season and the winter surges have made it even more vital that New Yorkers continue to get vaccinated, as individuals continue to engage in indoor activities and family gatherings.

13) The CDC has stated that data from South Africa and the United Kingdom demonstrate that vaccine effectiveness against infection is 75% with the booster dose. Additionally, "COVID-19 vaccination decreases the risk of severe disease, hospitalization, and death from COVID-19." A copy of the CDC's Media Release *CDC Updates and Shortens Recommended Isolation and Quarantine Period for General Population* is attached hereto as **Exhibit D**.

14) Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases acknowledged the extraordinary transmissibility of the Omicron variant but stated that those who have been vaccinated and boosted, although they will be exposed, will likely not suffer from the more severe aspects of the strain. A copy of CNN's *The Highly Contagious Omicron Variant will 'Find Just About Everybody,' Fauci says, but Vaccinated People will Still Fare Better* is attached hereto as **Exhibit E**.

15) A study recently published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") reiterates the importance of COVID-19 vaccination and booster doses. This study examined COVID-19 incidence and hospitalization rates among adults over the age of 18 in Los Angeles County during the Omicron surge from November 7, 2021 to January 8, 2022. The study found that for the period dominated by the Omicron surge (between mid- December to January 8,

2022), unvaccinated persons had infection and hospitalization rate 3.6 and 23.0 times, respectively, of those of fully vaccinated individuals with a booster. Additionally, during the entire period of study, incidence and hospitalization rates were consistently lowest for fully vaccinated persons with a booster. The study concluded that the risk for infection and COVID-19 associated hospitalization are lower among fully vaccinated individuals, and the “reduction is even more pronounced among those who have received additional or booster doses”. A copy of *SARS-CoV-2 Infection and Hospitalization Among Adults Aged ≥ 18 Years by Vaccination Status, Before and During SARS-CoV-2 B.1.1.529 (Omicron) Variant Predominance- Los Angeles County, California, November 7, 2021- January 8, 2022* is attached hereto as **Exhibit F**.

16) Another study published in the CDC’s MMWR examined COVID-19 case and death rates and incidence rate ratios among unvaccinated and fully vaccinated adults during pre-Delta, Delta emergence, Delta predominance, and Omicron emergence periods in 25 U.S. jurisdictions. Ultimately, the study showed that booster doses provided additional protection against infection and death during the Delta predominant period and against infection during the Omicron emergence, especially among those aged 60-64 and those over the age of 65. A copy of *COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence – 25 U.S. Jurisdictions, April 4- December 25, 2021* is attached hereto as **Exhibit G**.

17) The Department continues to emphasize the importance of vaccination. On January 19, 2022, a study co-authored by the Department was published in the CDC’s MMWR report. The study, evaluating COVID-19 cases and hospitalizations from May to November 2021 (prior to the emergence of the Omicron variant) found that both vaccination and prior infection provided

protection against future infection and hospitalization.⁵ A copy of *COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis – California and New York, May-November 2021* is attached hereto as **Exhibit H**. Although prior infection may protect against reinfection, initial infection among unvaccinated individuals increases the risk of serious illness, hospitalization, and death. Id. Therefore, the Department continues to recommend vaccination as “the most effective and *only recommended way* to gain immunity to COVID-19,” and the safest way “to prevent SARS-CoV-2 infections, associated complications, and onward transmission.” A copy of the Department’s January 19, 2022 press release is attached hereto as **Exhibit I**; see also Exhibit H.

18) Recent data from the Department, for the week of beginning January 31st, show that vaccine effectiveness for those 18 and older was 78.7% (meaning that fully-vaccinated New Yorkers had about a 79% lower chance of becoming a COVID-19 case as compared to unvaccinated New Yorkers).⁶

19) Recent data from the Department for the past few weeks show between 90.8% - 91.0% vaccine effectiveness against COVID-19 hospitalizations for fully-vaccinated New Yorkers, as compared to an unvaccinated New Yorker (for those 18 and older).⁷

20) On February 10, 2022, Johns Hopkins reported that globally, 404,282,446 individuals to date had tested positive for COVID-19, and a total of 5,780,806 confirmed COVID-

⁵ The study noted that further research is needed to establish the “duration of protection from previous infection by variant type, severity, and symptomatology, including for the Omicron variant”. Id.

⁶ Data is still accruing and there remains an amount of uncertainty to the data. It is subject to change. NYS Department of Health, *COVID-19 Breakthrough Data*, <https://coronavirus.health.ny.gov/covid-19-breakthrough-data> (last visited February 10, 2022).

⁷ Data is still accruing for these weeks and there remains an amount of uncertainty to the data. It is subject to change. NYS Department of Health, *COVID-19 Breakthrough Data*, <https://coronavirus.health.ny.gov/covid-19-breakthrough-data> (last visited February 10, 2022).

19 deaths worldwide.⁸ In addition, 77,268,991 individuals in the United States had tested positive for COVID-19 to date, and 912,260 had died of COVID-19.⁹

21) On June 13, 2021, a low of 0.35% positivity rate occurred in New York State.¹⁰ Since then, cases steadily increased due to the Delta and Omicron surges. For example, on January 1, 2022, 275,563 individuals were tested for COVID-19, with a total of 62,526 testing positive.¹¹ This is a total positivity rate of 22.69%.

22) Since the holidays have passed and the Omicron surge is abating, on February 8, 2022, the positivity rate has dropped to 3.67%, with 6,041 testing positive out of 164,612 total tested.¹²

23) Governor Hochul acknowledged that data showing a drop in new infections offered a “glimmer of hope” that the State’s discipline was paying off. A copy of *Governor Hochul Updates New Yorkers on State’s Progress Combating COVID-19* is attached hereto as **Exhibit J**.

24) The statewide trends will continue to be monitored to ensure the State is proportionately addressing the public health risks of the current variants based on the current science. It is critical that any restrictions put in place are ultimately lifted after evaluating the relevant data.

⁸ See COVID-19 Dashboard, John Hopkins University of Medicine, found at <https://coronavirus.jhu.edu/map.html> (last viewed February 10, 2022).

⁹ *Id.*

¹⁰ See NYSDOH Positive Tests Over Time, by Region and County, found at <https://coronavirus.health.ny.gov/positive-tests-over-time-region-and-county> (last viewed February 10, 2022.)

¹¹ See NYSDOH COVID-19 Tracker, Daily Totals: Persons Tested and Persons Tested Positive, found at <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-DailyTracker?%3Aembed=yes&%3Atoolbar=no&%3Atabs=n> (last viewed February 10, 2022).

¹² See NYSDOH COVID-19 Testing Tracker, found at <https://coronavirus.health.ny.gov/covid-19-testing-tracker> (last viewed February 10, 2022.)

25) New York State will continue to take all necessary efforts to mitigate risk to the public and reduce the opportunity for the virus to spread.

Regulatory Background

26) The Department and the Commissioner of Health (“Commissioner”) are charged with the overarching responsibility to protect the public health pursuant to Public Health Law (“PHL”) §§ 201 and 206. Specifically, pursuant to PHL § 201(1)(m), the Department “shall ... supervise and regulate the sanitary aspects ... businesses and activities affecting public health.” Pursuant to PHL § 206, the Commissioner “shall ... take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto.” These statutes obligate the Department and the Commissioner to take action when the public health is put at risk by an unprecedented and unpredictable global pandemic, and the rapid outbreak of severe and fatal respiratory illnesses associated therewith.

27) The Department of Health and the Public Health and Health Planning Council (“PHHPC”) have utilized their authority in recent years to promulgate emergency regulations. Examples include:

- a) Requiring standards for operation of “cooling towers” that can harbor legionella bacteria and spread disease (NY Reg, Sept. 2, 2015 at 14-17; 10 NYCRR Part 4);
- b) Creating civil penalties for possession of “bath salts” and synthetic marijuana (NY Reg, Aug. 26, 2015 at 8-11; 10 NYCRR Subpart 9-1);

- c) Requiring local health department to develop action plans to address the potential spread of the Zika virus (NY Reg, Apr. 6, 2016 at 23-24; 10 NYCRR § 40-2.24);
- d) Facilitating the prescribing and dispensing of controlled substances, administering treatment for narcotics addiction, and creating an opioid overdose program (NY Reg, Aug. 27, 2014 at 11-13, and Oct. 18, 2017 at 16-17; 10 NYCRR §§ 80.136 and 80.138).

28) On August 23, 2021, DOH published a proposed Emergency Regulation to be reviewed and adopted by the Public Health and Health Planning Council (“PHHPC”) titled “Prevention of COVID-19 Transmission by Covered Entities”.¹³ This Emergency Regulation superseded a prior Department-issued August 18, 2021 Summary Order, issued pursuant to PHL § 16. The Emergency Regulation was adopted by PHHPC and the Department on August 26, 2021, and became effective August 26, 2021, for 90 days.¹⁴ A copy of the Emergency Regulation is annexed hereto as **Exhibit K**.

29) This Emergency Regulation was adopted based on rational determinations by the Department and PHHPC that it was necessary to immediately address an ongoing and rapidly worsening public health emergency.

30) At the time the emergency regulation was initially adopted, despite the ending of

¹³ PHHPC is a council within DOH that, in accordance with Section 225 of the Public Health Law, advises the Commissioner on issues related to the preservation and improvement of public health. PHHPC’s functions include the approval of regulations related to health codes, among other things. PHHPC also has a broad array of advisory and decision-marking responsibilities with respect to New York State public health and health care delivery system. *See* Department’s *Public Health and Health Planning Council*, found at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/ (last viewed September 22, 2021).

¹⁴ In accordance with SAPA § 202(6)(b), the Emergency Regulation went into effect immediately upon filing. In accordance with SAPA § 202, emergency regulations are effective for 90 days, subject to renewal.

the state disaster emergency on June 25, 2021, “[w]ith the emergence of the Delta variant, a strain twice as transmissible as the SARS-CoV-2 strain, this does not mean that COVID-19 is gone. Cases have risen 10-fold since early July, with the Delta variant accounting for 95% of recent sequenced positives in New York State.” See **Exhibit K**.

31) On November 24, 2021, a new Notice of Emergency Adoption for 10 NYCRR § 2.61 was filed with the Department of State. The Department made changes to the actual text of the regulation from the August 26th version (see § 2.61(c) (amending the required due dates for receiving the vaccination) and § 2.61(d)(1) (adding a physician assistant as an individual who could certify a medical exemption)). The November 24th Emergency Regulation is attached hereto as **Exhibit L**. It is effective for 90 days.

32) On the same day, a Notice of Proposed Rulemaking to move the Emergency Regulation to be permanently adopted was filed with the Department of State. It was published in the State Register on December 15, 2021, with the public comment period set to expire on February 14, 2022. A copy of the Notice of Proposed Rulemaking is attached hereto as **Exhibit M**.

33) On January 21, 2022, a new Notice of Emergency Adoption for 10 NYCRR § 2.61 was filed with the Department of State. PHHPC approved and the Department added a requirement for personnel in covered entities to receive the booster or supplemental dose of the COVID-19 vaccine, as recommended by the CDC. The January 21st Emergency Regulation is attached hereto as **Exhibit N**. It is effective for 90 days.

Basis for Mandating COVID-19 Vaccines for Health Care Personnel

34) In September 2021, shortly after the Department’s emergency rule went into

effect, the Annals of Internal Medicine published an article finding that health care workers have higher rates of infection than people in other fields. A copy of the Annals of Internal Medicine, *The Case for Mandating COVID-19 Vaccines for Health Care Workers* is attached hereto as **Exhibit O**.

35) As of February 9, 2022, the CDC reported that there were a total of 913,075 COVID-19 cases among healthcare personnel and 3,530 recorded healthcare personnel deaths associated with COVID-19 to date. Notably, only 16.20% of the case reports received by the CDC have known healthcare personnel status, and only 63.49% of the reported cases among healthcare personnel have death status.¹⁵

36) This emergency regulation focuses on the vaccination of healthcare workers in the already highly-regulated covered entities under the Department's direct statutory and regulatory authority as a means to protect the public health and reduce the incidence of COVID-19 during a time when the Delta and Omicron COVID-19 variants have caused multiple surges in COVID-19 cases. This regulation will protect both the State's frontline healthcare workers and the vulnerable patient populations in the healthcare sector where COVID-19 transmission poses heightened risks.

37) The regulation is tailored to focus on healthcare facilities as settings that pose a unique risk of COVID-19 transmission, as compared to other settings. For example, it is difficult for healthcare workers who practice hands-on patient care to achieve the same types of social distancing measures that are put in place in other settings. There is also an increased risk of

¹⁵ CDC, *Cases and Deaths among Healthcare Personnel*, <https://covid.cdc.gov/covid-data-tracker/#health-care-personnel> (last viewed February 10, 2022).

severe illness associated with COVID-19 transmission in healthcare or long-term care settings due to the vulnerable patient or elderly populations that healthcare providers are serving, particularly those with underlying conditions.¹⁶

38) Further, healthcare workers tend to care for persons who are elderly, sick, and vulnerable, who might not gain sufficient immunity from the vaccine to provide adequate protection from severe illness, such as immunocompromised individuals. A copy of the *Safety and Immunogenicity of Anti-SARS-CoV-2 Messenger RNA Vaccines in Recipients of Solid Organ Transplants* is attached hereto as **Exhibit P**.

39) The CDC has also recognized that achieving high vaccination rates in particularly vulnerable settings, such as long-term care facilities (“LTCF”), is of the utmost importance, since residents of these facilities are at high risk for COVID-19 associated mortality. “As of March 2021, deaths among LTCF residents and HCP have accounted for almost one third . . . of COVID-19 associated deaths in the United States.” This is why early vaccination of these groups were prioritized. A copy of the CDC’s *Disparities in COVID-19 Vaccination Coverage Among Health Care Personnel Working in Long-Term Care Facilities, by Job Category, National Healthcare Safety Network – United States, March 2021* is attached hereto as **Exhibit Q**.

40) The CDC has expressed concern that “COVID-19 outbreaks have occurred in LTCF in which residents were highly vaccinated, but transmission occurred through unvaccinated staff members.” *Id.* Low staff vaccination rates provide insufficient protection.

¹⁶ CDC, People with Certain Medical Conditions, found at <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html> (last viewed September 29, 2021).

For example, in Kentucky, an outbreak occurred in a skilled nursing facility with 90.4% of its residents vaccinated, after introduction from “an unvaccinated, symptomatic” healthcare provider. In this facility, only 52.6% of healthcare personnel were fully vaccinated (e.g., received two vaccine doses). A copy of the CDC’s *COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program – Kentucky, March 2021* is attached hereto as **Exhibit R**. The CDC’s study found that “[a]ttack rates were three to four times as high among unvaccinated residents and HCP as among those who were vaccinated; vaccinated persons were significantly less likely to experience symptoms or require hospitalization.” *Id.* Ultimately, 46 residents and HCP were infected. *Id.*

41) While masking and routine testing are essential parts of a multi-layered COVID-19 mitigation strategy to reduce transmission, these mitigation measures *alone* are insufficient to protect against the increased and unique risk of COVID-19 transmission in healthcare settings with vulnerable populations. As set forth in the regulatory impact statement for the subject regulation, acceptable 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 vaccinations will help reduce the numbers of infections in these settings even further.” Additionally, another alternative to require healthcare facilities to test *all* personnel in their facility before each shift was rejected as ineffective and burdensome. It would be near impossible for healthcare entities to turn around PCR test results quickly before the commencement of each workers’ shift, especially given the number of workers in larger facilities; additionally, it would place an “unreasonable resource and financial burden” on these facilities. Rapid antigen tests could be used as an alternative but are, in general, somewhat less

sensitive than PCR tests. An additional layer of protection is needed for healthcare workers, who frequently care for vulnerable individuals. Also, the testing approach alone is limited in effectiveness for healthcare facilities because a person's COVID infection status (i.e., ability to infect others) can change quickly, possibly even during the course of a long shift. In general, "testing every person in a healthcare facility every day is impractical." See Exhibit K.

42) The January 21st Emergency Regulation's Emergency Justification emphasized the importance of continuing to require healthcare worker vaccinations, stating that recent New York State data "show that unvaccinated individuals continue to be more likely to be diagnosed with COVID-19 compared to vaccinated individuals." With the emergence of Omicron, there have been new infections in vaccinated individuals; however "[t]hose who are unvaccinated have over 10 times the risk of being hospitalized with COVID-19 compared with vaccinated individuals." Additionally, the addition of the booster requirement is well reasoned, given that "[r]ecent data show that booster doses of the COVID-19 vaccine offer more protection against the Omicron variant compared with the primary series alone" and are important "to maximize protection against infection." See also supra ¶¶ 15 and 16 (discussing COVID-19 booster effectiveness).

43) One of the key concerns is that New York State does not return to levels that would overwhelm the hospital system, which can lead to further unnecessary deaths. It is critical that New York State continue to take measures to protect not only vulnerable patients, but also frontline healthcare workers.

44) For example, on November 26, 2021, in anticipation of the winter spikes in COVID-19 cases (even before Omicron had been documented in New York State) Governor

Hochul announced that she would be signing an Executive Order to allow the Department to limit “non-essential, non-urgent procedures for in-hospitals or systems with limited capacity” to “boost hospital capacity and address staffing shortages.” However, the Governor warned that despite these urgent steps being taken to protect the hospital systems, “[t]he vaccine remains one of our greatest weapons in fighting the pandemic.” A copy of *Governor Hochul Announces Urgent Action to Boost Hospital Capacity and Address Staffing Shortages* is attached hereto as **Exhibit S**. Executive Order No. 11 is attached hereto as **Exhibit T**.

45) From November 2020 to the present, as expected with the winter surges and the holiday season, hospitalization and ICU admissions steadily increased. With regard to hospital admissions, on November 24, 2020, there were 377 new COVID-19 hospital admissions (1.93 per 100k, with a 1.86 7-day average). On January 7, 2022, this number reached 2,144 (10.97 per 100k, with a 9.58 7-day average). Since then, this number has started to decline. On February 8, 2022, there were 495 COVID-19 new hospital admissions (2.53 per 100k, with a 2.79 7-day average). With regard to total hospitalizations and ICU patients, on November 24, 2021, there were 2,583 total COVID-19 patients hospitalized, 509 total COVID-19 patients in the ICU. These totals hit a peak on January 11, 2022, with 12,671 total COVID-19 patients hospitalized and 1,593 total COVID-19 patients in the ICU. As of January 18, 2022, there were 4,670 total COVID-19 patients hospitalized, with 755 COVID-19 patients in the ICU.¹⁷

46) A study published in the CDC’s MMWR found that the rapid rise of Omicron cases in December 2021 “has resulted in the highest number of COVID-19 associated ED visits and

¹⁷NYS Department of Health, Daily Hospitalization Summary, <https://coronavirus.health.ny.gov/daily-hospitalization-summary> (last viewed February 10, 2022).

hospital admissions since the beginning of the pandemic, staining the health care system” despite that disease severity has been lower than during the Delta surge. The study reiterated the importance of, among other things, “the ability to adequately staff local health care systems . . . [and] being up to date on vaccination and following other recommended prevention strategies.” A copy of *Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS-CoV-2 High Transmission Periods – United States, December 2020 – January 2022* is attached hereto as **Exhibit U**.

47) Another study published in the MMWR reiterated that “a rapid increase in infections during Omicron predominance has resulted in a relatively substantial volume of hospitalizations” and this high volume “can compound the effects of staffing shortages and staff member burnout, which puts a strain on the health care sector.” The study concluded that the rise in hospitalization rates in this specific study was most pronounced among unvaccinated individuals and lower among those who are fully vaccinated and lowest among those who had received a booster. Essentially, “[b]eing up to date with COVID-19 vaccinations is a critical component of reducing the strain on health care facilities.” **Exhibit F**.

48) The vaccination requirement is imperative to protect those who need medical treatment during this pandemic from transmission from infected healthcare personnel and, secondarily, from potentially devastating staffing shortages and overstrained hospitals that could follow a COVID-19 outbreak among our frontline healthcare workers. The pandemic has already caused staffing challenges in New York State because of the increase in COVID-19 cases and hospitalizations due to the Omicron surge. A COVID-19 outbreak among healthcare workers that could spread to vulnerable patients would exacerbate these challenges.

49) Governor Hochul has put measures in place to address potential healthcare worker staffing shortages. Among other measures, Executive Order No. 4 authorizes out-of-state and retired professionals and recent graduates to practice in New York and allows additional healthcare workers to administer COVID-19 testing and vaccinations. A copy of Executive Order No. 4 is attached hereto as **Exhibit V**. This was most recently extended through March 1, 2022 by Executive Order No. 4.5. A copy of Executive Order No. 4.5 is attached hereto as **Exhibit W**. Governor Hochul also “directed a 24/7 Operations Center, led by the New York State Department of Health, to constantly monitor staffing operations and trends statewide, provide guidance to healthcare facilities and help troubleshoot acute situations with providers as necessary.” A copy of the September 27, 2021 Press Release is attached hereto as **Exhibit X**.

50) The Department’s comprehensive guidance and mandates issued during the COVID-19 surge acknowledge the threat of staffing shortages and the importance of maintaining critical infrastructure. For example, the CDC and the Department recently updated their guidance documents pertaining to work restrictions for healthcare workers after COVID-19 exposure or infection. Protecting the State’s healthcare system is a priority during this COVID surge and the healthcare worker vaccination requirements, along with updates in the healthcare worker work-related restrictions, both act in furtherance of this goal.

51) New York State is not alone in emphasizing the importance of vaccinations for healthcare workers. More than “50 health care professional societies and organizations called for all health care employers to require their employees to be vaccinated against COVID-19 in a joint statement released” on July 26, 2021. These include, but are not limited to, the “American Medical Association, American Nurses Association, American Academy of Pediatrics,

Association of American Medical Colleges, and National Association for Home Care and Hospice”, as well as the American Academy of PAs, American Pharmacists Association, the National Hispanic Medical Association, the American Public Health Association, American Academy of Child and Adolescent Psychiatry and the Infectious Diseases Society of America. A copy of *Major Health Care Professional Organizations Call for COVID-19 Vaccine Mandates for All Health Workers* is attached hereto as **Exhibit Y**.

52) Dr. Audiey Kao, MD, PhD, the American Medical Association’s Vice President of Ethics, made it clear that “Do no harm is a core ethic for all those who care for the sick and injured. . . . [A]ll those working in the health care system have a fundamental obligation to patients by getting vaccinated for preventable diseases such as COVID-19.” A copy the American Medical Association’s *Why COVID-19 Vaccination Should be Required for Health Professionals* is attached hereto as **Exhibit Z**. Dr. Ezekiel Emanuel, the vice provost for global initiatives at the University of Pennsylvania, also emphasized that ““No patient should have to worry that they could become infected by one of their care providers, and no provider should put their patient at risk.”” **Exhibit AA**. For example, the president of the American Society of Clinical Oncology stated that “[p]atients with cancer need to know that their environment, including the people who care for them, is as safe as possible.”” *Id.* This collective statement unequivocally supports the requirement for universal vaccination of health workers.

53) Other organizations have separately stated their support for healthcare worker vaccination requirements. For example, the American Association of Nurse Anesthesiology, American Association of Critical-Care Nurses, National Association of Neonatal Nurses, and the American College of Occupational and Environmental Medicine. A copy these statements are

attached hereto as **Exhibits BB-EE**. These organizations have stated that vaccinations to health care team members will not only reduce the burden of this disease on acute and critical -care units and communities, but will prevent further harm to front line workers. **Exhibit CC**. Further, healthcare workers and their employers benefit from required vaccinations because “COVID-19 is more disruptive to the workforce and hospital/health care operations than any disease encountered in the last century due to required quarantining and potential length of illness.” **EE**.

54) On July 26, 2021, the Department of Veterans Affairs mandated COVID-19 vaccines for health care personnel who work in Veterans Health Administration facilities, visit those facilities or provide direct care to those the VA serves. A copy of the July 26, 2021 News Release is attached hereto as **Exhibit FF**. On August 12, 2021, the Department of Health and Human Services Secretary announced that “more than 25,000 members of its health care workforce [will be required] to be vaccinated against COVID-19.” A copy of the August 12, 2021 Press Release is attached hereto as **Exhibit GG**. This includes staff at the Indian Health Service and National Institutes of Health who either “interact with, or have the potential to come into contact with, patients.” Id. The U.S. Surgeon General also immediately required “members of the U.S. Public Health Service Commissioned Corps” to be vaccinated. Id.

55) On November 4, 2021, through an emergency regulation issued by the Centers for Medicare Services (“CMS”) the federal government required COVID-19 vaccination for staff at healthcare facilities that participate in the Medicare and Medicaid programs. CMS stressed that “[w]hen health care staff cannot work because of illness or exposure to COVID-9, the strain on the health care system becomes more severe and further limits patient access to safe and essential

care.”¹⁸

The Development of COVID-19 Vaccines

56) There is an important distinction between what is in the actual makeup of the vaccines versus what was used in the research and development of the vaccines. None of the COVID-19 vaccine products currently approved by the FDA or authorized under emergency provisions (“authorized”) contain any fetal cells.

57) Each of the manufacturers of COVID-19 vaccines currently approved or authorized for use in the U.S. have statements on their websites that they do not contain fetal cell lines nor human-derived materials.

58) The Moderna website states “[t]he Moderna COVID-19 Vaccine does not contain any preservatives, antibiotics, adjuvants, or materials of human or animal origin. The Moderna COVID-19 vaccine does not use fetal cell lines during the vaccine manufacturing or lot testing.” A copy of the Moderna website text is attached hereto as **Exhibit HH**.

59) The Pfizer website states that “[a]nimal or human fetal-derived cell lines are not used to produce Comirnaty (also known as Pfizer-BioNTech COVID-19 Vaccine), which consists of synthetic and enzymatically produced components.” A copy of the Pfizer website text is attached hereto as **Exhibit II**.

60) The Janssen website states that “[t]here is no fetal tissue nor any human cells present in the Janssen COVID-19 Vaccine (Ad26.COV2.S; JNJ-78436735).” A copy of the Janssen website text is attached hereto as **Exhibit JJ**.

¹⁸ <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care>

61) In sum, while none of the FDA authorized or approved COVID-19 vaccines contain any fetal cells, fetal cell lines were only “used in testing during research and development of the mRNA vaccines [Moderna or Pfizer], and during production of the Johnson and Johnson [Janssen] vaccine.” A copy of the Nebraska Medicine’s *You asked, we answered: Do the COVID-19 Vaccines Contain Aborted Fetal Cells* is attached hereto as **Exhibit KK**.

62) A North Dakota Department of Health COVID-19 vaccine handout also notes that “[h]istorical fetal cell lines were derived in the 1960’s and 1970’s from two elective abortions and have been used to create vaccines for diseases such as hepatitis A, rubella, and rabies.” The North Dakota Department of Health handout *COVID-19 Vaccines & Fetal Cell Lines* is attached hereto as **Exhibit LL**.

63) Further, fetal cell lines have been used in other medical technologies. This process is not new.

64) For instance, fetal cell lines have been used to develop rubella, hepatitis A and varicella-containing vaccines. A copy of CNN’s *How Exactly Fetal Tissue is Used for Medicine* is attached hereto as **Exhibit MM**.

65) Fetal cells have also been used in “hundreds of thousands of other research projects” including the improvement of techniques for and the study of in vitro fertilization, “birth defects, eye diseases, Parkinson’s Alzheimer’s disease, AIDS, and spinal cord injuries.” A copy of NBC News *What is fetal tissue research? And why is it important to medicine?* is attached hereto as **Exhibit NN**.

Religious Exemption to COVID-19 Vaccinations

66) The absence of religious exemptions in mandatory vaccination laws is not a novel concept in New York State and the Emergency Regulation's silence as to a religious exemption is consistent with other mandatory vaccination laws for healthcare workers.

67) Existing regulations require that all persons who work at hospitals, nursing homes, diagnostic and treatment centers, home health agencies and programs and hospices be immune to measles and rubella. While these regulations all provide for a medical exemption, *none* of these regulations provide for a religious exemption. See 10 NYCRR § 405.3 (requiring measles and rubella immunizations for all hospital personnel with an exception for physicians practicing medicine from remote location); 10 NYCRR § 415.26 (requiring measles and rubella immunizations for all nursing home personnel except for those with no clinical or patient contact responsibilities and who are located in a building with no patient care services); 10 NYCRR § 751.6 (requiring measles and rubella vaccinations for all employees of diagnostic and treatment centers); 10 NYCRR § 763.13 (requiring measles and rubella vaccinations prior to patient care duties, for all personnel of certified home health agencies, long term home health care programs, and AIDS home care programs); 10 NYCRR § 766.11 (requiring measles and rubella vaccinations for all health care personnel of licensed home care services agencies who have direct patient contact); and 10 NYCRR § 794.3 (requiring measles and rubella vaccinations for all hospice personnel, including direct employees, contract staff, and volunteers who have direct patient or family contact); 10 NYCRR § 1001.11 (requiring measles and rubella vaccinations for all assisted living residences personnel, including all direct care staff).

68) The absence of a religious exemption in 10 NYCRR § 2.61 is consistent with all of the above pre-existing regulations relevant to healthcare workers. To provide otherwise for

solely the COVID-19 vaccination mandate would be inconsistent with similar regulations, which all seek to advance similar goals of preventing the transmission of infectious diseases among health care personnel, staff, and patients.

69) Similar to the majority of the above regulations, 10 NYCRR § 2.61 recognizes that the greatest threat of transmission is posed by healthcare personnel who have direct contact with other staff and patients. Therefore, the vaccination mandate in 10 NYCRR § 2.61 is appropriately limited to only those personnel “who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients, residents to the disease.”

70) Mandatory school entry vaccination laws similarly do not provide for a religious exemption.

As part of the multi-faceted approach to addressing the 2018-2019 measles outbreak, on June 13, 2019, New York State signed into law legislation which removed religious exemptions from school vaccination requirements for children in prekindergarten-12th grade (“religious exemption repeal”). (Laws of 2019, Chapter 35, which, among other things, repealed former NYS Public Health Law § 2164(9)). The law now treats individuals with religious beliefs contrary to immunization exactly the same as individuals with non-religious beliefs contrary to immunization.

Dated: February 11, 2022



EMILY LUTTERLOH



COVID-19

We have the tools to
Fight Omicron



Vaccines & Booster



Masks



Testing

Delta Variant: What We Know About the Science

Updated Aug. 26, 2021

On July 27, 2021, CDC released [updated guidance](#) on the need for urgently increasing COVID-19 vaccination coverage and a recommendation for everyone in areas of [substantial or high transmission](#) to wear a mask in public indoor places, even if they are fully vaccinated. CDC issued this new guidance due to several concerning developments and newly emerging data signals.

First, a significant increase in new cases reversed what had been a steady decline since January 2021. In the days leading up to our guidance update, CDC saw a rapid and alarming rise in the COVID-19 case and hospitalization rates around the country.

- In late June, the 7-day moving average of reported cases was around 12,000. On July 27, the 7-day moving average of cases reached over 60,000. This case rate looked more like the rate of cases we had seen before the vaccine was widely available.

Second, new data began to emerge that the Delta variant was more infectious and was leading to increased transmissibility when compared with other variants, even in some vaccinated individuals. This includes recently published data from CDC and our public health partners, unpublished surveillance data that will be publicly available in the coming weeks, information included in CDC's updated [Science Brief on COVID-19 Vaccines and Vaccination](#), and ongoing outbreak investigations linked to the Delta variant.

Delta is currently [the predominant variant](#) of the virus in the United States. Below is a high-level summary of what CDC scientists have recently learned about the Delta variant. More information will be made available when more data are published or released in other formats.

Infections and Spread

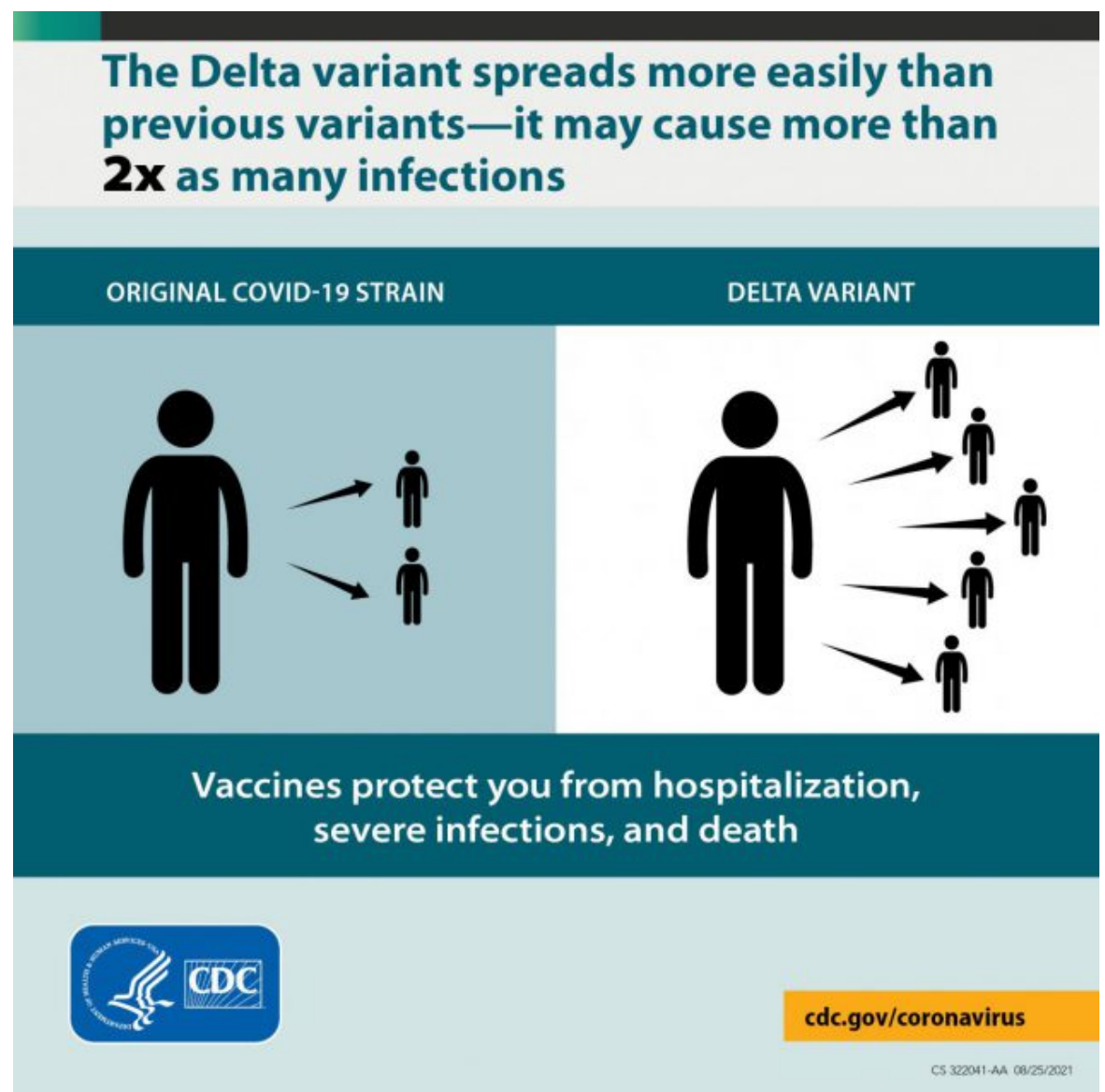
The Delta variant causes more infections and spreads faster than early forms of SARS-CoV-2, the virus that causes COVID-19

- **The Delta variant is more contagious:** The Delta variant is highly contagious, more than 2x as contagious as previous variants.
- **Some data suggest the Delta variant might cause more severe illness than previous variants in unvaccinated people.** In two different studies from Canada and Scotland, patients infected with the Delta variant were more likely to be hospitalized than patients infected with Alpha or the original virus that causes COVID-19. Even so, the vast majority of hospitalization and death caused by COVID-19 are in unvaccinated people.
- **Unvaccinated people remain the greatest concern:** The greatest risk of transmission is among unvaccinated people who are much more likely to get infected, and therefore transmit the virus. Fully vaccinated people get COVID-19 (known as [breakthrough infections](#)) less often than unvaccinated people. People infected with the Delta variant, including fully vaccinated people with symptomatic breakthrough infections, can transmit the virus to others. CDC is continuing to assess data on whether fully vaccinated people with asymptomatic breakthrough infections can transmit the virus.
- **Fully vaccinated people with Delta variant breakthrough infections can spread the virus to others. However, vaccinated people appear to spread the virus for a shorter time:** For prior variants, lower amounts of viral genetic material were found in samples taken from fully vaccinated people who had breakthrough infections than from unvaccinated people with COVID-19. For people infected with the Delta variant, similar amounts of viral genetic material have been found among both unvaccinated and fully vaccinated people. However, like prior variants, the amount of viral genetic material may go down faster in fully vaccinated people when compared to unvaccinated people. This means fully vaccinated people will likely spread the virus for less time than unvaccinated people.

Vaccines

Vaccines in the US are highly effective, including against the Delta variant

- The COVID-19 vaccines approved or authorized in the United States are highly effective at preventing severe disease and death, including against the Delta variant. But they are not 100% effective, and some fully vaccinated people will become infected (called a breakthrough infection) and experience illness. For all people, the vaccine provides the best protection against serious illness and death.
- Vaccines are playing a crucial role in limiting spread of the virus and minimizing severe disease. Although vaccines are highly effective, they are not perfect, and there will be vaccine breakthrough infections. Millions of Americans are vaccinated, and that number is growing. This means that even though the risk of breakthrough infections is low, there will be thousands of fully vaccinated people who become infected and able to infect others, especially with the surging spread of the Delta variant. [Low vaccination coverage](#) in many communities is driving the current rapid surge in cases involving the Delta variant, which also increases the chances that even more concerning variants could emerge.
- Vaccination is the best way to protect yourself, your family, and your community. High vaccination coverage will reduce spread of the virus and help prevent new variants from emerging. CDC recommends that everyone aged 12 years and older get vaccinated as soon as possible.



[View Larger](#)

Masks

Given what we know about the Delta variant, vaccine effectiveness, and current vaccine coverage, layered prevention strategies, including wearing masks, are needed to reduce the transmission of this variant

- At this time, as we build the level of vaccination nationwide, we must also use all the prevention strategies available, including masking indoors in public places, to stop transmission and stop the pandemic. Everyone who is able, including fully vaccinated people, should wear masks in public indoor places in areas of [substantial or high transmission](#).

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Last Updated Aug. 26, 2021



COVID-19

Omicron Variant: What You Need to Know

Updated Dec. 20, 2021



Free At-Home COVID-19 Tests: [Order 4 free tests now so you have them when you need them.](#) [↗](#)

Omicron in the United States

CDC is working with state and local public health officials to [monitor the spread of Omicron](#). As of December 20, 2021, Omicron has been detected in most states and territories and is rapidly increasing the proportion of COVID-19 cases it is causing.

Omicron Spread

CDC is monitoring the current surge of COVID-19 cases. Learn more about the Omicron variant and its expected impact on hospitalizations.

[COVID Data Tracker](#)[Hospitalization Forecast](#)

What We Know about Omicron

CDC has been collaborating with global public health and industry partners to learn about Omicron, as we continue to monitor its course. We don't yet know how easily it spreads, the severity of illness it causes, or how well available vaccines and medications work against it.

Spread

The Omicron variant likely will spread more easily than the original SARS-CoV-2 virus and how easily Omicron spreads compared to Delta remains unknown. CDC expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms.

Severe Illness

More data are needed to know if Omicron infections, and especially reinfections and breakthrough infections in people who are fully vaccinated, cause more severe illness or death than infection with other variants.

Vaccines

Current vaccines are expected to protect against severe illness, hospitalizations, and deaths due to infection with the Omicron variant. However, [breakthrough infections](#) in people who are fully vaccinated are likely to occur. With other variants, like Delta, vaccines have remained effective at preventing severe illness, hospitalizations, and death. The recent emergence of Omicron further emphasizes the importance of vaccination and boosters.

Treatments

Scientists are working to determine how well existing treatments for COVID-19 work. Based on the changed genetic make-up of Omicron, some treatments are likely to remain effective while others may be less effective.

We have the Tools to Fight Omicron

Vaccines

Vaccines remain the best public health measure to protect people from COVID-19, slow transmission, and reduce the likelihood of new variants emerging.

- COVID-19 vaccines are highly effective at preventing severe illness, hospitalizations, and death.
- Scientists are currently investigating Omicron, including how protected fully vaccinated people will be against infection, hospitalization, and death.
- CDC recommends that everyone 5 years and older protect themselves from COVID-19 by getting [fully vaccinated](#).
- CDC recommends that everyone ages 16 years and older get a [booster](#) shot after completing their primary COVID-19 vaccination series. You are eligible for a booster at 5 months after completing Pfizer-BioNTech primary series, 6 months after completing Moderna primary series, and 2 months after the initial J&J/Janssen vaccine. Individuals ages 16-17 are only eligible for the Pfizer-BioNTech COVID-19 vaccine.

Masks

Masks offer protection against all variants.

- CDC continues to recommend wearing a mask in public indoor settings in areas of substantial or high [community transmission](#), regardless of vaccination status.
- CDC provides [advice about masks](#) for people who want to learn more about what [type of mask](#) is right for them depending on their circumstances.

Testing

Tests can tell you if you are currently infected with COVID-19.

- Two types of tests are used to [test for current infection](#): nucleic acid amplification tests ([NAATs](#)) and [antigen tests](#). NAAT and antigen tests can only tell you if you have a current infection.
- Individuals can use the [COVID-19 Viral Testing Tool](#) to help determine what kind of test to seek.
 - Additional tests would be needed to determine if your infection was caused by Omicron.
 - Visit your [state](#), [tribal](#), local, or [territorial](#) health department's website to look for the latest local information on testing.
- [Self-tests](#) can be used at home or anywhere, are easy to use, and produce rapid results.
 - If your self-test has a positive result, stay home or isolate for 10 days, wear a mask if you have contact with others, and call your healthcare provider.
 - If you have any questions about your self-test result, call your healthcare provider or public health department.

Until we know more about the risk of Omicron, it is important to use **all tools available** to [protect yourself and others](#).

What CDC is Doing to Learn about Omicron

Virus Characteristics

CDC scientists are working with partners to gather data and virus samples that can be studied to answer important questions about the Omicron variant. Scientific experiments have already started. CDC will provide updates as soon as possible.

Variant Surveillance

In the United States, CDC uses [genomic surveillance](#) to track variants of SARS-CoV-2, the virus that causes COVID-19 to more quickly identify and act upon these findings to best protect the public’s health. CDC established multiple ways to connect and share genomic sequence data being produced by CDC, public health laboratories, and commercial diagnostic laboratories within publicly accessible databases maintained by the [National Center for Biotechnology Information](#) [↗](#) (NCBI) and the [Global Initiative on Sharing Avian Influenza Data](#) [↗](#) (GISAID). If a variant is circulating at 0.1% frequency, there is a >99% chance that it will be detected in CDC’s national genomic surveillance.



Science Brief: Omicron (B.1.1.529) Variant

On November 24, 2021, South Africa reported the identification of a new SARS-CoV-2 variant, B.1.1.529, to the World Health Organization (WHO). B.1.1.529 was first detected in specimens collected on November 11, 2021 in Botswana and on November 14, 2021 in South Africa.

[More on the Omicron \(B.1.1.529\) Variant](#)

Emergence of Omicron

CDC has been using [genomic surveillance](#) throughout the course of the pandemic to track variants of SARS-CoV-2, the virus that causes COVID-19, and inform public health practice.

- **November 24, 2021:** A new variant of [SARS-CoV-2](#), B.1.1.529, was reported to the World Health Organization (WHO). This new variant was first detected in specimens collected on November 11, 2021 in Botswana and on November 14, 2021 in South Africa.
- **November 26, 2021:** WHO named the B.1.1.529 Omicron and classified it as a Variant of Concern (VOC).
- **November 30, 2021:** The United States designated Omicron as a [Variant of Concern](#).
- **December 1, 2021:** The first confirmed U.S. case of Omicron was identified.

Related Pages

- › [Symptoms](#)
- › [Omicron Potential Spread](#)
- › [Omicron Data](#)
- › [About Variants](#)

Last Updated Dec. 20, 2021



December 10, 2021 / Infectious Disease

What To Know About the Omicron Variant

What we do – and don’t – know about the latest COVID-19 variant

As the COVID-19 pandemic stretches on, yet another variant to watch has emerged that’s causing apprehension as it spreads across the globe.

The omicron variant, also known as variant B.1.1.529, is considered a “variant of concern” by both the World Health Organization (WHO) and the Centers for Disease Control (CDC). First detected in South Africa in early November, the variant has spread to dozens of countries, including much of Europe and the United States.

There’s still a lot we don’t know about the omicron variant. But after the dominant spread of the delta variant this summer, experts are busy gathering as much information as possible. To get an idea of what we do know about the omicron variant and what’s next, we spoke with infectious disease specialist Kristin Englund, MD.

How is the omicron variant different from other variants?

The main difference between omicron and previous variants has to do with its mutations. “Omicron has 50 mutations in its genetic code, many more than we have seen on any other variant,” says Dr. Englund. “Thirty of these mutations affect the spike protein, which the vaccines currently available utilize.”

The delta variant caused alarm because it spread more easily than previous variants. So far, early data suggests that the omicron variant is even more contagious, says Dr. Englund. “But we don’t yet know if it causes more severe illness,” she says.

What’s still unknown about the omicron variant?

Experts around the world are still digging deep into data about the omicron variant to learn as much as they can, as quickly as they can. Besides the level of illness caused by omicron, scientists are looking into how all of those mutations affect the virus, says Dr. Englund.

Other questions that remain to be answered include:

- How much more easily is it to spread?
- Is it as deadly as previous mutations?
- Does it cause as many “long COVID-19” symptoms?
- Do symptoms differ compared with other variants?

As frustrating as the unanswered questions can be, it’s important to remember that research is unfolding in real-time since COVID-19 is caused by a new coronavirus. Experts continue to work quickly and diligently to uncover all they can as each new variant emerges.

Do current vaccines protect against the omicron variant?

Like everything else with the omicron variant, more research is needed for a clear-cut idea of how well current vaccines protect us against the new mutation. But, notes Dr. Englund, early data is promising.

“Early data from Pfizer seems to show that while the initial two-shot dose is less effective against the Omicron variant, the booster increased the antibodies in our immune systems 25-fold, and should offer much more protection,” she says.

There’s no word yet regarding how effective the Moderna or Johnson & Johnson vaccines are against the omicron variant, but research from those companies is ongoing. Dr. Englund adds that if the existing vaccines need to be updated, the wait won’t be a long one.

Companies that produce the vaccines are already looking into how the vaccines can be altered to fight omicron directly. “The mRNA technology is making it much easier to modify the vaccines more quickly,” Dr. Englund points out. “If needed, those companies feel they could have a new vaccine against a new variant within three to four months.

The bottom line: get vaccinated, stay vigilant

While the omicron variant gains attention as it continues to spread — and Dr. Englund says its spread is already probably well beyond what we currently know — it’s also important to worry about the variant that’s actually dominant right now. As of early December, the CDC reported that the delta variant was responsible for 99.8 to 99.9% of current COVID-19 cases in the United States.

“Omicron likely will spread rapidly but we must still stay vigilant of the variant that’s already here — the delta variant — and do all we can to protect ourselves and others,” she says. “The only way we can avoid further variants is to decrease the amount of virus, and that means getting vaccinated and getting your booster when it’s time.”

Besides protecting against variants, continuing to practice safe, proper guidelines will help to curb the ongoing mutations. “New variants will continue to develop as long as the

virus can make copies of itself and spread,” she says. “We need to be smarter than the virus and stop it with vaccines, social distancing, masking and proper hand hygiene.”



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CDC Updates and Shortens Recommended Isolation and Quarantine Period for General Population

Media Statement

For Immediate Release: Monday, December 27, 2021

Contact: [Media Relations](#)

(404) 639-3286

Given what we currently know about COVID-19 and the Omicron variant, CDC is shortening the recommended time for isolation for the public. People with COVID-19 should isolate for 5 days and if they are asymptomatic or their symptoms are resolving (without fever for 24 hours), follow that by 5 days of wearing a mask when around others to minimize the risk of infecting people they encounter. The change is motivated by science demonstrating that the majority of SARS-CoV-2 transmission occurs early in the course of illness, generally in the 1-2 days prior to onset of symptoms and the 2-3 days after.

Additionally, CDC is updating the recommended quarantine period for anyone in the general public who is [exposed to COVID-19](#). For people who are unvaccinated or are more than six months out from their second mRNA dose (or more than 2 months after the J&J vaccine) and not yet boosted, CDC now recommends quarantine for 5 days followed by strict mask use for an additional 5 days. Alternatively, if a 5-day quarantine is not feasible, it is imperative that an exposed person [wear a well-fitting mask](#) at all times when around others for 10 days after exposure. Individuals who have received their booster shot do not need to quarantine following an exposure, but should wear a mask for 10 days after the exposure. For all those exposed, best practice would also include a test for SARS-CoV-2 at day 5 after exposure. If symptoms occur, individuals should immediately quarantine until a negative test confirms symptoms are not attributable to COVID-19.

Isolation relates to behavior after a confirmed infection. Isolation for 5 days followed by wearing a well-fitting mask will minimize the risk of spreading the virus to others. Quarantine refers to the time following exposure to the virus or close contact with someone known to have COVID-19. Both updates come as the Omicron variant continues to spread throughout the U.S. and reflects the current science on when and for how long a person is maximally infectious. These recommendations do not supersede state, local, tribal, or territorial laws, rules, and regulations, nor do they apply to healthcare workers for whom CDC has [updated guidance](#).

Data from South Africa and the United Kingdom demonstrate that vaccine effectiveness against infection for two doses of an mRNA vaccine is approximately 35%. A COVID-19 vaccine booster dose restores vaccine effectiveness against infection to 75%. COVID-19 vaccination decreases the risk of severe disease, hospitalization, and death from COVID-19. CDC strongly encourages COVID-19 vaccination for everyone 5 and older and boosters for everyone 16 and older. Vaccination is the best way to protect yourself and reduce the impact of COVID-19 on our communities.

The following is attributable to CDC Director, Dr. Rochelle Walensky:

"The Omicron variant is spreading quickly and has the potential to impact all facets of our society. CDC's updated recommendations for isolation and quarantine balance what we know about the spread of the virus and the protection provided by vaccination and booster doses. These updates ensure people can safely continue their daily lives. Prevention is our best option: get vaccinated, get boosted, wear a mask in public indoor settings in areas of substantial and high community transmission, and take a test before you gather."

If You Test Positive for COVID-19 (Isolate)

Everyone, regardless of vaccination status.

- Stay home for 5 days.
- If you have no symptoms or your symptoms are resolving after 5 days, you can leave your house.
- Continue to wear a mask around others for 5 additional days.

If you have a fever, continue to stay home until your fever resolves.

If You Were Exposed to Someone with COVID-19 (Quarantine)

If you:

Have been boosted

OR

Completed the primary series of Pfizer or Moderna vaccine within the last 6 months

OR

Completed the primary series of J&J vaccine within the last 2 months

- Wear a mask around others for 10 days.
- Test on day 5, if possible.

If you develop symptoms get a test and stay home.

If you:

Completed the primary series of Pfizer or Moderna vaccine over 6 months ago and are not boosted

OR

Completed the primary series of J&J over 2 months ago and are not boosted

OR

Are unvaccinated

- Stay home for 5 days. After that continue to wear a mask around others for 5 additional days.
- If you can't quarantine you must wear a mask for 10 days.
- Test on day 5 if possible.

If you develop symptoms get a test and stay home

###

[U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES](#)

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

Page last reviewed: December 29, 2021



The Dow fell 1,000 points. See how it's doing now.

The highly contagious Omicron variant will 'find just about everybody,' Fauci says, but vaccinated people will still fare better

By Travis Caldwell, Jason Hanna, Deidre McPhillips and

Christina Maxouris, CNN

🕒 Updated 9:04 AM ET, Wed January 12, 2022

(CNN) — As the [Omicron variant](#) spreads like wildfire across the United States, it's likely just about everybody will be exposed to the strain, but vaccinated people [will still fare better](#), the nation's leading infectious disease expert said Tuesday.

"Omicron, with its extraordinary, unprecedented degree of efficiency of transmissibility, will ultimately find just about everybody," Dr. Anthony Fauci told J. Stephen Morrison, senior vice president of the Center for Strategic and International Studies. "Those who have been vaccinated ... and boosted would get exposed. Some, maybe a lot of them, will get infected but will very likely, with some exceptions, do reasonably well in the sense of not having hospitalization and death."

In contrast, those who are not vaccinated are "going to get the brunt of the severe aspect of this," he added.

Across the United States, at least one in five eligible Americans -- roughly 65 million people-- are not vaccinated against Covid-19. More than 62% of the country has been fully vaccinated, but only 23% are fully vaccinated and boosted, according to [data](#) from the US Centers for Disease Control and Prevention.

Fauci's comments came in response to a question about whether the pandemic has entered a new phase. That will come when there's enough protection in the community and drugs to easily treat severe Covid-19, he said, adding, "We may be on the threshold of that right now."

Related Article: Omicron devastates services, schools, travel as workers are sick or in quarantine

Also Tuesday, US Food and Drug Administration acting commissioner Dr. Janet Woodcock said that while most people could catch the virus, the focus now should be on making sure hospitals and essential services function.

Woodcock was responding to a question from Sen. Mike Braun about whether it's time for the United States to change its Covid-19 strategy. Her statement was not a new assessment of Covid-19, but rather an attempt to make clear the need to prioritize essential services as the Omicron variant surges.

"I think it's hard to process what's actually happening right now, which is: Most people are going to get Covid," Woodcock said Tuesday at a Senate Health, Education, Labor and Pensions Committee hearing. "And what we need to do is make sure the hospitals can still function, transportation, you know, other essential services are not disrupted while this happens."

On Tuesday, the number of US patients hospitalized with Covid-19 hit a record high, adding strain to health care networks and pushing states toward emergency staffing and other measures as they struggle to cope.



data from the Department of Health and Human Services.

The hospitalization record comes amid a surge in cases fueled by the highly transmissible [Omicron variant](#).

The United States averaged more than 754,200 new Covid-19 cases daily over the past week, according to Johns Hopkins University data. That's about three times last winter's peak average (251,987 on January 11, 2021), and 4.5 times the peak from the Delta-driven surge (166,347 on September 1), according to JHU.

The country has averaged 1,646 Covid-19 deaths a day over the past week -- 33% higher than a week ago, according to JHU. The peak average was 3,402 daily on January 13, 2021, JHU data shows.

The Omicron variant caused 98.3% of new coronavirus cases in the United States last week, according to [estimates posted Tuesday](#) by the US Centers for Disease Control and Prevention.

A technician administers a Covid-19 test Monday at a drive-thru location at Churchill Downs, Kentucky.

Leaders activate new measures to combat surging numbers

Hospitals are increasingly [juggling staffing issues](#) -- not just because of the increased demand, but also because their employees, who are at a high risk of infection, have to isolate and recover after testing positive.

In Virginia, Gov. Ralph Northam declared a limited state of emergency Monday after the number of intensive care unit hospitalizations more than doubled since December 1. The order allows hospitals to expand bed capacity and gives more flexibility in staffing, he said, adding that it also expands the use of telehealth as well as expanding which medical professionals can give vaccines.



statement to CNN.

Kentucky has mobilized the National Guard to provide support, with 445 members sent to 30 health care facilities, the state announced.

"Omicron continues to burn through the commonwealth, growing at levels we have never seen before. Omicron is significantly more contagious than even the Delta variant," said Kentucky Gov. Andy Beshear, noting the earlier variant that spurred a surge of cases in the summer and fall.

"If it spreads at the rate we are seeing, it is certainly going to fill up our hospitals," he said, and Kentucky is "down to 134 adult ICU beds available."

And New Jersey [reinstated](#) a public health emergency, Gov. Phil Murphy announced, saying the state needed to "commit every resource available to beating back the wave" caused by Omicron. In the past two weeks alone, the state saw more than 10,000 people requiring hospitalization due to Covid-19, the governor [said](#) in a video announcement.

Mitigation measures such as mandatory masking are also being revived in some areas.

Delaware Gov. John Carney signed a universal indoor mask mandate Monday because of hospitalization increases, with some hospitals "over 100% inpatient bed capacity amid crippling staffing shortages," he said. Churches and places of worship are exempt, while businesses should provide masks to customers and have signage about indoor mask requirements.

Related Article: How 10 parents of school-age kids are coping with Omicron, in their own words

"It's time for everyone to pitch in and do what works. Wear your mask indoors. Avoid gatherings or expect to get and spread Covid. Get your vaccine and, if eligible, get boosted. That's how we'll get through this surge without endangering more lives," Carney said.

Share of hospitalizations from breakthrough infections is growing, but risks for unvaccinated are higher

The HHS data on Covid-19 hospitalizations includes both those patients who are hospitalized because of Covid-19 complications and those who may have been admitted for something else but test positive for Covid-19. This has been true throughout the pandemic, though the share of patients who fall into each category may have changed over time.

Fully vaccinated people are accounting for a growing share of people hospitalized with Covid-19 -- but hospitalizations among people who received a booster shot are still rare, and the gap in risk by vaccination status has been wide.

Between April and July 2021, before the emergence of the Omicron variant, more than 90% of Covid-19 hospitalizations were among people who were either unvaccinated or partially vaccinated, according to a study published by the CDC.



starting Saturday

days and months:

- In Pennsylvania, about 75% of Covid-19 hospitalizations between September and early December 2021 were among people who were not fully vaccinated, according to data from the state health department.
- In New York, about 61% of Covid-19 hospitalizations during the week ending January 2, 2022 were among people who were not fully vaccinated, according to data from the state health department.
- Beaumont Health, the largest health care system in Michigan, reported on Thursday that 62% of Covid-19 patients in its eight hospitals were unvaccinated.

In some hospitals, up to 40% of patients with Covid-19 "are coming in not because they're sick with Covid, but because they're coming in with something else and have had Covid or the Omicron variant detected," CDC Director Dr. Rochelle Walensky told Fox News on Sunday.

But Covid-19 cases in hospitals strain resources, regardless of whether a patient was hospitalized because of Covid-19, CNN chief medical correspondent [Dr. Sanjay Gupta](#) said.

"If they get (incidentally) diagnosed with Covid in the hospital, they still need to go into infection protocol -- personal protective equipment, all of that still needs to be utilized. So it's a huge drain on the system overall," Gupta said Tuesday.

While fully vaccinated people are accounting for a larger share of Covid-19 hospitalizations, multiple accounts suggest that those who are fully vaccinated and boosted account for a small share.

In the University of Maryland Medical System, less than 5% of hospitalized patients were fully vaccinated and boosted, President and CEO Dr. Mohan Suntha said Thursday. Beaumont Health reported Thursday that only 8% of Covid-19 patients were fully vaccinated and boosted.

The CDC did not respond to CNN's multiple requests for data on the share of Covid-19 hospitalizations by vaccination status.

The agency publishes data on its website regarding the relative risk by vaccination status. Cumulatively, the risk of hospitalization has been eight times higher for unvaccinated people than for fully vaccinated people. But in the last week of November, CDC data showed that hospitalization rates were about 17 times higher for unvaccinated people than for fully vaccinated people.

Schools and industries face Omicron issues

The debate over safety in schools from Covid-19 continues to play out as only about one in six children ages 5 to 11 is fully vaccinated, [according to](#) data from the CDC.

As Los Angeles prepared to return to school on Tuesday, approximately 62,000 students and staff had tested positive for Covid-19 and will have to stay home, data from the Los Angeles Unified School District showed Monday, equating to a 14.99% positivity rate. The positivity rate of Los Angeles County at large, by comparison, has spiked to 22%.

In Chicago, educators returned to school Tuesday and students are expected to resume in-person learning Wednesday following a [nearly weeklong](#) dispute. The Chicago Teachers Union had voted to teach remotely last week, and the school district responded by canceling classes for four days.



levels.

In areas where [schools have returned](#) to in-person learning after the holiday break, the time needed for those with Covid-19 to recover has impacted some essential services.

Other sectors also are struggling due to high infection rates.

Some municipalities have seen nearly a quarter of their trash collection workforce call in sick in recent weeks due to Covid-19, leading to delays, according to the Solid Waste Association of North America.

"This coincided, unfortunately, with increased trash and recycling volumes associated with the holidays. However, we hope that as volumes decline and sanitation workers return to

Related Article: From Europe to the US, Covid cases in children are surging. Schools aren't prepared

work, these delays will prove temporary," executive director and CEO David Biderman said in a statement Monday.

In travel, US airlines canceled thousands of [additional flights](#) over the weekend due to Covid-19 callouts and winter storms, and cruise line Royal Caribbean International announced it has canceled voyages on four ships because of "ongoing Covid-related circumstances around the world." Last week, Norwegian Cruise Line [canceled the voyages](#) of eight ships.

Public transit systems in major metropolitan areas such as New York City and Washington, DC, have had to scale back service with employees ill from Covid-19. In Detroit, 20-25% of SMART bus service is canceled or delayed, the agency said in a statement Saturday.

CNN's Rosa Flores, Virginia Langmaid, Claudia Dominguez, David Shortell, Pete Muntean, Melissa Alonso, Hannah Sarisohn, Cheri Mossburg and Jenn Selva contributed to this report.



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SARS-CoV-2 Infection and Hospitalization Among Adults Aged ≥ 18 Years, by Vaccination Status, Before and During SARS-CoV-2 B.1.1.529 (Omicron) Variant Predominance — Los Angeles County, California, November 7, 2021–January 8, 2022

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On February 1, 2022, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

COVID-19 vaccines are effective at preventing infection with SARS-CoV-2, the virus that causes COVID-19, as well as severe COVID-19–associated outcomes in real-world conditions (1,2). The risks for SARS-CoV-2 infection and COVID-19–associated hospitalization are lower among fully vaccinated than among unvaccinated persons; this reduction is even more pronounced among those who have received additional or booster doses (boosters) (3,4). Although the B.1.1.529 (Omicron) variant spreads more rapidly than did earlier SARS-CoV-2 variants, recent studies suggest that disease severity is lower for Omicron compared with that associated with the B.1.617.2 (Delta) variant; but the high volume of infections is straining the health care system more than did previous waves (5).^{*,†} The Los Angeles County (LAC) Department of Public Health (LACDPH) used COVID-19 surveillance and California Immunization Registry 2 (CAIR2) data to describe age-adjusted 14-day cumulative incidence and hospitalization rates during November 7, 2021–January 8, 2022, by COVID-19 vaccination status and variant predominance. For the 14-day period ending December 11, 2021, the last week of Delta predominance, the incidence and hospitalization rates among unvaccinated persons were 12.3 and 83.0 times, respectively, those of fully vaccinated persons with a booster and 3.8 and 12.9 times, respectively, those of fully vaccinated persons without a booster. These rate ratios were lower during Omicron predominance (week ending January 8, 2022), with unvaccinated persons having infection and hospitalization rates 3.6 and 23.0 times, respectively, those of fully vaccinated persons with a booster and 2.0 and 5.3 times, respectively, those of fully vaccinated persons without a booster. In addition, during the entire analytic period, admission to intensive care units (ICUs), intubation for mechanical ventilation, and death were more likely to occur among unvaccinated persons than among fully vaccinated persons without or with a booster ($p < 0.001$). Incidence and hospitalization rates were consistently highest for unvaccinated persons and lowest for fully vaccinated persons with a booster. Being up to date with COVID-19 vaccination is

critical to protecting against SARS-CoV-2 infection and associated hospitalization.

LACDPH conducted a cross-sectional analysis of LAC residents aged ≥ 18 years with laboratory-confirmed SARS-CoV-2 infection (a positive SARS-CoV-2 result from a nucleic acid amplification or antigen test) during November 7, 2021–January 8, 2022.[§] Persons were considered fully vaccinated ≥ 14 days after receipt of the final dose in the primary series of a BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), or Ad.26.COV2.S (Janssen [Johnson & Johnson]) vaccine and considered unvaccinated if < 14 days had elapsed since receipt of the first dose in the primary series of an mRNA or Janssen vaccine or if no matching immunization record was found in CAIR2.[¶] Fully vaccinated persons who received a booster were considered fully vaccinated with a booster ≥ 14 days after the date of the booster.^{**} Infections occurring in partially vaccinated persons (persons who had received the first dose in a 2-dose series > 14 days earlier, but who were either missing a second dose or < 14 days had elapsed since receipt of the second dose) were excluded because of small sample size.^{††} COVID-19–associated hospitalizations were

[§] The population of Los Angeles County residents is based on 2019 population estimates prepared for Los Angeles County Internal Services Department. These population estimates exclude the populations of Pasadena and Long Beach, which have independent public health departments.

[¶] Vaccination status was determined using a deterministic and probabilistic matching algorithm to link cases with immunization records in CAIR2 and followed CDC guidelines. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>

^{**} CDC recommends that persons aged ≥ 5 years who are moderately or severely immunocompromised receive a third dose of an mRNA COVID-19 vaccine 28 days after completion of the primary series to enhance the likelihood of mounting an adequate immune response. A booster is recommended for persons aged ≥ 12 years to protect against waning of vaccine-induced immunity. Recommendations for booster timing and vaccine manufacturer differs by age group and vaccine product received during the primary series (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>). This analysis does not distinguish between fully vaccinated persons who are immunocompromised and received a booster and fully vaccinated persons who are not immunocompromised and received a booster.

^{††} Partially vaccinated persons were those who had received the first dose in a 2-dose series ≥ 14 days earlier, but who were either missing a second dose or < 14 days had elapsed since receipt of the second dose. Recipients of the Janssen vaccine < 14 days earlier were considered unvaccinated. Partially vaccinated persons accounted for 4% of the sample (18,988). It was also not possible to differentiate between persons who received 1 dose in a 2-dose series (Pfizer-BioNTech or Moderna vaccines) and persons who were misclassified because of missing data.

^{*} <https://www.medrxiv.org/content/10.1101/2021.12.30.21268495v1>

[†] <https://www.medrxiv.org/content/10.1101/2022.01.07.22268919v2>

defined as hospital admissions occurring ≤ 14 days after the first laboratory-confirmed positive SARS-CoV-2 test result (6). Whole genome sequencing data from laboratories conducting routine genomic surveillance for LAC were used to calculate weekly variant proportions.^{§§} All available variant data were reported by date of specimen collection and used to assess periods of predominance ($>50\%$ of sequenced specimens) for the Delta and Omicron variants.

Demographic and clinical characteristics of SARS-CoV-2 infections were compared by vaccination status using Pearson's chi-square tests for categorical variables and Kruskal-Wallis tests for medians. P-values <0.05 were considered statistically significant. Age-adjusted rolling 14-day SARS-CoV-2 infection and hospitalization rates and rate ratios among LAC residents aged ≥ 18 years were estimated by vaccination status using 2019 population estimates and standardized using the year 2000 U.S. standard population.^{¶¶} Analyses were conducted using SAS (version 9.4; SAS Institute) and R (version 3.6.2; R Foundation). This activity was determined by LACDPH's Institutional Review Board to be a surveillance activity necessary for public health work and therefore did not require Institutional Review Board review.

From mid-August 2021 until the emergence of Omicron in November 2021, nearly 100% of SARS-CoV-2 infections among LAC residents with sequenced specimens were caused by the Delta variant. The earliest known Omicron variant infection in LAC was identified in a specimen collected during the final week of November 2021. As Omicron emerged in LAC, Delta prevalence decreased 95% during the week ending December 11. Omicron became the predominant SARS-CoV-2 variant in LAC during the week ending December 18, accounting for 57% of all sequenced specimens; Omicron prevalence continued to increase, accounting for 99% of all sequenced specimens for the week ending January 8, 2022 (Supplementary Figure, <https://stacks.cdc.gov/view/cdc/113859>).

^{§§} Whole genome sequencing lineage data were from all sequencing results reported to LACDPH or sequenced after specimens were referred to LACDPH laboratories. Additional variant data were available for specimens sequenced for enhanced Omicron variant surveillance. During the Delta predominant period, sequencing data were available for 20%–25% of SARS-CoV-2 specimens. As infections increased during the Omicron predominant period, capacity for whole genome sequencing did not increase proportionally; sequencing data were available for 1%–18% of SARS-CoV-2 specimens.

^{¶¶} Adjusted rates were calculated using methods documented by CDC (https://www.cdc.gov/cancer/uscs/technical_notes/stat_methods/rates.htm). A continuity correction was applied to estimates of the unvaccinated population to ensure that $\geq 5\%$ of the population remains unvaccinated using the methods outlined elsewhere (<https://kingcounty.gov/depts/health/covid-19/data/-/media/depts/health/communicable-diseases/documents/C19/calculation-method-technical-appendix.ashx>). Adjusted rate ratios were calculated as the cumulative incidence among unvaccinated persons divided by the cumulative incidence among those fully vaccinated with or without booster.

Among 422,966 reported SARS-CoV-2 infections in LAC residents aged ≥ 18 years during November 7, 2021–January 8, 2022, a total of 141,928 (33.6%) were in unvaccinated persons, 56,185 (13.3%) were in fully vaccinated persons with a booster, and 224,853 (53.2%) were in fully vaccinated persons without a booster (Table). Unvaccinated persons were most likely to be hospitalized (2.8%), admitted to an ICU (0.5%), and require intubation for mechanical ventilation (0.2%); these outcomes were less common in fully vaccinated persons with a booster (0.7%, 0.08%, and 0.03%, respectively) and fully vaccinated persons without a booster (1.0%, 0.12%, and 0.05%, respectively) ($p<0.001$). Deaths were also more likely to occur among unvaccinated persons (0.3%) than among fully vaccinated persons with a booster (0.07%) or without (0.08%) ($p<0.001$).

During the last week of Delta predominance (week ending December 11), age-adjusted 14-day cumulative incidence and hospitalization rates were highest among unvaccinated persons (443.9 and 45.9 per 100,000 persons, respectively), and lower among fully vaccinated persons with a booster (36.1 and 0.6, respectively) and fully vaccinated persons without a booster (115.9 and 3.6, respectively). As Omicron became predominant, age-adjusted incidence and hospitalization rates increased in all groups, irrespective of vaccination status, compared with rates during the Delta predominant period (Figure 1). As of January 8, 2022, age-adjusted 14-day cumulative incidence and hospitalization rates remained highest among unvaccinated persons (6,743.5 and 187.8 per 100,000, respectively), and lowest among fully vaccinated persons with a booster (1,889.0 and 8.2, respectively) and fully vaccinated persons without a booster (3,355.5 and 35.4, respectively).

Overall, during November 7, 2021–January 8, 2022, incidence and hospitalization rates were highest among unvaccinated persons. During the last week of Delta predominance, compared with fully vaccinated persons with a booster, incidence and hospitalization rates among unvaccinated persons were 12.3 and 83.0 times higher, respectively (Figure 2), and compared with rates for fully vaccinated persons without a booster, incidence and hospitalization rates among unvaccinated persons were 3.8 and 12.9 times higher, respectively. As of January 8, 2022, during Omicron predominance, these rate ratios were lower for both comparisons, with infection and hospitalization rates among unvaccinated persons 3.6 times and 23.0 times, respectively, those in fully vaccinated persons with a booster, and 2.0 and 5.3 times, respectively, those in fully vaccinated persons without a booster.

Discussion

During November 7, 2021–January 8, 2022, SARS-CoV-2 infections increased rapidly among LAC adults with the largest

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TABLE. Selected characteristics of cases of SARS-CoV-2 infection in residents aged ≥18 years (N = 422,966), by vaccination status — Los Angeles County, California, November 7, 2021–January 8, 2022^{*,†}

Characteristic	Vaccination status, no. (column %)		
	Unvaccinated	Fully vaccinated without booster	Fully vaccinated with booster
Total no. of cases (row %)	141,928 (33.6)	224,853 (53.2)	56,185 (13.3)
Median age, yrs (IQR)	35 (27–48)	36 (27–49)	46 (33–59)
18–29	48,940 (34.5)	74,352 (33.1)	9,523 (16.9)
30–49	61,380 (43.2)	97,771 (43.5)	22,649 (40.3)
50–64	22,338 (15.7)	40,680 (18.1)	14,580 (25.9)
65–79	7,253 (5.1)	9,796 (4.4)	7,960 (14.2)
≥80	2,017 (1.4)	2,254 (1.0)	1,473 (2.6)
Sex			
Women	69,382 (48.9)	123,927 (55.1)	30,864 (54.9)
Men	66,163 (46.6)	94,258 (41.9)	23,713 (42.2)
Other or unknown	6,383 (4.5)	6,668 (3)	1,608 (2.8)
Race/Ethnicity[§]			
American Indian or Alaska Native	342 (0.2)	426 (0.1)	104 (0.2)
Asian	7,451 (5.2)	18,043 (8.0)	8,341 (14.8)
Black or African American	12,319 (8.7)	13,359 (5.9)	2,632 (4.6)
Hispanic or Latino	42,973 (30.3)	79,198 (35.2)	14,023 (25.0)
Multiple race	494 (0.3)	968 (0.4)	210 (0.3)
Native Hawaiian or Other Pacific Islander	1,429 (1.0)	1,740 (0.7)	608 (1.0)
Other	18,720 (13.2)	32,552 (14.5)	6,808 (12.1)
White	20,529 (14.5)	34,108 (15.2)	12,504 (22.3)
Missing	37,671 (26.5)	44,459 (19.8)	10,955 (19.5)
Previously documented SARS-CoV-2 infection	12,360 (8.7)	22,153 (9.9)	3,246 (5.8)
Hospitalized	3,989 (2.8)	2,295 (1.0)	413 (0.7)
Admitted to an intensive care unit	641 (0.5)	276 (0.12)	47 (0.08)
Required mechanical ventilation	256 (0.2)	116 (0.05)	15 (0.03)
Died	485 (0.3)	172 (0.08)	40 (0.07)
Vaccine manufacturer[¶]			
Johnson & Johnson	—	18,543 (8.2)	4,869 (8.7)
Moderna	—	82,435 (36.7)	19,742 (35.1)
Pfizer-BioNTech	—	123,875 (55.1)	31,574 (56.2)
Median interval between final vaccine dose and infection, days (IQR)**	—	241 (200–271)	49 (31–70)
Sequencing result available	7,087 (5.0)	9,663 (4.3)	1,296 (2.3)
Sequencing result			
Delta	3,817 (53.9)	3,471 (35.9)	128 (9.9)
Omicron	3,248 (45.8)	6,180 (64.0)	1,164 (89.8)
Other	22 (0.3)	12 (0.1)	4 (0.3)

* Partially vaccinated persons were excluded from this analysis.

† A Pearson's chi-square test was conducted for categorical variables and Kruskal-Wallis test for medians; $p < 0.001$.

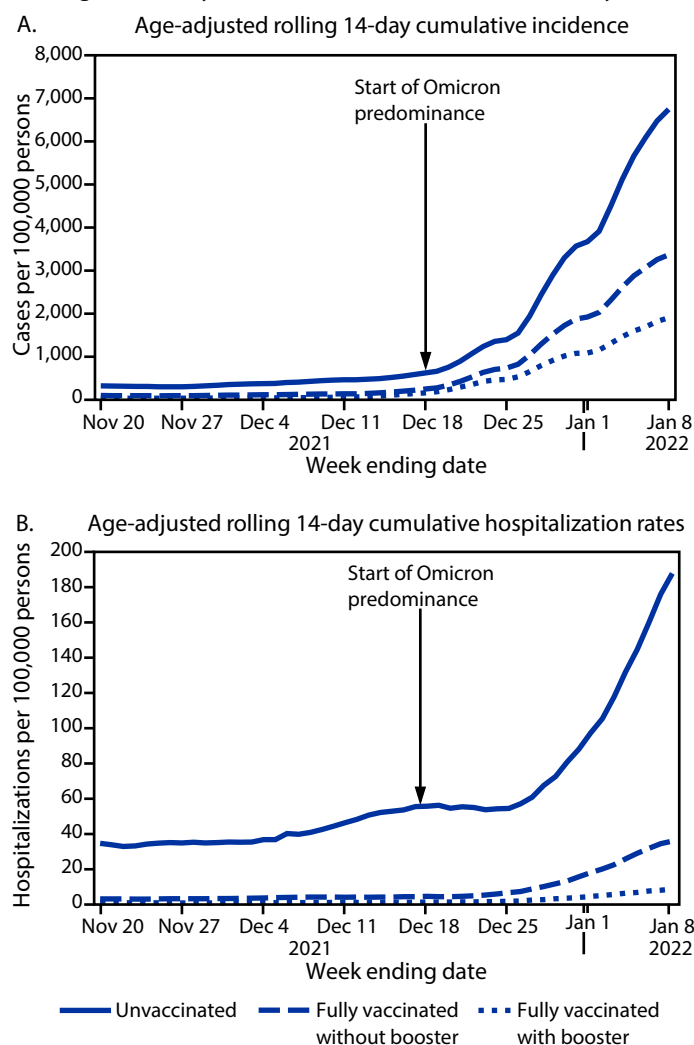
§ Race and ethnicity were defined as mutually exclusive categories. Hispanic or Latino includes all persons with ethnicity reported as "Hispanic or Latino" regardless of reported race. "Other" Race/Ethnicity includes persons of multiple races, and persons for whom reported race was "Other." Missing values were included in statistical testing.

¶ The primary vaccine series was used to categorize persons by vaccine manufacturer type regardless of which vaccine manufacturer was received for the booster dose.

** Infection date refers to the earliest of either the date of symptom onset, diagnosis, death, report received, or specimen collection.

increase occurring as Omicron displaced Delta as the predominant circulating variant, leading to decreased incidence and hospitalization rate ratios among unvaccinated persons relative to vaccinated persons with and without a booster. Whereas incidence and hospitalization rates were higher during the Omicron-predominant weeks compared with those during Delta predominance, rate ratios indicated continued protection conferred by vaccine against severe disease, especially

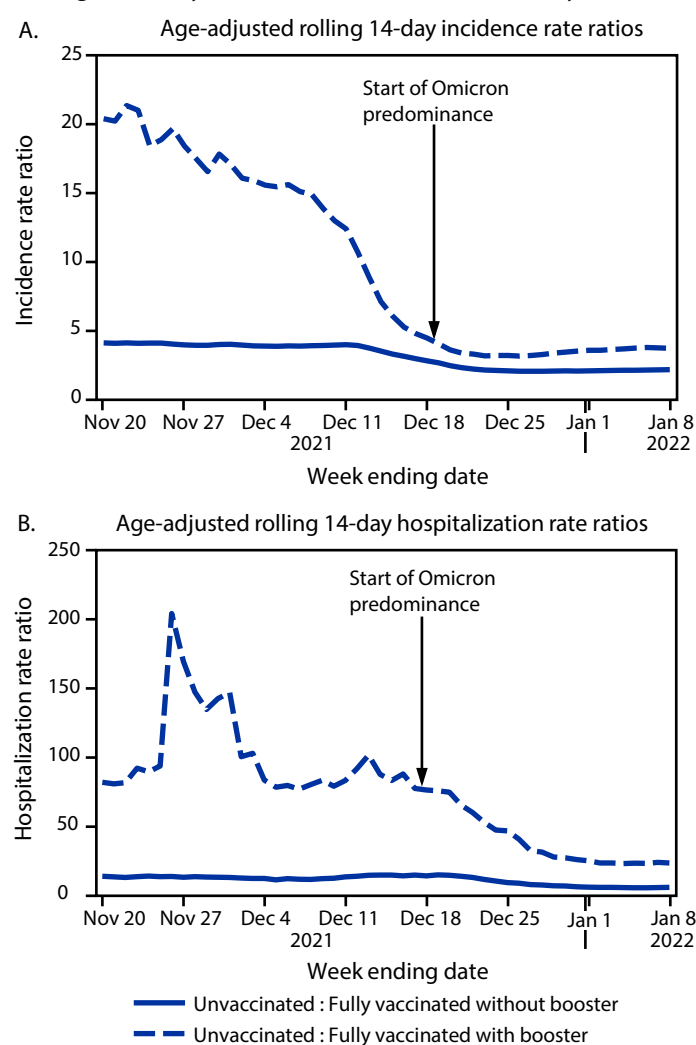
among those who had received a booster, although reduced for Omicron compared with Delta. All incidence and hospitalization rate ratios exceeded 1, regardless of predominant variant, indicating that the risks were consistently highest for unvaccinated persons and that COVID-19 vaccines were protective against SARS-CoV-2 infection and COVID-19–associated hospitalization among fully vaccinated persons, and most protective among those with a booster.

FIGURE 1. Age-adjusted rolling 14-day SARS-CoV-2 cumulative incidence* (A) and hospitalization rates (B), by vaccination status — Los Angeles County, California, November 7, 2021–January 8, 2022

* Rates were estimated using 2019 population estimates and standardized using the year 2000 standard population.

Although disease severity appears to be lower for Omicron, a rapid increase in infections during Omicron predominance has resulted in a relatively substantial volume of hospitalizations (5). The high volume of hospitalizations during a surge can compound the effects of staffing shortages and staff member burnout, which puts a strain on the health care sector. The rise in hospitalization rates in LAC was most pronounced among unvaccinated persons, whereas hospitalization rates remained lower among those who were fully vaccinated, and lowest among those who had received a booster. Being up to date with COVID-19 vaccinations is a critical component of reducing the strain on health care facilities.

The findings in this report are subject to at least five limitations. First, vaccination data for persons who lived in

FIGURE 2. Age-adjusted rolling 14-day SARS-CoV-2-associated incidence rate ratios* (A) and hospitalization rate ratios (B), by vaccination status — Los Angeles County, California, November 7, 2021–January 8, 2022

* Rate ratios were estimated by comparing rates in unvaccinated persons with those in vaccinated persons with and without a booster dose, using 2019 population estimates and standardized using the year 2000 standard population.

LAC at the time of their laboratory-confirmed infection, but who were vaccinated outside of California, were unavailable, leading to misclassification of their vaccination status; if vaccinated persons without accessible records were considered unvaccinated, the incidence in unvaccinated persons could be underestimated. Some boosters might have been misclassified as first doses, and the persons receiving these might have been incorrectly classified as partially vaccinated and excluded. Second, aside from age adjustment, it was not possible to control for other factors that are associated with vaccine coverage, such as sex and race/ethnicity. Differences in vaccination and booster coverage by these characteristics, especially if proportionally different from that of SARS-CoV-2 infections, could affect

Summary**What is already known about this topic?**

COVID-19 vaccines are highly effective against severe SARS-CoV-2–associated outcomes, including those caused by the Delta variant.

What is added by this report?

As of January 8, 2022, during Omicron predominance, COVID-19 incidence and hospitalization rates in Los Angeles County among unvaccinated persons were 3.6 and 23.0 times, respectively, those of fully vaccinated persons with a booster, and 2.0 and 5.3 times, respectively, those among fully vaccinated persons without a booster. During both Delta and Omicron predominance, incidence and hospitalization rates were highest among unvaccinated persons and lowest among vaccinated persons with a booster.

What are the implications for public health practice?

Being up to date with COVID-19 vaccination is critical to protecting against SARS-CoV-2 infection and hospitalization.

generalizability of these results to LAC and other populations or jurisdictions. Third, the risks for SARS-CoV-2 infection are not equal for everyone; the likelihood of exposure might influence the likelihood of COVID-19 vaccine acceptance and coverage. External risk factors related to the possibility of infection and hospitalization, such as sample characteristics and social determinants of health, are important to consider when interpreting these findings. Fourth, COVID-19–associated hospitalizations were determined based on hospital admission and SARS-CoV-2 test dates alone, potentially leading to the inclusion of incidental positive SARS-CoV-2 test results in patients whose hospitalizations were not caused by COVID-19. Finally, genomic sequencing data were available for only a sample of SARS-CoV-2 specimens and not representative of all infections; however, the variant predominance trends were consistent with what has been reported nationally during these periods.

These findings align with those from recent studies, indicating that COVID-19 vaccination protects against severe COVID-19 caused by SARS-CoV-2 variants, including Omicron (7,8).*** Efforts to promote COVID-19 vaccination and boosters are critical to preventing COVID-19–associated hospitalizations and severe outcomes. Ongoing COVID-19

surveillance with data linkages to vaccination and SARS-CoV-2 variant genomic sequencing data are critical for monitoring vaccine effectiveness and increased protection from boosters, particularly during the Omicron predominant period.

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COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence — 25 U.S. Jurisdictions, April 4–December 25, 2021

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Previous reports of COVID-19 case, hospitalization, and death rates by vaccination status[†] indicate that vaccine protection against infection, as well as serious COVID-19 illness for some groups, declined with the emergence of the B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, and waning of vaccine-induced immunity (1–4). During August–November 2021, CDC recommended[§] additional primary COVID-19 vaccine doses among immunocompromised persons and booster doses among persons aged ≥18 years (5). The SARS-CoV-2 B.1.1.529 (Omicron) variant emerged in the United States during December 2021 (6) and by December 25 accounted for 72% of sequenced

lineages (7). To assess the impact of full vaccination with additional and booster doses (booster doses),[¶] case and death rates and incidence rate ratios (IRRs) were estimated among unvaccinated and fully vaccinated adults by receipt of booster doses during pre-Delta (April–May 2021), Delta emergence (June 2021), Delta predominance (July–November 2021), and Omicron emergence (December 2021) periods in the United States. During 2021, averaged weekly, age-standardized case IRRs among unvaccinated persons compared with fully vaccinated persons decreased from 13.9 pre-Delta to 8.7 as Delta emerged, and to 5.1 during the period of Delta predominance. During October–November, unvaccinated persons had 13.9 and 53.2 times the risks for infection and COVID-19–associated death, respectively, compared with fully vaccinated persons who received booster doses, and 4.0 and 12.7 times the risks

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† A COVID-19 case in a fully vaccinated person occurred when SARS-CoV-2 RNA or antigen was detected in a respiratory specimen collected ≥14 days after completing the primary series of a COVID-19 vaccine with Food and Drug Administration (FDA) approval or emergency use authorization. The COVID-19 case definition, including criteria to distinguish a new case from an existing case, is per the July 2021 update to the national standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID-19) (21-ID-01) (<https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/>). Fully vaccinated persons were those with a completed primary series of 2 doses of the Pfizer-BioNTech or Moderna mRNA vaccine or a single dose of the Janssen vaccine (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>). A COVID-19 case in an unvaccinated person occurred when the person did not receive any FDA-authorized COVID-19 vaccine doses before the specimen collection date. Cases were excluded in partially vaccinated persons who received at least one FDA-authorized or approved vaccine dose but did not complete a primary series ≥14 days before collection of a respiratory specimen with SARS-CoV-2 RNA or antigen detected. Ascertaining vaccination status for COVID-19 patients through active linkage of case surveillance and immunization information systems typically assumes that cases among persons who are unmatched to the registry are unvaccinated. This analysis represents the combined impact of the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines, which had different clinical efficacies against confirmed infection. Information on different FDA-authorized and approved COVID-19 vaccine products, including clinical efficacy, is available online. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>

§ On August 13, 2021, CDC recommended an additional Pfizer-BioNTech or Moderna primary series dose for persons moderately or severely immunocompromised (<https://www.cdc.gov/media/releases/2021/s0813-additional-mrna-mrna-dose.html>). On September 24, 2021, CDC recommended a Pfizer-BioNTech booster dose for certain Pfizer-BioNTech primary series recipients, including all adults aged ≥65 years and persons aged ≥18 years in certain populations and high risk occupational and institutional settings (<https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations.html>). On October 21, 2021, CDC recommended a booster dose for adults aged ≥18 years who had received the Janssen vaccine and for Pfizer-BioNTech or Moderna primary series vaccine recipients, including all adults aged ≥65 years and persons aged ≥18 years in certain populations and high risk occupational and institutional settings (<https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html>). On November 19, 2021, and November 29, 2021, CDC expanded recommendations for booster doses to include all adults aged ≥18 years (<https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html>, <https://www.cdc.gov/media/releases/2021/s1129-booster-recommendations.html>).

¶ A COVID-19 case in a fully vaccinated person with a booster dose occurred when a person had SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after receipt of at least 1 additional or booster dose of any COVID-19 vaccine on or after August 13, 2021 (this definition does not distinguish between vaccine recipients who are immunocompromised and are receiving an additional dose versus those who are not immunocompromised and receiving a booster dose).

compared with fully vaccinated persons without booster doses. When the Omicron variant emerged during December 2021, case IRRs decreased to 4.9 for fully vaccinated persons with booster doses and 2.8 for those without booster doses, relative to October–November 2021. The highest impact of booster doses against infection and death compared with full vaccination without booster doses was recorded among persons aged 50–64 and ≥65 years. Eligible persons should stay up to date with COVID-19 vaccinations.

Weekly COVID-19 cases (April 4–December 25, 2021) and associated deaths (April 4–December 4, 2021) by vaccination status, including additional and booster doses starting October 3, were reported from 25 state and local health departments that routinely link case surveillance to vaccination data from immunization registries; 2- and 5-week reporting lag times for cases and deaths, respectively, allowed for more complete reporting, data linkage, and mortality ascertainment. Standardized definitions were used for COVID-19 cases in fully vaccinated or unvaccinated persons, COVID-19 cases in fully vaccinated persons with booster doses, and COVID-19–associated deaths,** with specimen collection dates used as time points. Partially vaccinated persons were excluded; reinfections occurring after >90 days were counted as new cases, per current guidance. Analysis periods were determined based on variant proportion estimates in the United States.†† Age-specific vaccine administration data were used for incidence rate denominators; numbers of unvaccinated persons were estimated by subtracting the numbers of fully and partially vaccinated persons from 2019 U.S. intercensal population estimates.§§ A continuity correction assumed at ≥5% of each age group and jurisdiction would always be unvaccinated (i.e., fully vaccinated coverage ≤95%). Average weekly incidences were calculated by age group (18–49, 50–64, and ≥65 years), vaccination status, and primary series vaccine product (Ad.26.COV2.S [Janssen

[Johnson & Johnson]], BNT162b2 [Pfizer-BioNTech], and mRNA-1273 [Moderna]) during each period; rates overall and by vaccine product were age-standardized using the 2000 U.S. Census standard population.¶¶ IRRs were calculated by dividing incidence among unvaccinated persons by incidence among fully vaccinated persons (overall and by receipt of booster doses); after detrending the underlying linear changes in incidence, 95% CIs were calculated based on the remaining variation in observed weekly rates (8,9). To interpret IRR changes, age-standardized crude vaccine effectiveness (VE) was estimated as $(1 - [\text{incidence in vaccinated} / \text{incidence in unvaccinated}])$. SAS (version 9.4; SAS Institute) and R (version 4.1.0; R Foundation) were used to conduct all analyses. This activity was conducted consistent with applicable federal law and CDC policy.***

During April 4–December 25, 2021, a total of 6,812,040 COVID-19 cases among unvaccinated persons and 2,866,517 cases among fully vaccinated persons were reported among persons aged ≥18 years in 25 U.S. jurisdictions; 94,640 and 22,567 COVID-19–associated deaths among unvaccinated and fully vaccinated persons, respectively, were reported by December 4 (Table 1). Average weekly, age-standardized rates of cases and deaths (events per 100,000 population) were higher during periods of Delta predominance and Omicron emergence than during pre-Delta and Delta emergence periods and were consistently higher in all periods among unvaccinated persons (range = 64.0–725.6 [cases] and 1.5–11.4 [deaths]) than among fully vaccinated persons (range = 7.4–230.9 and 0.1–0.7).

The age-standardized IRR for cases in unvaccinated versus fully vaccinated persons was 13.9 during April–May and progressively declined to 8.7 during June, 5.1 during July–November, and 3.1 during December, coinciding with the periods of Delta emergence, Delta predominance, and Omicron emergence, respectively. This decline suggests a change in crude VE for infection from 93% during April–May, to 89% during June, 80% during July–November, and to 68% during December. Age-standardized IRRs for deaths among unvaccinated versus fully vaccinated persons were relatively stable; crude VE for deaths was 95% during April–May, 94% during June, and 94% during July–November.

Rates of COVID-19 cases were lowest among fully vaccinated persons with a booster dose, compared with fully vaccinated persons without a booster dose, and much lower than rates among unvaccinated persons during October–November (25.0, 87.7, and 347.8 per 100,000 population, respectively) and December 2021 (148.6, 254.8, and 725.6 per 100,000 population, respectively) (Table 2). Similar trends

** A COVID-19–associated death occurred in a person with a documented COVID-19 diagnosis who died, and whose report local health authorities reviewed (e.g., using vital records, public health investigation, or other data sources) to make that determination. Per national guidance, this group should include persons whose death certificate lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or as a significant condition contributing to death (https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/20211222_interim-guidance.pdf). Rates of COVID-19 deaths by vaccination status are reported based on when the patient was tested for COVID-19, not the date the patient died.

†† National weighted estimates of the proportions of infections attributed to SARS-CoV-2 variants by week are based on analyses of whole-genome sequencing results submitted to or performed by CDC (<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>). Analysis periods were categorized as April 4–May 29, 2021 (pre-Delta: 0.1%–7% proportion range), May 30–July 3, 2021 (Delta emergence: 14%–69%), July 4–November 27, 2021 (Delta predominance: 81%–99%), and November 28–December 25, 2021, (Omicron emergence: 1%–72%). Other lineages in the analysis period before the Delta transition included Alpha (>50%), Gamma, Epsilon, Iota, Mu, and other lineages.

§§ <https://www.census.gov/programs-surveys/popest/data/tables/2019.html>

¶¶ <https://www.cdc.gov/nchs/data/statnt/statnt20.pdf>

*** 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect.241(d); 5 U.S.C.0 Sect.552a; 44 U.S.C. Sect. 3501 et seq.

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were noted for differences in the mortality rates among these three groups (0.1, 0.6, and 7.8 per 100,000 population, respectively) during October–November. Age-standardized case IRRs among unvaccinated persons compared with fully vaccinated persons with a booster dose declined from 13.9 during October–November to 4.9 during December, representing potential decreases in crude VE for infection from 93% to 80%, respectively. Comparing unvaccinated persons with fully vaccinated persons without a booster dose, age-standardized case IRRs during October–November and December were 4.0 and 2.8 respectively, representing decreases in VE from 75% to 64%. During October–November, age-standardized IRRs for deaths among unvaccinated persons were 53.2 compared with those in fully vaccinated persons with a booster dose and 12.7 compared with persons without a booster dose; these results represented crude VE against death of 98% and 92%, respectively. Protection improved among persons who received

a booster dose compared with not receiving a booster, regardless of primary series vaccine product type. Booster doses provided the largest gains in protection among persons aged ≥ 65 years followed by persons aged 50–64 years when compared with those aged 18–49 years.

Peaks in age-standardized case and death rates occurred during August ($>95\%$ of infections attributed to the Delta variant); case rates also peaked during the 2 weeks ending December 18 and 25 (39% and 72% infections attributed to the Omicron variant, respectively) (Figure). IRRs during the pre-Delta period and period of Delta predominance periods were relatively stable, followed by declines corresponding to transitions in variant prevalence (Supplementary Figure, <https://stacks.cdc.gov/view/cdc/113543>). Differences in case rates between fully vaccinated persons with and without a booster dose decreased over time; however, more protection was afforded from booster doses, even during Omicron emergence.

TABLE 1. Average weekly age-standardized incidence of COVID-19 cases (April 4–December 25, 2021) and associated deaths (April 4–December 4, 2021) and incidence rate ratios* for unvaccinated and fully vaccinated persons,[†] by period[§] — 25 U.S. jurisdictions,[¶] April–December 2021

	Unvaccinated persons		Fully vaccinated persons		
Event/Variant emergence/ Predominance period [§]	Total no.	Average weekly incidence*	Total no.	Average weekly incidence*	Average weekly IRR (95% CI)**
COVID-19 cases					
Pre-Delta (April–May 2021)	1,006,686	163.8	48,111	11.8	13.9 (12.4–15.5)
Delta emergence (June 2021)	196,988	64.0	30,317	7.4	8.7 (6.1–12.4)
Delta predominance (July–November 2021)	4,546,682	460.1	1,862,090	90.9	5.1 (4.3–6.0)
Omicron emergence (December 2021)	1,061,684	725.6	925,999	230.9	3.1 (1.7–5.8)
Total	6,812,040	—	2,866,517	—	—
COVID-19–associated deaths					
Pre-Delta (April–May 2021)	11,047	2.7	1,016	0.1	21.9 (17.8–26.8)
Delta emergence (June 2021)	3,107	1.5	556	0.1	16.4 (13.2–20.4)
Delta predominance (July–November 2021)	78,256	11.4	20,313	0.7	16.3 (13.8–19.3)
Omicron emergence (first week in December 2021) ^{††}	2,230	9.7	682	0.5	NC
Total	94,640	—	22,567	—	—

Abbreviations: FDA = Food and Drug Administration; IRR = incidence rate ratio; NC = not calculated for the single reported week of deaths in December 2021.

* Events per 100,000 population. Average weekly incidences and rate ratios are provided by age group, primary series vaccine type, and overall; overall and vaccine-specific rates were standardized by age, according to the enumerated 2000 U.S. Census age distribution. IRRs were calculated by dividing incidence among unvaccinated persons by incidence among fully vaccinated persons overall.

[†] A COVID-19 case in a fully vaccinated person occurred when SARS-CoV-2 RNA or antigen was detected in a respiratory specimen collected ≥ 14 days after completing the primary series of a COVID-19 vaccine with FDA approval or emergency use authorization. A COVID-19 case in an unvaccinated person occurred when the person did not receive any FDA-authorized COVID-19 vaccine doses before the specimen collection date. Excluded were partially vaccinated persons who had received at least one FDA-authorized or approved vaccine dose but did not complete a primary series ≥ 14 days before collection of a specimen with SARS-CoV-2 RNA or antigen detected. This analysis represents the combined impact of BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and Ad.26.COV2.S (Janssen [Johnson & Johnson]) COVID-19 vaccines, which had different clinical efficacies against confirmed infection; fully vaccinated persons also include those persons who received additional primary doses and booster doses starting in mid-August. A COVID-19–associated death occurred in a person with a documented COVID-19 diagnosis who died, and whose report local health authorities reviewed (e.g., using vital records, public health investigation, or other data sources) to make that determination. Per national guidance, this should include persons whose death certificate lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or as a significant condition contributing to death. Rates of COVID-19 deaths by vaccination status are reported based on when the patient was tested for COVID-19, not the date they died.

[§] Four analysis periods were designated based on the threshold week when the weighted proportions of lineages from whole-genome sequencing results submitted to or performed by CDC: pre-Delta (April 4–May 29, 2021: 0.1%–7% proportion range), Delta emergence (May 30–July 3, 2021: 14%–69%), Delta predominance (July 4–November 27, 2021: 81%–99%), and Omicron emergence (November 28–December 25, 2021: 1%–72%).

[¶] Alabama, Arkansas, California, Colorado, District of Columbia, Florida, Georgia, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Nebraska, New Jersey, New Mexico, New York, New York City (New York), Rhode Island, Seattle/King County (Washington), Tennessee, Texas, Utah, and Wisconsin.

** 95% CIs were calculated after detrending underlying linear changes in weekly incidence rates using piecewise linear regression. Each CI represents the remaining variation in observed weekly incidence rates and resulting incidence rate ratios. The number of observations informing each CI reflects the number of weeks per period: April–May (7), June (5), July–November (21), and December (4).

^{††} For deaths, a single week (November 28–December 4, 2021) of data was reported during the December 2021 period of Omicron emergence, but the proportion of Omicron variant during that first week was approximately 1%.

Discussion

COVID-19 vaccines reduced risks for SARS-CoV-2 infection and COVID-19–associated death during periods of Delta variant predominance and infection risk during Omicron variant emergence. Because of reporting lags, the influence of the Omicron variant on COVID-19–associated deaths by vaccination status in December could not be evaluated. Substantial case rate increases were recorded among unvaccinated and vaccinated persons when Omicron became the predominant variant in December, resulting in decreased IRRs and declining crude VE estimates (7). IRRs and VE were higher among persons who were fully vaccinated and had received a booster dose than among fully vaccinated persons who had not received a booster dose for cases and deaths during the period of Delta predominance and

for cases during the period of Omicron emergence in December. The added benefits of booster doses were especially prominent among persons aged 50–64 and ≥65 years.

The findings in this report are subject to at least five limitations. First, booster doses could not be distinguished from additional primary doses administered to immunocompromised persons, which could result in reduced IRRs because of lower VE in this population. Second, this ecological study lacked multivariable adjustments, and causality could not be determined. Possible differences in testing, infection-derived immunity, waning of vaccine-derived immunity, or prevention behaviors by age and vaccination status might partly explain differences in rates between groups; trends are likely affected by temporal changes in testing or reporting. Third, national variant prevalence estimates

TABLE 2. Average weekly incidence* of cases and deaths and incidence rate ratios† for unvaccinated compared with fully vaccinated persons§ with and without booster doses,¶ by age, vaccine type, and period†† — 25 U.S. jurisdictions§§ October 3–December 25, 2021**

Event/Time/ Characteristic	COVID-19 vaccination status							
	Unvaccinated		Fully vaccinated (no booster dose)			Fully vaccinated (with booster dose)		
	Total no.	Average weekly incidence*	Total no.	Average weekly incidence*	Average weekly IRR (95% CI)¶¶	Total no.	Average weekly incidence*	Average weekly IRR (95% CI)¶¶
COVID-19 cases								
October–November								
Overall (age-standardized)	1,108,298	347.8	650,820	87.7	4.0 (3.6–4.4)	19,954	25.0	13.9 (12.2–15.9)
Age group, yrs								
18–49	760,042	330.3	343,602	89.9	3.6 (3.2–4.3)	6,265	27.4	12.0 (10.0–14.5)
50–64	225,290	355.3	174,071	86.5	4.1 (3.5–4.8)	4,911	23.2	15.3 (12.8–18.3)
≥65	122,966	403.6	133,147	80.7	5.0 (4.4–5.6)	8,778	18.1	22.3 (19.0–26.1)
Vaccine product								
Moderna	NR	NR	219,623	75.0	4.6 (4.2–5.1)	4,911	20.0	17.4 (14.5–21.1)
Pfizer-BioNTech	NR	NR	358,933	93.9	3.7 (3.4–4.1)	14,292	27.1	12.9 (11.4–14.5)
Janssen (Johnson & Johnson)	NR	NR	71,897	107.5	3.2 (2.9–3.6)	745	26.0	13.4 (10.6–16.9)
December								
Overall (age-standardized)	1,061,684	725.6	800,940	254.8	2.8 (1.6–5.2)	125,059	148.6	4.9 (2.7–8.9)
Age group, yrs								
18–49	781,969	745.6	547,733	302.5	2.5 (1.1–5.6)	65,710	191.7	3.9 (1.8–8.6)
50–64	189,789	680.8	176,639	208.8	3.3 (1.7–6.4)	31,753	97.0	7.0 (3.0–16.3)
≥65	89,926	704.9	76,568	133.5	5.3 (3.3–8.4)	27,596	50.4	14.0 (6.4–30.6)
Vaccine								
Moderna	NR	NR	251,784	221.6	3.3 (1.7–6.1)	39,813	130.4	5.6 (3.1–10.1)
Pfizer-BioNTech	NR	NR	473,115	280.1	2.6 (1.4–4.7)	77,844	162.6	4.5 (2.4–8.3)
Janssen (Johnson & Johnson)	NR	NR	75,903	246.6	2.9 (1.8–4.8)	7,377	132.7	5.5 (3.2–9.4)
COVID-19–associated deaths								
October–November								
Overall (age-standardized)	16,527	7.8	5,493	0.6	12.7 (11.6–13.8)	285	0.1	53.2 (37.5–75.4)
Age, yrs								
18–49	2,094	1.0	124	0.0	27.6 (16.3–46.5)	5	0.0	NC***
50–64	4,427	7.3	659	0.4	21.0 (18.9–23.2)	38	0.2	38.0 (17.1–78.9)
≥65	10,006	33.4	4,710	3.1	11.0 (9.8–12.2)	242	0.5	61.4 (47.8–78.9)
Vaccine								
Moderna	NR	NR	2,379	0.5	14.6 (13.0–16.4)	96	0.2	40.1 (19.5–82.5)
Pfizer-BioNTech	NR	NR	2,550	0.7	11.8 (10.8–12.9)	187	0.1	58.7 (36.8–93.9)
Janssen (Johnson & Johnson)	NR	NR	560	1.0	7.9 (6.0–10.3)	2	0.1	NC***

See table footnotes on the next page.

TABLE 2. (Continued) Average weekly incidence* of cases and deaths and incidence rate ratios† for unvaccinated compared with fully vaccinated persons§ with and without booster doses,¶ by age, vaccine type, and period†† — 25 U.S. jurisdictions§§ October 3–December 25, 2021**

Abbreviations: FDA = Food and Drug Administration; IRR = incidence rate ratio; NC = not calculated for categories with counts <20; NR = not relevant for individual vaccine types because the comparison being made is to overall unvaccinated counts and age-adjusted rates.

* Events per 100,000 population.

† Average weekly incidence rates and rate ratios are provided by age group, primary series vaccine type, and overall; overall and vaccine-specific rates were standardized by age, according to the enumerated 2000 U.S. Census age distribution. IRRs were calculated by dividing incidence among unvaccinated persons by incidence among fully vaccinated persons (overall and by receipt of booster doses).

§ A COVID-19 case in a fully vaccinated person occurred when SARS-CoV-2 RNA or antigen was detected in a respiratory specimen collected ≥14 days after completing the primary series of a COVID-19 vaccine with FDA approval or emergency use authorization. A COVID-19 case in an unvaccinated person occurred when the person did not receive any FDA-authorized COVID-19 vaccine doses before the specimen collection date. Excluded were partially vaccinated persons who had received at least one FDA-authorized or approved vaccine dose but did not complete a primary series ≥14 days before collection of a specimen with SARS-CoV-2 RNA or antigen detected. This analysis represents the combined impact of BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and Ad.26.COV2.S (Janssen [Johnson & Johnson]) COVID-19 vaccines, which had different clinical efficacies against confirmed infection; fully vaccinated persons also include those persons who received additional primary doses and booster doses starting in mid-August. A COVID-19–associated death occurred in a person with a documented COVID-19 diagnosis who died, and whose report local health authorities reviewed (e.g., using vital records, public health investigation, or other data sources) to make that determination. Per national guidance, this should include persons whose death certificate lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or as a significant condition contributing to death. Rates of COVID-19 deaths by vaccination status are reported based on when the patient was tested for COVID-19, not the date they died.

¶ A COVID-19 case in a fully vaccinated person with a booster dose occurred when a person had SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after receipt of at least one additional or booster dose of any COVID-19 vaccine on or after August 13, 2021. On August 13, 2021, CDC recommended an additional Pfizer-BioNTech or Moderna primary series dose for persons with moderately or severely immunocompromise. On September 24, 2021, CDC recommended a Pfizer-BioNTech booster dose for certain Pfizer-BioNTech primary series recipients, including all adults aged ≥65 years and persons aged ≥18 years in certain populations and high risk occupational and institutional settings. On October 21, 2021, CDC recommended a booster dose for adults aged ≥18 years who received the Janssen vaccine and for Pfizer-BioNTech or Moderna primary series recipients, including all adults aged ≥65 years and persons aged ≥18 years in certain populations and high risk occupational and institutional settings. On November 19, 2021, and November 29, 2021, CDC expanded recommendations for booster doses to include all adults aged ≥18 years.

** Reporting is by primary series vaccine type rather than additional or booster dose vaccine type. The booster dose vaccine type may be different than the primary series vaccine type. For primary mRNA vaccination series, the vaccine product of the second dose was used to determine primary series product type. If the Janssen vaccine was either the first dose or the second dose, the series type was called Janssen. The overall fully vaccinated group includes FDA-approved vaccinations of unknown vaccine type.

†† Analysis periods for this table were designated based on robust reporting of cases among persons with booster doses from October 2021 and the threshold week when the weighted proportions of lineages from whole-genome sequencing results submitted to or performed by CDC: October 3–November 27, 2021 (Delta predominance: 99%), and November 28–December 25, 2021 (Omicron emergence: 1%–72%).

§§ Alabama, Arkansas, California, Colorado, District of Columbia, Florida, Georgia, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Nebraska, New Jersey, New Mexico, New York, New York City (New York), Rhode Island, Seattle/King County (Washington), Tennessee, Texas, Utah, and Wisconsin.

¶¶ 95% CIs were calculated after detrending underlying linear changes in weekly incidence rates using piecewise linear regression. Each CI represents the remaining variation in observed weekly incidence rates and resulting incidence rate ratios. The number of observations informing each CI reflects the number of weeks per period: October–November (7), and December (4).

*** <https://www.cdc.gov/nchs/data/statnt/statnt24.pdf>

were used, but prevalence differed by jurisdiction over time. Fourth, variable data linkage completeness might have resulted in misclassifications (e.g., booster doses not being linked to primary series) that could influence IRR estimates (5). Finally, these data represent 62% of the overall U.S. population, and therefore might not be generalizable.

Early analysis of surveillance data provided crude signals of VE that were consistent with other studies reporting decreased VE against Omicron infection compared with Delta and increased protection from booster doses compared with a primary series of COVID-19 vaccination alone††† (10). Ongoing analyses will help monitor the impact of the Omicron variant and other emerging variants on VE against COVID-19 cases and associated deaths; rates by vaccination status will be updated monthly on CDC's COVID Data Tracker website (3). All eligible persons should stay up to date with primary series, additional, and booster doses of COVID-19 vaccine.

††† <https://www.medrxiv.org/content/10.1101/2022.01.07.22268919v1.full>; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4011905

Summary

What is already known about this topic?

Although COVID-19 vaccine effectiveness decreased with emergence of the Delta variant and waning of vaccine-induced immunity, protection against hospitalization and death has remained high.

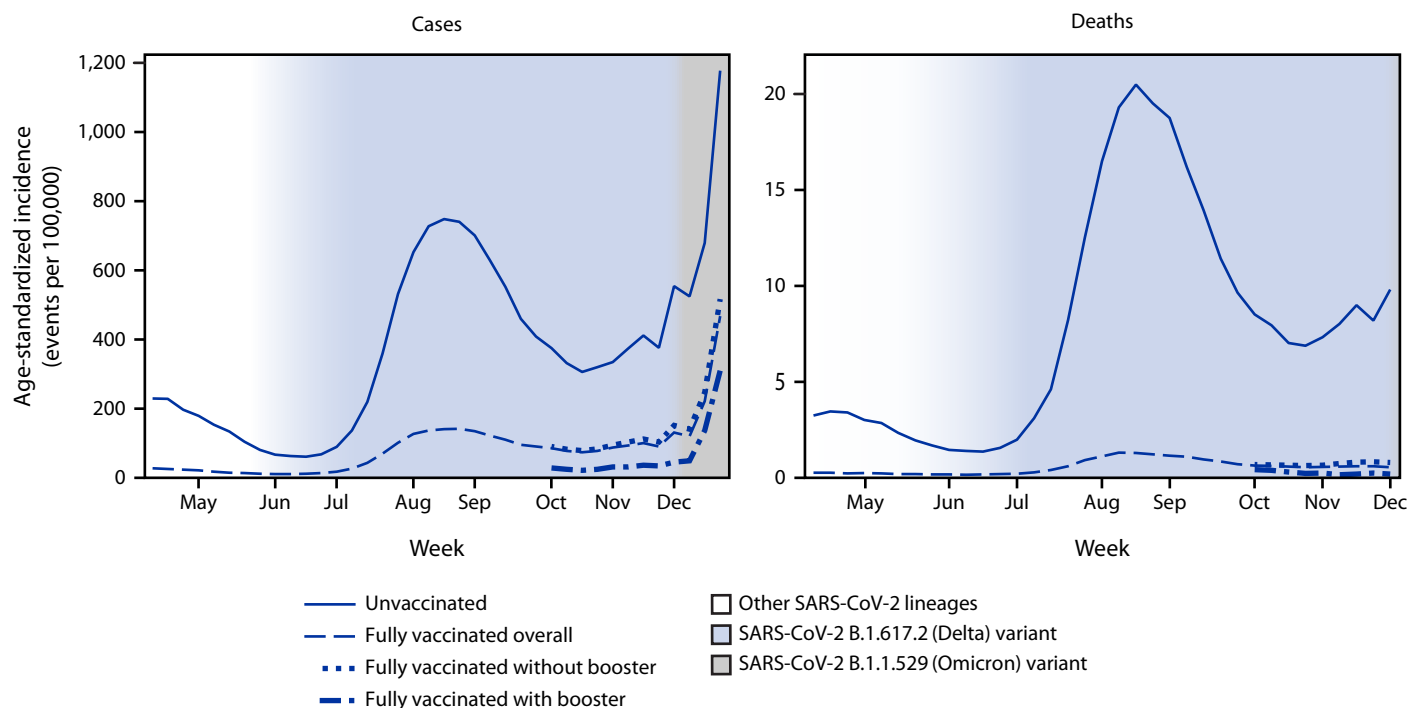
What is added by this report?

In 25 U.S. jurisdictions, decreases in case incidence rate ratios for unvaccinated versus fully vaccinated persons with and without booster vaccine doses were observed when the Omicron variant emerged in December 2021. Protection against infection and death during the Delta-predominant period and against infection during Omicron emergence were higher among booster vaccine dose recipients, especially among persons aged 50–64 and ≥65 years.

What are the implications for public health practice?

COVID-19 vaccination protected against SARS-CoV-2 infection, even as the Omicron variant became predominant. All eligible persons should stay up to date with COVID-19 vaccination.

FIGURE. Weekly trends in age-standardized incidence of COVID-19 cases (April 4–December 25, 2021) and deaths (April 4–December 4, 2021) for unvaccinated compared with fully vaccinated persons,* overall and by receipt of booster doses† and national weighted estimates of variant proportions§ — 25 U.S. jurisdictions¶



Abbreviation: FDA = Food and Drug Administration.

* A COVID-19 case in a fully vaccinated person occurred when SARS-CoV-2 RNA or antigen was detected in a respiratory specimen collected ≥ 14 days after completing the primary series of a COVID-19 vaccine with FDA approval or emergency use authorization. A COVID-19 case in an unvaccinated person occurred when the person did not receive any FDA-authorized COVID-19 vaccine doses before the specimen collection date. Excluded were partially vaccinated persons who had received at least one FDA-authorized or approved vaccine dose but did not complete a primary series ≥ 14 days before collection of a specimen with SARS-CoV-2 RNA or antigen detected. This analysis represents the combined impact of the BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and Ad.26.COV2.S (Janssen [Johnson & Johnson]) COVID-19 vaccines, which had different clinical efficacies against confirmed infection. A COVID-19-associated death occurred in a person with a documented COVID-19 diagnosis who died, and whose report local health authorities reviewed (e.g., using vital records, public health investigation, or other data sources) to make that determination. Per national guidance, this should include persons whose death certificate lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or as a significant condition contributing to death. Rates of COVID-19 deaths by vaccination status are reported based on when the patient was tested for COVID-19, not the date they died.

† A COVID-19 case in a fully vaccinated person with a booster dose occurred when a person had SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥ 14 days after receipt of at least one additional or booster dose of any COVID-19 vaccine on or after August 13, 2021. On August 13, 2021, CDC recommended an additional Pfizer-BioNTech or Moderna primary series dose for persons with moderately or severely immunocompromise. On September 24, 2021, CDC recommended a Pfizer-BioNTech booster dose for certain Pfizer-BioNTech primary series recipients, including all adults aged ≥ 65 years and persons aged ≥ 18 years in certain populations and high risk occupational and institutional settings. On October 21, 2021, CDC recommended a booster dose for adults aged ≥ 18 years who received the Janssen vaccine and for Pfizer-BioNTech or Moderna primary series recipients, including all adults aged ≥ 65 years and persons aged ≥ 18 years in certain populations and high risk occupational and institutional settings. On November 19, 2021, and November 29, 2021, CDC expanded recommendations for booster doses to include all adults aged ≥ 18 years.

§ National weighted estimates of the proportions of infections attributed to SARS-CoV-2 variants by week are based on whole-genome sequencing results submitted to or performed by CDC (<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>). Other lineages prior to the Delta transition included Alpha ($>50\%$), Gamma, Epsilon, Iota, Mu, and other lineages.

¶ Alabama, Arkansas, California, Colorado, District of Columbia, Florida, Georgia, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Nebraska, New Jersey, New Mexico, New York, New York City (New York), Rhode Island, Seattle/King County (Washington), Tennessee, Texas, Utah, and Wisconsin.

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COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May–November 2021

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By November 30, 2021, approximately 130,781 COVID-19–associated deaths, one in six of all U.S. deaths from COVID-19, had occurred in California and New York.* COVID-19 vaccination protects against infection with SARS-CoV-2 (the virus that causes COVID-19), associated severe illness, and death (1,2); among those who survive, previous SARS-CoV-2 infection also confers protection against severe outcomes in the event of reinfection (3,4). The relative magnitude and duration of infection- and vaccine-derived protection, alone and together, can guide public health planning and epidemic forecasting. To examine the impact of primary COVID-19 vaccination and previous SARS-CoV-2 infection on COVID-19 incidence and hospitalization rates, statewide testing, surveillance, and COVID-19 immunization data from California and New York (which account for 18% of the U.S. population) were analyzed. Four cohorts of adults aged ≥18 years were considered: persons who were 1) unvaccinated with no previous laboratory-confirmed COVID-19 diagnosis, 2) vaccinated (14 days after completion of a primary COVID-19 vaccination series) with no previous COVID-19 diagnosis, 3) unvaccinated with a previous COVID-19 diagnosis, and 4) vaccinated with a previous COVID-19 diagnosis. Age-adjusted hazard rates of incident laboratory-confirmed COVID-19 cases in both states were compared among cohorts, and in California, hospitalizations during May 30–November 20, 2021, were also compared. During the study period, COVID-19 incidence in both states was highest among unvaccinated persons without a previous COVID-19 diagnosis compared with that among the other three groups. During the week beginning May 30, 2021, compared with COVID-19 case rates among unvaccinated persons without a previous COVID-19 diagnosis, COVID-19 case rates were 19.9-fold (California) and 18.4-fold (New York) lower among vaccinated persons without a previous diagnosis; 7.2-fold (California) and 9.9-fold lower (New York) among unvaccinated persons with a previous COVID-19 diagnosis; and 9.6-fold (California) and 8.5-fold lower (New York) among vaccinated persons with a previous COVID-19 diagnosis. During the same period, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates in California followed a similar pattern. These relationships

changed after the SARS-CoV-2 Delta variant became predominant (i.e., accounted for >50% of sequenced isolates) in late June and July. By the week beginning October 3, compared with COVID-19 cases rates among unvaccinated persons without a previous COVID-19 diagnosis, case rates among vaccinated persons without a previous COVID-19 diagnosis were 6.2-fold (California) and 4.5-fold (New York) lower; rates were substantially lower among both groups with previous COVID-19 diagnoses, including 29.0-fold (California) and 14.7-fold lower (New York) among unvaccinated persons with a previous diagnosis, and 32.5-fold (California) and 19.8-fold lower (New York) among vaccinated persons with a previous diagnosis of COVID-19. During the same period, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates in California followed a similar pattern. These results demonstrate that vaccination protects against COVID-19 and related hospitalization, and that surviving a previous infection protects against a reinfection and related hospitalization. Importantly, infection-derived protection was higher after the Delta variant became predominant, a time when vaccine-induced immunity for many persons declined because of immune evasion and immunologic waning (2,5,6). Similar cohort data accounting for booster doses needs to be assessed, as new variants, including Omicron, circulate. Although the epidemiology of COVID-19 might change with the emergence of new variants, vaccination remains the safest strategy to prevent SARS-CoV-2 infections and associated complications; all eligible persons should be up to date with COVID-19 vaccination. Additional recommendations for vaccine doses might be warranted in the future as the virus and immunity levels change.

Four cohorts of persons aged ≥18 years were assembled via linkages of records from electronic laboratory reporting databases and state-specific immunization information systems.[†]

[†] Statewide immunization databases in California are the California Immunization Registry, Regional Immunization Data Exchange, and San Diego Immunization Registry; the laboratory system is the California COVID Reporting System (CCRS). In New York, immunization information systems include Citywide Immunization Registry and the New York State Immunization Information System; the laboratory system is the Electronic Clinical Laboratory Reporting System (ECLRS). California data were matched between the immunization and case registries using a probabilistic algorithm with exact match for zip code and date of birth and fuzzy match on first name and last name. New York data were matched to the ECLRS with the use of a deterministic algorithm based on first name, last name, and date of birth. In California, person-level hospitalization data from CCRS and supplementary hospitalization reports were used to identify COVID-19–associated hospitalizations.

* https://covid.cdc.gov/covid-data-tracker/#cases_deathsper100klast7days

Persons were classified based on whether they had had a laboratory-confirmed SARS-CoV-2 infection by March 1, 2021 (i.e., previous COVID-19 diagnosis)[§]; had received at least the primary COVID-19 vaccination series[¶] by May 16, 2021; had a previous COVID-19 diagnosis and were fully vaccinated^{**}; or had neither received a previous COVID-19 diagnosis by March 1 nor received a first COVID-19 vaccine dose by the end of the analysis period. The size of the unvaccinated group without a previous diagnosis was derived by subtracting the observed groups from U.S. Census estimates.^{††} To maintain each defined cohort, persons who received a COVID-19 diagnosis during March 1–May 30, 2021, or who died before May 30, 2021, were excluded (to maintain eligibility for incident cases for all cohorts on May 30, 2021),^{§§} as were persons who received a first vaccine dose during May 30–November 20, 2021. During May 30–November 20, 2021, incident cases were defined using a positive nucleic acid amplification test (NAAT) result from the California COVID-19 Reporting System (CCRS) or a positive NAAT or antigen test result from the New York Electronic Clinical Laboratory Reporting System. In California, person-level hospitalization data from CCRS and supplementary hospitalization reports were used to identify COVID-19–associated hospitalizations. A lifetable method was used to calculate hazard rates (average daily cases during a 7-day interval or hospitalizations over a 14-day interval), hazard ratios, and 95% CIs for each cohort. Rates were age-adjusted to 2000 U.S. Census data using direct standardization.^{¶¶} Supplementary analyses stratified case rates by timing

of previous diagnoses and primary series vaccine product. SAS (version 9.4; SAS Institute) and R (version 4.0.4; The R Foundation) were used to conduct all analyses. Institutional review boards (IRBs) in both states determined this surveillance activity to be necessary for public health work, and therefore, it did not require IRB review.

Approximately three quarters of adults from California (71.2%) and New York (72.2%) included in this analysis were vaccinated and did not have a previous COVID-19 diagnosis; however, 18.0% of California residents and 18.4% of New York residents were unvaccinated with no previous COVID-19 diagnosis (Table 1). In both states, 4.5% of persons were vaccinated and had a previous COVID-19 diagnosis; 6.3% in California and 4.9% in New York were unvaccinated with a previous diagnosis. Among 1,108,600 incident COVID-19 cases in these cohorts (752,781 in California and 355,819 in New York), the median intervals from vaccination or previous COVID-19 diagnosis to incident diagnosis were slightly shorter in California (138–150 days) than in New York (162–171 days).

Before the Delta variant became predominant in each state's U.S. Department of Health and Human Services region (June 26 in Region 9 [California] and July 3 in Region 2 [New York]),^{***} the highest incidence was among unvaccinated persons without a previous COVID-19 diagnosis; during this time, case rates were relatively low among the three groups with either previous infection or vaccination and were lowest among vaccinated persons without a previous COVID-19 diagnosis (Supplementary Figure 1, <https://stacks.cdc.gov/view/cdc/113253>) (Supplementary Figure 2, <https://stacks.cdc.gov/view/cdc/113253>). During the week beginning May 30, 2021, compared with COVID-19 case rates among unvaccinated persons without a previous COVID-19 diagnosis, COVID-19 case rates were 19.9-fold (California) and 18.4-fold (New York) lower among vaccinated persons without a previous diagnosis; rates were 7.2-fold (California) and 9.9-fold (New York) lower among unvaccinated persons with a previous COVID-19 diagnosis and 9.6-fold (California) and 8.5-fold (New York) lower among vaccinated persons with a previous COVID-19 diagnosis (Table 2).

As the Delta variant prevalence increased to >95% (97% in Region 9 and 98% in Region 2 on August 1), rates increased more rapidly among the vaccinated group with no previous COVID-19 diagnosis than among both the vaccinated and unvaccinated groups with a previous COVID-19 diagnosis (Supplementary Figure 1, <https://stacks.cdc.gov/view/cdc/113253>) (Supplementary Figure 2, <https://stacks.cdc.gov/view/cdc/113253>). For example, during the week of

[§] For both classification into cohorts of persons with previous COVID-19 diagnoses and for measuring incident cases, laboratory-confirmed infection was defined as the receipt of a new positive SARS-CoV-2 nucleic acid amplification test (NAAT) or antigen test (both for New York and NAAT only for California) result, but not within 90 days of a previous positive result.

[¶] Fully vaccinated with the primary vaccination series is defined as receipt of a second dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) or 1 dose of the Janssen (Johnson & Johnson) vaccine ≥14 days before May 30, 2021.

^{**} Because of the timing of full vaccination, the cohort definitions, and analysis timeframe, this cohort consisted nearly exclusively of persons who had previously received a laboratory-confirmed diagnosis of COVID-19 and later were fully vaccinated (California: 99.9%, New York: 99.7%), as opposed to the reverse order.

^{††} Whereas vaccinated cohorts were directly observed in the immunization information system databases, unvaccinated persons without a previous COVID-19 diagnosis were defined using U.S. Census population estimates minus the number of persons partially or fully vaccinated by December 11, 2021, and unvaccinated persons with a previous laboratory-confirmed infection before May 30, 2021. In California, the California Department of Finance population estimates were used for 2020, and the 2018 CDC National Center for Health Statistics Bridged Race file for U.S. Census population estimates were used in New York, consistent with other COVID-19 surveillance reporting.

^{§§} In California, a person-level match was performed to exclude deaths in each cohort before May 30, 2021. In New York, COVID-19 deaths were removed in aggregate from the starting number of unvaccinated persons with a previous COVID-19 diagnosis on May 30, 2021.

^{¶¶} <https://www.cdc.gov/nchs/data/statnt/statnt20.pdf>

^{***} <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

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TABLE 1. Cohort sizes and cohort-specific incident laboratory-confirmed COVID-19 cases in California (N = 752,781) and New York (N = 355,819) and hospitalizations in California (N = 56,177) — May 30–November 20, 2021

State/Vaccination and diagnosis status ^{*,†}	No. of persons in each cohort (%)	Incident laboratory-confirmed COVID-19 cases			Incident COVID-19 hospitalizations ^{**}
		No. (cumulative incidence) ^{§,¶}	Median (IQR) interval from vaccination to positive test, days	Median (IQR) interval from previous diagnosis to positive test, days	No. (cumulative incidence) ^{§,¶}
California					
Vaccinated					
Previous COVID-19 diagnosis	968,167 (4.5)	3,471 (3.6)	138 (95–181)	262 (218–322)	273 (0.3)
No previous diagnosis	15,484,235 (71.2)	240,045 (15.5)	150 (112–189)	NA	10,737 (0.7)
Unvaccinated					
Previous COVID-19 diagnosis	1,370,782 (6.3)	6,805 (5.0)	NA	277 (229–356)	378 (0.3)
No previous diagnosis	3,911,146 (18.0)	502,460 (128.5)	NA	NA	44,789 (11.5)
New York					
Vaccinated					
Previous COVID-19 diagnosis	485,649 (4.5)	2,355 (4.9)	162 (118–201)	276 (227–348)	NA
No previous diagnosis	7,809,968 (72.2)	142,388 (18.2)	171 (133–203)	NA	NA
Unvaccinated					
Previous COVID-19 diagnosis	527,140 (4.9)	3,250 (6.2)	NA	295 (242–427)	NA
No previous diagnosis	1,993,709 (18.4)	207,826 (104.2)	NA	NA	NA

Abbreviations: NA = not applicable; NAAT = nucleic acid amplification test.

* Statewide immunization databases in California are the California Immunization Registry, Regional Immunization Data Exchange, and San Diego Immunization Registry, and the laboratory system is the California COVID Reporting System; in New York, Immunization Information Systems include Citywide Immunization Registry and the New York State Immunization Information System; the laboratory system is the Electronic Clinical Laboratory Reporting System. California data were matched between the immunization and case registries using a probabilistic algorithm with exact match for zip code and date of birth and fuzzy match on first name and last name. New York data were matched to the Electronic Clinical Laboratory Reporting System with the use of a deterministic algorithm based on first name, last name, and date of birth. In California, person-level hospitalization data from the California COVID Reporting System and supplemental hospitalization reports were used to identify COVID-19-associated hospitalizations.

† For both classification into cohorts of persons with previous COVID-19 diagnoses and for measuring incident cases, laboratory-confirmed infection was defined as the receipt of a new positive SARS-CoV-2 NAAT or antigen test (both for New York and NAAT only for California) result, but not within 90 days of a previous positive result. Fully vaccinated is defined as having received a second dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) or 1 dose of the Janssen (Johnson & Johnson) vaccine ≥ 14 days before May 30, 2021. Whereas vaccinated cohorts were directly observed in the immunization information system databases, unvaccinated persons without a previous COVID-19 diagnosis were defined using U.S. Census population estimates minus persons partially or fully vaccinated by December 11, 2021, and unvaccinated persons with a previous laboratory-confirmed infection before May 30, 2021. In California, the California Department of Finance population estimates were used for 2020, and the 2018 CDC National Center for Health Statistics Bridged Race file for census population estimates were used in New York, consistent with other COVID-19 surveillance reporting.

§ Cumulative cases per 1,000 persons.

¶ These summaries of cumulative incidence are estimated across a period of variability in the epidemic for all cohorts.

** Hospitalization data for New York are not included in this analysis.

October 3, compared with rates among unvaccinated persons without a previous COVID-19 diagnosis, rates among vaccinated persons without a previous diagnosis were 6.2-fold lower (95% CI = 6.0–6.4) in California and 4.5-fold lower (95% CI = 4.3–4.7) in New York (Table 2). Further, rates among unvaccinated persons with a previous COVID-19 diagnosis were 29-fold lower (95% CI = 25.0–33.1) than rates among unvaccinated persons without a previous COVID-19 diagnosis in California and 14.7-fold lower (95% CI = 12.6–16.9) in New York. Rates among vaccinated persons who had had COVID-19 were 32.5-fold lower (95% CI = 27.5–37.6) than rates among unvaccinated persons without a previous COVID-19 diagnosis in California and 19.8-fold lower (95% CI = 16.2–23.5) in New York. Rates among vaccinated persons without a previous COVID-19 diagnosis were consistently higher than rates among unvaccinated persons with a history of COVID-19 (3.1-fold higher [95% CI = 2.6–3.7] in California and 1.9-fold higher [95% CI = 1.5–2.3] in New York) and rates among vaccinated persons with a history of

COVID-19 (3.6-fold higher [95% CI = 2.9–4.3] in California and 2.8-fold higher [95% CI = 2.1–3.4] in New York).

COVID-19 hospitalization rates in California were always highest among unvaccinated persons without a previous COVID-19 diagnosis (Table 2) (Figure). In the pre-Delta period during June 13–June 26, for example, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates were 27.7-fold lower (95% CI = 22.4–33.0) among vaccinated persons without a previous COVID-19 diagnosis, 6.0-fold lower (95% CI = 3.3–8.7) among unvaccinated persons with a previous COVID-19 diagnosis, and 7.1-fold lower (95% CI = 4.0–10.3) among vaccinated persons with a previous COVID-19 diagnosis. However, this pattern also shifted as the Delta variant became predominant. During October 3–16, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates were 19.8-fold lower (95% CI = 18.2–21.4) among vaccinated persons without a previous COVID-19 diagnosis, 55.3-fold lower (95% CI = 27.3–83.3) among unvaccinated

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TABLE 2. Hazard ratios for incident laboratory-confirmed COVID-19 cases — New York and California and hospitalizations* — California, May 30–November 20, 2021

State and date range	Hazard ratio (95% CI) [†]				
	Unvaccinated, no previous COVID-19 diagnosis versus			Vaccinated, no previous COVID-19 diagnosis versus	
	Vaccinated, no previous COVID-19 diagnosis	Unvaccinated, previous COVID-19 diagnosis	Vaccinated, previous COVID-19 diagnosis	Unvaccinated, previous COVID-19 diagnosis	Vaccinated, previous COVID-19 diagnosis
Cases, California					
May 30–Jun 5	20.9 (18.9–22.9)	8.2 (6.6–9.9)	10.6 (8.1–13.2)	0.4 (0.3–0.5)	0.5 (0.4–0.6)
Jun 6–12	17.9 (16.2–19.5)	8.6 (6.8–10.4)	10.5 (7.9–13.0)	0.5 (0.4–0.6)	0.6 (0.4–0.7)
Jun 13–19	16.0 (14.7–17.4)	10.8 (8.5–13.2)	10.6 (8.2–13.1)	0.7 (0.5–0.8)	0.7 (0.5–0.8)
Jun 20–26	12.3 (11.4–13.1)	14.5 (11.2–17.8)	17.3 (12.8–21.8)	1.2 (0.9–1.5)	1.4 (1.0–1.8)
Jun 27–Jul 3	9.7 (9.2–10.2)	16.6 (13.5–19.7)	20.9 (16.0–25.8)	1.7 (1.4–2.0)	2.2 (1.6–2.7)
Jul 4–10	8.7 (8.4–9.0)	24.0 (20.1–28.0)	29.3 (23.1–35.6)	2.8 (2.3–3.2)	3.4 (2.6–4.1)
Jul 11–17	7.8 (7.5–8.0)	29.0 (25.0–32.9)	33.4 (27.3–39.4)	3.7 (3.2–4.2)	4.3 (3.5–5.1)
Jul 18–24	7.4 (7.2–7.6)	31.8 (28.1–35.6)	35.2 (29.8–40.6)	4.3 (3.8–4.8)	4.7 (4.0–5.5)
Jul 25–31	7.5 (7.4–7.7)	26.5 (24.1–29.0)	38.6 (33.3–43.9)	3.5 (3.2–3.8)	5.1 (4.4–5.8)
Aug 1–7	7.8 (7.6–7.9)	32.6 (29.5–35.6)	42.2 (36.7–47.7)	4.2 (3.8–4.6)	5.4 (4.7–6.1)
Aug 8–14	8.1 (7.9–8.2)	33.4 (30.4–36.5)	43.1 (37.6–48.6)	4.1 (3.8–4.5)	5.3 (4.7–6.0)
Aug 15–21	8.4 (8.3–8.6)	31.3 (28.5–34.1)	42.0 (36.7–47.3)	3.7 (3.4–4.0)	5.0 (4.3–5.6)
Aug 22–28	8.4 (8.3–8.6)	31.3 (28.4–34.3)	41.0 (35.5–46.5)	3.7 (3.4–4.1)	4.9 (4.2–5.5)
Aug 29–Sep 4	8.5 (8.3–8.6)	31.2 (28.1–34.3)	42.0 (36.1–48.0)	3.7 (3.3–4.1)	5.0 (4.3–5.7)
Sep 5–11	8.3 (8.1–8.5)	35.0 (31.0–39.0)	48.0 (40.2–55.9)	4.2 (3.7–4.7)	5.8 (4.8–6.7)
Sep 12–18	8.4 (8.2–8.6)	33.8 (29.9–37.8)	48.0 (39.8–56.2)	4.0 (3.6–4.5)	5.7 (4.7–6.7)
Sep 19–25	8.0 (7.8–8.2)	27.0 (23.8–30.1)	37.8 (31.5–44.1)	3.4 (3.0–3.8)	4.7 (4.0–5.5)
Sep 26–Oct 2	7.7 (7.5–7.9)	28.6 (24.9–32.2)	34.8 (28.9–40.7)	3.7 (3.2–4.2)	4.5 (3.7–5.3)
Oct 3–9	7.2 (7.0–7.4)	30.0 (26.0–34.1)	33.5 (28.5–38.6)	4.1 (3.6–4.7)	4.6 (3.9–5.3)
Oct 10–16	7.2 (7.0–7.4)	31.2 (26.8–35.7)	33.9 (27.8–40.0)	4.3 (3.7–5.0)	4.7 (3.9–5.5)
Oct 17–23	7.1 (7.0–7.3)	31.9 (27.6–36.1)	40.7 (33.3–48.1)	4.5 (3.9–5.0)	5.7 (4.7–6.7)
Oct 24–30	7.1 (6.9–7.3)	26.6 (23.3–29.9)	40.1 (32.9–47.3)	3.7 (3.3–4.2)	5.6 (4.6–6.6)
Oct 31–Nov 6	6.8 (6.6–7.0)	33.1 (28.7–37.6)	37.9 (31.0–44.7)	4.9 (4.2–5.5)	5.5 (4.5–6.6)
Nov 7–13	7.1 (6.9–7.3)	30.6 (26.3–35.0)	41.2 (33.0–49.5)	4.3 (3.7–4.9)	5.8 (4.6–7.0)
Nov 14–20	7.3 (7.0–7.5)	25.4 (21.4–29.3)	32.5 (25.5–39.5)	3.5 (2.9–4.0)	4.5 (3.5–5.5)
Cases, New York					
May 30–Jun 5	19.4 (16.9–21.8)	10.9 (7.5–14.3)	9.5 (6.7–12.4)	0.6 (0.4–0.7)	0.5 (0.3–0.7)
Jun 6–12	15.2 (13.2–17.2)	8.0 (5.5–10.6)	10.4 (6.6–14.3)	0.5 (0.4–0.7)	0.7 (0.4–0.9)
Jun 13–19	12.8 (11–14.5)	8.2 (5.3–11.2)	5.4 (3.7–7.0)	0.6 (0.4–0.9)	0.4 (0.3–0.6)
Jun 20–26	10.1 (8.8–11.4)	7.9 (5.1–10.7)	6.0 (4.0–8.0)	0.8 (0.5–1.1)	0.6 (0.4–0.8)
Jun 27–Jul 3	7.3 (6.5–8.1)	8.8 (5.8–11.8)	11.2 (6.7–15.7)	1.2 (0.8–1.6)	1.5 (0.9–2.2)
Jul 4–10	6.1 (5.6–6.7)	17.8 (10.6–25.0)	11.5 (7.5–15.6)	2.9 (1.7–4.1)	1.9 (1.2–2.6)
Jul 11–17	4.5 (4.2–4.8)	11.7 (8.5–15.0)	14.7 (9.9–19.6)	2.6 (1.9–3.3)	3.2 (2.2–4.3)
Jul 18–24	4.7 (4.5–5.0)	21.7 (15.6–27.8)	14.1 (10.5–17.7)	4.6 (3.3–5.9)	3.0 (2.2–3.8)
Jul 25–31	5.1 (4.9–5.3)	16.1 (13.1–19.2)	18.3 (14.1–22.6)	3.2 (2.6–3.8)	3.6 (2.8–4.4)
Aug 1–7	5.3 (5.2–5.5)	19.2 (15.9–22.6)	18.3 (14.7–21.9)	3.6 (3.0–4.2)	3.4 (2.7–4.1)
Aug 8–14	5.3 (5.2–5.5)	16.2 (13.8–18.6)	19.2 (15.6–22.7)	3.0 (2.6–3.5)	3.6 (2.9–4.3)
Aug 15–21	5.5 (5.3–5.7)	19.5 (16.5–22.6)	22.7 (18.4–26.9)	3.6 (3.0–4.1)	4.1 (3.4–4.9)
Aug 22–28	5.4 (5.2–5.6)	19.2 (16.4–22.1)	26.5 (21.2–31.8)	3.6 (3.0–4.1)	4.9 (3.9–5.9)
Aug 29–Sep 4	5.5 (5.3–5.6)	17.9 (15.3–20.5)	20.9 (17.2–24.6)	3.3 (2.8–3.8)	3.8 (3.1–4.5)
Sep 5–11	5.4 (5.2–5.5)	18.9 (16.1–21.6)	22.3 (18.3–26.4)	3.5 (3.0–4.0)	4.2 (3.4–4.9)
Sep 12–18	5.8 (5.6–5.9)	15.0 (13.1–16.9)	23.2 (19.1–27.4)	2.6 (2.3–2.9)	4.0 (3.3–4.8)
Sep 19–25	5.6 (5.4–5.7)	15.4 (13.3–17.5)	23.8 (19.3–28.3)	2.8 (2.4–3.1)	4.3 (3.5–5.1)
Sep 26–Oct 2	5.4 (5.2–5.5)	18.4 (15.5–21.2)	24.2 (19.3–29.1)	3.4 (2.9–4.0)	4.5 (3.6–5.4)
Oct 3–9	5.5 (5.3–5.7)	15.7 (13.6–17.9)	20.8 (17.2–24.5)	2.9 (2.5–3.3)	3.8 (3.1–4.4)
Oct 10–16	5.5 (5.3–5.6)	17.2 (14.7–19.8)	25.9 (20.6–31.1)	3.2 (2.7–3.6)	4.7 (3.8–5.7)
Oct 17–23	5.4 (5.2–5.6)	18.9 (15.7–22.1)	27.6 (21.2–34.0)	3.5 (2.9–4.1)	5.1 (3.9–6.3)
Oct 24–30	5.2 (5.0–5.4)	21.0 (17.2–24.7)	25.9 (20.2–31.6)	4.0 (3.3–4.7)	5.0 (3.9–6.1)
Oct 31–Nov 6	4.8 (4.6–4.9)	17.3 (14.7–20.0)	20.1 (16.3–23.8)	3.6 (3.1–4.2)	4.2 (3.4–5.0)
Nov 7–13	4.8 (4.7–4.9)	23.9 (20.1–27.6)	24.5 (20.1–28.9)	5.0 (4.2–5.8)	5.1 (4.2–6.1)
Nov 14–20	4.8 (4.6–4.9)	22.6 (19.4–25.7)	23.0 (19.3–26.6)	4.7 (4.1–5.4)	4.8 (4.1–5.6)

See table footnotes on the next page.

persons with a previous COVID-19 diagnosis, and 57.5-fold lower (95% CI = 29.2–85.8) among vaccinated persons with a previous COVID-19 diagnosis.

Among the two cohorts with a previous COVID-19 diagnosis, no consistent incidence gradient by time since the previous diagnosis was observed (Supplementary Figure 3, <https://stacks.cdc.gov/view/cdc/113253>). When the vaccinated cohorts were stratified by the vaccine product received,

among vaccinated persons without a previous COVID-19 diagnosis, the highest incidences were observed among persons receiving the Janssen (Johnson & Johnson), followed by Pfizer-BioNTech, then Moderna vaccines (Supplementary Figure 4, <https://stacks.cdc.gov/view/cdc/113253>). No pattern by product was observed among vaccinated persons with a previous COVID-19 diagnosis.

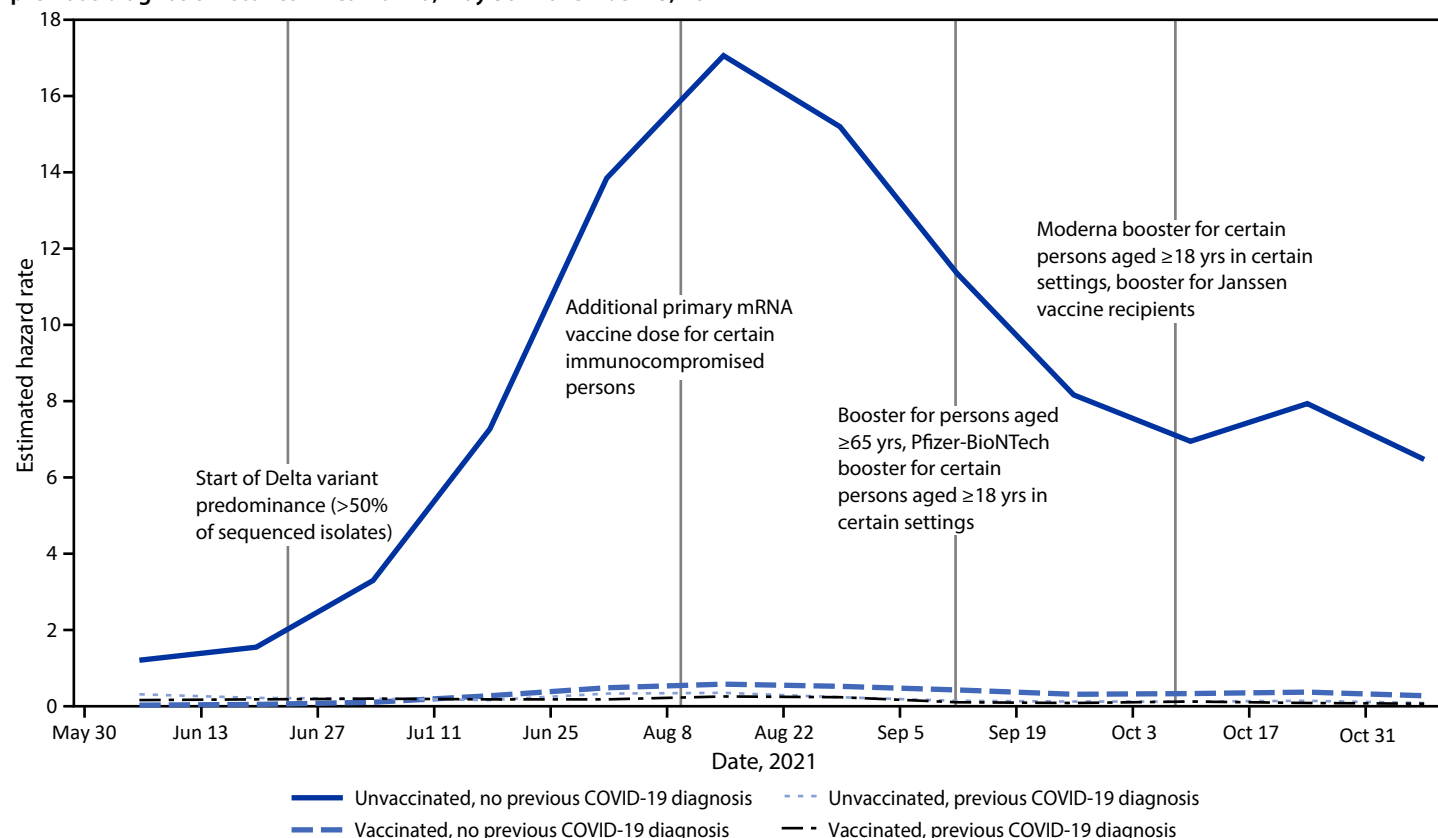
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TABLE 2. (Continued) Hazard ratios for incident laboratory-confirmed COVID-19 cases — New York and California and hospitalizations* — California, May 30–November 20, 2021

State and date range	Hazard ratio (95% CI) [†]				
	Unvaccinated, no previous COVID-19 diagnosis versus			Vaccinated, no previous COVID-19 diagnosis versus	
	Vaccinated, no previous COVID-19 diagnosis	Unvaccinated, previous COVID-19 diagnosis	Vaccinated, previous COVID-19 diagnosis	Unvaccinated, previous COVID-19 diagnosis	Vaccinated, previous COVID-19 diagnosis
Hospitalizations, California					
May 30–Jun 12	29.8 (23.5–36.1)	3.7 (2.5–5.0)	7.2 (4.2–10.1)	0.1 (0.1–0.2)	0.2 (0.1–0.3)
Jun 13–26	28.7 (23.4–34.0)	7.0 (4.3–9.7)	8.1 (5.0–11.3)	0.2 (0.1–0.3)	0.3 (0.2–0.4)
Jun 27–10	30.1 (26.1–34.0)	16.4 (10.0–22.8)	16.0 (10.0–22.1)	0.5 (0.3–0.8)	0.5 (0.3–0.7)
Jul 11–24	25.8 (23.7–28.0)	45.0 (27.6–62.4)	41.5 (25.2–57.8)	1.7 (1.1–2.4)	1.6 (1.0–2.2)
Jul 25–Aug 7	28.8 (27.1–30.6)	41.7 (29.2–54.1)	72.9 (44.4–101.4)	1.4 (1.0–1.9)	2.5 (1.5–3.5)
Aug 8–21	29.7 (28.0–31.4)	49.0 (35.0–62.9)	64.0 (43.0–85.1)	1.6 (1.2–2.1)	2.2 (1.4–2.9)
Aug 22–Sep 4	29.1 (27.4–30.8)	62.4 (41.4–83.3)	63.9 (42.2–85.5)	2.1 (1.4–2.9)	2.2 (1.4–2.9)
Sep 5–18	26.3 (24.6–28.1)	74.4 (40.9–107.9)	96.4 (48.3–144.4)	2.8 (1.5–4.1)	3.7 (1.8–5.5)
Sep 19–Oct 2	25.0 (23.1–26.9)	61.9 (34.5–89.3)	99.4 (43.8–155.0)	2.5 (1.4–3.6)	4.0 (1.7–6.2)
Oct 3–16	20.8 (19.2–22.4)	56.3 (28.3–84.3)	58.5 (30.2–86.8)	2.7 (1.4–4.1)	2.8 (1.4–4.2)
Oct 17–30	21.5 (19.9–23.0)	56.5 (31.5–81.5)	92.1 (39.1–145.1)	2.6 (1.5–3.8)	4.3 (1.8–6.8)
Oct 31–Nov 13	22.7 (20.8–24.6)	70.7 (32.0–109.4)	86.1 (34.2–138.1)	3.1 (1.4–4.8)	3.8 (1.5–6.1)

* Life tables estimated at 7-day intervals for cases and 14-day intervals for hospitalizations.

[†] Hazard ratios and 95% CIs reported in this table differ numerically from presentation of corresponding results in the text as “X-fold lower” rates (i.e., a hazard rate of 1.0 is zero-fold lower). For example, a hazard ratio of 20.9 (95% CI = 18.9–22.9) for those “Unvaccinated–no previous COVID-19 diagnosis” versus “Vaccinated, no previous COVID-19 diagnosis” is equivalent to a 19.9-fold lower (95% CI = 17.9–21.9) rate for those “Vaccinated, no previous COVID-19 diagnosis” relative to those “Unvaccinated, no previous COVID-19 diagnosis.”

FIGURE. Incident laboratory-confirmed COVID-19–associated hospitalizations among immunologic cohorts defined by vaccination and previous diagnosis histories — California, May 30–November 13, 2021*,†

* The SARS-CoV-2 Delta variant exceeded 50% of sequences in U.S. Department of Health and Human Services Region 9 (containing California) during the week of June 26. <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

[†] Estimated hazard rate is laboratory-confirmed COVID-19–associated hospitalizations per 100,000 person-days visualized at midpoint of each reporting interval.

Summary**What is already known about this topic?**

Data are limited regarding the risks for SARS-CoV-2 infection and hospitalization after COVID-19 vaccination and previous infection.

What is added by this report?

During May–November 2021, case and hospitalization rates were highest among persons who were unvaccinated without a previous diagnosis. Before Delta became the predominant variant in June, case rates were higher among persons who survived a previous infection than persons who were vaccinated alone. By early October, persons who survived a previous infection had lower case rates than persons who were vaccinated alone.

What are the implications for public health practice?

Although the epidemiology of COVID-19 might change as new variants emerge, vaccination remains the safest strategy for averting future SARS-CoV-2 infections, hospitalizations, long-term sequelae, and death. Primary vaccination, additional doses, and booster doses are recommended for all eligible persons. Additional future recommendations for vaccine doses might be warranted as the virus and immunity levels change.

Discussion

This analysis integrated laboratory testing, hospitalization surveillance, and immunization registry data in two large states during May–November 2021, before widespread circulation of the SARS-CoV-2 Omicron variant and before most persons had received additional or booster COVID-19 vaccine doses to protect against waning immunity. Rate estimates from the analysis describe different experiences stratified by COVID-19 vaccination status and previous COVID-19 diagnosis and during times when different SARS-CoV-2 variants predominated. Case rates were initially lowest among vaccinated persons without a previous COVID-19 diagnosis; however, after emergence of the Delta variant and over the course of time, incidence increased sharply in this group, but only slightly among both vaccinated and unvaccinated persons with previously diagnosed COVID-19 (6). Across the entire study period, persons with vaccine- and infection-derived immunity had much lower rates of hospitalization compared with those in unvaccinated persons. These results suggest that vaccination protects against COVID-19 and related hospitalization and that surviving a previous infection protects against a reinfection. Importantly, infection-derived protection was greater after the highly transmissible Delta variant became predominant, coinciding with early declining of vaccine-induced immunity in many persons (5). Similar data accounting for booster doses and as new variants, including Omicron, circulate will need to be assessed.

The understanding and epidemiology of COVID-19 has shifted substantially over time with the emergence and circulation of new SARS-CoV-2 variants, introduction of vaccines, and changing immunity as a result. Similar to the early period

of this study, two previous U.S. studies found more protection from vaccination than from previous infection during periods before Delta predominance (3,7). As was observed in the present study after July, recent international studies have also demonstrated increased protection in persons with previous infection, with or without vaccination, relative to vaccination alone^{†††},^{§§§} (4). This might be due to differential stimulation of the immune response by either exposure type.^{¶¶¶} Whereas French and Israeli population-based studies noted waning protection from previous infection, this was not apparent in the results from this or other large U.K. and U.S. studies^{****} (4,8). Further studies are needed to establish duration of protection from previous infection by variant type, severity, and symptomatology, including for the Omicron variant.

The findings in this report are subject to at least seven limitations. First, analyses were not stratified by time since vaccine receipt, but only by time since previous diagnosis, although earlier studies have examined waning of vaccine-induced immunity (Supplementary Figure 3, <https://stacks.cdc.gov/view/cdc/113253>) (2). Second, persons with undiagnosed infection are misclassified as having no previous COVID-19 diagnosis; however, this misclassification likely results in a conservative bias (i.e., the magnitude of difference in rates would be even larger if misclassified persons were not included among unvaccinated persons without a previous COVID-19 diagnosis). California seroprevalence data during this period indicate that the ratio of actual (presumptive) infections to diagnosed cases among adults was 2.6 (95% CI = 2.2–2.9).^{††††} Further, California only included NAAT results, whereas New York included both NAAT and antigen test results. However, antigen testing made up a smaller percentage of overall testing volume reported in California (7% of cases) compared with New York (25% of cases) during the study period. Neither state included self-tests, which are not easily reportable to public health. State-specific hazard ratios were generally comparable, although differences in rates among unvaccinated persons with a previous COVID-19 diagnosis were noteworthy. Third, potential exists for bias related to unmeasured confounding (e.g., behavioral or geographic differences in exposure risk) and uncertainty in the population size of the unvaccinated group without a previous COVID-19 diagnosis. Persons might be more or less likely to receive testing based on previous diagnosis or vaccination status; however, different trajectories between vaccinated persons with and without a previous COVID-19 diagnosis, and similar findings for cases and hospitalizations, suggest that these biases were minimal. Fourth, this analysis did not include information on the severity of

^{†††} <https://www.medrxiv.org/content/10.1101/2021.09.12.21263461v1>

^{§§§} <https://www.medrxiv.org/content/10.1101/2021.11.29.21267006v1>

^{¶¶¶} https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html#anchor_1635540449320

^{****} <https://www.medrxiv.org/content/10.1101/2021.12.04.21267114v1>

^{††††} <https://www.medrxiv.org/content/10.1101/2021.12.09.21267565v1>

initial infection and does not account for the full range of morbidity and mortality represented by the groups with previous infections. Fifth, this analysis did not ascertain receipt of additional or booster COVID-19 vaccine doses and was conducted before many persons were eligible or had received additional or booster vaccine doses, which have been shown to confer additional protection.^{§§§§} Sixth, some estimates lacked precision because of sample size limitations. Finally, this analysis was conducted before the emergence of the Omicron variant, for which vaccine or infection-derived immunity might be diminished.^{¶¶¶¶} This study offers a surveillance data framework to help evaluate both infections in vaccinated persons and reinfections as new variants continue to emerge.

Vaccination protected against COVID-19 and related hospitalization, and surviving a previous infection protected against a reinfection and related hospitalization during periods of predominantly Alpha and Delta variant transmission, before the emergence of Omicron; evidence suggests decreased protection from both vaccine- and infection-induced immunity against Omicron infections, although additional protection with widespread receipt of booster COVID-19 vaccine doses is expected. Initial infection among unvaccinated persons increases risk for serious illness, hospitalization, long-term sequelae, and death; by November 30, 2021, approximately 130,781 residents of California and New York had died from COVID-19. Thus, vaccination remains the safest and primary strategy to prevent SARS-CoV-2 infections, associated complications, and onward transmission. Primary COVID-19 vaccination, additional doses, and booster doses are recommended by CDC's Advisory Committee on Immunization Practices to ensure that all eligible persons are up to date with COVID-19 vaccination, which provides the most robust protection against initial infection, severe illness, hospitalization, long-term sequelae, and death.^{*****} Additional recommendations for vaccine doses might be warranted in the future as the virus and immunity levels change.

^{§§§§} <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>

^{¶¶¶¶} <https://www.medrxiv.org/content/10.1101/2021.12.30.21268565v1>;
<https://www.medrxiv.org/content/10.1101/2022.01.07.22268919v1>

^{*****} <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

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New York State Department of Health Announces New Study and New Data Website On COVID-19 Reinfection

Largest Study of Its Kind Conducted in Collaboration with California and Published by the Centers for Disease Control and Prevention

Vaccination Remains Safest Way to Prevent COVID-19 Infections and Severe Outcomes

ALBANY, N.Y. (January 19, 2022) – The New York State Department of Health today announced the publication of the largest comparative [study](#) of its kind on immunity to COVID-19 from vaccines and from previous infection, continuing its groundbreaking work on vaccine effectiveness.

The study, which also contains new data on reinfections, was conducted in collaboration with researchers from the California Department of Public Health and the Centers for Disease Control and Prevention (CDC), and published in the CDC's [Morbidity and Mortality Weekly Report \(MMWR\)](#). It found that both vaccination and a prior infection provided protection against future infection and hospitalization.

Researchers found that from May to November 2021, COVID-19 cases and related hospitalization were substantially lower among those who had been vaccinated and/or survived a previous infection, compared to those who were unvaccinated and without a previous infection. The study concluded that although after the Delta variant emerged, new infections and hospitalizations were lowest among people with prior infection, especially those who were also vaccinated. The results show vaccination remains the safest way to prevent future COVID-19 infections and severe outcomes, including death. Since the beginning of the pandemic, more than 63,500 New Yorkers have died from COVID-19.

"This study conducted by our premier scientists continues to underscore the importance of vaccination as a critical tool in the COVID-19 response," **said study co-author and Acting State Health Commissioner Dr. Mary T. Bassett**. "Although the epidemiology of this virus may continue to change as new variants emerge, vaccination remains the safest way to prevent infection, hospitalization and death. We continue to urge every eligible New Yorker to get vaccinated and boosted, wear a mask and take every step possible to protect yourselves and your loved ones."

The study is based on over 32 million adults who had at least one COVID-19 test, grouped as follows:

Group 1: Unvaccinated with no previous laboratory confirmed COVID-19 diagnosis;

Group 2: Vaccinated (14 days after completion of a primary COVID-19 vaccination series) with no previous COVID-19 diagnosis;

Group 3: Unvaccinated who survived a previous COVID-19 diagnosis; and

Group 4: Vaccinated who survived a previous COVID-19 diagnosis.

During the study period of May 30 through November 20, 2021, new COVID-19 cases in both states were highest among unvaccinated people without a previous COVID-19 diagnosis compared with the other three groups. After the Delta variant became prominent in late June and July, case rates were lower among those

vaccinated with no previous COVID-19 diagnosis, and lowest among the two groups with a previous COVID-19 diagnosis.

For example, in New York State in the week beginning October 3, unvaccinated people without a previous COVID-19 diagnosis, were 4.5 fold more likely to have a positive COVID-19 test than vaccinated people without a previous COVID-19 diagnosis (Group 1 vs. 2), 14.7-fold more likely than unvaccinated people with a previous diagnosis (Group 1 vs. 3), and 19.8-fold more likely than vaccinated people with a previous COVID-19 diagnosis (Group 1 vs. 4).

During the same period, compared with unvaccinated people without a previous COVID-19 diagnosis, numbers and hospitalization rates in California followed a similar pattern. For example, during October 3–16, hospitalization rates among unvaccinated people without a previous COVID-19 diagnosis were 19.8-fold higher than among vaccinated people without a previous COVID-19 diagnosis (Group 1 vs. 2), 55.3-fold higher than among unvaccinated people with a previous COVID-19 diagnosis (Group 1 vs. 3), and 57.5-fold higher than among vaccinated people with a previous COVID-19 diagnosis (Group 1 vs. 4).

These results, in two large states that comprised one-in-six U.S. deaths from COVID-19 through the end of November, suggest that vaccination protected against infection and related hospitalization, but also that surviving a previous infection protected against a reinfection and hospitalization. These findings apply to the period before the emergence of the Omicron variant and the widespread use of booster doses.

Becoming vaccinated and staying up-to-date with booster doses remains the most effective and *only recommended way* to gain immunity to COVID-19. Getting infected carries serious risks, including hospitalization and death, and makes it more likely that you will give others COVID-19, including people who are most at risk of hospitalization and death.

Senior study author Dr. Eli Rosenberg of the Department of Health said: " This analysis represents another chapter in our ongoing studies of this virus and the most effective ways to be protected from illness. Our knowledge evolves along with the virus and together with our public health partners, we will continue to study these issues in order to best inform and protect the public."

This work comprises an unprecedented examination of reinfections, which are new infections among those with a previous COVID-19 diagnosis. To provide ongoing information on reinfections to the public, the Department also announced the launch of a [new dashboard](#) with data on COVID-19 reinfection in New York State. The Department similarly launched a pioneering [dashboard on breakthrough data](#) after the publication of its [study](#) on vaccine effectiveness last year.

Data from the new [Reinfection Dashboard](#) extend the results from the new study to illustrate that while reinfections have historically been uncommon, the number increased in December 2021 as the [Omicron variant emerged](#) in New York State. This information will continue to be important in understanding the extent of infection in New York State during the current wave, complementing the other dashboards available on the Department's [webpage](#).

Updates to this Reinfection Dashboard will be published weekly.

More information about the Department's study is available [here](#). This study is also available in the CDC's [Morbidity and Mortality Weekly Report \(MMWR\)](#).

For the reinfection webpage, see [here](#).

January 24, 2022 | 2:27 pm

COVID-19 Vaccines

Children ages 5+ are eligible for the COVID-19 vaccine and children ages 12+ are eligible for a booster. Parents and guardians: make sure your child gets vaccinated and stays up to date with all recommended doses.

VAX FOR KIDS >



GOVERNOR
KATHY HOCHUL

JANUARY 12, 2022 | Albany, NY

Governor Hochul Updates New Yorkers on State's Progress Combating COVID-19

CORONAVIRUS (/K/ COVID-19 VACCINE IS) (/K/ HEALTH)VID/KEYWORDS/HEALTH)
19-
VACCINE)

97,135 Vaccine Doses Administered Over Last 24 Hours

166 COVID-19 Deaths Statewide Yesterday

Governor Kathy Hochul today updated New Yorkers on the state's progress combating COVID-19.

"The slowdown in new cases gives us a glimmer of hope, but cases still remain high and we are nowhere near the end of the winter surge," **Governor Hochul said.** "Let's not undo all of the hard work we've put in to get to this point. Please make sure to get your second dose and

booster shot. Parents and guardians, the best way to protect our children is to get them vaccinated and boosted, once they're eligible. And let's continue to use the tools we know will help stop the spread: Wear a non-cloth mask and stay home if you're feeling sick."

Today's data is summarized briefly below:

- **Test Results Reported** – 338,280
- **Total Positive** – 58,770
- **Percent Positive** – 17.37%
- **7-Day Average Percent Positive** - 20.22%
- **Patient Hospitalization** - 12,671 (+131)
- **Patients Newly Admitted** – 2,007
- **Patients in ICU** - 1593 (-4)
- **Patients in ICU with Intubation** - 830 (-1)
- **Total Discharges** - 247,354 (+1,687)
- **New deaths reported by healthcare facilities through HERDS** - 166
- **Total deaths reported by healthcare facilities through HERDS** - 49,955

The Health Electronic Response Data System is a NYS DOH data source that collects confirmed daily death data as reported by hospitals, nursing homes and adult care facilities only.

- **Total deaths reported to and compiled by the CDC** - 62,698

This daily COVID-19 provisional death certificate data reported by NYS DOH and NYC to the CDC includes those who died in any location, including hospitals, nursing homes, adult care facilities, at home, in hospice and other settings.

- **Total vaccine doses administered** - 34,611,241
- **Total vaccine doses administered over past 24 hours** – 97,135
- **Total vaccine doses administered over past 7 days** – 636,628
- **Percent of New Yorkers ages 18 and older with at least one vaccine dose** - 89.9%
- **Percent of New Yorkers ages 18 and older with completed vaccine series** - 81.0%
- **Percent of New Yorkers ages 18 and older with at least one vaccine dose (CDC)** - 95.0%
- **Percent of New Yorkers ages 18 and older with completed vaccine series (CDC)** - 83.4%
- **Percent of all New Yorkers with at least one vaccine dose** - 78.9%
- **Percent of all New Yorkers with completed vaccine series** - 70.5%
- **Percent of all New Yorkers with at least one vaccine dose (CDC)** - 85.6%
- **Percent of all New Yorkers with completed vaccine series (CDC)** - 72.6%

Each region's 7-day average of cases per 100K population is as follows

Region	Sunday, January 9, 2022	Monday, January 10, 2022	Tuesday, January 11, 2022
Capital Region	242.13	252.44	246.12
Central New York	288.05	288.27	280.62
Finger Lakes	207.03	211.27	209.46
Long Island	402.63	394.70	372.58
Mid-Hudson	359.58	349.94	332.27
Mohawk Valley	210.47	212.06	209.62
New York City	487.21	482.20	462.65
North Country	182.90	190.16	193.84
Southern Tier	201.07	204.01	210.55
Western New York	251.29	250.77	254.98

Statewide	381.66	378.30	364.35

Each region's 7-day average percentage of positive test results reported over the last three days is as follows:

Region	Sunday, January 9, 2022	Monday, January 10, 2022	Tuesday, January 11, 2022
Capital Region	19.53%	19.48%	19.30%
Central New York	21.97%	22.01%	21.51%
Finger Lakes	19.94%	19.94%	19.72%
Long Island	25.58%	25.14%	24.33%
Mid-Hudson	22.59%	21.96%	21.09%
Mohawk Valley	17.64%	17.53%	17.63%
New York City	20.63%	20.15%	19.38%
North Country	17.26%	17.62%	17.49%

Southern Tier	15.44%	15.29%	14.94%
Western New York	22.36%	22.71%	22.77%
Statewide	21.30%	20.91%	20.22%

Each New York City borough's 7-day average percentage of positive test results reported over the last three days is as follows:

Borough in NYC	Sunday, January 9, 2022	Monday, January 10, 2022	Tuesday, January 11, 2022
Bronx	24.00%	22.96%	21.81%
Kings	19.24%	18.64%	17.80%
New York	16.25%	16.20%	15.73%
Queens	23.41%	22.99%	22.34%
Richmond	22.44%	21.74%	20.56%

Yesterday, 58,770 New Yorkers tested positive for COVID-19 in New York State, bringing the total to 4,298,809. A geographic breakdown is as follows:

County	Total Positive	New Positive
Albany	48,640	575

Allegany	7,502	47
Broome	38,090	364
Cattaraugus	12,613	157
Cayuga	13,218	161
Chautauqua	19,761	199
Chemung	17,405	294
Chenango	7,534	57
Clinton	11,909	138
Columbia	8,156	203
Cortland	8,373	111
Delaware	6,324	60
Dutchess	55,009	654
Erie	177,332	2,708

Essex	4,370	58
Franklin	7,285	82
Fulton	10,112	119
Genesee	11,532	122
Greene	7,134	148
Hamilton	724	5
Herkimer	11,449	169
Jefferson	15,433	210
Lewis	5,279	55
Livingston	9,594	131
Madison	10,412	113
Monroe	131,209	1,518

Montgomery	9,671	121
Nassau	361,426	3,987
Niagara	40,675	527
NYC	2,005,104	31,183
Oneida	44,484	421
Onondaga	87,307	1,343
Ontario	16,175	211
Orange	92,487	1,182
Orleans	7,262	103
Oswego	20,002	211
Otsego	7,812	176
Putnam	20,671	232
Rensselaer	25,358	336

Rockland	80,991	1,020
Saratoga	37,305	471
Schenectady	26,871	297
Schoharie	3,926	55
Schuyler	2,787	56
Seneca	4,548	75
St. Lawrence	16,724	170
Steuben	16,123	174
Suffolk	383,816	3,942
Sullivan	15,355	282
Tioga	8,727	124
Tompkins	13,721	219
Ulster	26,093	374

Warren	10,883	154
Washington	9,677	129
Wayne	13,919	137
Westchester	222,732	2,474
Wyoming	7,081	88
Yates	2,697	38

Below is data that shows how many hospitalized individuals who have tested positive for COVID-19 were admitted for COVID-19/COVID-19 complications and how many were admitted for non-COVID-19 conditions:

R e g i o n	COVID -19 Patient s current ly hospit alized	Admitted due to COVID or complicat ions of COVID	% Admitted due to COVID or complicati ons of COVID	Admitted where COVID was not included as one of the reasons for admission	% Admitted where COVID was not included as one of the reasons for admission
C a p i t a l R e g i	399	307	77%	92	23%

o n					
C e n t r a l N e w Y o r k	302	224	74%	78	26%
F i n g e r L a k e s	711	438	62%	273	38%
L o n g I s l a n d	2,254	1,403	62%	851	38%
M i d -	1,375	906	66%	469	34%

H u d s o n					
M o h a w k V a l l e y	158	108	68%	50	32%
N e w Y o r k C i t y	6,523	3,362	52%	3,161	48%
N o r t h C o u n t r y	103	64	62%	39	38%
S o	214	121	57%	93	43%

u t h e r n T i e r					
W e s t e r n N e w Y o r k	632	415	66%	217	34%
S t a t e w i d e	12,671	7,348	58%	5,323	42%

The Omicron variant now represents more than 95% of the viruses in circulation. For more information on variant tracking, please visit here: ([COVID-19 Variant Data | Department of Health \(ny.gov\)](https://coronavirus.health.ny.gov/covid-19-variant-data))(<https://coronavirus.health.ny.gov/covid-19-variant-data>).

Yesterday, 166 New Yorkers died due to COVID-19, bringing the total to 49,955. A geographic breakdown is as follows, by county of residence:

Deaths by County of Residence	

County	New Deaths
Albany	1
Bronx	20
Cayuga	1
Clinton	1
Dutchess	3
Erie	7
Essex	1
Franklin	1
Fulton	1
Herkimer	1
Kings	31
Manhattan	14

Monroe	3
Nassau	8
Niagara	1
Oneida	2
Onondaga	2
Ontario	1
Orange	4
Oswego	1
Putnam	1
Queens	22
Rensselaer	1
Richmond	5
Rockland	2

Saratoga	1
Schenectady	2
Schoharie	1
Seneca	1
St. Lawrence	1
Steuben	2
Suffolk	17
Warren	1
Westchester	5

All New York State mass vaccination sites are open to eligible New Yorkers aged 5 and older, with walk-in vaccination available at all sites on a first-come, first-serve basis for people aged 12 and older. Information on which sites require appointments for children in the 5-11 age group is available on [our website \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fam-i-eligible.covid19vaccine.health.ny.gov%2F%23_blank&data=04%7C01%7CAshley.Struble%40digital\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fam-i-eligible.covid19vaccine.health.ny.gov%2F%23_blank&data=04%7C01%7CAshley.Struble%40digital). People who prefer to make an appointment at a state-run mass vaccination site can do so on the [Am I Eligible App \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fam-i-eligible.covid19vaccine.health.ny.gov%2F%23_blank&data=04%7C01%7CAshley.Struble%40digital\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fam-i-eligible.covid19vaccine.health.ny.gov%2F%23_blank&data=04%7C01%7CAshley.Struble%40digital) by calling 1-833-NYS-4-VAX. People may also contact their local health department, pharmacy, doctor or hospital to schedule appointments where vaccines are available, or visit [vaccines.gov \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fvaccines.gov\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fvaccines.gov).

[url=https%3A%2F%2Fwww.vaccines.gov%2F&data=04%7C01%7CAshley.Struble%40digital.ny.gov](https://www.vaccines.gov)
find information on vaccine appointments near them.

New Yorkers looking to schedule vaccine appointments for 5-11-year-old children are encouraged to contact their child's pediatrician, family physician, county health departments, Federally Qualified Health Centers (FQHCs), rural health centers, or pharmacies that may be administering the vaccine for this age group. Parents and guardians can visit [vaccines.gov](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.vaccines.gov%2F&data=04%7C01%7CAshley.Struble%40digital.ny.gov) (<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.vaccines.gov%2F&data=04%7C01%7CAshley.Struble%40digital.ny.gov>) their ZIP code to 438829, or call 1-800-232-0233 to find nearby locations. Make sure that the provider offers the Pfizer-BioNTech COVID-19 vaccine, as the other COVID-19 vaccines are not yet authorized for this age group.

Visit our [website](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.vaccines.gov%2F&data=04%7C01%7CAshley.Struble%40digital.ny.gov) (<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.vaccines.gov%2F&data=04%7C01%7CAshley.Struble%40digital.ny.gov>)
[parents and guardians for new information, frequently asked questions and answers, and resources specifically designed for parents and guardians of this age group.](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.vaccines.gov%2F&data=04%7C01%7CAshley.Struble%40digital.ny.gov)

Yesterday, 21,484 New Yorkers received their first vaccine dose, and 17,375 completed their vaccine series. A geographic breakdown of New Yorkers who have been vaccinated by region is as follows:

	People with at least one vaccine dose		People with complete vaccine series	
Region	Cumulative Total	Increase over past 24 hours	Cumulative Total	Increase over past 24 hours
Capital Region	948,374	937	863,595	782
Central New York	633,685	415	584,950	377
Finger Lakes	845,808	823	780,357	730
Long Island	2,115,170	3,490	1,864,450	2,541

Mid-Hudson	1,654,652	2,513	1,441,523	1,920
Mohawk Valley	319,154	265	295,144	241
New York City	7,752,191	11,307	6,772,137	9,356
North Country	296,679	302	267,550	187
Southern Tier	430,558	446	392,868	333
Western New York	933,656	986	851,790	908
Statewide	15,929,927	21,484	14,114,364	17,375

Booster/Additional Shots			
Region	Cumulative Total	Increase over past 24 hours	Increase over past 7 days
Capital Region	392,045	3,874	24,698

Central New York	248,960	2,549	16,965
Finger Lakes	397,765	3,590	26,731
Long Island	764,482	8,805	56,954
Mid-Hudson	617,314	7,066	44,863
Mohawk Valley	135,109	1,129	8,080
New York City	1,905,812	19,544	135,207
North Country	116,204	1,424	8,070
Southern Tier	182,349	1,744	12,567
Western New York	436,835	4,138	25,041
Statewide	5,196,875	53,863	359,176

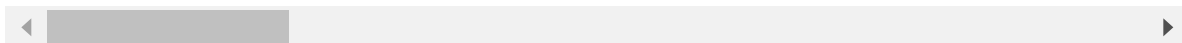
The COVID-19 Vaccine Tracker Dashboard (<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2F covid19vaccine.health.ny.gov%2F covid-19-vaccine-tracker&data=04%7C01%7Ckyle.kotary%40health.ny.gov%7Cf168cd687d9d45a1f64408d9a2f7f4f>) available to update New Yorkers on the distribution of the COVID-19 vaccine. The New York State Department of Health requires vaccinating facilities to report all COVID-19 vaccine administration data within 24 hours; the vaccine administration data on the dashboard is updated daily to reflect the most up-to-date metrics in the state's vaccination effort. New York State Department of Health-reported data from NYSIS and CIR differs slightly from

federally-reported data, which is inclusive of federally-administered doses and other minor differences. Both numbers are included in the release above.

As of 1/11	Hospit al		Nursin g Home		ACF		LHCS A		Hospic e		CHHA		Total	
Total employ ee terminat ions due to being unvacci nated	5 , 8 2 3	1 .1 3 %	2 , 4 7 %	1 .6 4 %	3 3 4	1 .0 8 %	8 , 1 0 7	2 .8 7 %	9 0	1 .4 7 %	1 .3 9	1 .0 4 %	1 6 , 9 7 0	1 .7 0 %
Total employ ee resignati ons and retireme nts due to being unvacci nated	2 , 3 1 5	0 .4 5 %	5 2	0 .0 3 %	1 1	0 .0 4 %	3 , 1 2 1	1 .1 0 %	8 0	1 .3 1 %	1 1 6	0 .8 6 %	5 , 6 9 5	0 .5 7 %
Total on furlough /unpaid leave due to being unvacci nated and unwillin g to get vaccinat ed	1 , 3 8 2	0 .2 7 %	6 5 7	0 .4 4 %	8 0	0 .2 6 %	7 , 7 9 8	2 .7 6 %	8	0 .1 3 %	6 7	0 .5 0 %	9 , 9 9 2	1 .0 0 %
Total on furlough	1 1	0 .	1, 5	1 .	5 1	1 .	2 , .	0 .	1 1	0 .	4	0 .	4	0 .

/unpaid leave due to being unvaccinated BUT now awaiting first dose	3	02 %	15	00 %	2	66 %	489	88 %		18 %		03 %	,644	46 %
Total INACTIVE employees from categories above	9,633		4,701		937		21,515		189		326		37,301	
Total ACTIVE employees reported 1/11/22	505,748		146,084		29,986		261,448		5,923		13,097		962,286	
Grand Total	515,381		150,785		30,923		282,963		6,112		13,423		999,587	

Percentages are estimates. They are based on self-reported data for 1/11/22. The denominators are active employees reported for 1/11/22 plus the inactive categories above; they do not include workforce fluctuations that may have occurred in addition to these categories above.



**Contact the Governor's
Press Office**



Contact us by phone:

Albany: [\(518\) 474-8418](tel:5184748418)

New York City: [\(212\) 681-4640](tel:2126814640)



Contact us by email:

Press.Office@exec.ny.gov

Translations

Arabic Translation

الترجمة إلى العربية

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Arabic.pdf)

Bengali Translation

বাংলা অনুবাদ

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Bengali.pdf)

Chinese Translation

中文翻譯

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Chinese.pdf)

Haitian-Creole Translation

Tradiksyon kreyòl ayisyen

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_HaitianCreole.pdf)

Italian Translation

Traduzione italiana

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Italian.pdf)

Korean Translation

한국어 번역

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Korean.pdf)

Polish Translation

Polskie tłumaczenie

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Polish.pdf)

Russian Translation

Перевод на русский язык

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Russian.pdf)

Spanish Translation

Traducción al español

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Spanish.pdf)

Yiddish Translation

אידישע איבערטייטשונג

(https://www.governor.ny.gov/sites/default/files/2022-01/1.12.22.rel_.PROGRESS_Yiddish.pdf)

Prevention of COVID-19 Transmission by Covered Entities

Effective date: 8/26/21

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Department of State, to read as follows:

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 addressing 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 (v) of subdivision (q) of Section 1001.11 is added to read as follows:

(v) 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.

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.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Type 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
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware 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	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange 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.

EMERGENCY JUSTIFICATION

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.

Prevention of COVID-19 Transmission by Covered Entities

Effective date: 11/24/21

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Department of State, to read as follows:

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, absent receipt of an exemption as allowed below. Covered entities shall require all personnel to receive at least their first dose before engaging in activities covered under paragraph (2) of subdivision (a) of this section. 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, physician assistant, 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 addressing 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.

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 vaccine mandate for health care workers, which required general hospital and nursing home personnel to receive their first dose of COVID-19 vaccine by September 27, 2021, and required all other covered entities to receive their first dose of COVID-19 vaccine by October 7, 2021, has greatly increased the percentage of health care workers who are vaccinated against COVID-19. COVID cases, hospitalizations, and deaths are decreasing in New York State, and the continuation of these regulations will help ensure that the epidemiology curve continues downward in furtherance of the New York State Department of Health's mission to reduce morbidity and mortality. These regulations are helping New York State reduce sickness and death from COVID-19.

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 more than 10-fold, and over 99 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 10 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.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Type 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 44 counties have an estimated population of less than 200,000 based upon 2020 United States Census data:

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware 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	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange 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.

EMERGENCY JUSTIFICATION

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 over 99 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.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

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, absent receipt of an exemption as allowed below. Covered entities shall require all personnel to receive at least their first dose before engaging in activities covered under paragraph (2) of subdivision (a) of this section. 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, physician assistant, 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 addressing 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.

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 vaccine mandate for health care workers, which required general hospital and nursing home personnel to receive their first dose of COVID-19 vaccine by September 27, 2021, and required all other covered entities to receive their first dose of COVID-19 vaccine by October 7, 2021, has greatly increased the percentage of health care workers who are vaccinated against COVID-19. COVID cases, hospitalizations, and deaths are decreasing in New York State, and the continuation of these regulations will help ensure that the epidemiology curve continues downward in furtherance of the New York State Department of Health's mission to reduce morbidity and mortality. These regulations are helping New York State reduce sickness and death from COVID-19.

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 more than 10-fold, and over 99 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 10 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 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:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

Contact Person:

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Type 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 44 counties have an estimated population of less than 200,000 based upon 2020 United States Census data:

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware 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	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange 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.

Prevention of COVID-19 Transmission by Covered Entities

Effective date: 1/21/22

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Department of State, to read as follows:

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, and to have received any booster or supplemental dose as recommended by the CDC, absent receipt of an exemption as allowed below. Covered entities shall require all personnel to receive at least their first dose before engaging in activities covered under paragraph (2) of subdivision (a) of this section. 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, physician assistant, 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 addressing 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.

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 vaccine mandate for health care workers, which required general hospital and nursing home personnel to receive their first dose of COVID-19 vaccine by September 27, 2021, and required all other covered entities to receive their first dose of COVID-19 vaccine by October 7, 2021, has greatly increased the percentage of health care workers who are vaccinated against COVID-19. COVID cases, hospitalizations, and deaths are decreasing in New York State, and the continuation of these regulations will help ensure that the epidemiology curve continues downward in furtherance of the New York State Department of Health's mission to reduce morbidity and mortality. These regulations are helping New York State reduce sickness and death from COVID-19.

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 more than 10-fold, and over 99 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 10 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.

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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.

Contact Person:

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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:

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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

Type 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 44 counties have an estimated population of less than 200,000 based upon 2020 United States Census data:

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Broome County	Hamilton County	Schuyler County
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Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware 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	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange 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.

EMERGENCY JUSTIFICATION

The Centers for Disease Control and Prevention (CDC) and health authorities around the world have identified recent surges in the number of new cases since the emergence of the SARS-CoV-2 Omicron variant, which is known to be more easily transmissible than previous variants of SARS-CoV-2. The World Health Organization classified the Omicron variant as a Variant of Concern due to its increased transmissibility on November 26, 2021. The emergence of the Omicron variant follows concerning national trends of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, the number of new cases per 100,000 residents has risen from fewer than 2 to over 300 per 100,000 residents. Recent New York State data show that unvaccinated individuals continue to be more likely to be diagnosed with COVID-19 compared to vaccinated individuals, however the Omicron variant's spread corresponds with an increase in new infections among vaccinated individuals. Those who are unvaccinated have over 10 times the risk of being hospitalized with COVID-19 compared with vaccinated individuals. Recent data show that booster doses of the COVID-19 vaccine offer more protection against the Omicron variant compared with the primary series alone.

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 and Omicron variants, which is a critical component to protecting public health. Booster doses of the COVID-19 vaccine are important to maximize protection against infection. 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. Personnel in such settings who have not received all recommended doses of the COVID-19 vaccine 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 an 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 have received all doses of the COVID-19 recommended by ACIP, including boosters and supplemental doses, 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.



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The Case for Mandating COVID-19 Vaccines for Health Care Workers

FREE

Michael Klompas, MD, MPH, Madelyn Pearson, DNP, RN, Charles Morris, MD, MPH

[Author, Article and Disclosure Information](#)<https://doi.org/10.7326/M21-2366>

Almost 15 years have passed since hospitals first began mandating influenza vaccines for health care workers. This initially innovative but now common policy was prompted by a dual desire to protect patients from health care–acquired influenza and to protect the workplace from the disruption and expense of worker illnesses. Health care organizations are now wrestling with whether to mandate SARS-CoV-2 vaccination for all employees. We believe that the case for mandating SARS-CoV-2 vaccines for health care workers is substantially stronger than the case was for mandating influenza vaccines ([Table](#)).

Table The Case for Mandating COVID-19 Vaccines for Health Care Workers: Comparison of Influenza Versus COVID-19

Table. The Case for Mandating COVID-19 Vaccines for Health Care Workers: Comparison of Influenza Versus COVID-19		
Effect	Influenza	COVID-19
Mortality	~1 in 1000	~4-10 in 1000
Number of people infected	Infects ~10% of the U.S. population each year	Infected ~30% of the U.S. population in 2020
Threat to patients	Nosocomial spread well documented but understudied	Nosocomial spread well documented but understudied
Impact on operations	Absorbed by routine operations	Unprecedented disruption of routine operations (e.g., masking, distancing, virtual meetings, visitor

Time lost to work	Employees return to work 1 d after fever resolves	restrictions, testing requirements, attestations)
Vaccine effectiveness	30%-50%	Mandatory absence of at least 10 d
Vaccine experience	~50% of adults get influenza vaccine each year	70% for adenovirus vector; 90%-95% for mRNA
		>65% of U.S. adults vaccinated thus far

mRNA = messenger RNA.

The Morbidity and Mortality of COVID-19 Far Exceeds That of Influenza

The mortality rate for influenza is estimated to be 1 in 1000, whereas that for SARS-CoV-2 is closer to 1 in 100 to 250 (1). Patients with COVID-19 are more likely to require hospital admission, have respiratory failure, and require prolonged intensive care than those with influenza (2). In 2020 alone, SARS-CoV-2 is estimated to have caused more than 522 000 excess deaths in the United States (3). Post-COVID-19 symptoms also seem to be more common, more pronounced, and more long-lasting than those after influenza.

SARS-CoV-2 Threatens Essential Workers' Lives

Vaccines for SARS-CoV-2 save lives (4). Health care workers and other essential workers have higher rates of infection than people in other fields (5). According to the Centers for Disease Control and Prevention, more than 1600 U.S. health care workers have died of COVID-19 thus far. Although it is unclear how many of these infections were acquired in the workplace versus the community, vaccine mandates will prevent infections, severe illness, and deaths in health care workers no matter where they are exposed.

Nosocomial Transmission of SARS-CoV-2 Is Common

Up to two thirds of cases of SARS-CoV-2 infection are attributable to asymptomatic and presymptomatic transmissions. Hospitals have undertaken considerable efforts to stop staff from working while sick, but these policies do not prevent staff with silent infections from coming to work and potentially infecting patients and colleagues. In some cases, staff-to-patient and staff-to-staff transmissions have led to large clusters (6). Universal masking diminishes this risk, but perfect adherence is not realistic and surgical masks are not perfectly protective; nosocomial transmission despite masks has been well documented (7). Vaccines, by contrast, provide constant protection without requiring reminders, persuasion, mask-fitting aids, or behavioral changes.

SARS-CoV-2 Vaccination for Health Care Workers Is Health Care Delivery

We believe that there is an extra onus on health care workers to protect themselves from SARS-CoV-2 in order to protect patients. Health care workers routinely tend to the elderly, ill, and vulnerable, in whom SARS-CoV-2 infection is more likely to be deadly. We cannot rely on patients being vaccinated to prevent nosocomial transmission because some patients cannot get the vaccine, some will decline, and vaccine may not be effective in immunocompromised patients (8). Vaccinating health care workers, however, helps protect even unvaccinated patients because SARS-CoV-2 vaccines are associated with fewer infections overall, less silent carriage, and less risk for transmission (4, 9).

COVID-19 Vaccines Are More Effective Than Influenza Vaccines

The estimated effectiveness of influenza vaccines varies by season but generally ranges from 30% to 50%. The 2 messenger RNA vaccines for SARS-CoV-2, by contrast, are more than 90% effective. Notwithstanding the moderate effectiveness of influenza vaccines, randomized trials suggest that vaccinating health care workers in congregate health care settings may decrease patient deaths by 30% (10). The life-saving effects of vaccinating health care workers against COVID-19 will be that much greater given these vaccines' greater effectiveness against a pathogen that is more common and more deadly than influenza.

SARS-CoV-2 Is More Disruptive to Hospital Operations Than Influenza

The SARS-CoV-2 pandemic has had an unprecedented effect on day-to-day operations in health care. Changes include universal masking, daily attestations of health, limitations on visitors, cancellations of surgery and elective admissions, cancellation of in-person meetings and education sessions, cancellation of travel, and much more. Universal vaccination is the pathway to rolling back these disruptions and returning to normal operations.

SARS-CoV-2 Is More Disruptive to Workforce Continuity Than Influenza

Vaccinating health care workers will help preserve workforce continuity. Workers with influenza are typically allowed to return to work 24 hours after their fever subsides. Staff with SARS-CoV-2 infection, however, are required to isolate for at least 10 days, even if their symptoms resolve well before then. Staff shortages have pushed some hospitals to cancel procedures, close units, and reduce elective admissions, thereby putting patients at risk due to deferred care. Vaccines will help keep more staff healthy and at work.

SARS-CoV-2 Vaccines Are Safe

More adults have now been inoculated against SARS-CoV-2 than are typically vaccinated against influenza in a given year. More than 300 million doses of SARS-CoV-2 vaccine have been administered in the United States alone, and more than 65% of U.S. adults have been vaccinated. By contrast, in a typical influenza season only about 150 million to 175 million doses of influenza vaccine are administered and fewer than 50% of adults are immunized.

Despite the enormous number of people who have now received SARS-CoV-2 vaccines, serious side effects have been exceedingly rare. We acknowledge that some life-threatening adverse effects and deaths have occurred, but the incidence of these complications is vanishingly small, is substantially lower than the risk for complications of COVID-19, and is far outweighed in our opinion by the likelihood of benefit to both health care workers and their patients. Similarly, we believe that these benefits also outweigh the other possible reasons that health care workers may object to vaccination, including fear of postvaccine side effects, concerns about fetal safety,

philosophical disagreement, and perceived invulnerability to serious infection.

Many organizations contemplating mandating SARS-CoV-2 vaccines are reluctant to move forward while vaccines remain under emergency use authorization. Some are also concerned about legal challenges. As more safety data on the vaccines rapidly accumulate, however, there is every expectation of full approval from the U.S. Food and Drug Administration later this year, and the courts have ruled in favor of health care organizations on the legal challenges that have come forward thus far. Now is the time for organizations to ready themselves to adopt mandatory vaccination policies as soon as full approval is granted. This includes drafting policies, educating employees about vaccine safety and effectiveness, developing strategies to address unvaccinated employees' specific concerns, ensuring easy vaccine access, partnering with employee leaders and unions to make a shared case for universal vaccination, weighing potential exemptions, and foreshadowing the road ahead for all.

Comments

3 Comments

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Alex Sherriffs • UCSF-Fresno • 10 August 2021

First do no harm.

An abiding ethic for physicians is "first do no harm". We expect to face some personal risks as we care for patients. I feel a duty to all patients to try to protect them from harm that I might cause, including exposing them to infections. The personal protection (and risk) I might gain (or be exposed to) from an immunization is



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Safety and Immunogenicity of Anti–SARS-CoV-2 Messenger RNA Vaccines in Recipients of Solid Organ Transplants

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Olivier Marion, MD, Arnaud Del Bello, MD, Florence Abravanel, PharmD, PhD, ... [View all authors](#) +[Author, Article and Disclosure Information](#)<https://doi.org/10.7326/M21-1341>

Background: Recipients of solid organ transplant (SOT) are a high-risk group for severe SARS-CoV-2 infection. The mortality rate of patients with SOT during the COVID-19 pandemic has been reported to be approximately 20% (1). The anti–SARS-CoV-2 vaccines represent a hope to protect this population against this life-threatening infection.

Objective: To assess the humoral response to messenger RNA (mRNA)–based vaccination in recipients of SOT.

Methods: All patients with heart, kidney, liver, or pancreas transplants from the Midi-Pyrénées region (southwest France) are followed in our department. When the vaccination campaign started (7 January 2021), these patients were invited via text message, e-mail, or transplant patients' associations to be vaccinated. Patients were asked to register via a dedicated telephone number or website. They were vaccinated consecutively according to their registration date. According to the recommendations of the Francophone Society of

Transplantation, anti-SARS-CoV-2 spike protein antibodies were monitored before and after vaccination. We used the SARS-CoV-2 total antibodies enzyme-linked immunosorbent assay test (Beijing Wantai Biological Pharmacy Enterprise) (80% of patients) or another validated anti-SARS-CoV-2 spike protein assay. According to French law (*loi Jardé*), anonymous retrospective studies do not require institutional review board approval.

Findings: By 16 April 2021, 950 patients of the 2666 from our cohort had received at least 1 dose of an mRNA vaccine (BNT162b2 vaccine [Pfizer-BioNTech], $n = 942$; mRNA-1273 vaccine [Moderna], $n = 8$) and had anti-SARS-CoV-2 antibodies monitored. Fifty patients had vaccination without monitoring of antibodies, 80 patients are planned to be vaccinated within the next month, and 257 patients declined the vaccine. We had no feedback from the remaining 1329 patients.

A total of 895 of the 950 patients had an available serologic screening just before the first injection. The prevalence of anti-SARS-CoV-2 antibodies was 2.1% (95% CI, 1.3% to 3.3%; $n = 19$ of 895). Only 5 of the 19 patients who were seropositive previously had symptomatic COVID-19. A total of 576 patients benefited from a second injection at day 28. The prevalence of anti-SARS-CoV-2 antibodies before the second injection was 6.4% (CI, 4.6% to 8.8%; $n = 37$ of 576).

In 367 patients who had a 4-week follow-up after the second dose, the prevalence of anti-SARS-CoV-2 antibodies increased from 1.4% (CI, 0.4% to 3.2%; $n = 5$ of 367) at baseline to 6.3% (CI, 4.0% to 9.3%; $n = 23$ of 367) at day 28 and 33.8% (CI, 29.0% to 38.9%; $n = 124$ of 367) 1 month after the second dose ([Figure](#)). Characteristics of patients who were vaccinated with and without a 4-week follow-up after the second dose are presented in the [Table](#).



Figure. Prevalence of anti-SARS-CoV-2 antibodies at 4 wk after the second vaccine dose in all transplant patients and by type of organ transplant.

Percentages with exact binomial 95% CIs are presented.

[Download figure](#) | [Download PowerPoint](#)

Table Characteristics of Recipients of SOT With and Without a 4-Week Follow-up After 2-Dose Messenger RNA–Based Vaccination



The tolerance of mRNA vaccines was excellent, with no serious adverse events reported, except in 1 patient with a liver transplant who developed paresthesia of the lower limb. Kidney function and liver enzymes remained stable in recipients of kidney and liver transplants before and 28 days after the first dose (data not shown). One recipient of a kidney transplant presented 3 weeks after the first injection with a 50% increase in serum creatinine level related to drug-induced dehydration. The patient recovered after rehydration and reduction of diuretics. Only 1 patient, who had vaccination without the requested biological monitoring and who is not included in this report, had an acute cellular rejection.

Discussion: In immunocompetent patients, mRNA vaccines have shown strong antibody response, even after a single dose (2). In immunocompromised patients, such as recipients of SOT, a weak humoral response to mRNA vaccines was reported. Boyarsky and colleagues (3) reported the appearance of specific antibodies in 17% of transplant recipients 3 weeks after a single dose of an mRNA vaccine. Recently, in a small series of patients with SOT, including mainly those who had a kidney transplant, anti-SARS-CoV-2 antibodies were detected in 37.5% to 58.8% of patients at 4 weeks after the second dose (4, 5). Our

study, which included many patients with SOT, confirms a weak immunogenicity of mRNA vaccines in those who had a transplant. Recipients of liver transplant showed a better humoral response than recipients of other organs. Considering the good tolerance of mRNA vaccines, an increased antigen dose or a third vaccine dose can be proposed to improve the vaccination response in this specific population. In France, the French National Authority for Health has recently recommended offering a third dose to immunosuppressed patients.

Further studies are required to assess both cellular and humoral responses to vaccines and to determine their long-term protective capacity. Meanwhile, enhanced barrier measures should be maintained, and vaccination of household members and close contacts is recommended.

Comments

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Disparities in COVID-19 Vaccination Coverage Among Health Care Personnel Working in Long-Term Care Facilities, by Job Category, National Healthcare Safety Network — United States, March 2021

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Residents of long-term care facilities (LTCFs) and health care personnel (HCP) working in these facilities are at high risk for COVID-19–associated mortality. As of March 2021, deaths among LTCF residents and HCP have accounted for almost one third (approximately 182,000) of COVID-19–associated deaths in the United States (1). Accordingly, LTCF residents and HCP were prioritized for early receipt of COVID-19 vaccination and were targeted for on-site vaccination through the federal Pharmacy Partnership for Long-Term Care Program (2). In December 2020, CDC’s National Healthcare Safety Network (NHSN) launched COVID-19 vaccination modules, which allow U.S. LTCFs to voluntarily submit weekly facility-level COVID-19 vaccination data.* CDC analyzed data submitted during March 1–April 4, 2021, to describe COVID-19 vaccination coverage among a convenience sample of HCP working in LTCFs, by job category, and compare HCP vaccination coverage rates with social vulnerability metrics of the surrounding community using zip code tabulation area (zip code area) estimates. Through April 4, 2021, a total of 300 LTCFs nationwide, representing approximately 1.8% of LTCFs enrolled in NHSN, reported that 22,825 (56.8%) of 40,212 HCP completed COVID-19 vaccination.† Vaccination coverage was highest among physicians and advanced practice providers (75.1%) and lowest among nurses (56.7%) and aides (45.6%). Among aides (including certified nursing assistants, nurse aides, medication aides, and medication assistants), coverage was lower in facilities located in zip code areas with higher social vulnerability (social and structural factors associated with adverse health outcomes), corresponding to vaccination disparities present in the wider community (3). Additional efforts are needed to improve LTCF immunization policies and practices, build confidence in COVID-19 vaccines, and promote COVID-19 vaccination. CDC and partners have prepared education and training resources to help educate HCP and promote COVID-19 vaccination coverage among LTCF staff members.§

LTCFs voluntarily reported HCP COVID-19 vaccination data using the NHSN COVID-19 vaccination modules through April 4, 2021. Coverage was assessed among LTCF HCP, stratified by job category (denominator).¶ Vaccinated HCPs (numerator) were those who were vaccinated at the facility or had documentation of receipt of COVID-19 vaccination elsewhere. The module required responses for the total number of HCP and their COVID-19 vaccinations status; subtotals by job categories were optional. Facilities were included for analysis only if they had reported nonzero values for the number of HCP and their vaccination status by every job category in the most recent weekly report submitted through NHSN during March 1–April 4, 2021. Reported HCP job categories were 1) physicians and advanced practice providers (residents, fellows, advanced practice nurses, and physician assistants); 2) therapists (respiratory, occupational, physical, speech, and music therapists, and therapy assistants); 3) ancillary services employees (environmental, laundry, maintenance, and dietary services); 4) nurses (registered nurses and licensed practical/vocational nurses); 5) aides (certified nursing assistants, nurse aides, medication aides, and medication assistants); and 6) other HCP (personnel not included in the preceding categories, including contract staff members, students, and other nonemployees).

Vaccination coverage for aides, the largest HCP category, was further assessed by social indicators within the zip code area of the LTCF, including median income and percentage of adults belonging to racial and ethnic minority groups, percentage living in poverty, and percentage without a high school diploma; social indicator data were obtained from the 2019 American Community Survey.** Tertiles (higher, moderate, and low) were calculated for each indicator based on the national distribution of zip code areas; facilities in the corresponding zip code area were assigned to each tertile. Because this was a convenience sample, with likely intra-facility or locality clustering in vaccination behavior, confidence intervals were not calculated, nor was statistical testing for percentages performed. One LTCF was excluded from this analysis because a corresponding zip code area was missing. Data were downloaded

* <https://www.medrxiv.org/content/10.1101/2021.05.14.21257224v1>

† Completed COVID-19 vaccination was defined as 2 doses of Pfizer-BioNTech or Moderna or 1 dose of the Janssen (Johnson & Johnson) COVID-19 vaccines. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

§ <https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/index.html>

¶ <https://www.cdc.gov/nhsn/forms/57.219-p.pdf>

** <https://www.census.gov/programs-surveys/acs>

for analysis on April 7, 2021, and all analyses were conducted using SAS statistical software (version 9.4; SAS Institute). This activity was reviewed by CDC and conducted consistent with applicable federal law and CDC policy.^{††}

During March 1–April 4, a total of 1,898 LTCFs voluntarily reported HCP COVID-19 vaccination data, including 300 (16%) facilities from 47 states^{§§} that reported numbers for HCP and vaccination status for every job category in the most recent weekly report submitted through NHSN (Supplementary Table 1, <https://stacks.cdc.gov/view/cdc/108137>). Among 40,212 HCP from these LTCFs, 22,825 (56.8%) had completed COVID-19 vaccination (Table 1). In this convenience sample, the group with the highest percentage of reported fully vaccinated HCP were physicians and other advanced practice providers (75.1%), followed by therapists (69.2%), ancillary services employees (58.5%), nurses (56.7%), and aides (45.6%). Coverage was 68.5% among other HCP not reported in these categories (e.g., students and contractors). The proportion of persons who declined COVID-19 vaccination ranged from 11.1% among physicians to 33.2% among aides. Reported recent COVID-19 infections ranged from 0.7% among physicians to 3.0% among aides. The percentage of aides who were completely vaccinated was lower among those working in facilities located in zip code areas with higher proportions of ethnic and racial minorities (43.5% versus 50.5%), lower household median income (40.5% versus 48.1%), higher poverty (42.4% versus 49.2%), and lower high school completion (42.2% versus 49.3%) (Table 2).

Discussion

In March 2021, data from a convenience sample of 300 LTCFs across the United States indicated disparities in HCP COVID-19 vaccination coverage, with a 30 percentage-point difference in coverage between physicians and other advanced practice providers (75.1%) and aides (45.6%). Among aides, lower vaccination coverage was observed in those facilities located in more socially vulnerable zip code areas. Together, these data suggest that vaccination disparities among job categories likely mirror social disparities in general as well as disparities in the surrounding communities. These findings suggest that vaccination promotion and outreach efforts focused on socially vulnerable and marginalized groups and communities could help address inequities (4).

One concern is that nurses and aides in this sample, who have the most patient contact, had the lowest vaccination coverage. COVID-19 outbreaks have occurred in LTCFs in which residents were highly vaccinated, but transmission

TABLE 1. COVID-19 vaccination coverage of health care professionals, by job category, in 300 long-term care facilities reporting to the National Healthcare Safety Network — United States, March 1–April 4, 2021

HCP job category	No. of HCP	No. (%)		
		Fully vaccinated	Declined vaccination	Recent SARS-CoV-2 infection
Aides*	12,670	5,778 (45.6)	4,204 (33.2)	382 (3.0)
Ancillary services employees [†]	9,116	5,337 (58.5)	2,374 (26.0)	172 (1.9)
Nurses [§]	8,622	4,887 (56.7)	2,359 (27.4)	196 (2.3)
Therapists [¶]	3,028	2,095 (69.2)	527 (17.4)	51 (1.7)
Physicians and advanced practice providers**	1,284	964 (75.1)	142 (11.1)	9 (0.7)
Other HCP ^{††}	5,492	3,764 (68.5)	794 (14.5)	78 (1.4)
All staff members	40,212	22,825 (56.8)	10,400 (25.9)	888 (2.2)

Abbreviation: HCP = health care personnel.

* Certified nursing assistants, nurse aides, medication aides, and medication assistants.

[†] Environmental, laundry, maintenance, and dietary services.

[§] Registered nurses and licensed practical/vocational nurses.

[¶] Respiratory, occupational, physical, speech, and music therapists, and therapy assistants.

** Physicians, residents, fellows, advanced practice nurses, and physician assistants.

^{††} Personnel not included in the preceding categories, including contract staff members, students, and other nonemployees.

TABLE 2. COVID-19 vaccination coverage among aides,* by selected social vulnerability metrics and tertile — United States, March 1–April 4, 2021

Social vulnerability metric	Vulnerability tertile, no. vaccinated/total (%)		
	Higher	Moderate	Low
Percentage in racial/ethnic minority group [†]	2,794/6,416 (43.5)	2,379/5,056 (47.1)	605/1,198 (50.5)
Median income [§]	1,245/3,072 (40.5)	1,843/4,005 (46.0)	2,690/5,593 (48.1)
Percentage living in poverty [¶]	1,865/4,397 (42.4)	1,705/3,783 (45.1)	2,208/4,490 (49.2)
Percentage without high school diploma ^{**}	1,577/3,739 (42.2)	1,997/4,460 (44.8)	2,204/4,471 (49.3)

* Certified nursing assistants, nurse aides, medication aides, and medication assistants.

[†] Higher vulnerability tertile: zip code areas with >17.4% persons belonging to racial/ethnic minorities; moderate: 17.4%–96.0%; low: <4.0%.

[§] Higher vulnerability tertile: zip code areas with household median income ≤\$48,770; moderate: median income >\$48,770 through ≤\$64,741; low: median income >\$64,741.

[¶] Higher vulnerability tertile: zip code areas with >15.5% of households living under the federal poverty line; moderate: 15.5%–8.1%; low: ≤8.0%.

** Higher vulnerability tertile: zip code areas with >13.6% of persons aged ≥25 years without a high school diploma or equivalent; moderate: 13.6%–6.9%; low: <6.9%.

occurred through unvaccinated staff members (5). This finding also has equity implications: national data indicated that aides in nursing homes are disproportionately women and members of racial and ethnic minority groups, with median hourly wages of \$13–\$15 per hour^{¶¶} (6); aides are also more likely to have underlying conditions that put them at risk for adverse outcomes from COVID-19 (7). As vaccination was

^{††} 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

^{§§} No LTCFs were included from Delaware, Minnesota, or Montana.

^{¶¶} <https://phinational.org/wp-content/uploads/2020/01/Its-Time-to-Care-2020-PHI.pdf>

Summary**What is already known about this topic?**

Residents of long-term care facilities (LTCFs) and health care personnel (HCP) who work in these facilities were prioritized for early COVID-19 vaccination. Achieving high coverage in this setting is critical to preventing additional outbreaks.

What is added by this report?

During March 2021, 300 LTCFs reported COVID-19 vaccination coverage for their HCP. COVID-19 vaccination coverage was highest among physicians (75.1%) and lowest among aides (45.6%). Vaccination coverage among aides was lower in facilities located in zip code areas with higher levels of social vulnerability.

What are the implications for public health practice?

Additional efforts to improve LTCF immunization practices, build confidence in COVID-19 vaccines, and promote COVID-19 vaccination are needed.

made available on site and lower vaccination rates reflected higher declination rates, vaccine hesitancy might have been an important contributor to undervaccination in these facilities.

The finding that vaccination coverage among aides was lower among those working at LTCFs located in zip code areas with higher social vulnerability is consistent with an earlier analysis of overall county-level vaccination coverage by indices of social vulnerability (3); however, similar patterns among LTCF staff members are notable because on-site vaccination removed a number of barriers to vaccination, including travel, scheduling, and need to take time off from work.

The findings in this report are subject to at least five limitations. First, facilities included in this analysis had completed a series of optional fields in a voluntary NHSN COVID-19 vaccination module. The 300 facilities presented represent <2% of the >17,000 LTCFs enrolled in NHSN; thus, the findings from this nonprobability-based convenience sample are not generalizable to all LTCFs. Second, LTCFs reported aggregate weekly data, preventing person-level analysis (e.g., by race/ethnicity) and possibly resulting in duplication of reports, if, for example, HCP work at multiple facilities. Third, data on staff member numbers and numbers vaccinated were self-reported by LTCFs and were not independently validated. Fourth, excluding LTCFs reporting zero values might exclude LTCFs with no vaccine coverage (as opposed to nonreporting), thus inflating the estimated vaccination coverage. Finally, this analysis captured vaccination patterns during March 2021, when most facilities had completed on-site vaccination through the federal pharmacy program. Increasing availability and acceptance of COVID-19 vaccinations in subsequent months might have resulted in higher coverage. However, higher staff

member turnover in some job categories, including aides, relative to other job categories, might lead to changes in vaccination coverage.

Low vaccination coverage among LTCF staff members highlights disparities across HCP groups, and in the surrounding communities. Additional efforts are warranted to improve LTCF immunization policies and vaccination practices, build HCP confidence in COVID-19 vaccines, and encourage vaccination among persons who have been economically or socially marginalized. On May 11, 2021 the Centers for Medicare & Medicaid Services (CMS) published an interim final rule requiring LTCFs to educate HCP on COVID-19 vaccines, offer vaccination, and report vaccination status to NHSN^{***} (8). CDC and partners have prepared education and training resources to help educate HCP and promote vaccination coverage among LTCF staff members.^{†††} Finally, LTCFs could consider best practices from influenza campaigns, which found that employer vaccination requirements were associated with the highest vaccination coverage (9).

^{***} CDC and CMS data are available at the following: <https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html> and <https://data.cms.gov/covid-19/covid-19-nursing-home-data>

^{†††} <https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/index.html>

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COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021

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On April 21, 2021, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

Although COVID-19 mRNA vaccines demonstrated high efficacy in clinical trials (1), they were not 100% efficacious. Thus, some infections postvaccination are expected. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants. The Kentucky Department for Public Health (KDPH) and a local health department investigated a COVID-19 outbreak in a SNF that occurred after all residents and health care personnel (HCP) had been offered vaccination. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received 2 vaccine doses. Twenty-six residents and 20 HCP received positive test results for SARS-CoV-2, the virus that causes COVID-19, including 18 residents and four HCP who had received their second vaccine dose >14 days before the outbreak began. An R.1 lineage variant was detected with whole genome sequencing (WGS). Although the R.1 variant has multiple spike protein mutations, vaccinated residents and HCP were 87% less likely to have symptomatic COVID-19 compared with those who were unvaccinated. Vaccination of SNF populations, including HCP, is critical to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also essential.

Investigation and Epidemiologic Findings

The SNF conducted vaccination clinics using Pfizer-BioNTech mRNA vaccine on January 10, January 31, and February 21, 2021. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received two vaccine doses. All vaccinated residents and HCP were vaccinated on-site, the majority on January 10 and 31. Four residents and five HCP received their second dose during the third clinic, which was <14 days before the outbreak onset.

Before and during the outbreak, SARS-CoV-2 testing was used for evaluating symptomatic illness in residents and HCP. Symptom screening of residents and HCP had been ongoing since March 2020, and twice-weekly screening testing of all HCP had been occurring since November 2020. A COVID-19 case was defined as a positive SARS-CoV-2 antigen or reverse transcription–polymerase chain reaction (RT-PCR) test result.

Possible reinfection was defined as a positive SARS-CoV-2 test result >90 days after a previous laboratory-confirmed infection.

The outbreak was identified during routine HCP antigen testing on March 1.* This was 8 days after the third vaccination clinic. The index case occurred in an unvaccinated, symptomatic HCP. Once the outbreak was identified, daily rapid point-of-care antigen testing of all residents, regardless of symptoms, was added to the twice-weekly HCP testing. Additional specimens were collected the same day for RT-PCR confirmation of positive antigen test results. One week after the outbreak was identified, resident antigen testing was reduced to three times weekly, then to twice weekly after no additional cases were identified for 1 week.

The local health department interviewed HCP and facility staff members to collect information about the cases. Vaccination status was ascertained through immunization registry review and facility interviews. COVID-19–related hospitalizations and deaths were confirmed by medical records reviews. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.†

Relative risks (RRs) were calculated comparing unvaccinated and vaccinated residents and HCP; vaccine effectiveness (VE [1–RR of vaccinated versus unvaccinated × 100]) was calculated for the following outcomes: SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death. Persons who received their second vaccine dose ≥14 days before the outbreak began were considered vaccinated, consistent with CDC postvaccination guidance§ and breakthrough case definition. Ten persons who had received at least 1 dose but had not received a second vaccine dose ≥14 days before the outbreak were excluded from analyses.

A sensitivity analysis was conducted using a 7-day threshold to classify persons as vaccinated, consistent with the Pfizer-BioNTech vaccine clinical trials (1). Four residents and five HCP who received their second vaccine dose 8 days before outbreak identification were classified as vaccinated in this sensitivity analysis. One HCP who received a single vaccine

* <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>
† 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. 241(d); 5 U.S.C. 552a; 44 U.S.C. 3501 et seq.

§ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>

dose remained excluded (Supplementary Table <https://stacks.cdc.gov/view/cdc/105235>).

KDPH Division of Laboratory Services performed WGS (2). Genomes were assembled using the Staph-B Monroe pipeline,[¶] followed by Nextclade** for clade assignment and mutation calling, Pangolin^{††} for lineage assignment, and Nextstrain for phylogenetic analysis (3).

During the outbreak, 46 COVID-19 cases were identified, including cases in 26 residents (18 fully vaccinated) and 20 HCP (four vaccinated) (Figure) (Table). Two cases occurred in residents who had received their second vaccine dose within 14 days; these two cases were excluded from the primary analysis. Vaccinated residents and HCP were less likely to be infected than were unvaccinated persons. Attack rates in unvaccinated residents (75.0%) were 3 times as high as those in vaccinated residents (25.4%; RR = 3.0; 95% confidence interval [CI] = 1.7–5.2) and in unvaccinated HCP (29.6%) were 4.1 times as high as those in vaccinated HCP (7.1%; RR = 4.1; 95% CI = 1.5–11.6). The estimated VE against SARS-CoV-2 infection among residents was 66.2% (95% CI = 40.5%–80.8%) and among HCP was 75.9% (95% CI = 32.5%–91.4%).

VE against symptomatic COVID-19 was 86.5% (95% CI = 65.6%–94.7%) among residents and 87.1% (95% CI = 46.4%–96.9%) among HCP. VE against hospitalization was 94.4% (95% CI = 73.9%–98.8%) among residents; no HCP were hospitalized. Three residents died, two of whom were unvaccinated (VE = 94.4%; 95% CI = 44.6%–99.4%).

Four possible reinfections were identified (one resident and three HCP); of these, one HCP was vaccinated. All four persons experienced symptomatic illness. One resident was infected 300 days earlier and had nine consecutive negative RT-PCR tests before reinfection, including two within 30 days of the outbreak. This resident was hospitalized and died.

Laboratory and Bioinformatics Findings

WGS was performed for 28 specimens (27 persons, including one who was reinfecting); all had >97% genome coverage at a depth of >30x, therefore passing required quality control matrices.^{§§} Examination of phylogeny revealed 28 clustered sequences sharing 14 amino acid mutations not present in the reference Wuhan-1 genome: ORF1a:A2584T,

ORF1b:P314L, ORF1b:G1362R, ORF1b:P1936H, S:E484K, S:D614G, S:G769V, S:W152L, M:F28L, N:M1X, N:S187L, N:R203K, N:G204R, and N:Q418H. This cluster aligns with the R.1 lineage, which had not previously been identified in Kentucky. Whereas the 28 sequences share spike protein mutations E484K, D614G, G769V, and W152L with the R.1 root, the mutation ORF1a:A2584T places the cluster in a separate group on the phylogenetic tree.

Public Health Response

The local health department, along with the KDPH regional epidemiologist and regional infection preventionist, provided guidance on implementation of infection prevention strategies. These included the use of transmission-based precautions and hand hygiene, ongoing testing to identify new cases, exclusion of symptomatic HCP from work, isolation and quarantine of HCP, and provision of dedicated and separate spaces for care of infected and exposed residents, regardless of vaccination status.^{¶¶}

Discussion

In a SNF with 90.4% of residents vaccinated, an outbreak of COVID-19 occurred after introduction from an unvaccinated, symptomatic HCP. WGS identified an R.1 lineage variant, characterized by E484K and other mutations within the spike protein. Attack rates were three to four times as high among unvaccinated residents and HCP as among those who were vaccinated; vaccinated persons were significantly less likely to experience symptoms or require hospitalization.

Although the R.1 variant is not currently identified as a CDC variant of concern or interest,^{***} it does have several mutations of importance. The D614G mutation demonstrates evidence of increasing virus transmissibility (4). The E484K mutation, found within the receptor-binding domain of the spike protein, is also seen in the variants of concern B.1.351 and P.1, which show evidence of reduced neutralization by convalescent and postvaccination sera (5,6). Mutation W152L might reduce the effectiveness of neutralizing antibodies (7). Although vaccination was associated with decreased likelihood of infection and symptomatic illness, 25.4% of vaccinated residents and 7.1% of vaccinated HCP were infected, supporting concerns about potential reduced protective immunity to R.1. In addition, four possible reinfections were identified, providing some evidence of limited or waning natural immunity to this variant.

Point estimates for VE against SARS-CoV-2 infections were lower than were those reported from Israel's national vaccination program (8). Whereas this could reflect reduced

[¶] https://staph-b.github.io/staphb_toolkit/workflow_docs/monroe/

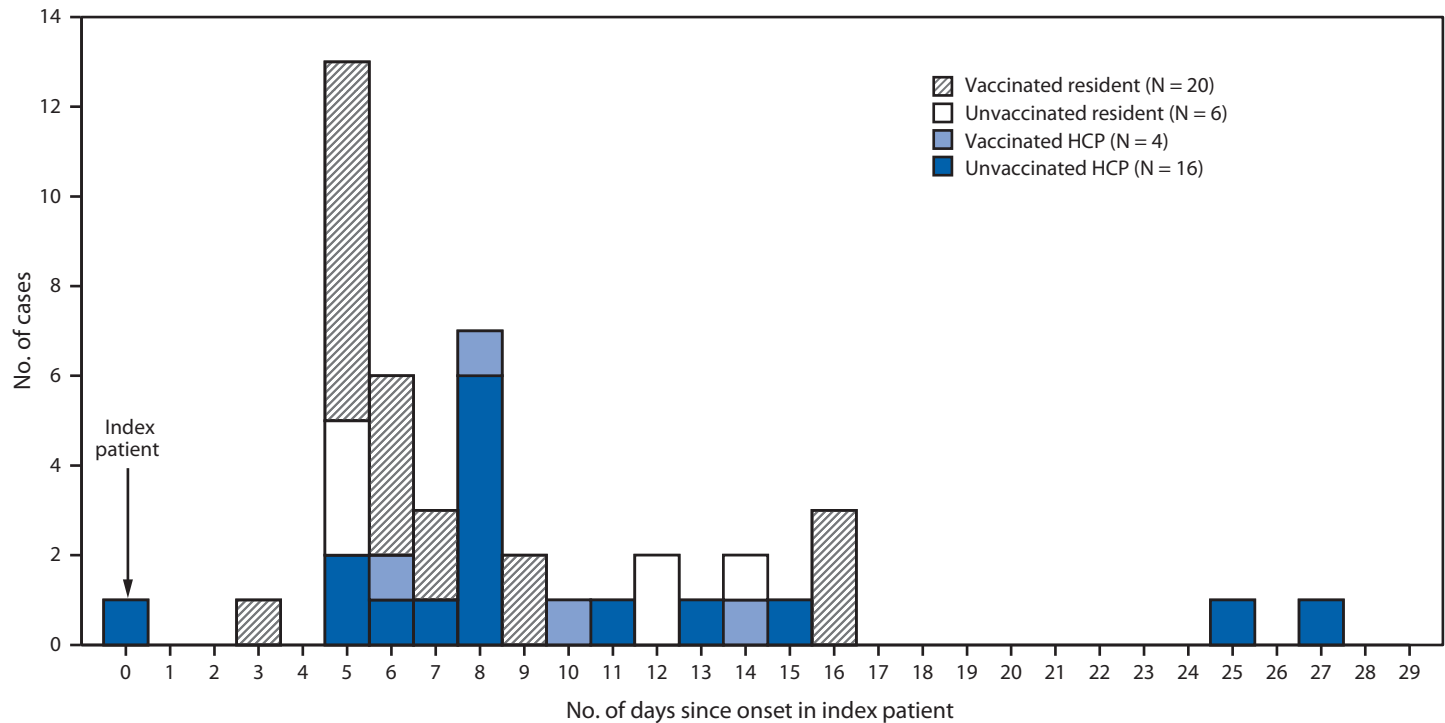
^{**} <https://clades.nextstrain.org/>

^{††} <https://github.com/cov-lineages/pangolin>

^{§§} Percentage of coverage and depth of coverage are metrics computed during genome assembly that correspond with data quality. The data quality threshold used by the Association of Public Health Laboratories is ≥90% and 10X depth for Illumina sequencing technology. <https://www.aplh.org/programs/preparedness/Crisis-Management/Documents/APHL-SARS-CoV-2-Sequencing.pdf>

^{¶¶} <https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

^{***} <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html>

FIGURE. SARS-CoV-2 illness onset* among residents and health care personnel (HCP) in a skilled nursing facility, relative to onset in the index patient, by vaccination status† — Kentucky, March 2021

* Symptom onset date or specimen collection date, if asymptomatic.

† Persons who received 2 doses of Pfizer-BioNTech vaccine are indicated as vaccinated; unvaccinated persons received no vaccine doses. Persons who received a second dose of vaccine <14 days before outbreak onset (four residents and five HCP) and those who received only a single dose of vaccine (one HCP) were excluded from the primary analysis; this resulted in exclusion of two cases that occurred in residents.

protection against R.1, other factors to consider include the smaller sample size in this study and the higher exposure risk associated with an outbreak in a congregate setting. In addition, testing, regardless of symptoms, was performed with high frequency for both residents and HCP, which contrasts with VE studies that use a primary reliance on individual test-seeking behavior. Such differences could influence VE estimates for infection; therefore, caution is urged when comparing these studies. Regardless of VE differences in SARS-CoV-2 infection, the estimated VE for COVID-19 symptom prevention (86.5% for residents; 87.1% for HCP) demonstrates a strong protective effect of vaccination.

The risk for poor outcomes among unvaccinated SNF residents is highlighted by the hospitalization of four of the six unvaccinated, infected residents, and two subsequent deaths, including in one previously infected resident. This underscores the importance of the Advisory Committee on Immunization Practices' recommendation that all persons, including those who have recovered from COVID-19, be vaccinated.^{†††}

^{†††} <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Low acceptance of vaccination among SNF HCP might increase the likelihood of SARS-CoV-2 introduction and transmission within a facility. Nationally, a median of 37.5% of HCP working in long-term care facilities had received at least 1 dose of vaccine by mid-January 2021 (9). Although the vaccination rate in this SNF surpassed this early national rate, approximately one half of HCP were vaccinated. To protect SNF residents, it is imperative that HCP, as well as SNF residents, be vaccinated. A continued emphasis on strategies for prevention of disease transmission, even among vaccinated populations, is also critical. Timely implementation of infection control strategies after outbreak identification likely contributed to the rapid decline in new cases during the second week of the outbreak.

The findings in this report are subject to at least three limitations. First, the health status of residents who declined vaccination might have differed from those who consented to vaccination. Thus, hospitalization and death outcomes might be biased when comparing the groups without controlling for underlying health conditions. Second, underlying health status and advance directives might affect decisions for resident hospitalization; therefore, association of vaccination with

TABLE. Relative risk and estimated vaccine effectiveness for prevention of SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death for fully vaccinated persons compared with unvaccinated persons during a COVID-19 outbreak in a skilled nursing facility (SNF) — Kentucky, 2021

Population and outcome	No. (% attack rate)		Unvaccinated versus vaccinated RR (95% CI)	Vaccine effectiveness [§] (95% CI)
	Vaccinated*	Unvaccinated [†]		
Total SNF population[¶]	(n = 127)	(n = 62)	—	—
SARS-CoV-2 infection	22 (17.3)	22 (35.5)	—	—
Symptomatic	8 (6.3)	20 (32.3)	—	—
Hospitalization	2 (1.6)	4 (6.5)	—	—
Death	1 (0.8)	2 (3.2)	—	—
Residents	(n = 71)	(n = 8)	—	—
SARS-CoV-2 infection	18 (25.4)	6 (75.0)	3.0 (1.7–5.2)	66.2 (40.5–80.8)
Symptomatic	6 (8.5)	5 (62.5)	7.4 (2.9–18.8)	86.5 (65.6–94.7)
Hospitalization	2 (2.8)	4 (50.0)	17.8 (3.8–82.1)	94.4 (73.9–98.8)
Death	1 (1.4)	2 (25.0)	17.8 (1.8–174.7)	94.4 (44.6–99.4)
Health care personnel	(n = 56)	(n = 54)	—	—
SARS-CoV-2 infection	4 (7.1)	16 (29.6)	4.1 (1.5–11.6)	75.9 (32.5–91.4)
Symptomatic	2 (3.6)	15 (27.8)	7.8 (1.9–32.4)	87.1 (46.4–96.9)
Hospitalization	0 (—)	0 (—)	—	—
Death	0 (—)	0 (—)	—	—

Abbreviations: CI = confidence interval; RR = relative risk.

* Receipt of 2 doses of Pfizer-BioNTech vaccine ≥ 14 days before identification of the SNF outbreak; persons who received a second dose of vaccine < 14 days before the outbreak (four residents and five health care personnel) and those who received a single dose of vaccine (one health care worker) were excluded, which resulted in exclusion of two resident cases.

[†] Receipt of zero doses of COVID-19 vaccine.

[§] Calculated as $(1 - \text{RR of vaccinated versus unvaccinated}) \times 100$.

[¶] Includes residents and health care personnel.

hospitalization in this SNF population might have limited generalizability. Finally, because of the reduced sensitivity of antigen testing in asymptomatic populations,^{§§§} it is possible that some asymptomatic cases were not identified. If this introduced differential bias for identification of cases in either the vaccinated or unvaccinated groups, actual VE for the prevention of SARS-CoV-2 infections could differ from measured effectiveness.

An R.1 lineage variant, not previously detected in Kentucky, was identified in a SNF outbreak where 46 residents and HCP were infected. Compared with unvaccinated persons, vaccinated persons had reduced risk for SARS-CoV-2 infection and symptomatic COVID-19. A continued emphasis on vaccination of SNF populations, including HCP, is essential to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also critical.

^{§§§} <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

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Summary

What is already known about this topic?

COVID-19 vaccines have demonstrated high efficacy in clinical trials. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants.

What is added by this report?

In a COVID-19 outbreak at a Kentucky SNF involving a newly introduced variant to the region, unvaccinated residents and health care personnel (HCP) had 3.0 and 4.1 times the risk of infection as did vaccinated residents and HCP. Vaccine was 86.5% protective against symptomatic illness among residents and 87.1% protective among HCP.

What are the implications for public health practice?

Vaccination of SNF residents and HCP is essential to reduce the risk for symptomatic COVID-19, as is continued focus on infection prevention and control practices.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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January 24, 2022 | 2:27 pm

COVID-19 Vaccines

Children ages 5+ are eligible for the COVID-19 vaccine and children ages 12+ are eligible for a booster. Parents and guardians: make sure your child gets vaccinated and stays up to date with all recommended doses.

VAX FOR KIDS >



NOVEMBER 26, 2021 | Albany, NY

Governor Hochul Announces Urgent Action to Boost Hospital Capacity and Address Staffing Shortages

CORONAVIRUS (/KI HEALTH)RQWKI COVID-19 VACCINE (/KEYWORDS/COVID-19-VACCINE)

State of Emergency to Trigger Use of Surge and Flex System and Expand Purchasing Ability

Department of Health Will Be Permitted to Limit Non-Essential, Non-Urgent Scheduled Hospital Procedures If Necessary to Ensure Capacity

New Omicron Variant Not Detected in New York State Yet, but Hochul Warns: 'It's Coming'

Governor Kathy Hochul today announced urgent action to boost hospital capacity and address staffing shortages ahead of potential spikes in COVID-19 cases this upcoming winter. Through an Executive Order signed by Governor Hochul, the Department of Health will be allowed to limit non-essential, non-urgent procedures for in-hospitals or systems with limited capacity to protect access to critical health care services. Limited capacity is defined as below 10% staffed bed capacity, or as determined by the Department of Health based on regional and health care utilization factors.

The new protocols will begin on Friday, December 3, and will be re-assessed based on the latest COVID-19 data on January 15. The Executive Order will also enable New York State to acquire more quickly any critical supplies to combat the pandemic.

"We've taken extraordinary action to prevent the spread of COVID-19 and combat this pandemic. However, we continue to see warning signs of spikes this upcoming winter, and while the new Omicron variant has yet to be detected in New York State, it's coming," **Governor Hochul said.** "In preparation, I am announcing urgent steps today to expand hospital capacity and help ensure our hospital systems can tackle any challenges posed by the pandemic as we head into the winter months. The vaccine remains one of our greatest weapons in fighting the pandemic, and I encourage every New Yorker to get vaccinated, and get the booster if you're fully vaccinated."

The Hochul Administration continues to take comprehensive steps to prevent the spread of COVID-19, including mask protocols in health care and P-12 school settings, correctional facilities and detentions centers, public transportation and at transportation hubs, and implementation of the HERO Act which requires all employers to implement workplace safety plans in response to COVID-19.

The Administration continues to focus on boosting vaccination rates among New Yorkers, including bolstering the State's network of vaccine access points, and working to expand testing supplies. That also includes acting on our comprehensive plan to vaccinate school-aged children 5-17, provide incentive programs, combat vaccine misinformation campaigns, increase vaccine awareness, deploy pop-up vaccines in targeted low-vaccination areas, and implement vaccine requirements for health care workers. On August 24, the vaccination rate among adults with one dose was 78.8%. Today, it is 90.2%.

Further, the Administration continues to ramp up booster shots and urges all New Yorkers to get the booster dose once fully vaccinated. As of November 24, over 2.2 million boosters and/or additional doses have been administered. Nearly 4,500 locations across are administering booster shots.

The Administration will continue to partner with local leaders to make vaccines, boosters and testing more widely available.

Contact the Governor's Press Office

 **Contact us by phone:**

Albany: [\(518\) 474-8418](tel:(518)474-8418)

New York City: [\(212\) 681-4640](tel:(212)681-4640)

 **Contact us by email:**

Press.Office@exec.ny.gov

Translations

Arabic Translation

الترجمة إلى العربية

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Arabic.pdf)

Bengali Translation

বাংলা অনুবাদ

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Bengali.pdf)

Chinese Translation

中文翻譯

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Chinese.pdf)

Haitian-Creole Translation

Tradiksyon kreyòl ayisyen

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_HaitianCreole.pdf)

Italian Translation

Traduzione italiana

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Italian.pdf)

Korean Translation

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Korean.pdf)

한국어 번역

Polish Translation

Polskie tłumaczenie

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Polish.pdf)

Russian Translation

Перевод на русский язык

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Russian.pdf)

Spanish Translation

Traducción al español

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Spanish.pdf)

Yiddish Translation

אידישע איבערזייטשונג

(https://www.governor.ny.gov/sites/default/files/2021-12/11.26.21.rel_BOOST_Yiddish.pdf)



No. 11

EXECUTIVE ORDER

Declaring a Disaster Emergency in the State of New York

WHEREAS, the COVID-19 global pandemic has been declared a Public Health Emergency of International Concern by the World Health Organization since early 2020;

WHEREAS, the United States Health and Human Services Secretary declared a public health emergency for the entire United States to aid the nation's healthcare community in responding to COVID-19 on January 31, 2020;

WHEREAS, New York is now experiencing COVID-19 transmission at rates the State has not seen since April 2020;

WHEREAS, the rate of new COVID-19 hospital admissions has been increasing over the past month to over 300 new admissions a day;

WHEREAS, the state must pursue a coordinated approach to ensure hospital capacity statewide is able to meet regional needs;

WHEREAS, the State government must support the municipalities and counties in their efforts to facilitate and administer vaccinations and tests for COVID-19, and to prevent the virus from continuing to spread at such rates;

NOW, THEREFORE, I, Kathy Hochul, Governor of the State of New York, by virtue of the authority vested in me by the Constitution and the Laws of the State of New York, hereby find, pursuant to Section 28 of Article 2-B of the Executive Law, that a disaster has occurred in New York State, for which the affected local governments are unable to respond adequately, and I do hereby declare a State disaster emergency for the entire State of New York through January 15, 2022; and

IN ADDITION, this declaration satisfies the requirements of Part 360 of the New York State Codes, Rules and Regulations to allow the state to utilize the Surge and Flex system, which may include, but is not limited to, postponement of non-essential elective procedures.

FURTHER, pursuant to Section 29 of Article 2-B of the Executive Law, I direct the implementation of the State Comprehensive Emergency Management Plan and authorize all necessary State agencies to take appropriate action to assist local governments and individuals in containing, preparing for, responding to and recovering from this state disaster emergency, to protect state and local property, and to provide such other assistance as is necessary to protect public health, welfare, and safety.

IN ADDITION, by virtue of the authority vested in me by Section 29-a of Article 2-B of the Executive Law to temporarily suspend or modify any statute, local law, ordinance, order, rule, or regulation, or parts thereof, of any agency during a State disaster emergency, if compliance with such statute, local law, ordinance, order, rule, or regulation would prevent, hinder, or delay action necessary to cope with the disaster emergency or if necessary to assist or aid in coping with such disaster, I hereby temporarily suspend or modify, for the period from the date of this Executive Order through December 26, 2021 the following:

- Section 112 of the State Finance Law to the extent necessary to add additional work, sites, funding, and time to State contracts or to award contracts, including but not limited to contracts or leases for relocation and support of State operations under Section 3 of the Public Buildings Law; or contracts under Section 9 of the Public Buildings Law; or contracts for professional services under Section 136-a of the State Finance Law; or contracts for purchases of commodities, services, and technology through any federal GSA schedules, federal 1122 programs, or other state, regional, local, multi-jurisdictional, or cooperative contract vehicles;
- Section 163 of the State Finance Law and Article 4-C of the Economic Development Law, to the extent necessary to allow the purchase of necessary commodities, services, technology, and materials without following the standard notice and procurement processes;
- Section 97-G of the State Finance Law, to the extent necessary to purchase food, supplies, services, and equipment or furnish or provide various centralized services to assist affected local governments, individuals, and other non-State entities in responding to and recovering from the disaster emergency.



G I V E N under my hand and the Privy Seal of the
State in the City of Albany this
twenty-sixth day of November in the
year two thousand twenty-one

BY THE GOVERNOR

Secretary to the Governor

Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS-CoV-2 High Transmission Periods — United States, December 2020–January 2022

A. Danielle Iuliano, PhD¹; Joan M. Brunkard, PhD¹; Tegan K. Boehmer, PhD¹; Elisha Peterson, PhD²; Stacey Adjei, MPH¹; Alison M. Binder, MS¹; Stacy Cobb, PhD^{1,3}; Philip Graff, PhD²; Pauline Hidalgo²; Mark J. Panaggio, PhD²; Jeanette J. Rainey, PhD¹; Preetika Rao, MPH¹; Karl Soetebeier, MAPW¹; Susan Wacaster¹; ChinEn Ai, MPH⁴; Vikas Gupta, PharmD⁴; Noelle-Angelique M. Molinari, PhD¹; Matthew D. Ritchey, DPT¹

On January 25, 2022 this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

The B.1.1.529 (Omicron) variant of SARS-CoV-2, the virus that causes COVID-19, was first clinically identified in the United States on December 1, 2021, and spread rapidly. By late December, it became the predominant strain, and by January 15, 2022, it represented 99.5% of sequenced specimens in the United States* (1). The Omicron variant has been shown to be more transmissible and less virulent than previously circulating variants (2,3). To better understand the severity of disease and health care utilization associated with the emergence of the Omicron variant in the United States, CDC examined data from three surveillance systems and a large health care database to assess multiple indicators across three high-COVID-19 transmission periods: December 1, 2020–February 28, 2021 (winter 2020–21); July 15–October 31, 2021 (SARS-CoV-2 B.1.617.2 [Delta] predominance); and December 19, 2021–January 15, 2022 (Omicron predominance). The highest daily 7-day moving average to date of cases (798,976 daily cases during January 9–15, 2022), emergency department (ED) visits (48,238), and admissions (21,586) were reported during the Omicron period, however, the highest daily 7-day moving average of deaths (1,854) was lower than during previous periods. During the Omicron period, a maximum of 20.6% of staffed inpatient beds were in use for COVID-19 patients, 3.4 and 7.2 percentage points higher than during the winter 2020–21 and Delta periods, respectively. However, intensive care unit (ICU) bed use did not increase to the same degree: 30.4% of staffed ICU beds were in use for COVID-19 patients during the Omicron period, 0.5 percentage points lower than during the winter 2020–21 period and 1.2 percentage points higher than during the Delta period. The ratio of peak ED visits to cases (event-to-case ratios) (87 per 1,000 cases), hospital admissions (27 per 1,000 cases), and deaths (nine per 1,000 cases [lagged by 3 weeks]) during the

Omicron period were lower than those observed during the winter 2020–21 (92, 68, and 16 respectively) and Delta (167, 78, and 13, respectively) periods. Further, among hospitalized COVID-19 patients from 199 U.S. hospitals, the mean length of stay and percentages who were admitted to an ICU, received invasive mechanical ventilation (IMV), and died while in the hospital were lower during the Omicron period than during previous periods. COVID-19 disease severity appears to be lower during the Omicron period than during previous periods of high transmission, likely related to higher vaccination coverage,[†] which reduces disease severity (4), lower virulence of the Omicron variant (3,5,6), and infection-acquired immunity (3,7). Although disease severity appears lower with the Omicron variant, the high volume of ED visits and hospitalizations can strain local health care systems in the United States, and the average daily number of deaths remains substantial.[§] This underscores the importance of national emergency preparedness, specifically, hospital surge capacity and the ability to adequately staff local health care systems. In addition, being up to date on vaccination and following other recommended prevention strategies are critical to preventing infections, severe illness, or death from COVID-19.

CDC used data from three surveillance systems to assess U.S. disease related to COVID-19 during December 1, 2020–January 15, 2022. COVID-19 aggregate cases and deaths reported to CDC by state and territorial health departments[¶] were tabulated by report date.** ED visits with COVID-19 diagnosis codes were obtained from the National Syndromic

[†] https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (Accessed January 15, 2022).

[§] https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths (Accessed January 15, 2022).

[¶] CDC official counts of COVID-19 cases and deaths, released daily (<https://covid.cdc.gov/covid-data-tracker>), are aggregate counts from reporting jurisdictions. A COVID-19 case is defined by detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person with a confirmed or probable case of COVID-19 according to the Council of State and Territorial Epidemiologists' updated case definition. https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/ps2021/21-ID-01_COVID-19.pdf

** Date of report is used for consistency because most jurisdictions are not reporting case by onset or test date. The same applies to deaths, where there might be an even larger lag between date of death and date of report of death.

* Predominance defined as >50% of specimens sequenced. Proportion that was Omicron variant during the week ending December 18: 39.4%; December 25: 71.6%; January 1: 92.3%; January 8: 98.3%; and January 15: 99.5%. <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

Surveillance Program (NSSP).^{††} Hospital admissions and inpatient and ICU bed use among patients with laboratory-confirmed COVID-19 were obtained from the Unified Hospital Data Surveillance System.^{§§} ED visits and hospital admissions were tabulated by admission date and stratified by the following age groups: 0–17, 18–49, and ≥50 years.

The maximum 7-day moving averages of the daily number of COVID-19 cases, ED visits, hospital admissions, and deaths during the Omicron period were compared with the peak 7-day moving averages for the winter 2020–21 and Delta periods. The maximum percentages of inpatient and ICU bed use overall and by COVID-19 patients were compared between periods. For each period analyzed, ratios of ED visits, hospital admissions, and deaths per 1,000 COVID-19 cases were calculated.^{¶¶}

CDC used the BD Insights Research Database (BD), a U.S. health care facility database,^{***} to assess hospitalized COVID-19 patients as a percentage of total hospital admissions: the percentage of hospitalized COVID-19 patients who were admitted to

an ICU, received IMV, or died while in the hospital; and the mean and median length of hospital stay.^{†††} Indicators were tabulated based on discharge date and stratified by age group: 0–17, 18–50, and >50 years.^{§§§} Three-week windows were analyzed during each period to stabilize estimates.^{¶¶¶} Statistical differences between the Omicron and winter 2020–21 and Delta periods were assessed using z-tests for proportions and t-tests for mean length of stay; statistical significance criterion was $p < 0.05$.

Analyses were carried out in Python (version 3.8.6, Python Software Foundation) and Kotlin (version 1.4, Kotlin Foundation).^{****} This activity was reviewed by CDC and conducted consistent with applicable federal law and CDC policy.^{††††}

The daily 7-day moving average of COVID-19 cases, ED visits, and hospital admissions rapidly increased during the Omicron period (Figure). However, during the week ending January 15, 2022, ED visits appeared to be decreasing and the rapid increase in cases and hospital admissions appeared to be slowing. As of January 15, 2022, the maximum daily 7-day moving average number of cases (798,976), ED visits (48,238), admissions (21,586), and deaths (1,854) observed during the Omicron period reflects changes of 219%, 137%, 31%, and

^{††} NSSP collects electronic health data, including ED visits with COVID-19 diagnoses, from a subset of hospitals in 49 states and the District of Columbia (71% of nonfederal EDs in the United States). ED visits for COVID-19 are defined as ED visits with any of the following: *International Classification of Diseases, Tenth Revision* codes U07.1 or J12.82 or Systematized Nomenclature of Medicine codes 840539006, 840544004, or 840533007. <https://www.cdc.gov/nssp/overview.html>

^{§§} The U.S. Department of Health and Human Services (HHS) Unified Hospital Data Surveillance System includes data from all U.S. hospitals registered with the Centers for Medicare & Medicaid Services (CMS) as of June 1, 2020, and from hospitals not CMS-registered but reporting COVID-19 data through this system since July 1, 2020. Data, including counts of new hospital admissions of patients with confirmed COVID-19 by age group, are reported to HHS either directly from facilities or via a state health department submission; on January 11, 2022, 96% of hospitals reported data. This analysis includes children's, short-term acute care, long-term acute care, critical access, Veterans Administration, Defense Health Agency, and Indian Health Services hospitals and excludes psychiatric, rehabilitation, and religious nonmedical hospitals. Reporting guidelines are published in the HHS COVID-19 Guidance for Hospital Reporting and FAQs document. <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>

^{¶¶} Ratios of ED visits and hospital admissions per 1,000 COVID-19 cases were calculated as peak daily 7-day moving averages of ED visits or hospital admissions divided by the corresponding daily 7-day moving average of COVID-19 cases observed when peak ED visits and hospital admissions occurred. The ratio of deaths per 1,000 COVID-19 cases was calculated with a 3-week lag in cases from the date when peak daily 7-day moving averages of deaths occurred to account for the time between case ascertainment, occurrence of death, and reporting.

^{***} BD is a large U.S. health care facility database that includes patient-level electronically captured laboratory results; pharmacy orders; and admission, discharge, and transfer data from 267 hospitals. CDC receives aggregate BD data via a surveillance dashboard that is updated every Tuesday with data for the previous week (Sunday through Saturday) (release date January 18, 2022; access date January 18, 2022). This analysis used data from 199 hospitals that reported data during all three periods; of these hospitals, 135 (68%) had information for IMV, and 148 (74%) had information on in-hospital deaths. Geographically, hospital distribution is uneven; hospitals are overrepresented in the South (53%) and Northeast (17%) U.S. Census regions and underrepresented in the West (9%) and Midwest (21%) regions. Monthly trends in disease severity indicators from BD and two other data sources are available on CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#hospitalizations-severity>

^{†††} Hospitalized COVID-19 patients were identified by the presence of a positive SARS-CoV-2 polymerase chain reaction or antigen test result during the 14 days before or 14 days after date of admission; 43% of all admissions did not have a SARS-CoV-2 test result available (January 2021–January 2022). To identify patients admitted to an ICU, care settings were classified using the CDC National Healthcare Safety Network classification and then further classified as ICU (critical care) or non-ICU (inpatient adult wards, specialty care areas, and step-down wards); <https://academic.oup.com/ofid/article/5/10/ofy241/5104818>. Because of lack of timely device data to identify ventilator use, the following surrogate definition for IMV use was used: a) the patient was started on intravenous/intravenous push (IV/IVP) sedation medications (propofol, lorazepam, midazolam, dexmedetomidine, or ketamine) or IV/IVP opioids (fentanyl, remifentanyl, sufentanil, or hydromorphone) with a duration ≥24 hours, and b) at least two arterial blood gas results were collected at least 24 hours apart (on the first day of sedation medication and a subsequent result 24 hours later) (<https://academic.oup.com/ofid/article/8/6/ofab232/6285220>). In-hospital death was defined by a designation of death, mortality, or presence in morgue in the admission, discharge, and transfer data feeds. A validity check of this method had been previously performed by randomly selecting 50 mortality cases and evaluating encounter-level data for clinical signs of mortality (e.g., uncorrected severe metabolic acidosis determined by pH from arterial blood gases and uncorrected electrolyte changes incompatible with life). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2778237>

^{§§§} Age groups for patients are preestablished on the BD surveillance dashboard and do not align exactly with older age grouping (i.e., aged <50 years versus ≥50 years) available in the surveillance data.

^{¶¶¶} The 7-day daily average peak in the case surveillance data was used as the central day of the 3-week window for the winter 2020–21 (January 1–January 21, 2021) and Delta (August 22–September 11, 2021) periods; the most recent 3 weeks of available data were used for the Omicron period (December 26, 2021–January 15, 2022). Date ranges are based on date of hospital discharge.

^{****} Surveillance data cleaning, processing, and calculation of peak rates were conducted using Python and Kotlin.

^{††††} 45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

–46%, respectively, compared with those during the winter 2020–21 period, and 386%, 86%, 76%, and –4%, respectively, compared with those during the Delta period (Table 1). The largest relative differences in ED visits and admissions were observed among children and adolescents aged 0–17 years during the Omicron period; however, this age group represented only 14.5% of COVID-19 ED visits and 4.2% of COVID-19 admissions. During the Omicron period, a maximum of 20.6% of staffed inpatient beds were in use for COVID-19 patients, 3.4 and 7.2 percentage points higher than during the winter 2020–21 and Delta periods, respectively. However, ICU bed use did not increase to the same degree: 30.4% of staffed ICU beds were in use for COVID-19 patients during the Omicron period, 0.5 percentage points lower than during the winter 2020–21 period and 1.2 percentage points higher than during the Delta period. When comparing the indicators at their peaks during the Omicron period, event-to-case ratios for ED visits (87 visits per 1,000 cases), hospitalizations (27 hospitalizations per 1,000 cases), and deaths (nine deaths per 1,000 cases [lagged by 3 weeks]) were lower than those observed during the peak winter 2020–21 (92, 68, and 16, respectively) and Delta (167, 78, and 13, respectively) periods (Supplementary Figure, <https://stacks.cdc.gov/view/cdc/113628>).

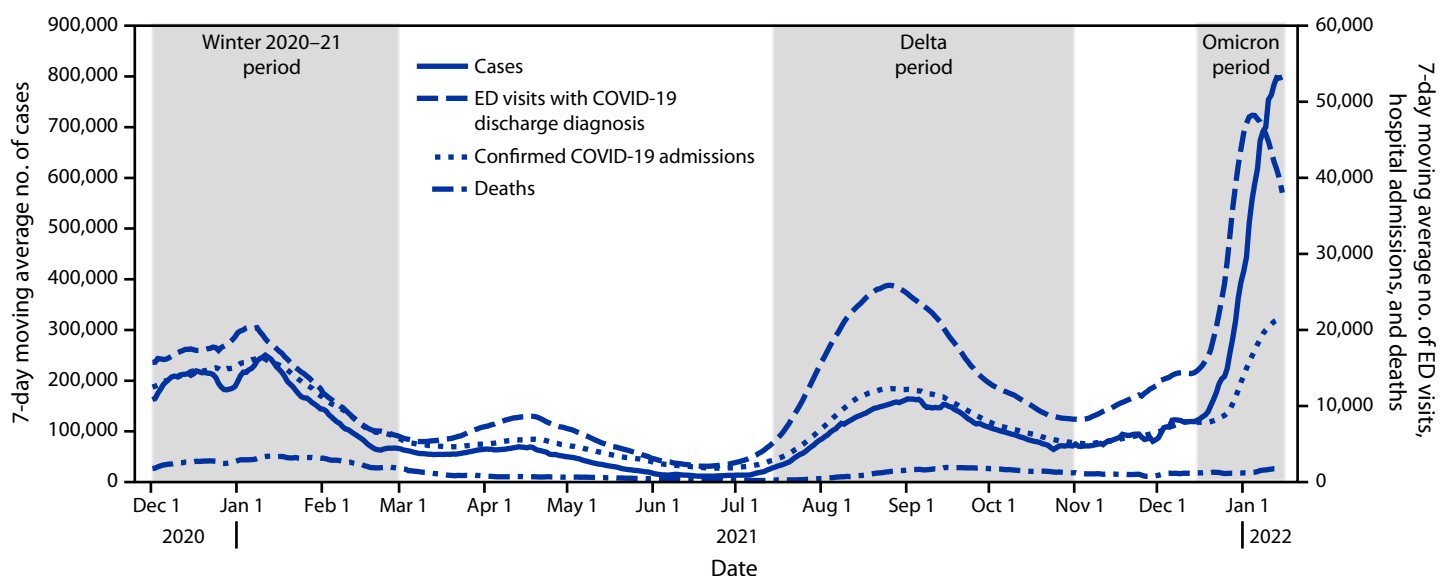
In BD, hospitalized COVID-19 patients represented 12.0%, 9.4%, and 12.9% of all admissions during the winter 2020–21, Delta, and Omicron periods, respectively. Disease severity

among hospitalized COVID-19 patients was associated with increasing age; IMV and in-hospital deaths were rare among patients aged 0–17 years, therefore, differences between periods were not assessed. The percentage of hospitalized COVID-19 patients admitted to an ICU during Omicron (13.0%) was 28.8% lower than during the winter 2020–21 (18.2%) and 25.9% lower than during Delta (17.5%) periods overall, and for all three age groups ($p < 0.05$) (Table 2). The percentage of hospitalized COVID-19 patients who received IMV (3.5%) or died while in the hospital (7.1%) during Omicron was lower than during the winter 2020–21 (IMV = 7.5%; deaths = 12.9%) and Delta (IMV = 6.6%; deaths = 12.3%) periods overall, and for both adult age groups ($p < 0.001$). Mean length of hospital stay during Omicron (5.5 days) was 31.0% lower than during the winter 2020–21 (8.0 days) and 26.8% lower than during Delta (7.6 days) periods overall, and for both adult age groups ($p < 0.001$).

Discussion

Emergence of the Omicron variant in December 2021 led to a substantial increase in COVID-19 cases in the United States. Although the rapid rise in cases has resulted in the highest number of COVID-19–associated ED visits and hospital admissions since the beginning of the pandemic, straining the health care system, disease severity appears to be lower than compared with previous high disease-transmission periods. In addition to

FIGURE. Seven-day moving average number of COVID-19 cases, emergency department visits, hospital admissions, and deaths — United States,* December 1, 2020–January 15, 2022



Sources: CDC state-reported data (cases and deaths), Unified Hospital dataset (admissions), and National Syndromic Surveillance Program (ED visits with COVID-19 discharge diagnoses).

Abbreviation: ED = emergency department.

* COVID-19 hospital admissions include admissions for COVID-19 as well as patients who receive a positive SARS-CoV-2 test result after being admitted for other reasons. National Syndromic Surveillance Program represents approximately 70% of all U.S. ED visits.

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TABLE 1. COVID-19 disease, hospital, and death indicators during the Omicron period compared with the winter 2020–21 and Delta periods* — United States, December 2020–January 2022†

Indicator/ Age group, yrs	Winter 2020–21 period		Delta period		Omicron period		Comparison of Omicron with winter 2020–21 period		Comparison of Omicron with Delta period	
	Peak value date range	Peak value (7-day moving average)	Peak value date range	Peak value (7-day moving average)	Date of maximum assessed value [§]	Maximum 7-day moving average	Number or percentage point difference [¶]	Relative % difference ^{**}	Number or percentage point difference [¶]	Relative % difference ^{**}
Disease (cases, ED visits)										
COVID-19 cases, N	Jan 4–11, 2021	250,335	Aug 25– Sep 1, 2021	164,249	Jan 15, 2022	798,976	548,641	219.2	634,727	386.4
COVID-19 ED visits, by age group, N (% of total)	Dec 29, 2020–Jan 5, 2021	20,372	Aug 19–26, 2021	25,873	Jan 4, 2022	48,238	27,866	136.8	22,365	86.4
0–17		901 (4.4)		3,177 (12.3)		6,990 (14.5)	6,089 (10.1)	676.1	3,813 (2.2)	120.0
18–49		6,872 (33.7)		11,853 (45.8)		23,372 (48.5)	16,500 (14.7)	240.1	11,519 (2.6)	97.2
≥50		12,406 (60.9)		10,546 (40.8)		17,471 (36.2)	5,066 (–24.7)	40.8	6,926 (–4.5)	65.7
Hospital (admissions)										
COVID-19 admissions, by age group, N (% of total)	Jan 2–9, 2021	16,497	Aug 20–27, 2021	12,285	Jan 15, 2022	21,586	5,089	30.8	9,301	75.7
0–17		207 (1.3)		319 (2.6)		914 (4.2)	707 (3.0)	341.9	595 (1.6)	186.5
18–49		2,761 (16.7)		3,559 (29.0)		5,218 (24.2)	2,457 (7.4)	89.0	1,659 (–4.8)	46.6
≥50		12,840 (77.8)		7,828 (63.7)		14,773 (68.4)	1,933 (–9.4)	15.1	6,945 (4.7)	88.7
Inpatient beds in use for COVID-19, N	Jan 4–11, 2021	125,100	Aug 28– Sep 4, 2021	94,503	Jan 15, 2022	142,687	17,587	14.1	48,184	51.0
Staffed beds in use for COVID-19, %		17.2		13.4		20.6	3.4	20.0	7.2	53.7
Staffed beds in use, %		74.1		76.8		79.2	5.1	6.9	2.4	3.1
ICU beds in use for COVID-19, N	Jan 9–16, 2021	27,958	Sep 6–13, 2021	24,774	Jan 15, 2022	24,776	–3,182	–11.4	2	0.0
Staffed ICU beds in use for COVID-19, %		30.9		29.2		30.4	–0.5	–1.7	1.2	4.2
Staffed ICU beds in use, %		78.2		79.6		82.2	4.0	5.1	2.6	3.2
Deaths										
COVID-19 deaths, N	Jan 6–13, 2021	3,422	Sep 9–15, 2021	1,924	Jan 15, 2022	1,854	–1,568	–45.8	–70	–3.6

Sources: CDC state-reported data (case and death totals), CDC case line-level data (cases by age), Unified Hospital data set (hospital admissions, inpatient, and ICU), and National Syndromic Surveillance Program (ED visits with COVID-19 discharge diagnoses).

Abbreviations: ED = emergency department; ICU = intensive care unit; N = no. of hospital admissions.

* COVID-19 hospital admissions include admissions for COVID-19 as well as patients who receive a positive test result for COVID-19 after being admitted for other reasons. National Syndromic Surveillance Program data are not inclusive of all ED visits, representing approximately 71% of all visits. The peak value and associated date are calculated independently for each indicator as the highest 7-day moving average value during Dec 1, 2020–Jan 31, 2021 (winter 2020–21 period), Aug 1–Sep 30, 2021 (Delta period), or Dec 19, 2021–Jan 15, 2022 (Omicron period). The date and value of peaks might change slightly if data are backfilled.

† Data were pulled on January 20, 2022.

§ Maximum value date for the Omicron period was assessed for December 19, 2021–January 15, 2022. This date is defined as the maximum value for each of the severity indicators at the time that the data were pulled for this report on January 20, 2022. The date of the maximum value might be different at the time of publication.

¶ Total difference is presented for the number of cases, ED visits, hospital admissions, deaths, and inpatient and ICU beds in use. Percentage point difference is presented for the percentage of ED visits and hospital admissions by age groups and for the percentages of inpatient and ICU beds in use for COVID-19 patients.

** Relative percent difference is calculated as the value for cases, ED visits, hospital admissions, inpatient bed use, ICU bed use, and deaths from the Omicron period minus the same indicator value from the comparison period (winter 2020–21 or Delta period) divided by the same indicator value from the comparison period.

lower ratios of ED visits, hospitalizations, and deaths to cases observed during the Omicron period, disease severity indicators were also lower among hospitalized COVID-19 patients, including ICU admission, receipt of IMV, length of stay, and in-hospital death. This apparent decrease in disease severity is likely related to multiple factors, most notably increases in vaccination coverage among eligible persons (4,8), and the use

of vaccine boosters among recommended subgroups^{§§§§} (9). For example, during the Omicron period, 207 million persons were fully vaccinated compared with 178 million persons and 1.5 million persons during the Delta and the winter 2020–21 periods, respectively (8). Further, during the Omicron period, 78 million persons had received vaccine boosters compared

^{§§§§} <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>

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TABLE 2. Total hospitalizations, hospitalized COVID-19 patients, and indicators of disease severity among hospitalized COVID-19 patients during the Omicron period compared with the winter 2020–21 and Delta periods,* by age group, 199 hospitals—United States, January 2021–January 2022

Indicator/ Age group, yrs	No. (%)			Comparison of Omicron with winter 2020–21 period		Comparison of Omicron with Delta period	
	Winter 2020–21 period	Delta period	Omicron period	Percentage point or mean difference	Relative % difference	Percentage point or mean difference	Relative % difference
	Jan 1–21, 2021	Aug 22–Sep 11, 2021	Dec 26, 2021– Jan 15, 2022				
Total hospitalizations							
All	108,360	110,950	98,920	—	—	—	—
0–17	11,504	13,946	11,517	—	—	—	—
18–50	31,070	34,537	28,040	—	—	—	—
>50	65,786	62,467	59,363	—	—	—	—
Hospitalized COVID-19 patients as a percentage of total hospitalizations							
All	12,963 (12.0)	10,440 (9.4)	12,800 (12.9)	–1.0 [†]	8.2	3.5 [†]	37.5
0–17	147 (1.3)	272 (2.0)	405 (3.5)	2.2 [†]	175.2	1.6 [†]	80.3
18–50	2,474 (8.0)	3,304 (9.6)	3,988 (14.2)	6.3 [†]	78.6	4.7 [†]	48.7
>50	10,342 (15.7)	6,864 (11.0)	8,407 (14.2)	–1.6 [†]	–9.9	3.2 [†]	28.9
ICU admission among hospitalized COVID-19 patients							
All	2,359 (18.2)	1,824 (17.5)	1,658 (13.0)	–5.2 [†]	–28.8	–4.5 [†]	–25.9
0–17	25 (17.0)	50 (18.4)	42 (10.4)	–6.6 [§]	–39.0	–8.0 [§]	–43.6
18–50	346 (14.0)	438 (13.3)	377 (9.5)	–4.5 [†]	–32.4	–3.8 [†]	–28.7
>50	1,988 (19.2)	1,336 (19.5)	1,239 (14.7)	–4.5 [†]	–23.3	–4.7 [†]	–24.3
IMV among hospitalized COVID-19 patients [¶]							
All	764 (7.5)	503 (6.6)	358 (3.5)	–4.0 [†]	–53.4	–3.1 [†]	–46.5
0–17	1 (0.8)	1 (0.4)	0 (—)	NC	NC	NC	NC
18–50	122 (6.2)	118 (4.9)	73 (2.3)	–3.9 [†]	–63.2	–2.6 [†]	–53.2
>50	641 (8.0)	384 (7.7)	285 (4.3)	–3.7 [†]	–46.2	–3.4 [†]	–44.3
In-hospital death among hospitalized COVID-19 patients ^{**}							
All	976 (12.9)	803 (12.3)	533 (7.1)	–5.8 [†]	–44.9	–5.2 [†]	–42.3
0–17	1 (1.1)	0 (—)	0 (—)	NC	NC	NC	NC
18–50	57 (4.0)	110 (5.4)	38 (1.7)	–2.3 [†]	–58.3	–3.7 [†]	–69.2
>50	918 (15.2)	693 (16.0)	495 (10.0)	–5.2 [†]	–34.2	–6.0 [†]	–37.5
Length of stay among hospitalized COVID-19 patients, by age group, yrs							
Median							
All	5	5	3	—	—	—	—
0–17	2	2	2	—	—	—	—
18–50	3	4	2	—	—	—	—
>50	5	6	4	—	—	—	—
Mean (SD)							
All	8.0 (15.6)	7.6 (10.6)	5.5 (13.1)	–2.5 [†]	–31.0	–2.0 [†]	–26.8
0–17	4.4 (10.1)	3.9 (5.3)	3.5 (9.7)	–0.9	–20.3	–0.4	–9.5
18–50	5.8 (7.8)	6.1 (6.9)	4.3 (7.4)	–1.5 [†]	–25.6	–1.8 [†]	–29.9
>50	8.6 (17.0)	8.4 (12.0)	6.2 (15.1)	–2.4 [†]	–27.7	–2.2 [†]	–25.8

Source: BD Insights Research Database.

Abbreviations: ICU = intensive care unit; IMV = invasive mechanical ventilation; NC = not calculated.

* The winter period was defined as January 1–21, 2021, the Delta period was defined as August 22–September 11, 2021, and the Omicron period was defined as December 26, 2021–January 15, 2022 for BD analysis.

[†] p<0.001.[§] p<0.05.[¶] Data on IMV were available from a subset of 135 hospitals. The denominators of hospitalized COVID-19 patients for IMV percentages were as follows for each period and age group: winter 2020–21 (0–17 years [132]; 18–50 years [1,964]; and >50 years [8,039]); Delta (0–17 years [258]; 18–50 years [2,415]; and >50 years [4,988]); and Omicron (0–17 years [355]; 18–50 years [3,189]; and >50 years [6,646]).^{**} Data on in-hospital deaths were available from a subset of 148 hospitals. The denominators of hospitalized COVID-19 patients for in-hospital death percentages were as follows for each period and age group: winter 2020–21 (0–17 years [87]; 18–50 years [1,437]; and >50 years [6,048]); Delta (0–17 years [142]; 18–50 years [2,045]; and >50 years [4,333]); and Omicron (0–17 years [250]; 18–50 years [2,297]; and >50 years [4,954]).

with 1.6 million persons during the Delta period; boosters were not available during winter 2020–21 (8). Other key factors for lower disease severity include infection-acquired immunity (3,7), and potential lower virulence of the Omicron variant (3,5,6).

These findings are consistent with reports from South Africa (2), England (10), and Scotland,^{****} as well as from health

^{****} https://www.pure.ed.ac.uk/ws/portalfiles/portal/245818096/Severity_of_Omicron_variant_of_concern_and_vaccin%20e_effectiveness_against_symptomatic_disease.pdf%2012

systems in California (3) and Texas,^{*****} where the Omicron variant was not associated with an increase in hospital or disease severity indicators among patients with Omicron infections compared with those with Delta infections. Death and in-hospital severity indicators, including in the context of vaccination status, should continue to be monitored for changes or differential effects among subpopulations throughout the Omicron period.

Among children aged <18 years, in-hospital severity indicators, including length of stay and ICU admission, were similar to and lower, respectively, during the Omicron period compared with those during previous high-transmission periods. However, high relative increases in ED visits and hospitalizations were observed among children during the Omicron period, which might be related to lower vaccination rates in children compared with those in adults, especially among children aged 0–4 years who are currently not eligible for vaccination. Children's susceptibility to the Omicron variant and the impact of changes in exposure on severity risk require additional study. Among adults aged ≥18 years, all in-hospital severity indicators assessed were lower during the Omicron period, which might be related to increased population immunity against SARS-CoV-2 because of higher vaccination coverage and booster rates and previous infection providing protection (3,4,7,9). Receipt of a third mRNA vaccine dose was found to be highly effective at preventing urgent care encounters, ED visits, and hospital admissions during both Delta and Omicron periods (9). Booster doses were also found to be effective at preventing infection during the early Omicron period, particularly among persons aged ≥50 years (4).

The findings in this report are subject to at least seven limitations. First, BD is not nationally representative and NSSP does not capture all ED visits across the United States; therefore, geographic and demographic differences in disease transmission and severity might bias findings. Second, the variation in vaccination coverage during the three periods assessed was not taken into account when comparing severity indicators. This limitation is most relevant when comparing the Omicron period to the winter 2020–21 period, when vaccines were just becoming available in the United States. Third, person-level vaccination status was not available to compare severity indicators based on being up to date on vaccinations. Fourth, the hospital data do not exclude incidental SARS-CoV-2 infections, which might be higher during the Omicron period because of increased transmissibility of the Omicron variant; inclusion of incidental infections could inflate hospitalization-to-case ratios and have an unknown effect on in-hospital severity

Summary

What is already known about this topic?

The SARS-CoV-2 B.1.1.529 (Omicron) variant became predominant in the United States by late December 2021, leading to a surge in COVID-19 cases and associated ED visits and hospitalizations.

What is added by this report?

Despite Omicron seeing the highest reported numbers of COVID-19 cases and hospitalizations during the pandemic, disease severity indicators, including length of stay, ICU admission, and death, were lower than during previous pandemic peaks.

What are the implications for public health practice?

Although disease severity appears lower with the Omicron variant, the high volume of hospitalizations can strain local health care systems and the average daily number of deaths remains substantial. This underscores the importance of national emergency preparedness, specifically, hospital surge capacity and the ability to adequately staff local health care systems. In addition, being up to date on vaccinations and following other recommended prevention strategies are critical to preventing infections, severe illness, or death from COVID-19.

indicators. Fifth, changes in testing and reporting behaviors, including the likely increase in self-administered tests, might bias comparisons; specifically, reported case counts during the Omicron period might be biased downward because of self-administered test use compared with counts during other periods.^{†††††} Sixth, co-circulation of the Omicron and Delta variants might affect the magnitude of the severity indicators during the beginning of the Omicron period, particularly for in-hospital severity indicators based on date of hospital discharge. Finally, the findings reflect an ecologic analysis of event-based indicators; findings should not be misinterpreted as person-level indicators (e.g., case-fatality ratios).

Emergence of the Omicron variant has resulted in a rapid increase in COVID-19 cases. Concurrent increases in ED visits and hospital admissions appear to be driven by high case counts and not by increased disease severity following acute infection. Although patients hospitalized during the Omicron period have shorter stays and less frequent ICU admissions, the high volume of hospitalizations resulting from high transmission rates during a short period can strain local health care systems

^{†††††} Case data in this report are based on data reported by states. Some states report both confirmed and probable cases, and some states report only confirmed cases. For states that include probable cases, a case based on antigen test results with symptoms might meet the case definition and be included in the probable case count. However, positive self-administered tests alone (which are also antigen tests) might not be reported to public health authorities, and do not meet the current Council of State and Territorial Epidemiologists' case definition criteria, and thus, will likely not be included by states in probable case counts reported to CDC.

^{*****} <https://www.medrxiv.org/content/10.1101/2021.12.30.21268560v2>

in the United States, and the average daily number of deaths remains substantial. This underscores the importance of national emergency preparedness, specifically, hospital surge capacity and the ability to adequately staff local health care systems when critical care needs arise and before the system is overwhelmed. Previous studies have identified increased risk for severe outcomes among unvaccinated persons (4,9). Thus, being up to date with COVID-19 vaccinations and following other recommended prevention strategies are critical to prevent infections, severe illness, or death from COVID-19.

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No. 4

EXECUTIVE ORDER

**Declaring a Statewide Disaster Emergency Due to Healthcare Staffing Shortages
in the State of New York**

WHEREAS, the current staffing shortages in hospital and other healthcare facilities are expected to impact availability of care, threatening public health and safety;

WHEREAS, severe understaffing in hospitals and other healthcare facilities is expected to effect the ability to provide critical care and to adequately serve vulnerable populations;

WHEREAS, there is an immediate and critical need to supplement staffing to assure healthcare facilities can provide care;

NOW, THEREFORE, I, Kathy Hochul, Governor of the State of New York, by virtue of the authority vested in me by the Constitution and the Laws of the State of New York, do hereby find, pursuant to Section 28 of Article 2-B of the Executive Law, that a disaster is imminent in New York State, for which the affected local governments are unable to respond adequately, and I do hereby declare a Statewide disaster emergency for the entire State of New York. This Executive Order shall be in effect for thirty days from the date of this Executive Order; and

FURTHER, pursuant to Section 29 of Article 2-B of the Executive Law, I direct the implementation of the State Comprehensive Emergency Management Plan and authorize necessary State agencies to take appropriate action to assist local governments and individuals in the protection of public health, welfare, and safety.

IN ADDITION, by virtue of the authority vested in me by Section 29-a of Article 2-B of the Executive Law to temporarily suspend or modify any statute, local law, ordinance, order, rule, or regulation, or parts thereof, of any agency during a State disaster emergency, if compliance with such statute, local law, ordinance, order, rule, or regulation would prevent, hinder, or delay action necessary to cope with the disaster emergency, I hereby temporarily suspend or modify, for the period from the date of this Executive Order through October 27, 2021 the following:

- Sections 6512 through 6516, and 6524 of the Education Law and Part 60 of Title 8 of the NYCRR, to the extent necessary to allow physicians licensed and in current good standing in any state in the United States to practice medicine in New York State without civil or criminal penalty related to lack of licensure, and to allow physicians licensed and in current good standing in any province or territory of Canada, or any other country as approved by the Department of Health to practice medicine in New York State without civil or criminal penalty related to lack of licensure;
- Section 6502 of the Education Law and Section 59.8 of Title 8 of the NYCRR, to the extent necessary to allow physicians licensed and in current good standing in New York State but not registered in New York State to practice in New York State without civil or criminal penalty related to lack of registration;

- Sections 6512 through 6516, and 6905, 6906 and 6910 of the Education Law and Part 64 of Title 8 of the NYCRR, to the extent necessary to allow registered nurses, licensed practical nurses, and nurse practitioners licensed and in current good standing in any state in the United States to practice in New York State without civil or criminal penalty related to lack of licensure, and to allow registered nurses, licensed practical nurses, and nurse practitioners or a substantially similar title licensed and in current good standing in any province or territory of Canada, or any other country as approved by the Department of Health, to practice in New York State without civil or criminal penalty related to lack of licensure;
- Sections 6512 through 6516, and 6541 of the Education Law and Part 60.8 of Title 8 of the NYCRR, to the extent necessary to allow physician assistants licensed and in current good standing in any state in the United States to practice in New York State without civil or criminal penalty related to lack of licensure, and to allow physician assistants or a substantially similar title licensed and in current good standing in any province or territory of Canada, or any other country as approved by the Department of Health to practice in New York State without civil or criminal penalty related to lack of licensure;
- Sections 3502 and 3505 of the Public Health Law and Part 89 of Title 10 of the NYCRR to the extent necessary to permit radiologic technologists licensed and in current good standing in any state in the United States to practice in New York State without civil or criminal penalty related to lack of licensure;
- Sections 8502, 8504, 8504-a, 8505, and 8507 of the Education Law and Subpart 79-4 of Title 8 of the NYCRR, to the extent necessary to allow respiratory therapists licensed and in current good standing in any state in the United States to practice in New York State without civil or criminal penalty related to lack of licensure;
- Sections 6512 through 6516 and 8510 of the Education Law and 8 NYCRR Subpart 79-4 to the extent necessary to allow respiratory therapy technicians licensed and in current good standing in any state in the United States to practice in New York State without civil or criminal penalty related to lack of licensure;
- Section 6502 of the Education Law and 8 NYCRR 59.8, to the extent necessary to allow physician's assistants, registered professional nurses, licensed practical nurses, and nurse practitioners licensed and in current good standing in New York State but not registered in New York State to practice in New York State without civil or criminal penalty related to lack of registration, and to allow specialist assistants, respiratory therapists, respiratory therapist technicians, pharmacists, clinical nurse specialists, dentists, dental hygienists, registered dental assistants, midwives, perfusionists, clinical laboratory technologists, cytotechnologists, certified clinical laboratory technicians, certified histological technicians, licensed clinical social workers, licensed master social workers, podiatrists, physical therapists, physical therapist assistants, mental health counselors, marriage and family therapists, creative arts therapists, psychoanalysts and psychologists who have an unencumbered license and are currently in good standing in New York State but not registered in New York State to practice in New York State without civil or criminal penalty related to lack of registration;
- Sections 6951, 6952, 6953 and 6955 of the Education Law, to the extent necessary to allow midwives licensed and in current good standing in any state in the United States, or in any province or territory of Canada, or any other country as approved by the Department of Health to practice in New York State without civil or criminal penalty related to lack of licensure;
- Section 3507 of the Public Health Law and Part 89 of Title 10 of the NYCRR to the extent necessary to permit radiologic technologists licensed and in current good standing in New York State but not registered in New York State to practice in New York State without civil or criminal penalty related to lack of registration;
- Sections 6512 through 6516, 6548 and 6911 of the Education Law and sections 60.11 and 64.8 Title 8 of the NYCRR, to the extent necessary to allow clinical nurse specialists, specialist assistants, and substantially similar titles certified and in current good standing in any state in the United States, or any province or territory of Canada, or any other country as approved by the Department of Health to practice in New York State without civil or criminal penalty related to lack of certification;
- Sections 6512 through 6516, and 7704 of the Education Law and Part 74 of Title 8 of the NYCRR, to the extent necessary to allow licensed master social workers, licensed clinical social workers, and substantially similar titles licensed and in current good standing in any state in the United States, or in any province or territory of Canada, or any other country as approved by the Department of Health to practice in New York State without civil or criminal penalty related to lack of licensure;
- Section 6908 of the Education Law and associated regulations, to the extent necessary to permit graduates of State Education Department registered, licensure qualifying nurse practitioner education programs to be employed to practice nursing in a hospital or nursing home for 180 days immediately following successful

completion of a New York State Registered licensure qualifying education program, provided that the graduate files with the State Education Department an application for certification as a nurse practitioner;

- Section 8609 of the Education Law and associated regulations, to the extent necessary to permit graduates of State Education Department registered, licensure qualifying clinical laboratory technology and clinical laboratory technician education programs to be employed to practice for 180 days immediately following successful completion of a New York State Registered licensure qualifying education program, in a clinical laboratory with a valid New York State permit, provided that the graduate files an application for a New York State clinical laboratory practitioner license and limited permit;
- Subdivision 5 of Section 6907 of the Education Law and associated regulation, to the extent necessary to permit graduates of registered professional nurse and licensed practical nurse licensure qualifying education programs registered by the State Education Department to be employed to practice nursing under the supervision of a registered professional nurse and with the endorsement of the employing hospital or nursing home for 180 days immediately following graduation;
- Section 6524 of the Education Law, section 60.7 of title 8 of NYRR and section paragraph (1) of subdivision (g) 405.4 of title 10 of the NYCRR to the extent necessary to allow any physician who will graduate in 2021 or 2022 from an academic medical program accredited by a medical education accrediting agency for medical education by the Liaison Committee on Medical Education or the American Osteopathic Association, and has been accepted by an Accreditation Council for Graduate Medical Education accredited residency program within or outside of New York State to practice at any institution under the supervision of a licensed physician;
- Sections 6512 through 6516, and 6524 of the Education Law and Part 60 of Title 8 of the NYCRR, to the extent necessary to allow individuals, who graduated from registered or accredited medical programs located in New York State in 2021, to practice medicine in New York State, without the need to obtain a license and without civil or criminal penalty related to lack of licensure, provided that the practice of medicine by such graduates shall in all cases be supervised by a physician licensed and registered to practice medicine in the State of New York;
- Section 212 of the Retirement and Social Security Law, for the purpose of disregarding any income earned during the period of the emergency from the earnings limitation calculated under such section;
- Section 2805-k of the Public Health Law and sections 405.4, 405.5, 405.9, 405.14, 405.19, and 405.22 of Title 10 of the NYCRR, to the extent necessary to allow staff with the necessary professional competency and who are privileged and credentialed to work in a facility in compliance with such section of the Public Health Law and such sections of the NYCRR, or who are privileged and credentialed to work in a facility in another state in compliance with the applicable laws and regulations of that other state, to practice in a facility in New York State;
- Article 30 of the Public Health Law to the extent necessary to allow EMTs and Advanced EMTs to provide emergent and non-emergent services within their scope of practice beyond settings currently authorized, such as hospitals;
- Subdivision d and u of section 800.3 of Title 10 of the NYCRR, to the extent necessary to permit emergency medical service personnel to provide community paramedicine, use alternative destinations, telemedicine to facilitate treatment of patients in place, and such other services as may be approved by the Commissioner of Health;
- Subdivision (7) of Public Health Law section 3001, and subdivision (p) of section 800.3 of Title 10 of the NYCRR, to the extent necessary to allow certified emergency medical technician-paramedics, providing community paramedicine services with prior approval of the Department of Health, to administer vaccinations against influenza and COVID-19 pursuant to a non-patient specific order and under the medical direction of a licensed physician, provided, however, that emergency medical technician-paramedics must first meet conditions set by the Commissioner of Health;
- Section 6951 of the Education Law, and section 79-5.5 of Title 8 of NYCRR, insofar as such provisions limit the practice of midwifery to management of normal pregnancies, child birth and postpartum care as well as primary preventive reproductive health care of essentially healthy women, and newborn evaluation, resuscitation and referral for infants, and insofar as it limits the practice of midwifery to midwives who practice in accordance with collaborative relationships with licensed physicians or hospitals, so that for the purposes of this disaster emergency, midwives may administer vaccinations against influenza and COVID-19 to any patient pursuant to a non-patient specific order at sites overseen or approved by the New York State

Department of Health or local health departments, and operated under the medical supervision of licensed physicians, licensed physician assistants, or certified nurse practitioners, provided, however, that a midwife without a certificate issued by the State Education Department for administering immunizing agents, must meet conditions set by the Commissioner of Health;

- Article 139 of the Education Law, Section 576-b of the Public Health Law and Section 58-1.7 of Title 10 of the NYCRR, to the extent necessary to permit registered nurses to order the collection of throat or nasopharyngeal swab specimens from individuals suspected of being infected by COVID-19, for purposes of testing;
- Subdivision 1 of section 6902, Subdivision 4, 5 and 7 of section 6909 of the Education Law, subdivision 6 and 7 of section 6527 of the Education Law, and section 63.9 and 64.7 of Title 8 of the NYCRR, to the extent necessary to permit physicians and certified nurse practitioners to issue a non-patient specific regimen to nurses or any such other persons authorized by law or by this executive order to (1) collect throat or nasopharyngeal swab specimens from individuals suspected of suffering from a COVID-19 infection, for purposes of testing, or to perform such other tasks as may be necessary to provide care for individuals diagnosed or suspected of suffering from a COVID-19 infection; (2) collect blood specimens for the diagnosis of acute or past COVID-19 disease; (3) administer vaccinations against influenza or COVID-19 pursuant to the most recent recommendations by the Advisory Committee for Immunization Practices (ACIP) and/or an applicable United States Food and Drug Administration approval or Emergency Use Authorization (EUA), subject to any other conditions set forth in this Order, including but not limited to conditions related to training and supervision, where applicable; and (4) where applicable and to the extent necessary, to perform tasks, under the supervision of a nurse, otherwise limited to the scope of practice of a licensed or registered nurse to provide care for individuals ;
- Sections 6521 and 6902 of the Education Law, subdivisions 4, 5, and 7 of section 6909 of the Education Law, subdivisions 6 and 7 of section 6527 of the Education Law, and sections 63.9 and 64.7 of Title 8 of the NYCRR insofar as they limit the execution of medical regimens prescribed by a licensed physicians or other licensed and legally authorized health care providers to registered nurses licensed pursuant to Article 139 of the Education Law, to the extent necessary to permit non-nursing staff, as permitted by law and upon completion of training deemed adequate by the Commissioner of Health, to: (1) collect throat, nasal, or nasopharyngeal swab specimens, as applicable and appropriate, from individuals suspected of being infected by COVID-19 or influenza, for purposes of testing; (2) collect blood specimens for the diagnosis of acute or past COVID-19 disease; (3) administer vaccinations against influenza or COVID-19 pursuant to the most recent recommendations by the Advisory Committee for Immunization Practices (ACIP) and/or an applicable United States Food and Drug Administration approval or Emergency Use Authorization (EUA), subject to any other conditions set forth in this Order, including but not limited to conditions related to training and supervision, where applicable; and (4) where applicable and to the extent necessary, to perform tasks, under the supervision of a nurse, otherwise limited to the scope of practice of a licensed or registered nurse to provide care for individuals;
- Subdivision (b) of section 405.3 of Title 10 of the NYCRR, to the extent necessary to allow general hospitals to use qualified volunteers or personnel affiliated with different general hospitals, subject to the terms and conditions established by the Commissioner of Health;
- Section 400.9 and paragraph 7 of subdivision h of section 405.9 of Title 10 of the NYCRR, to the extent necessary to permit general hospitals and nursing homes licensed pursuant to Article 28 of the Public Health Law that are treating patients during the disaster emergency to discharge, transfer, or receive such patients, as authorized by the Commissioner of Health if necessary due to staffing shortages, provided such facilities take all reasonable measures to protect the health and safety of such patients and residents, including safe transfer and discharge practices, and to comply with the Emergency Medical Treatment and Active Labor Act (42 U.S.C. section 1395dd) and any associated regulations;
- Section 64.7 of Title 8 of the NYCRR to expand nurse-initiated protocols to include electrocardiogram (EKG) for signs and symptoms of acute coronary syndrome, blood glucose for altered mental state, Labs and intravenous lines for potential sepsis and pre-procedure pregnancy testing to expedite evaluation and diagnosis;
- Section 415.15 of Title 10 of the NYCRR to the extent necessary to allow physician visits for nursing home residents to be performed via telemedicine;
- Sections 405.13 and 755.4 of Title 10 of the NYCRR to the extent necessary to permit an advanced practice registered nurse with a doctorate or master's degree specializing in the administration of anesthesia

administering anesthesia in a general hospital or free-standing ambulatory surgery center without the supervision of a qualified physician in these health care settings;

- Sections 800.3, 800.8, 800.9, 800.10, 800.12, 800.17, 800.18, 800.23, 800.24, and 800.26 of Title 10 of the NYCRR to the extent necessary to extend all existing emergency medical services provider certifications for one year; to permit the Commissioner of Health to modify the examination or recertification requirements for emergency medical services provider certifications; to suspend or modify, at the discretion of the Commissioner of Health, any requirements for the recertification of previously certified emergency medical services providers; and, at the discretion of the Commissioner of Health, develop a process determined by the Department of Health, to permit any emergency medical services provider certified or licensed by another State to provide emergency medical services within New York state; at the discretion of the Commissioner of Health, to suspend or modify equipment or vehicle requirements in order to ensure sustainability of EMS operations;
- Subdivision (15) of section 3001, and sections 800.3, 800.15 and 800.16 of Title 10 of the NYCRR with approval of the Department of Health, to the extent necessary to define "medical control" to also include emergency and non-emergency direction to emergency medical services personnel by a regional or state medical control center and to permit emergency medical services personnel to operate under the advice and direction of a nurse practitioner, physician assistant, or paramedic, provided that such medical professional is providing care under the supervision of a physician and pursuant to a plan approved by the Department of Health;
- Section 3001, 3005-a, 3008, and 3010 of the Public Health Law to the extent necessary to modify the definition of "emergency medical services" to include emergency, non-emergency and low acuity medical assistance only for the purpose of eliminating restrictions on an approved ambulance services or providers operating outside of the primary territory listed on such ambulance service's operating certificate with prior approval by the Department of Health; to permit the Commissioner of Health to issue provisional emergency medical services provider certifications to qualified individuals with modified certification periods as approved; and to allow emergency medical services to transport patients to locations other than healthcare facilities with prior approval by Department of Health;
- Sections 6502, 6524, 6905, 6906 and 6910 of the education law and Part 59.8 of Title 8 of the NYCRR to the extent necessary to authorize retired physicians, registered professional nurses, licensed practical nurses, and nurse practitioners licensed to practice and in current good standing in New York State, but not currently registered in New York State, to re-register through use of an expedited automatic registration form developed by the state and to waive any registration fee for the triennial registration period for such registrants;
- Paragraph 1 of section 6542 of the Education Law, Paragraph 1 of section 6549 of the Education Law, and Subdivisions (a) and (b) of Section 94.2 of Title 10 of the NYCRR to the extent necessary to permit a physician assistant, and to permit a specialist assistant, to provide medical services appropriate to their education, training and experience without oversight from a supervising physician without civil or criminal penalty related to a lack of oversight by a supervising physician;
- Subdivision (3) of section 6902 of Education Law, and any associated regulations, including, but not limited to, Section 64.5 of Title 10 of the NYCRR, to the extent necessary to permit a nurse practitioner to provide medical services appropriate to their education, training and experience, without a written practice agreement, or collaborative relationship with a physician, without civil or criminal penalty related to a lack of written practice agreement, or collaborative relationship, with a physician;
- Subparagraph (ii) of paragraph (2) of subdivision (g) of 10 N.Y.C.R.R. section 405.4, to the extent necessary to allow graduates of foreign medical schools having at least one year of graduate medical education to provide patient care in hospitals, is modified so as to allow such graduates without licenses to provide patient care in hospitals if they have completed at least one year of graduate medical education;
- Subdivision 4 of section 6909 of the Education Law, subdivision 6 of section 6527 of the Education Law, and section 64.7 of Title 8 of the NYCRR, to the extent necessary to permit physicians and certified nurse practitioners to issue a non-patient specific regimen to nurses or any such other persons authorized by law or by this executive order to collect throat or nasopharyngeal swab specimens from individuals suspected of suffering from a COVID-19 infection, for purposes of testing, or to perform such other tasks as may be necessary to provide care for individuals diagnosed or suspected of suffering from a COVID-19 infection;
- Sections 8602 and 8603 of the Education Law, and section 58-1.5 of Title 10 of the NYCRR, to the extent necessary to permit individuals who meet the federal requirements for high complexity testing to perform

testing for the detection of SARS-CoV-2 in specimens collected from individuals suspected of suffering from a COVID-19 infection;

- Article 165 of the Education Law and section 58-1.3 of Title 10 of the NYCRR, to the extent necessary to allow clinical laboratory practitioners to perform testing in a clinical laboratory under remote supervision, provided a supervisor is on-site at least eight hours per week;
- Subdivision 32 of Section 6530 of the Education Law, Paragraph (3) of Subdivision (a) of Section 29.2 of Title 8 of the NYCRR, and Sections 58-1.11, 405.10, and 415.22 of Title 10 of the NYCRR, only to the extent necessary for health care providers to be relieved of recordkeeping requirements, including but not limited to assigning diagnostic codes or creating or maintaining other records for billing purposes, without civil or criminal penalty imposed by the Department of Health or State Education Department;
- Section 112 of the State Finance Law, to the extent consistent with Article V, Section 1 of the State Constitution, and to the extent necessary to add additional work, sites, and time to State contracts or to award emergency contracts, including but not limited to emergency contracts or leases for relocation and support of State operations under section 3 of the Public Buildings Law; or emergency contracts under Section 9 of the Public Buildings Law; or emergency contracts for professional services under Section 136-a of the State Finance Law; or emergency contracts for commodities, services, and technology under Section 163 of the State Finance Law; or emergency contracts for purchases of commodities, services, and technology through any federal GSA schedules, federal 1122 programs, or other state, regional, local, multi-jurisdictional, or cooperative contract vehicles;
- Section 163 of the State Finance Law and Article 4-C of the Economic Development Law, to the extent necessary to expedite contracting for necessary services, commodities, and technology;
- Section 4903 of the Insurance Law and Section 4903 of the Public Health Law only to the extent necessary to increase availability of healthcare staff, upon certification by the hospital to the health plan, by suspending requirements for preauthorization review for scheduled surgeries in hospital facilities, hospital admissions, hospital outpatient services, home health care services following a hospital admission, and inpatient and outpatient rehabilitation services following a hospital admission; and to suspend concurrent review for inpatient and outpatient hospital services; and to suspend retrospective review for inpatient and outpatient hospital services at in-network hospitals; during the pendency of this Executive Order only; and
- Subsection c of section 4904 of the Insurance Law, paragraph 1 of subsection b of section 4914 of the Insurance Law, subdivision 3 of section 4904 of the Public Health Law, and paragraph a of subdivision 2 of section 4914 of the Public Health Law, to toll statutory timeframes required for hospital submission of an internal appeal and external appeal only to the extent necessary to increase availability of healthcare staff during the pendency of this Executive Order only.



GIVEN under my hand and the Privy Seal of the State in
the City of Albany this twenty-seventh day of
September in the year two thousand twenty-
one.

Ruth Hochul

BY THE GOVERNOR

[Signature]
Secretary to the Governor



No. 4.5

EXECUTIVE ORDER

Continuing the Declaration of a Statewide Disaster Emergency Due to Healthcare Staffing Shortages in the State of New York

WHEREAS, there are staffing shortages in hospitals and other healthcare facilities and they are expected to continue;

WHEREAS, severe understaffing in hospitals and other healthcare facilities is expected to continue to affect the ability to provide critical care and to adequately serve vulnerable populations;

WHEREAS, there is an immediate and critical need to supplement staffing to assure healthcare facilities can provide care;

NOW, THEREFORE, I, Kathy Hochul, Governor of the State of New York, by virtue of the authority vested in me by the Constitution of the State of New York and Section 28 of Article 2-B of the Executive Law, do hereby extend the state disaster emergency as set forth in Executive Order 4, as continued in Executive Order 4.4, and continue the terms, conditions, and suspensions contained in Executive Orders 4, 4.1, 4.2, 4.3, and 4.4 through March 1, 2022.



GIVEN under my hand and the Privy Seal of the State
in the City of Albany this thirtieth day of
January in the year two thousand twenty-
two.

Kathy Hochul

BY THE GOVERNOR

A stylized, handwritten signature in black ink, likely belonging to the Secretary to the Governor.

Secretary to the Governor

February 11, 2022 | 3:35 pm

COVID-19 Vaccines

Children ages 5+ are eligible for the COVID-19 vaccine and children ages 12+ are eligible for a booster. Parents and guardians: make sure your child gets vaccinated and stays up to date with all recommended doses.

VAX FOR KIDS >



SEPTEMBER 27, 2021 | Albany, NY

Governor Hochul Takes Bold Action to Alleviate Potential Health Care Staffing Shortages

HEALTH (/KI COVID-19 VACCINE (/KI PUBLIC SAFETY (/KEYWORDS/PUBLIC-
19- SAFETY)
VACCINE)

Signs [Executive Order](#) to Significantly Expand Eligible Workforce and Allow Additional Health Care Workers to Administer COVID-19 Testing and Vaccinations

Directs 24/7 Command Center to Monitor and Troubleshoot Staffing Shortages

New York State First-in-Nation on Health Care Worker Vaccination Mandate — 92% of Nursing

Home Staff Compliant As of Monday Evening, Up from 70%

Suspension of Administrative Reviews Will Add Additional Source of Health Care Workers

Governor Kathy Hochul tonight signed an [executive order](https://www.governor.ny.gov/sites/default/files/2021-09/EO_4_Disaster.pdf) (https://www.governor.ny.gov/sites/default/files/2021-09/EO_4_Disaster.pdf) to alleviate potential staffing shortages in hospitals and other health care facilities statewide. The executive order significantly expands the eligible health care workforce and allows additional health care workers to administer COVID-19 testing and vaccinations.

"The only way we can move past this pandemic is to ensure that everyone eligible is vaccinated, and that includes those who are taking care of our vulnerable family members and loved ones," **Governor Hochul said**. "On Saturday I released a comprehensive plan in advance of the deadline for the vaccine mandate that keeps New Yorkers safe, and tonight I am adding even more provisions to take bold action to alleviate potential staffing shortages. To monitor developments on the ground, I am also directing an around-the-clock operations center to assist local partners and troubleshoot staffing issues in real time."

Governor Hochul has directed a 24/7 Operations Center, led by the New York State Department of Health, to constantly monitor staffing operations and trends statewide, provide guidance to healthcare facilities and help troubleshoot acute situations with providers as necessary. The Governor is engaged in ongoing outreach with local elected officials, hospitals, labor leaders, and other health care organizations to check-in on staffing status and offer State assistance.

Latest Vaccination Rates for Health Care Worker Populations

- The percentage of nursing home staff receiving at least one COVID-19 vaccine dose increased to 92% as of Monday evening, up from 70% on August 15 before the vaccine mandate was announced.
- The percentage of adult care facilities staff receiving at least one COVID-19 vaccine dose increased to 89% as of Monday evening, up from 76% on August 15 before the vaccine mandate was announced.
- The percentage of hospital staff fully vaccinated is 84% as of September 22, up from 77% on August 10 before the vaccine mandate was announced. Preliminary self-reported data

shows that hospital staff receiving at least one dose of vaccine is 92% as of Monday evening.

Expanding Eligible Health Care Workforce to Meet Staffing Needs

To remove barriers to allow additional categories of health care workers to provide care in order to meet staffing needs in New York, the executive order includes a series of provisions, including:

- Allowing out of state and out of country health care workers including physicians, RNs, LPNs, NPs, PAs, midwives, clinical nurse specialists, licensed master social workers, and licensed clinical social workers to practice in New York;
- Waiving re-registration fees, creating an expedited re-registration process, and eliminating barriers to re-enter the workforce for retirees;
- Allowing practitioners to work or volunteer in other facilities;
- Allowing physician visits in nursing homes to be done using telemedicine;
- Ensuring removal of barriers for EMTs and Advanced EMTs to practice and assist in additional settings, allowing basic EMTs to vaccinate and test for COVID-19, extending all EMS providers' certification period by one year, modifying certification requirements, and permitting out of state providers to operate in the New York State EMS System;
- Allowing New York State-licensed providers without current registrations to practice without penalty for lack of registration;
- Allowing graduates of SED-registered programs (NP, Lab, RN, LPN) to practice in a hospital or nursing home for 180 days following graduation; and
- Providing flexibilities for clinical labs to increase testing capacity

The executive order also expands the scope of practice for additional health care workers to allow for COVID-19 testing and vaccinations, including an expansion of the ability of midwives, registered nurses, physicians, and nurse practitioners to more easily administer and order COVID-19 vaccinations and testing as well as flu vaccinations.

To aid in facilitating faster efficient patient transfers to mitigate any staffing issues, the executive order also permits facilities to discharge, transfer, or receive patients quickly, provided they are protecting the health and safety of patients and residents and complying with federal law. Additionally, the executive order suspends requirements for preauthorization review for scheduled surgeries in hospital facilities, hospital admissions, hospital outpatient services, home health care services following a hospital admission, and inpatient rehabilitation services

following a hospital admission, as well as suspends concurrent and retrospective review of claims during the duration of the order.

Additionally, Governor Hochul plans to work with the federal government and other state leaders to explore ways to expedite visa requests for medical professionals and is monitoring whether the deployment of medically-trained National Guard members may be necessary to execute at any point.

Contact the Governor's Press Office

Contact us by phone:

Albany: (518) 474 - 8418
New York City: (212) 681 - 4640

Contact us by email:

Press.Office@exec.ny.gov

Translations

Arabic Translation الترجمة إلى العربية	 DOWNLOAD
Bengali Translation বাংলা অনুবাদ	 DOWNLOAD
Chinese Translation 中文翻譯	 DOWNLOAD
Haitian-Creole Translation Tradiksyon kreyòl ayisyen	 DOWNLOAD
Italian Translation Traduzione italiana	 DOWNLOAD

TRANSLATIONS AVAILABLE	
Korean Translation 한국어 번역	 DOWNLOAD
Polish Translation Polskie tłumaczenie	 DOWNLOAD
Russian Translation Перевод на русский язык	 DOWNLOAD
Spanish Translation Traducción al español	 DOWNLOAD
Yiddish Translation אידישע איבערזייטשונג	 DOWNLOAD



PRESS RELEASES (/SUB-TYPE/PRESS-RELEASES) | HEALTH CARE (/TOPIC/HEALTH-CARE) | NEWS (/TOPIC/NEWS)

Major Health Care Professional Organizations Call for COVID-19 Vaccine Mandates for All Health Workers

July 26, 2021

Groups include American Medical Association, American Nurses Association, American Academy of Pediatrics, Association of American Medical Colleges, and National Association for Home Care and Hospice

With COVID-19 case counts rising amid the spread of the Delta variant, more than 50 health care professional societies and organizations called for all health care employers to require their employees to be vaccinated against COVID-19 in a joint statement released today. These societies and organizations represent millions of workers throughout health and long-term care – from doctors and nurses to pharmacists and physician assistants, from public health workers and epidemiologists to long-term care, home care, and hospice workers.

Commentary: Mandating COVID-19 vaccination for health care workers

Ezekiel Emanuel, MD, vice provost for global initiatives at the University of Pennsylvania, and David J. Skorton, MD, AAMC president and CEO, have co-authored a commentary published in *Annals of Internal Medicine* examining the rationale for mandating COVID-19 vaccinations for health care workers.

READ MORE [\[HTTPS://WWW.ACPJOURNALS.ORG/DOI/10.7326/M21-3150\]](https://www.acpjournals.org/doi/10.7326/M21-3150)

Their endorsement of mandatory COVID-19 vaccination for health care workers aims to protect the safety of patients and residents of long-term care facilities and make the health care sector a leader in COVID-19 vaccination just as cases, hospitalizations, and deaths are once again rising throughout the United States.

“Health care workers have an ethical duty to put patients’ health and well-being first, and getting vaccinated for COVID-19 is integral to that duty,” said **Dr. Ezekiel Emanuel**, vice provost for global initiatives at the **University of Pennsylvania**, who organized the statement. “Employer vaccine mandates are effective and lifesaving, and they are especially appropriate in health care and long-term care settings. No patient should have to worry that they could become infected by one of their care providers, and no provider should put their patient at risk.”

Although vaccination rates among health care workers have been better than that of the general population, by the end of May, [one-in-four hospital workers](https://www.webmd.com/vaccines/covid-19-vaccine/news/20210628/huge-number-of-hospital-workers) [\[https://www.webmd.com/vaccines/covid-19-vaccine/news/20210628/huge-number-of-hospital-workers\]](https://www.webmd.com/vaccines/covid-19-vaccine/news/20210628/huge-number-of-hospital-workers) had not been vaccinated. This leaves patients – especially unvaccinated children, the elderly, and the immunocompromised – facing a growing risk of infection as the Delta variant surges. If implemented, this mandate would cover [17 million health care workers](https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D) [\[https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D\]](https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

“As the number of cases, hospitalizations and deaths continue to rise due to the COVID-19 Delta variant, especially among unvaccinated persons, requiring that all health care workers who can get vaccinated receive a COVID-19 vaccine will help protect them, their patients, loved ones and others who are vulnerable and immunocompromised,” said **George M. Abraham**, MD, MPH, FACP, President, **American College of Physicians**.

“As COVID-19 variants emerge and proliferate, it’s critical that we protect everyone who lives and works in long-term care, by ensuring staff are fully vaccinated. Throughout the pandemic, long-term care providers have demonstrated their dedication, commitment and bravery in the face of unprecedented, challenging circumstances. They must heed the scientific evidence and do everything possible to deliver safe, quality care to the older adults and others they serve,” said **Katie Smith Sloan**, president and CEO, **LeadingAge**.

“As frontline providers, PAs are committed to protecting our patients and the health of the public. Receiving the vaccine is a necessary step for fulfilling this commitment. AAPA supports requiring vaccinations for health workers to keep both the public and healthcare workforce safe,” said **Jennifer M. Orozco**, MMS, PA-C, DFAAPA, president of the **American Academy of PAs**.

"Employers have a fundamental responsibility to take all reasonable measures to ensure the safety and well-being of their employees and the people they serve," said **Sandra Leal**, PharmD, MPH, FAPhA, CDCES, president, **American Pharmacists Association**. "Due to the nature of the times we live in, this must include requiring their employees be vaccinated, to protect themselves and others from the COVID-19 virus."

"Health care workers are role models and families rely on them to care for their loved ones," said **Elena Rios**, MD, MSPH, FACP, president and CEO, **National Hispanic Medical Association**. "Now, the most important thing health care workers can do is get the COVID-19 vaccine, setting an example of the best thing we can all do to end the pandemic."

"Universal vaccination of health care workers is the single most important step healthcare institutions can do to stop the spread of COVID-19. It is essential for protecting the health of their workers, the safety of their patients and ultimately the health of their communities," said **Georges C. Benjamin**, MD, executive director, **American Public Health Association**.

"We need to do everything possible to help children, adolescents, and their families safely emerge from the global pandemic," said **Gabrielle A. Carlson**, MD, President, **American Academy of Child and Adolescent Psychiatry**. "It is imperative that those who can receive a COVID-19 vaccine do so, especially those who work in a healthcare facility where care is provided to the unvaccinated, including vulnerable children for whom a COVID-19 vaccine is not yet approved."

"Requiring COVID-19 vaccination as a condition of employment is a powerful tool for protecting frontline workers and patients against highly contagious variants and in communities with significant numbers of unvaccinated people. Health care organizations have an opportunity to lead by example, setting a precedent for other organizations to require vaccination to safeguard the health of employees and entire communities," said **Daniel P. McQuillen**, MD, FIDSA, president-elect, **Infectious Diseases Society of America**.

"The AAMC, whose members continue to provide patient care on the frontlines of this ongoing pandemic, did not come to this decision lightly," said **David J. Skorton**, MD, president and CEO of the **Association of American Medical Colleges**. "Based on the large and convincing body of evidence and real-world experience of the safety and efficacy of the COVID-19 vaccines, requiring vaccinations among those serving at health care institutions is the right decision to promote the health of our patients, their families, and communities."

"Patients with cancer need to know that their environment, including the people who care for them, is as safe as possible," said **Everett E. Vokes**, MD, FASCO, president, **American Society of Clinical Oncology**. "Mandatory vaccination is entirely consistent with ASCO's core values of evidence, care, and impact."

The joint statement and full list of signatories is below.

Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care

Due to the recent COVID-19 surge and the availability of safe and effective vaccines, our health care organizations and societies advocate that all health care and long-term care employers require their workers to receive the COVID-19 vaccine. This is the logical fulfillment of the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being.

Because of highly contagious variants, including the Delta variant, and significant numbers of unvaccinated people, COVID-19 cases, hospitalizations and deaths are once again rising throughout the United States.¹ Vaccination is the primary way to put the pandemic behind us and avoid the return of stringent public health measures.

Unfortunately, many health care and long-term care personnel remain unvaccinated. As we move towards full FDA approval of the currently available vaccines, all health care workers should get vaccinated for their own health, and to protect their colleagues, families, residents of long-term care facilities and patients. This is especially necessary to protect those who are vulnerable, including unvaccinated children and the immunocompromised. Indeed, this is why many health care and long-term care organizations already require vaccinations for influenza, hepatitis B, and pertussis.

We call for all health care and long-term care employers to require their employees to be vaccinated against COVID-19.

We stand with the growing number of experts and institutions that support the requirement for universal vaccination of health workers.^{2,3} While we recognize some workers cannot be vaccinated because of identified medical reasons and should be exempted from a mandate, they constitute a small minority of all workers. Employers should consider any applicable state laws on a case-by-case basis.

Existing COVID-19 vaccine mandates have proven effective.^{4,5} Simultaneously, we recognize the historical mistrust of health care institutions, including among many in our own health care workforce. We must continue to address workers' concerns, engage with marginalized populations, and work with trusted messengers to improve vaccine acceptance.

As the health care community leads the way in requiring vaccines for our employees, we hope all other employers across the country will follow our lead and implement effective policies to encourage vaccination. The health and safety of U.S. workers, families, communities, and the nation depends on it.

SIGNATORIES

Listed Alphabetically

- Academy of Managed Care Pharmacy
- American Academy of Ambulatory Care Nursing
- American Academy of Child and Adolescent Psychiatry
- American Academy of Family Physicians (AAFP)
- American Academy of Nursing
- American Academy of Ophthalmology
- American Academy of PAs (AAPA)
- American Academy of Pediatrics (AAP)
- American Association of Allergy, Asthma & Immunology
- American Association of Colleges of Pharmacy
- American Association of Clinical Endocrinology
- American Association of Neuroscience Nurses
- American College of Clinical Pharmacy (ACCP)
- American College of Physicians (ACP)
- American College of Preventive Medicine
- American College of Surgeons (ACS)
- American Epilepsy Society
- American Medical Association (AMA)
- American Nursing Association (ANA)
- American Pharmacist Association (APhA)
- American Psychiatric Association (APA)
- American Public Health Association (APHA)
- American Society for Clinical Pathology
- American Society for Hematology (ASH)
- American Society for Radiation Oncology (ASTRO)
- American Society of Health-System Pharmacists (ASHP)
- American Society of Nephrology
- American Thoracic Society
- Association for Clinical Oncology (ASCO)
- Association of American Medical Colleges (AAMC)
- Association of Rehabilitation Nurses
- Council of Medical Specialty Societies (CMSS)
- HIV Medicine Association
- Infectious Diseases Society of America (IDSA)
- LeadingAge
- National Association for Home Care & Hospice
- National Association of Indian Nurses of America
- National Association of Pediatric Nurse Practitioners
- National Council of State Boards of Nursing (NCSBN)
- National Hispanic Medical Association (NHMA)
- National League for Nursing
- National Medical Association
- National Pharmaceutical Association (NPhA)
- Nurses Who Vaccinate
- Organization for Associate Degree Nursing (OADN)
- Pediatric Infectious Diseases Society (PIDS)
- Philippine Nurses Association of America, Inc (PNAA)

- Society of Gynecologic Oncology
- Society for Healthcare Epidemiology of America (SHEA)
- Society of Hospital Medicine
- Society of Interventional Radiology
- Texas Nurses Association
- The John A. Hartford Foundation
- Transcultural Nursing Society
- Virgin Islands State Nurses Association
- Wound, Ostomy, and Continence Nurses Society

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2. Weber, D., Al-Tawfiq, J., Babcock, H., Bryant, K., Drees, M., Elshaboury, R., et al. (2021). Multisociety Statement on COVID-19 Vaccination as a Condition of Employment for Healthcare Personnel. *Infection Control & Hospital Epidemiology*, 1-46. doi:10.1017/ice.2021.322
3. American Hospital Association. AHA Policy Statement on Mandatory COVID-19 Vaccination of Health Care Personnel. July 21, 2021. <https://www.aha.org/public-comments/2021-07-21-aha-policy-statement-mandatory-covid-19-vaccination-health-care>  (<https://www.aha.org/public-comments/2021-07-21-aha-policy-statement-mandatory-covid-19-vaccination-health-care>).
4. Bacon J. 'Condition of employment': Hospitals in DC, across the nation follow Houston Methodist in requiring vaccination for workers. *USA Today*. Available from: <https://www.usatoday.com/story/news/health/2021/06/10/dc-hospitals-others-follow-houston-methodist-requiring-vaccination/7633481002/>  (<https://www.usatoday.com/story/news/health/2021/06/10/dc-hospitals-others-follow-houston-methodist-requiring-vaccination/7633481002/>). [Accessed 22 July 2021].
5. Paulin E. More Nursing Homes Are Requiring Staff COVID-19 Vaccinations. *AARP*. Available from: <https://www.aarp.org/caregiving/health/info-2021/nursing-homes-covid-vaccine-mandate.html>  (<https://www.aarp.org/caregiving/health/info-2021/nursing-homes-covid-vaccine-mandate.html>). [Accessed 22 July 2021].

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.



655 K Street, NW, Suite 100 Washington, DC, 20001-2399



Why COVID-19 vaccination should be required for health professionals

JUL 27, 2021

Jennifer Lubell

Contributing News Writer

Employers across the country are weighing the pros and cons of vaccine mandates as employees return to the office. Some see these mandates as an occupational health strategy, allowing for medical and nonmedical exemptions. For hospitals and health systems, vaccination is especially crucial from a public health perspective.

“Do no harm is a core ethic for all those who care for the sick and injured. I think that physicians and, frankly, all those working in the health care system, have a fundamental obligation to patients by getting vaccinated for preventable diseases such as COVID 19,” said Audiey Kao, MD, PhD, the AMA’s vice president of ethics. Dr. Kao discussed the ethical considerations of vaccine mandates for health care workers in an episode of the “AMA COVID-19 Update” that was published last week.

COVID-19 vaccines have prevented nearly 280,000 deaths and 1.25 million hospitalizations in the U.S. according to estimates from researchers at the Yale School of Public Health. If and when hospitals and health systems choose to mandate COVID-19 vaccination, Dr. Kao believes they’ll have solid ethical and legal grounds to do so.

Considering the time lag between rising COVID-19 cases and increased hospitalizations, “physicians and health care employers need to act with urgency to address concerns and encourage vaccinations among those in the health care workforce who remain unvaccinated,” Dr. Kao said.

Yesterday, the AMA and nearly 60 other organizations representing physicians, nurses, pharmacists and other health professionals signed a joint letter calling for all health care and long-term care employers to require their employees to be vaccinated against COVID-19.

“It is critical that all people in the health care workforce get vaccinated against COVID-19 for the safety of our patients and our colleagues,” said Susan R. Bailey, MD, the AMA’s immediate past president. “With more than 300 million doses administered in the United States and nearly 4 billion doses administered worldwide, we know the vaccines are safe and highly effective at preventing



severe illness and death from COVID-19.

“Increased vaccinations among health care personnel will not only reduce the spread of COVID-19 but also reduce the harmful toll this virus is taking within the health care workforce and those we are striving to serve,” Dr. Bailey added.

96% of physicians vaccinated

The AMA, the American Hospital Association and the American Nurses Association have repeatedly called on health professionals to get their COVID-19 vaccination. So far, the reception among doctors has been robust: a recent AMA survey found that more than 96% of physicians reported receiving the vaccine.

“It’s good to see that the great majority of my colleagues are setting an important example and practicing what we’ve been preaching,” said Dr. Kao.

Ethics policy adopted at the November 2020 AMA Special Meeting says that physicians have an ethical duty to get immunized against pandemic disease when a safe and effective vaccine becomes available, and if there are no medical contraindications.

Federal judge OKs hospital mandate

Vaccine mandates aren’t new to health care facilities, but the health care sector has seen its share of legal challenges against these requirements, and the COVID-19 vaccine is no exception.

Dr. Kao mentioned a high-profile lawsuit in Texas, in which 100 hospital employees claimed wrongful termination for being put on leave without pay for refusing a hospital-supplied vaccination. A federal judge recently ruled in favor of the hospital, noting that “if hospital’s employees didn’t want to receive a COVID-19 shot, they were free to work elsewhere,” said Dr. Kao.

Meanwhile, at least six have enacted new laws limiting mandatory COVID-19 shots.

“Fortunately, many of these states have not prohibited employers from requiring workers to get a vaccine but do carve out an exception for health care and public health workers,” Dr. Kao noted. “These new laws, however, only further contribute to politicizing a public health emergency that should not be a red versus blue or a left versus right issue.”



Full FDA approval a game-changer?

The three vaccines now available in the U.S.—those made by Pfizer-BioNTech, Moderna and Johnson & Johnson—have been granted emergency use authorization by the FDA. These vaccines have demonstrated strong, real-world efficacy and safety data, said Dr. Kao.

“We’ve given COVID vaccines to nearly 70% of the U.S. adult population. Safety and efficacy are holding up well, even against the variants that have emerged,” he said.

The FDA is expected to grant full approval to the Pfizer and Moderna vaccines in the coming weeks and months. Having this full approval “should help to get some people who are currently on the fence get vaccinated,” said Dr. Kao.

As individual facilities weigh their options, physicians and health systems should continue to get the message out that COVID-19 vaccines save lives, Dr. Kao advised.

“Can you imagine where we would be in this country if we did not have safe and effective COVID-19 vaccines?” he said.



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Commentary: Mandating COVID-19 vaccination for health care workers

Ezekiel Emanuel, MD, vice provost for global initiatives at the University of Pennsylvania, and David J. Skorton, MD, AAMC president and CEO, have co-authored a commentary published in *Annals of Internal Medicine* examining the rationale for mandating COVID-19 vaccinations for health care workers.

READ MORE [\[HTTPS://WWW.ACPJOURNALS.ORG/DOI/10.7326/M21-3150\]](https://www.acpjournals.org/doi/10.7326/M21-3150)

Their endorsement of mandatory COVID-19 vaccination for health care workers aims to protect the safety of patients and residents of long-term care facilities and make the health care sector a leader in COVID-19 vaccination just as cases, hospitalizations, and deaths are once again rising throughout the United States.

“Health care workers have an ethical duty to put patients’ health and well-being first, and getting vaccinated for COVID-19 is integral to that duty,” said **Dr. Ezekiel Emanuel**, vice provost for global initiatives at the **University of Pennsylvania**, who organized the statement. “Employer vaccine mandates are effective and lifesaving, and they are especially appropriate in health care and long-term care settings. No patient should have to worry that they could become infected by one of their care providers, and no provider should put their patient at risk.”

Although vaccination rates among health care workers have been better than that of the general population, by the end of May, [one-in-four hospital workers](https://www.webmd.com/vaccines/covid-19-vaccine/news/20210628/huge-number-of-hospital-workers) [\[https://www.webmd.com/vaccines/covid-19-vaccine/news/20210628/huge-number-of-hospital-workers\]](https://www.webmd.com/vaccines/covid-19-vaccine/news/20210628/huge-number-of-hospital-workers) had not been vaccinated. This leaves patients – especially unvaccinated children, the elderly, and the immunocompromised – facing a growing risk of infection as the Delta variant surges. If implemented, this mandate would cover [17 million health care workers](https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D) [\[https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D\]](https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

“As the number of cases, hospitalizations and deaths continue to rise due to the COVID-19 Delta variant, especially among unvaccinated persons, requiring that all health care workers who can get vaccinated receive a COVID-19 vaccine will help protect them, their patients, loved ones and others who are vulnerable and immunocompromised,” said **George M. Abraham**, MD, MPH, FACP, President, **American College of Physicians**.

“As COVID-19 variants emerge and proliferate, it’s critical that we protect everyone who lives and works in long-term care, by ensuring staff are fully vaccinated. Throughout the pandemic, long-term care providers have demonstrated their dedication, commitment and bravery in the face of unprecedented, challenging circumstances. They must heed the scientific evidence and do everything possible to deliver safe, quality care to the older adults and others they serve,” said **Katie Smith Sloan**, president and CEO, **LeadingAge**.

“As frontline providers, PAs are committed to protecting our patients and the health of the public. Receiving the vaccine is a necessary step for fulfilling this commitment. AAPA supports requiring vaccinations for health workers to keep both the public and healthcare workforce safe,” said **Jennifer M. Orozco**, MMS, PA-C, DFAAPA, president of the **American Academy of PAs**.

"Employers have a fundamental responsibility to take all reasonable measures to ensure the safety and well-being of their employees and the people they serve," said **Sandra Leal**, PharmD, MPH, FAPhA, CDCES, president, **American Pharmacists Association**. "Due to the nature of the times we live in, this must include requiring their employees be vaccinated, to protect themselves and others from the COVID-19 virus."

"Health care workers are role models and families rely on them to care for their loved ones," said **Elena Rios**, MD, MSPH, FACP, president and CEO, **National Hispanic Medical Association**. "Now, the most important thing health care workers can do is get the COVID-19 vaccine, setting an example of the best thing we can all do to end the pandemic."

"Universal vaccination of health care workers is the single most important step healthcare institutions can do to stop the spread of COVID-19. It is essential for protecting the health of their workers, the safety of their patients and ultimately the health of their communities," said **Georges C. Benjamin**, MD, executive director, **American Public Health Association**.

"We need to do everything possible to help children, adolescents, and their families safely emerge from the global pandemic," said **Gabrielle A. Carlson**, MD, President, **American Academy of Child and Adolescent Psychiatry**. "It is imperative that those who can receive a COVID-19 vaccine do so, especially those who work in a healthcare facility where care is provided to the unvaccinated, including vulnerable children for whom a COVID-19 vaccine is not yet approved."

"Requiring COVID-19 vaccination as a condition of employment is a powerful tool for protecting frontline workers and patients against highly contagious variants and in communities with significant numbers of unvaccinated people. Health care organizations have an opportunity to lead by example, setting a precedent for other organizations to require vaccination to safeguard the health of employees and entire communities," said **Daniel P. McQuillen**, MD, FIDSA, president-elect, **Infectious Diseases Society of America**.

"The AAMC, whose members continue to provide patient care on the frontlines of this ongoing pandemic, did not come to this decision lightly," said **David J. Skorton**, MD, president and CEO of the **Association of American Medical Colleges**. "Based on the large and convincing body of evidence and real-world experience of the safety and efficacy of the COVID-19 vaccines, requiring vaccinations among those serving at health care institutions is the right decision to promote the health of our patients, their families, and communities."

"Patients with cancer need to know that their environment, including the people who care for them, is as safe as possible," said **Everett E. Vokes**, MD, FASCO, president, **American Society of Clinical Oncology**. "Mandatory vaccination is entirely consistent with ASCO's core values of evidence, care, and impact."

The joint statement and full list of signatories is below.

Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care

Due to the recent COVID-19 surge and the availability of safe and effective vaccines, our health care organizations and societies advocate that all health care and long-term care employers require their workers to receive the COVID-19 vaccine. This is the logical fulfillment of the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being.

Because of highly contagious variants, including the Delta variant, and significant numbers of unvaccinated people, COVID-19 cases, hospitalizations and deaths are once again rising throughout the United States.¹ Vaccination is the primary way to put the pandemic behind us and avoid the return of stringent public health measures.

Unfortunately, many health care and long-term care personnel remain unvaccinated. As we move towards full FDA approval of the currently available vaccines, all health care workers should get vaccinated for their own health, and to protect their colleagues, families, residents of long-term care facilities and patients. This is especially necessary to protect those who are vulnerable, including unvaccinated children and the immunocompromised. Indeed, this is why many health care and long-term care organizations already require vaccinations for influenza, hepatitis B, and pertussis.

We call for all health care and long-term care employers to require their employees to be vaccinated against COVID-19.

We stand with the growing number of experts and institutions that support the requirement for universal vaccination of health workers.^{2,3} While we recognize some workers cannot be vaccinated because of identified medical reasons and should be exempted from a mandate, they constitute a small minority of all workers. Employers should consider any applicable state laws on a case-by-case basis.

Existing COVID-19 vaccine mandates have proven effective.^{4,5} Simultaneously, we recognize the historical mistrust of health care institutions, including among many in our own health care workforce. We must continue to address workers' concerns, engage with marginalized populations, and work with trusted messengers to improve vaccine acceptance.

As the health care community leads the way in requiring vaccines for our employees, we hope all other employers across the country will follow our lead and implement effective policies to encourage vaccination. The health and safety of U.S. workers, families, communities, and the nation depends on it.

SIGNATORIES

Listed Alphabetically

- Academy of Managed Care Pharmacy
- American Academy of Ambulatory Care Nursing
- American Academy of Child and Adolescent Psychiatry
- American Academy of Family Physicians (AAFP)
- American Academy of Nursing
- American Academy of Ophthalmology
- American Academy of PAs (AAPA)
- American Academy of Pediatrics (AAP)
- American Association of Allergy, Asthma & Immunology
- American Association of Colleges of Pharmacy
- American Association of Clinical Endocrinology
- American Association of Neuroscience Nurses
- American College of Clinical Pharmacy (ACCP)
- American College of Physicians (ACP)
- American College of Preventive Medicine
- American College of Surgeons (ACS)
- American Epilepsy Society
- American Medical Association (AMA)
- American Nursing Association (ANA)
- American Pharmacist Association (APhA)
- American Psychiatric Association (APA)
- American Public Health Association (APHA)
- American Society for Clinical Pathology
- American Society for Hematology (ASH)
- American Society for Radiation Oncology (ASTRO)
- American Society of Health-System Pharmacists (ASHP)
- American Society of Nephrology
- American Thoracic Society
- Association for Clinical Oncology (ASCO)
- Association of American Medical Colleges (AAMC)
- Association of Rehabilitation Nurses
- Council of Medical Specialty Societies (CMSS)
- HIV Medicine Association
- Infectious Diseases Society of America (IDSA)
- LeadingAge
- National Association for Home Care & Hospice
- National Association of Indian Nurses of America
- National Association of Pediatric Nurse Practitioners
- National Council of State Boards of Nursing (NCSBN)
- National Hispanic Medical Association (NHMA)
- National League for Nursing
- National Medical Association
- National Pharmaceutical Association (NPhA)
- Nurses Who Vaccinate
- Organization for Associate Degree Nursing (OADN)
- Pediatric Infectious Diseases Society (PIDS)
- Philippine Nurses Association of America, Inc (PNAA)

- Society of Gynecologic Oncology
- Society for Healthcare Epidemiology of America (SHEA)
- Society of Hospital Medicine
- Society of Interventional Radiology
- Texas Nurses Association
- The John A. Hartford Foundation
- Transcultural Nursing Society
- Virgin Islands State Nurses Association
- Wound, Ostomy, and Continence Nurses Society

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The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.



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COVID-19 Vaccination

Revised Position Statement

Certified Registered Nurse Anesthetists (CRNAs) provide essential life-saving services for patients impacted by COVID-19. Currently, COVID-19 cases, hospitalizations, and deaths are increasing across the United States.¹ This trend is driven by the Delta variant (B.1.617.2) which is a highly contagious SARS-CoV-2 virus strain.^{1,2} The highest spread of cases and severe outcomes is occurring in areas with low vaccination rates, and a majority of hospitalizations and deaths have been among the unvaccinated.^{1,3,4}

Position Statement

The American Association of Nurse Anesthesiology (AANA) supports offering COVID-19 vaccination to frontline healthcare personnel, including CRNAs and nurse anesthesiology students. The AANA also strongly encourages healthcare personnel to be vaccinated to protect their patients, colleagues, families, and themselves. While vaccine hesitancy exists among some patients and healthcare providers, AANA encourages education and review of scientific evidence about the vaccine and its impact on infection prevention, patient care, infection spread, and herd immunity.⁵⁻⁸ The COVID-19 vaccination is a critical prevention measure to reduce infection spread and mitigate the COVID-19 pandemic.

Healthcare systems and facilities may choose to mandate the COVID-19 vaccination for all personnel. It is important that these mandates take into account any state-level requirements and that facilities provide reasonable accommodations for personnel who are exempt from mandatory vaccination.⁹

Healthcare workers are more likely to be exposed to the SARS-CoV-2 virus and studies have shown that vaccination is highly effective in preventing spread under real-world conditions.¹⁰ The COVID-19 vaccine is an additional tool to support clinician and patient safety. CRNAs should continue to use appropriate personal protective equipment and follow safety precautions including infection prevention and control and hand hygiene practices.¹¹

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AACN Statement on Mandatory COVID-19 Vaccination

As of August 2, 2021, AACN calls for all healthcare and long-term care employers to require every member of the healthcare team—employees and all credentialed and contracted providers—to be vaccinated against COVID-19.

AACN has previously held that vaccination decisions are best left up to the individual. This new position, which calls for mandatory vaccination except when medically contraindicated, is a necessary response to the grave threat of COVID-19 and the dramatic rise in cases among unvaccinated individuals. In this unique case, we believe mandated vaccination is the best path to support the physical safety of patients, nurses, their colleagues, and their families and a means to prevent further trauma and moral injury imposed by the pandemic on our health care workforce.

To be effective, the COVID-19 vaccine must be received by a large percentage of the population. Health care team members who are vaccinated serve as role models and help to shorten the duration of the pandemic. Ultimately, widespread vaccination will reduce the massive burden of this disease on acute and critical-care units and our communities.

This call for mandatory vaccination aligns with more than 55 major healthcare organizations, including the American Nurses Association and the American Medical Association who recently [called for similar action](#).

It is reasonable for healthcare workers to have questions about new vaccines and requirements. AACN calls on healthcare leaders to recognize and honor the difficult and even traumatic conditions under which many employees have worked during the COVID-19 pandemic. It is crucial to ensure that employees and providers have opportunities to ask questions, express concerns and receive scientific information regarding vaccines and the organization's rationale for requiring them.

FDA approval of the currently available vaccines is moving forward, and the widely administered vaccines have been safe and effective. AACN will share information from reliable sources as we advance our understanding on this topic. Nurses, the most trusted profession, must scrutinize all sources of information, decline to accept misinformation and disseminate only accurate information from credible scientific sources.

About the American Association of Critical-Care Nurses: The American Association of Critical-Care Nurses (AACN) is the largest specialty nursing organization in the world with more than 120,000 members. AACN represents the interests of more than half a million acute and critical care nurses and includes more than 200 chapters in the United States.



COVID-19 Vaccination

Position Statement #3072

NANN Board of Directors
May 2021

To date, more than 130 million cases of COVID-19 have been reported globally. In the United States, more than 30 million cases and more than 500 thousand deaths have been reported (Johns Hopkins University & Medicine, n.d.). As frontline providers, nurses bear witness to the effects of the COVID-19 pandemic. In addition to following guidelines established by the Centers for Disease Control and Prevention (CDC) and your institution—including the use of masks, social distancing, and frequent thorough handwashing—vaccination is a vital step in controlling the spread of COVID-19. As the professional voice of neonatal nurses, the National Association of Neonatal Nurses (NANN) recommends nurses get vaccinated.



Association Position

The National Association of Neonatal Nurses (NANN) supports the COVID-19 vaccination recommendations from the Centers for Disease Control and Prevention (CDC). Vaccination is a personal choice. We recognize that data regarding the various COVID-19 vaccines continue to evolve, and we encourage nurses to educate themselves as new information arises. The current vaccines have undergone rigorous clinical trials and are safe and effective against COVID-19. The global impact of the virus has been devastating. Vaccination is our best defense. As such, NANN recommends nurses get vaccinated against COVID-19.

Background and Significance

As of April 3, 2021, more than 130 million cases of COVID-19 have been reported globally. Since the first reported case on January 21, 2020, the United States has experienced more than 30 million confirmed cases resulting in more than a half-million deaths (Johns Hopkins University and Medicine, n.d.). All individuals are presumed to be susceptible to the COVID-19 virus; however, illness presentation may vary. Individuals at risk for severe disease include people older than 60 years and people with chronic medical conditions. All age groups have experienced asymptomatic and milder versions of the disease.

Nurses are impacted by the COVID-19 pandemic both physically and psychologically. Frequent contact with infected individuals makes nurses more vulnerable to infection than the general population. According to *Lost on the Frontline* (The Guardian and Kaiser Health News, 2021), more than 3,500 healthcare workers in the United States have died from coronavirus since March 2020. Thirty-two percent were nurses. Nurses must care for and protect themselves from the virus first so that they may protect and care for their patients.

Vaccination is the first step in the prevention of illness from COVID-19. As the various vaccines emerge, it is essential to understand the types of vaccine platforms and their efficacy and safety profile. Three types of vaccine platforms are currently in use mRNA, viral vector, and protein subunit (currently in phase 3 clinical trials). None of these vaccine platforms can convey the COVID-19 infection. The vaccines work by expressing a protein from the virus, allowing your immune system to generate antibodies (Centers for Disease Control and Prevention, 2021a, 2021b, 2021c). Physical symptoms may be experienced after vaccination and represent the body's natural immune response.

COVID-19 vaccinations are held to the same safety standards as all other vaccines. In December 2020, the US Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for two COVID-19 vaccines to respond to the public health emergency caused by the pandemic. An mRNA vaccine developed by Pfizer and BioNTech was the first COVID-19 vaccine to receive EUA on December 11, 2020. The Pfizer-BioNTech vaccine is approved for use in individuals aged 16 years or older and is given as a two-dose vaccine,

3 weeks apart (Pfizer Inc. & BioNTech Manufacturing GmbH, 2021). On December 18, 2020, a vaccine developed by Moderna received EUA by the FDA for use against COVID-19. Moderna's vaccine is approved for individuals aged 18 years or older and is given as a two-dose vaccine, 1 month apart (Moderna US, Inc., 2021). Both the Pfizer-BioNTech and Moderna vaccines are more than 90% efficacious in protecting people from COVID-19 (Baden et al., 2021; Polack et al., 2020). Preliminary findings for mRNA vaccines did not identify safety concerns for vaccinated pregnant people (Shimabukuro et al., 2021).

Emerging variants of SARS-CoV-2, the virus that causes COVID-19, have garnered increased concerns. SARS-CoV-2, like other viruses, experience changes in their genetic code (also known as a mutation) over time. In fact, within the United States and globally, there are multiple variants of SARS-CoV-2. Sometimes these mutations emerge and disappear relatively quickly. Other times they persist. Scientists continue to track and research SARS-CoV-2 variants actively. As it stands, the COVID-19 vaccines that are approved for emergency use are believed to "provide at least some protection against new virus variants because these vaccines elicit a broad immune response involving a range of antibodies and cells. Therefore, changes or mutations in the virus should not make vaccines completely ineffective" (The effects of virus variants on COVID-19 vaccines, 2021).

Nurses are essential to the response to COVID-19. As members of the most trusted profession in the United States, nurses are positioned to inform each other and the consumer about the importance of vaccination. Many factors affect one's decision to receive a vaccine or not. Hesitancy is natural but should be countered with facts. By arming oneself with accurate information about the available vaccines, nurses can reinforce confidence and build trust.

Recommendations

1. Nurses should be vaccinated against COVID-19.
2. Nurses should keep abreast of the most updated information regarding vaccination.
3. Nurses should convey accurate information about the types of COVID-19 vaccines as well as their safety and efficacy.
4. Nurses should develop strategies to reinforce confidence in vaccination against the COVID-19 infection.

Conclusions

Vaccine hesitancy is one of the top threats to public health. Although all available COVID-19 vaccines were researched, developed, and authorized for emergency use in record time, this was mainly due to immense collaborations between groups. Development of the COVID-19 vaccines had to meet the same high standards as all other vaccines. Becoming vaccinated against COVID-19 is our strongest defense and best available intervention to keep ourselves, our families, and our

patients safe. The more fully vaccinated people, the closer we become to herd immunity.

NANN encourages all nurses to educate themselves on the vaccines. Although vaccination is a personal choice, NANN acknowledges the need to protect our vulnerable patient population. As such, NANN recommends getting vaccinated against COVID-19.

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ACOEM Supports COVID-19 Vaccine Mandates for Health Care Workers

07/31/2021

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The American College of Occupational and Environmental Medicine (ACOEM) recommends that COVID-19 vaccination be mandated for all health care workers (HCWs). Comprised of occupational and environmental medicine professionals responsible for ensuring the health, safety, and well-being of all workers, the College stands with the growing number of organizations urging that all workers in health care settings be vaccinated against COVID-19.

With the recent surge of SARS-CoV-2 infections in the United States (U.S.) due to the Delta variant, it is even more imperative that HCWs be vaccinated. Unvaccinated HCWs put themselves in danger of contracting the disease and pose a risk to potentially transmit the virus to patients (especially their vulnerable patients), colleagues, and families. In addition, COVID-19 is more disruptive to the workforce and hospital/health care operations than any disease encountered in the last century due to required quarantining and potential length of illness.

Currently, all COVID-19 vaccines authorized in the U.S. are effective against COVID-19, preventing serious outcomes of severe disease, hospitalization, and death. Data show that the authorized mRNA vaccines also provide protection against variants of concern, including the Delta strain that is now predominant in the U.S. Vaccine effectiveness against hospitalization and death is high for all current SARS-CoV-2 variants.¹ This effectiveness is further demonstrated by current data indicating that the overwhelming majority of serious COVID-19 cases are occurring among those who are not vaccinated.

However, the fact that HCW vaccination rates are not yet above 90% universally represents fears, misinformation, information mistrust, and some valid confusion about the optimum *post-infection* vaccination timing/dosage among this group. While ACOEM supports universal vaccination, it's also important to approach all of those concerns compassionately and not vilify unvaccinated HCWs who have given heroic service since the start of the pandemic. The College also recognizes that exemptions from this policy may apply to those HCWs with medical

contraindications to COVID-19 vaccines or with other medical or religious exemptions as specified by federal or state law.

Institutions with mandatory vaccine policies will benefit from the advice and counsel of occupational and environmental medicine physicians to ensure that policies and procedures protect HCWs' confidentiality, that exemption decisions are made fairly and consistently, and that the importance of a comprehensive vaccine program is emphasized. ACOEM also recommends that health care workers be provided time off to receive the vaccine, that sick time be allowed for those who develop side effects, and that employers ensure HCWs have access to confidential medical consultations to address individual concerns.

HCWs have been on the front line in the war against COVID-19. Not only will they be protecting themselves by receiving the vaccine, but they are in a unique position to serve as vaccine champions and positively influence vaccination decisions of peers, patients, friends, and family.

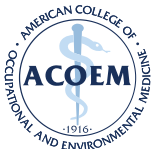
The American College of Occupational and Environmental Medicine (ACOEM) is an international society of 4,000 occupational and environmental physicians and other health care professionals. The College provides leadership to promote optimal health and safety of workers, workplaces, and environments.

Citations

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VA mandates COVID-19 vaccines among its medical employees including VHA facilities staff

July 26, 2021, 02:19:00 PM

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VA mandates COVID-19 vaccines among its medical employees including VHA facilities staff

WASHINGTON — July 26 Department of Veterans Affairs Secretary Denis McDonough announced he will make COVID-19 vaccines mandatory for Title 38 VA health care personnel — including physicians, dentists, podiatrists, optometrists, registered nurses, physician assistants, expanded-function dental auxiliaries and chiropractors — who work in Veterans Health Administration facilities, visit VHA facilities or provide direct care to those VA serves.

VA is taking this necessary step to keep the Veterans it serves safe.

Each employee will have eight weeks to be fully vaccinated.

“We’re mandating vaccines for Title 38 employees because it’s the best way to keep Veterans safe, especially as the Delta variant spreads across the country,” McDonough said. “Whenever a Veteran or VA employee sets foot in a VA facility, they deserve to know that we have done everything in our power to protect them from COVID-19. With this mandate, we can once again make — and keep — that fundamental promise.”

The department’s decision is supported by numerous medical organizations including the American Hospital Association (<https://www.aha.org/public-comments/2021-07-21-aha-policy-statement-mandatory-covid-19-vaccination-health-care>), America’s Essential Hospitals (<https://essentialhospitals.org/general/americas-essential-hospitals-urges-members-require-employee-vaccination/>) and a Multisociety group of the leading Infectious Disease Societies.

(<https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/multisociety-statement-on-covid19-vaccination-as-a-condition-of-employment-for-healthcare-personnel/690D1804B72FFF89C5FC0AED0043AD62>)

The American Medical Association, American Nurses Association, American College of Physicians, American Academy of Pediatrics, Association of American Medical Colleges, and National Association for Home Care and Hospice also endorsed mandating COVID-19 vaccination for health care workers (<https://www.hematology.org/newsroom/press-releases/2021/joint-statement-in-support-of-covid-19-vaccine-mandates-for-all-workers-in-health>).

In recent weeks, VA has lost four employees to COVID-19 — all of whom were unvaccinated. At least three of those employees died because of the increasingly prevalent Delta variant. There has also been an outbreak among unvaccinated employees and trainees at a VA Law Enforcement Training Center, the third such outbreak during the pandemic.

All VA employees are eligible to be vaccinated at no personal expense at any of our facilities (<https://www.va.gov/find-locations/?facilityType=health&serviceType=Covid19Vaccine>). Employees will also receive four hours of paid administrative leave after demonstrating they have been vaccinated. Information in these FAQs (<https://www.va.gov/health-care/covid-19-vaccine/>) or clinician and Veteran videos (<https://www.va.gov/initiatives/have-questions-before-you-get-your-covid-19-vaccine/>) has details about the vaccine, its safety and effectiveness.

The safety and wellbeing of our Veterans and personnel is paramount.

###

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FOR IMMEDIATE RELEASE

August 12, 2021

Contact: HHS Press Office

202-690-6343

media@hhs.gov (<mailto:media@hhs.gov>)

Secretary Becerra to Require COVID-19 Vaccinations for HHS Health Care Workforce

Becerra: 'Our Number One Goal Is the Health and Safety of the American Public, Including Our Federal Workforce'

Action Will Impact More Than 25,000 Workers at IHS, NIH, and Members of the U.S. Public Health Service Commissioned Corps

To increase vaccination coverage and protect more people from COVID-19, including the more transmissible Delta variant, the U.S. Department of Health and Human Services (HHS) will require more than 25,000 members of its health care workforce to be vaccinated against COVID-19.

Staff at the Indian Health Service (IHS) and National Institutes of Health (NIH) who serve in federally-operated health care and clinical research facilities and interact with, or have the potential to come into contact with, patients will be required to receive the COVID-19 vaccine. This includes employees, contractors, trainees, and volunteers whose duties put them in contact or potential contact with patients at an HHS medical or clinical research facility.

Additionally, U.S. Surgeon General Dr. Vivek Murthy will immediately require members of the U.S. Public Health Service Commissioned Corps to be vaccinated against COVID-19 as part of medical readiness procedures to prepare for any potential deployment need as emergency responders.

"Our number one goal is the health and safety of the American public, including our federal workforce. And vaccines are the best tool we have to protect people from COVID-19, prevent the spread of the Delta variant, and save lives," said HHS Secretary Xavier Becerra. "As President Biden has said, we have to do all we can to increase vaccinations to keep more people safe. Instructing our HHS health care workforce to get vaccinated will protect our federal workers and the patients and people they serve."

IHS, NIH and the Commissioned Corps already require such personnel to receive the seasonal influenza vaccine and other routine vaccinations, with processes for medical and religious exemptions, and all agencies would implement this new COVID-19 vaccination requirement using the same processes that are already in place for these other vaccines.

HHS is the latest department within the Biden-Harris Administration to implement vaccine requirements for members of its workforce. Recently, the Department of Veterans Affairs took the common-sense and important step of requiring their health care providers and personnel to be fully vaccinated against COVID-19. Similarly, the Department of Defense announced a plan to add the COVID-19 vaccine to the list of required vaccinations for our service members in the coming weeks.

###

Note: All HHS press releases, fact sheets and other news materials are available at <https://www.hhs.gov/news/>.

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Last revised: August 12, 2021

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Open statement ▼

 The Moderna COVID-19 Vaccine is available under an Emergency Use Authorization

◀ **FAQ Categories**

COVID-19 Vaccine - Categories



Does the Moderna COVID-19 Vaccine contain fetal cell lines or were fetal cell lines used in the development of the vaccine?

Last Updated on July 1, 2021

The Moderna COVID-19 Vaccine does not contain any preservatives, antibiotics, adjuvants, or materials of human or animal origin. The Moderna COVID-19 vaccine does not use fetal cell lines during the vaccine manufacturing or lot testing process.

Related FAQs

I've lost the carton. What is the expiration date for my vaccine? It is not shown on the vial. Am I missing any critical information? I do not have a way to scan the QR code.



Does the Moderna COVID-19 Vaccine contain any antibiotics, preservatives, or other ingredients such as egg, or bovine albumin?



Why does the vaccine expiry indicate year 2069 on the packing slip?



Didn't find the answers you were looking for?

Our contact team is here 24/7 to answer any of your questions and to supply you with any additional documentation you may need.

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Pfizer

Comirnaty (COVID-19 Vaccine, mRNA) - Pfizer-BioNTech COVID-19 Vaccine - Animal or Human Cell Lines

The Pfizer-BioNTech COVID-19 Vaccine is also known as COMIRNATY (COVID-19 Vaccine, mRNA). Comirnaty is U.S. Food and Drug Administration (FDA)-approved in individuals 16 years of age and older. Comirnaty is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS CoV 2) in individuals 16 years of age and older. Please refer to the full Prescribing Information for individuals 16 years of age and older for important treatment considerations for Comirnaty via the following link (<https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine>). In the event this link does not work, please access the product's approved prescribing information at www.pfizer.com/products.

In individuals 12-15 years of age, the Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19). The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please refer to the Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information on important treatment considerations for the Pfizer-BioNTech COVID-19 Vaccine via the following link: <https://www.pfizermedicalinformation.com/en-us/patient/pfizer-biontech-covid-19-vaccine> or www.cvdvaccine.com. In the event this link does not work, please access the product's Fact Sheet or Prescribing Information at www.pfizer.com.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA- authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

ARE ANIMAL OR HUMAN CELL LINES USED IN THE MANUFACTURING PROCESS OF THE VACCINE?

Please see below for an answer to this question. Pfizer Medical Information is also providing information regarding the presence of specific allergens or ingredients for select products, including this vaccine, via the [Ingredient & Allergen Checker](#).

Animal or human fetal-derived cell lines are not used to produce Comirnaty (also known as Pfizer-BioNTech COVID-19 Vaccine), which consists of synthetic and enzymatically produced components.^{1,2}

For further information regarding the vaccine, please refer to the Prescribing Information.

REFERENCES

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2. Pfizer-BioNTech COVID-19 vaccine. Data on File (25). Pfizer.

Janssen COVID-19 Vaccine

(Ad26.COV2.S)

Janssen COVID-19 Vaccine Janssen COVID-19 Vaccine - No Presence of Fetal Tissue or Human Cells

Date Last Updated: 08/02/2021

SUMMARY

- The Janssen COVID-19 Vaccine has been granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). The Janssen COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act unless the declaration is terminated or authorization revoked sooner.¹⁻³
- There is no fetal tissue nor any human cells present in the Janssen COVID-19 Vaccine (Ad26.COV2.S; JNJ-78436735).⁴
- Ad26.COV2.S uses an inactivated common cold virus, into which we insert a piece of the coronavirus spike protein DNA. The vaccine teaches the immune system to recognize the SARS-CoV-2 virus and help protect against future infection. To accomplish this, we use viral vector technology developed more than 30 years ago that relies on cells engineered and grown from a single fetal retinal cell. That single cell has been transformed into a new, fully engineered cell line which replicates indefinitely. Notably, there has been no further fetal cell collection. Our Janssen COVID-19 Vaccine contains no fetal tissue whatsoever.⁵⁻⁷
- The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6 TetR cells, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is processed through several purification steps, formulated with inactive ingredients and filled into vials.^{2, 8}

LITERATURE SEARCH

A literature search of Ovid MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File databases (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 30 July 2021.

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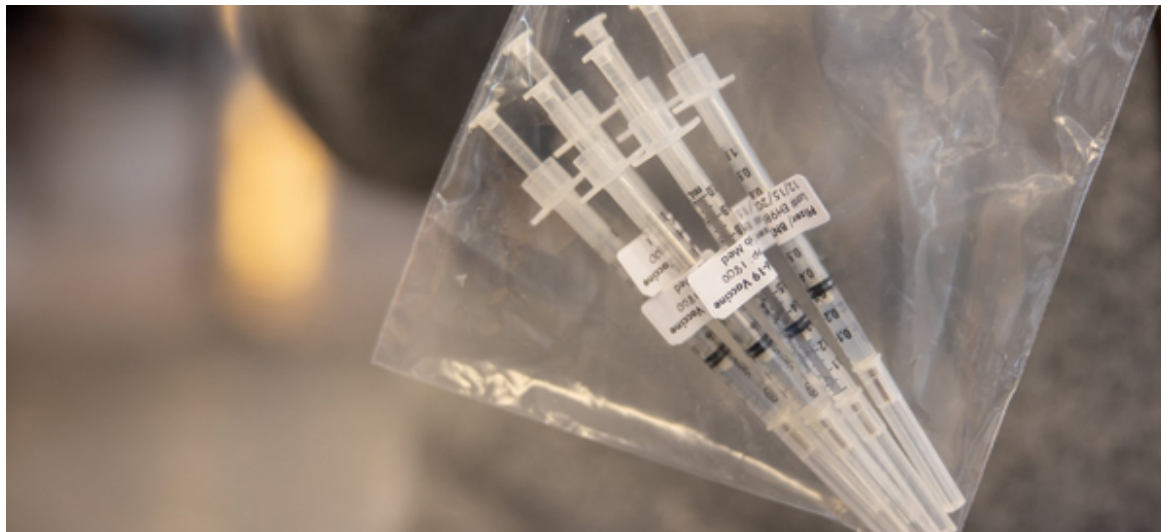
This page was last modified on August 02, 2021.



You asked, we answered: Do the COVID-19 vaccines contain aborted fetal cells?

Published August 18, 2021

This article was originally published December 28, 2020. It was updated on March 2, 2021, to include information about the Johnson & Johnson vaccine, and on August 18, 2021, to include a personal note from Dr. Lawler and further clarify some parts of the article that were causing confusion.



Question

Do the COVID-19 vaccines contain aborted fetal cells?

Answer from infectious disease expert and practicing Catholic James Lawler, MD (<https://www.nebraskamed.com/doctors/james-v-lawler>).

No, the COVID-19 vaccines do not contain any aborted fetal cells. However, fetal cell line cells grown in a laboratory based on aborted fetal cells collected generations ago – we used in testing during research and development of the mRNA vaccines, and during

production of the Johnson & Johnson vaccine.

Before we dig into the science, I'd like to have a word

It is true that decades ago, scientists decided to use fetal tissue to start the cell lines we use to test drugs today. However, the description of ongoing modern fetal tissue harvesting to create vaccines is dishonest sensationalism.

As a practicing Catholic, I think the moral balance of indirectly benefitting from an abortion that occurred 50 years ago in order to take a vaccine that will prevent further death in the community is a no-brainer – especially considering that so many of the over 620,000 American deaths have occurred in the most vulnerable and marginalized in our society. We need to focus on saving lives right now. We need to care for our neighbors.

The Vatican and bishops agree. The Vatican has issued clear guidance that permits Roman Catholics in good faith to receive COVID-19 vaccines that use fetal cell lines in development or production. [Read the Vatican's comments on the morality of receiving a COVID-19 vaccine \(https://www.catholicnews.com/vatican-without-alternatives-current-covid-19-vaccines-are-morally-acceptable/\)](https://www.catholicnews.com/vatican-without-alternatives-current-covid-19-vaccines-are-morally-acceptable/).

Now, let's break down the science

Fetal cell lines are cells that grow in a laboratory. They descend from cells taken from abortions in the 1970s and 1980s.

Those individual cells from the 1970s and 1980s have since multiplied into many new cells over the past four or five decades, creating the fetal cell lines I mentioned above. Current fetal cell lines are thousands of generations removed from the original fetal tissue. They do not contain any tissue from a fetus.

Vaccine makers may use these fetal cell lines during the following two phases:

- Research and development
- Production and manufacturing

When it comes to the Pfizer and Moderna COVID-19 vaccines, fetal cell line HEK 293 was used during the research and development phase. All HEK 293 cells are descended from tissue taken from a 1973 abortion that took place in the Netherlands. Using fetal cell lines to test the effectiveness and safety of medications is common practice, because they provide a consistent and well-documented standard.

For the Johnson & Johnson vaccine, fetal cell lines were used in the production and manufacturing stage. To make the Johnson & Johnson vaccine, scientists infect PER.C6 fetal cell lines to grow the adenovirus vector. ([Learn more about how viral vector vaccines work \(https://www.nebraskamed.com/COVID/how-the-johnson-johnson-covid-19-vaccine-works\)](https://www.nebraskamed.com/COVID/how-the-johnson-johnson-covid-19-vaccine-works).) All PER.C6 cells used to manufacture the Johnson & Johnson vaccine are descended from tissue taken from a 1985 abortion that took place in the Netherlands. This cell line is used because it is a well-studied industry standard for safe and reliable production of viral vector vaccines.

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You asked, we answered: Can mRNA vaccines cause infertility?

(/COVID/you-asked-we-answered-can-mrna-vaccines-cause-infertility)

I have read that the vaccine causes infertility. That would be devastating. I guess it interferes with the formation of the placenta.

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COVID-19 Vaccines & Fetal Cell Lines

In various stages of vaccine development and manufacturing, some of the COVID-19 vaccines used cells originally isolated from fetal tissue (often referred to as fetal cells), some of which were originally derived from an aborted fetus. The use of fetal cell lines is a very sensitive and important topic within some faith communities and among individuals with concerns about the ethics of using materials derived in this way.

It is crucial for everyone to have all of the appropriate information to make a fully informed decision regarding COVID-19 vaccination. For those with questions or concerns about the use of fetal cell lines in vaccine development, please view the information presented in this handout and keep the following considerations in mind when making your vaccine decision:

- For us to break the chain of disease transmission and protect our community from COVID-19, we will need the vast majority of the public to get vaccinated against the virus.
- Vaccinating not only protects you, but may also protect your family, friends, and those in our community most vulnerable to severe disease from COVID-19.
- The risks and benefits of COVID-19 vaccination will vary from person to person, and individuals may want to consider discussing this with their own healthcare provider.
- Several religious and bioethics groups have reviewed and commented on the ethical considerations of receiving the current COVID-19 vaccines. Many of those considerations are cited below.
- While vaccine supply remains limited, you may not be given a choice on which COVID-19 vaccine you can receive.
- Individuals may want to consider having a personal conversation with their faith leader or someone experienced in bioethics.

Why are fetal cells used to make vaccines?

Historical fetal cell lines were derived in the 1960's and 1970's from two elective abortions and have been used to create vaccines for diseases such as hepatitis A, rubella, and rabies. Abortions from which fetal cells were obtained were elective and were not done for the purpose of vaccine development.

The fetal cell lines being used to produce some of the potential COVID-19 vaccines are from two sources:

- HEK-293: A kidney cell line that was isolated from a fetus in 1973 ([undisclosed origin](#), from either a spontaneous miscarriage or an elective abortion)
- PER.C6: A retinal cell line that was isolated from an aborted fetus in 1985

Any vaccine that relies on these historic cell lines will not require nor solicit new abortions.



To develop and manufacture some vaccines, pharmaceutical companies prefer human cell lines over other cells because 1) viruses need cells to grow and the viruses tend to grow better in cells from humans than animals (because they infect humans), 2) fetal cells can be used longer than other cell types, and 3) fetal cells can be maintained at low temperatures, allowing scientists to continue using cell lines from decades ago. While fetal cell lines may be used to develop or manufacture COVID-19 vaccines, the vaccines themselves **do not contain any aborted fetal cells**. A comprehensive list of COVID-19 vaccines in development and any connection to abortion-derived cell lines is available [here](#).

Were the Pfizer and Moderna COVID-19 vaccines developed using fetal cell lines?

The mRNA COVID-19 vaccines produced by Pfizer and Moderna **do not require the use of any fetal cell cultures in order to manufacture (produce) the vaccine**.

Early in the development of mRNA vaccine technology, fetal cells were used for “proof of concept” (to demonstrate how a cell could take up mRNA and produce the SARS-CoV-2 spike protein) or to characterize the SARS-CoV-2 spike protein.

The Pfizer and Moderna vaccines were found to be **ethically uncontroversial** by the pro-life policy organization [the Charlotte Lozier Institute](#). Further, the [Secretariat of Pro-Life Activities](#), a committee within the United States Conference of Catholic Bishops, has stated: “neither Pfizer nor Moderna used an abortion-derived cell line in the development or production of the vaccine. However, such a cell line was used to test the efficacy of both vaccines. Thus, while neither vaccine is completely free from any use of abortion-derived cell lines, in these two cases the use is very remote from the initial evil of the abortion...one may receive any of the clinically recommended vaccines in good conscience with the assurance that reception of such vaccines does not involve immoral cooperation in abortion.”

Was the Johnson & Johnson (Janssen Pharmaceuticals) COVID-19 vaccine developed using fetal cell lines?

The non-replicating viral vector vaccine produced by Johnson & Johnson **did require the use of fetal cell cultures, specifically PER.C6, in order to produce and manufacture the vaccine**.

The [Catholic Church](#) and the [Southern Baptist Ethics & Religious Liberty Commission](#) have both stated that **receiving a COVID-19 vaccine that required fetal cell lines for production or manufacture is morally acceptable**. The [U.S. Conference of Catholic Bishops](#) goes further and has stated: “receiving a COVID-19 vaccine ought to be understood as an act of charity toward the other members of our community. In this way, being vaccinated safely against COVID-19 should be considered an act of love of our neighbor and part of our moral responsibility for the common good...Given the urgency of this crisis, the lack of available alternative vaccines, and the



fact that the connection between an abortion that occurred decades ago and receiving a vaccine produced today is remote, inoculation with the new COVID-19 vaccines in these circumstances can be morally justified."

On March 2nd, 2021, the U.S. Conference of Catholic Bishops issued a statement which addressed the use of Johnson & Johnson's COVID-19 vaccine. The Bishops stated: "if one can choose among equally safe and effective COVID-19 vaccines, the vaccine with the least connection to abortion-derived cell lines should be chosen. Therefore, if one has the ability to choose a vaccine, Pfizer or Moderna's vaccines should be chosen over Johnson & Johnson's...While we should continue to insist that pharmaceutical companies stop using abortion-derived cell lines, given the world-wide suffering that this pandemic is causing, we affirm again that being vaccinated can be an act of charity that serves the common good."

The Catholic Church has stated, "Those who, however, for reasons of conscience, refuse vaccine produced with cell lines from aborted fetuses, must do their utmost to avoid, by other prophylactic means and appropriate behavior, becoming vehicles for the transmission of the infectious agent. In particular, they must avoid any risk to the health of those who cannot be vaccinated for medical or other reasons, and who are the most vulnerable."

Where can I find more information?

Some religious groups and bioethics institutes that oppose the use of aborted fetal cells in the development or manufacturing of vaccines have noted that individuals may ethically receive these vaccines when there are no ethically derived alternatives.

For more information from these groups on this issue, check out the following links:

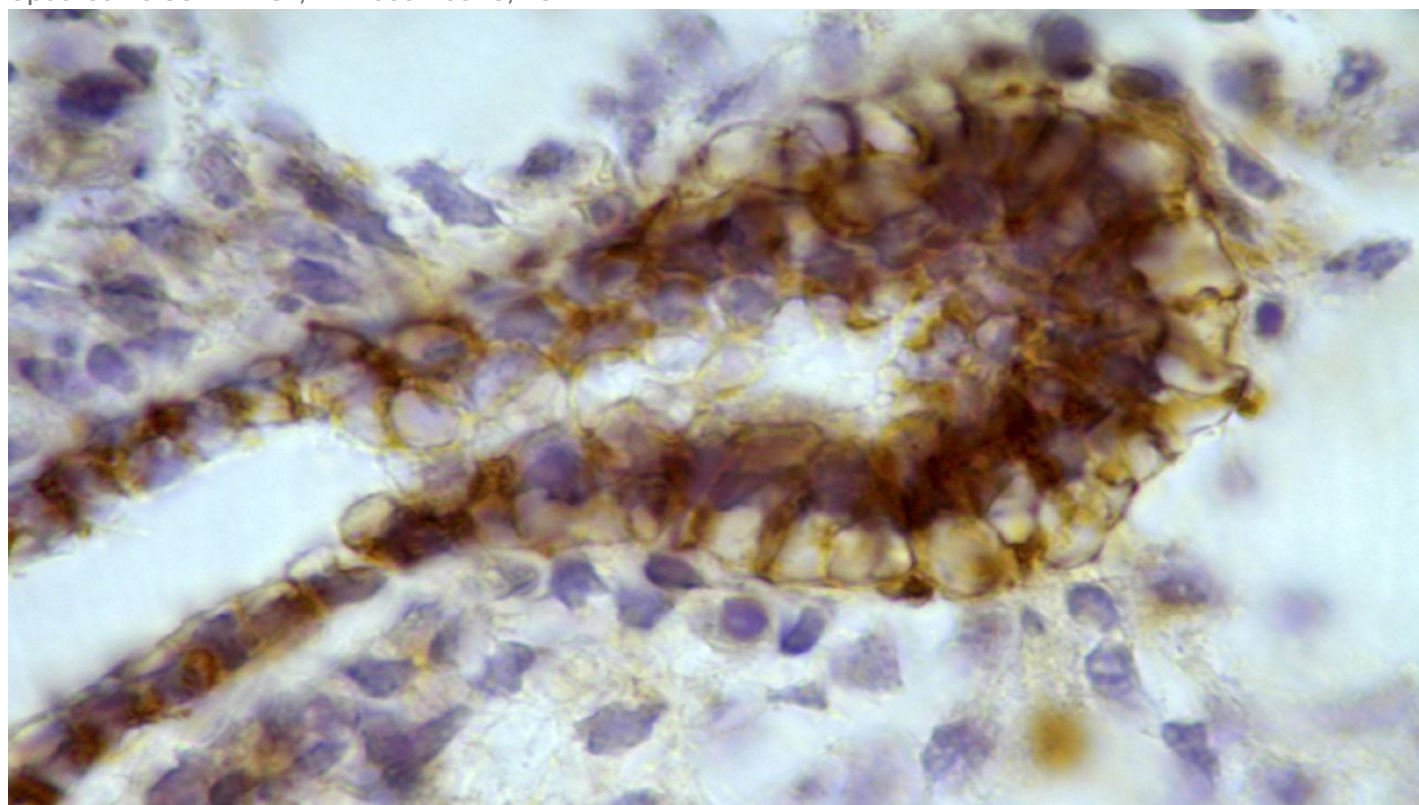
- [National Catholic Bioethics Center](#)
- [Pontifical Academy of Life Statement](#)
- [United States Conference of Catholic Bishops](#)
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- [The North Dakota Catholic Conference](#)
- [Charlotte Lozier Institute](#)
- [The Pillar – The ultimate Catholic coronavirus vaccine morality explainer](#)



How exactly fetal tissue is used for medicine

By Carina Storrs and Special to CNN

Updated 10:38 AM EST, Fri December 8, 2017



BSIP/UiG/Getty Images

A human fetal lung at 14 weeks of gestation.

STORY HIGHLIGHTS

Fetal tissue has been used in biomedical research since the 1930s, including for the first polio vaccine

Cells from fetal tissue are still in use in vaccine manufacturing and stem cell and transplantation research

(CNN) — Fetal tissue has been used since the 1930s for vaccine development, and more recently to help advance stem cell research and treatments for degenerative diseases such as Parkinson's disease. Researchers typically take tissue samples from a fetus that has been aborted (under conditions permitted by law) and grow cells from the tissue in Petri dishes.

Many of the uses of fetal tissue – and much of the debate – are not new. “It’s just that the

public is finding out about it,” said Insoo Hyun, associate professor of bioethics at Case Western Reserve University.

In addition, the ways that fetal tissue are allowed to be obtained and used are not new either, Hyun said. The U.S. Department of Health and Human Services released guidelines on the topic in the 1990s.



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Justice Dept. investigating use of fetal tissue

The federal regulations state that women must decide to have an abortion before clinicians can ask whether they would like to donate fetal tissue. One concern is that women would have more pregnancies or abortions because they want to donate fetal tissue. In addition, clinicians performing the abortions cannot receive payment from researchers who will receive fetal materials, except for reimbursement for costs such as shipping.

Despite the long history of using fetal tissue in medicine and research, the practice could be on the way out. Even though it has led to important medical advances in the last several decades, “in the future, the need for fetal tissue will go down because of advances in stem cell [technology] that will take over,” Hyun said.

One of the earliest advances with fetal tissue was to use fetal kidney cells to create the first poliovirus vaccines, which are now estimated to save 550,000 lives worldwide every year.



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In the early days of making the vaccine, researchers infected fetal kidney cells in Petri dishes to produce a large amount of virus that they could then harvest, purify and use to vaccinate people. (The virus evolves to become less deadly when it infects cells out of the body, and thus could safely be given to people to prime their immune system for the real thing.)

Today manufacturers of the polio vaccine use other types of human cells, which weren't available in the mid-1900s. They also use monkey cells, which they originally avoided for fear that making the vaccine in animal cells could put people at risk of diseases from other species.

Many of our other common vaccines, such as chicken pox, rubella and shingles, have been produced in tissue derived from fetuses, particularly two electively terminated pregnancies

produced in tissue derived from fetuses, particularly two electively terminated pregnancies from the 1960s. Advances in how researchers work with cells have allowed them to grow fetal cells indefinitely in Petri dishes, thus not requiring samples from any newly aborted fetuses.



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Advances in stem cell therapy, too, could help phase out the practice of collecting cells from fetal tissue. Many researchers can now make stem cells by reprogramming skin cells from an adult into a “blank check” stem cell state. These so-called induced pluripotent stem cells can then go on to develop into neurons or any other cell in the body that researchers can grow in labs and study to better understand diseases such as Alzheimer’s disease.

However, as Hyun explained, research on these stem cells is still in the early stages and scientists need to make sure the neurons or whatever other type of cells they steer the stem cells to become behave like the cells in the body they want them to emulate. So scientists may still grow fetal neuron cells, for example, in a Petri dish alongside stem cell-derived neuron cells as a reference point until they have more confidence in the stem cell technology, said Hyun, who specifically studies the bioethics of stem cell research.



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“The use of fetal tissue may also be supplanted in some cases by cells from umbilical cord blood. Amy Hudson, associate professor of microbiology and molecular genetics at Medical College of Wisconsin, has a grant from the National Institutes of Health to study how herpes viruses cause disease. Because it would be unethical to infect people and study disease in them, she and her colleagues plan to work with lab mice that have an altered immune system that behaves like that of humans. To achieve that, the researchers could transplant into the mice a small amount of liver tissue from fetuses: “a tiny number of cells that you can barely see,” Hudson said.



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Yet just the practical challenges of doing this work, and especially the fact that the fetal tissue may not be available at the exact time they need them, are making Hudson and her colleagues think instead about using stem cells from the umbilical cord, which could be easier to obtain. However these cells do not appear to give mice as human-like an immune system. “The fear is we spend time and money on experiments using a halfway-OK [approach] and we get a result that isn’t interpretable,” Hudson said.

There are also a number of clinical research studies that are investigating whether transplanting different types of fetal tissue into patients could help them recover from diseases, similar to the practice of organ donation. One such study is testing fetal eye (retinal) tissue as a possible treatment for retinitis pigmentosa, a disease that can lead to blindness.

A lot of research in the last 10 years has also focused on using fetal neuronal cells for Parkinson’s and another degenerative disease called Huntington’s. Although early research on this approach for Parkinson’s patients was not encouraging, a small subset of patients do appear to benefit from it.

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Nevertheless, clinical research on tissue transplantation as a disease treatment may eventually be able to replace fetal tissue with stem cells, Hyun said. One of the Health and Human Services requirements for using fetal tissue is that no other experimental settings, such as other cell types or lab mice, would be appropriate.

When fetal tissue is used in research, it is often sent from the hospital or clinic that performs the abortion to an affiliated research center, Hyun said. Another safeguard in the Health and Human Services guidelines is that a clinical team that performs the abortion cannot know that the fetus will be donated, to help ensure that they do not change how they perform the abortion, or jeopardize the safety of the woman, Hyun said.

These guidelines have been solidified and become more widespread since the 1990s, Hyun said, adding that, “I believe [all clinicians] are well aware of them now.”

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HEALTH NEWS

What is fetal tissue research? And why is it important to medicine?

The Trump administration is cutting back funding for research involving fetal tissue. Scientists say a total ban on such research would be "catastrophic."



— Scientists are looking for effective alternatives to fetal cells for research. Until that happens, fetal cells continue to be the gold standard for certain kinds of research, say doctors. nicolas_ / Getty Images

June 9, 2019, 1:26 PM EDT

By Erika Edwards

Doctors and scientists are denouncing the Trump administration's decision to cut funding for research that uses fetal tissue, saying that the material is essential for life-saving medical research.

The administration announced Wednesday that it would [drastically cut federal spending](#) on medical research that uses "fetal tissue from elective abortions." The move will affect multimillion-dollar research projects at the National Institutes of Health and the University of California, San Francisco.

Supporters of the administration's decision have likened the research to a marketplace that deals in "[aborted baby body parts](#)." That kind of language can elicit a visceral reaction. Researchers strongly disagree with that portrayal, however, and say fetal tissue research projects are meticulously vetted.

"There's a misconception that fetal tissue research is the wild, Wild West," said Ellie Dehoney, vice president of policy and advocacy for [Research!America](#), a nonprofit group that advocates for scientific research.

"There's a very careful look at every research grant. If a project makes the cut, it means there is a belief by scientists not involved in research that there's a beneficial purpose for advancing science," Dehoney told NBC News.

Indeed, the American Medical Association, which supports fetal tissue research, has a detailed [code of ethics](#) for how to carry out such research.

Sam Hawgood, the chancellor of the University of California, San Francisco, said the university's research using fetal tissue to find a cure for HIV – now halted by the administration's action – was based in sound science. "UCSF exercised appropriate oversight and complied with all state and federal laws," he [said in a statement](#).

Why is fetal tissue used in research?

Scientists use fetal tissue as a source of fetal cells. These cells have been used for research since the 1930s, and the government has funded such research since the 1950s, when it was used to create one of the [biggest medical advances](#) of the 20th century: the polio vaccine.

Since then, fetal cells have been used in hundreds of thousands of other research projects. Scientists have used them to create other vaccines, such as the rubella vaccine, and to improve a wide variety of techniques used in medicine, such as in vitro fertilization. They are also used to study birth defects, eye diseases, Parkinson's and Alzheimer's disease, [AIDS](#) and spinal cord injuries.

Scientists say fetal cells are superior to adult cells mainly because they can transform into any cell in the body. They also replicate quickly, and don't have the same immune response as adult cells.

This means researchers can inject them into lab mice to study human diseases without the risk of the cells being rejected by the animals' immune systems.

A ban or strict limitation on fetal tissue research would be "catastrophic," said Dr. Elias Zambidis, a pediatric oncologist at Johns Hopkins who does research on stem cells.

“

Why put [fetal] tissue in a biohazard box? Why not use it to help others?

Zambidis said he has given a great deal of thought to the medical ethics of fetal tissue research. "I understand there are two sides to the controversy, and I personally respect both sides," he told NBC News.

"But why put that tissue in a biohazard box?" Zambidis asked. "Why not use it to help others?"

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"If you establish that you're using tissue that's causing no harm to a living being, and it holds the potential to save lives or restore health and function, that's important work," Dehoney said.

Zambidis agreed. "Fetal tissue research absolutely saves patients," he said.

Are there effective alternatives?

Last December, the NIH announced a [\\$20 million initiative](#) aimed at finding alternatives to fetal tissue for research purposes. As part of Wednesday's announcement, Department of Health and Human Services said it would "ensure that efforts to develop such alternatives are funded and accelerated."

Some researchers, including those in Zambidis' lab at Johns Hopkins, are already using one potential alternative: induced pluripotent stem cells, or iPS cells. These don't come from fetal tissue; they come from skin or blood cells and have been reprogrammed back into an embryonic-like state.

But iPS cells aren't the perfect substitute. Experts say the cells aren't quite ready to be used as effective alternatives to fetal cells. Indeed, Zambidis calls them a "bad Xerox copy," but predicts the science will continue to advance so that one day they will work as well as fetal cells.

"Our holy grail is to create alternatives to fetal stem cells. But it's not going to happen tomorrow," Zambidis said.

Fetal cells continue to be the gold standard in certain types of research, and indeed, any alternatives developed will have to be comparable in quality and function. That's one reason why fetal cells are still needed, so scientists can see how new technologies stack up against them.

"Whatever the next best thing is, it will still have to be compared to the gold standard," he said.

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Erika Edwards



Erika Edwards is a health and medical news writer and reporter for NBC News and "TODAY."

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,

1:21-CV-1009

-against-

(DNH)(ML)

KATHY HOCHUL, Governor of the State of New York, in
his 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.

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS'
MOTION FOR A PRELIMINARY INJUNCTION**

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Date: February 11, 2022

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Defendants Kathy Hochul, in her official capacity as Governor of the State of New York, Dr. Howard A. Zucker¹, in his official capacity as Commissioner of the New York State Department of Health, and Letitia James, in her official capacity as Attorney General of the State of New York (collectively, “Defendants”), respectfully submit this memorandum of law, together with the accompanying Declaration of Dr. Emily Lutterloh and attached exhibits, in opposition to Plaintiffs’ renewed motion for a preliminary injunction.

PRELIMINARY STATEMENT

As the State of New York continues to confront the COVID-19 pandemic, including the highly contagious Omicron variant, the protection the healthcare system and the vulnerable populations it serves is critically important. To that end, the Department of Health promulgated, and recently renewed, an emergency regulation requiring healthcare facilities in New York to ensure that their personnel are fully vaccinated against COVID-19. 10 N.Y.C.R.R. § 2.61.

Earlier this fall, the federal government joined in this effort to ensure widespread vaccination of healthcare workers by issuing a regulation requiring Medicare and Medicaid facilities to ensure vaccination of their personnel. On November 5, 2021, the United States Secretary of Health and Human Services issued an interim final rule requiring facilities that receive Medicare and Medicaid funding to ensure that their staff receive the COVID-19 vaccine. *See* 86 Fed. Reg. 61555 (2021). The interim final rule, otherwise known as the “CMS Mandate,” requires that covered employers comply with existing federal law when evaluating requests for exemptions or accommodations from COVID-19 vaccine requirement.

¹ Dr. Howard Zucker resigned as Commissioner of the New York State Department of Health. The current Commissioner of the New York State Department of Health is Dr. Mary Bassett, who was appointed on September 29, 2021.

Plaintiffs now renew their motion for a preliminary injunction, arguing that the CMS Mandate preempts New York’s vaccine requirement for healthcare workers, and requires New York to offer a religious “exemption” to the vaccine requirement. Plaintiffs also argue that the denial of unemployment insurance benefits to employees who are terminated for refusing COVID-19 vaccination on religious grounds violates the Free Exercise Clause. Plaintiffs are incorrect, and their motion for a preliminary injunction should be denied.

First, Plaintiffs cannot show a likelihood of success on the merits. The CMS mandate does not preempt Section 2.61. To the contrary, the CMS mandate expressly states that it preempts only those State or local laws which provide *broader* exemptions from the vaccine requirement than are provided under federal law. Section 2.61 does not provide broader exemptions from the vaccine requirement than are provided under federal law.

There is no conflict between the CMS mandate and Section 2.61. The CMS Mandate requires employers to establish a process to review requests for exemptions or accommodations from the vaccine requirement to the extent required under existing federal law. Section 2.61 similarly permits covered personnel to seek accommodations under existing federal law, including accommodations based upon sincerely held religious beliefs under Title VII of the Civil Rights Act of 1964. The Second Circuit has already held in this case that Section 2.61 does not prevent an employee from seeking a religious accommodation under Title VII.

Plaintiffs also do not show a likelihood of success on their Free Exercise Clause claim. None of the Defendants are responsible for administering unemployment insurance (“UI”) benefits. Further, the New York State Department of Labor, which has such responsibility and which has not been named as a party to this action, does not categorically deny unemployment insurance benefits on the basis of religion. Every UI claim is evaluated on a case-by-case basis.

Any employee who refuses vaccination and is terminated may, or may not, be denied UI benefits, regardless of whether that refusal was based on a religious objection or any other reason.

Second, Plaintiffs have not shown that they will suffer irreparable injury absent the requested preliminary injunction. The Second Circuit has already rejected Plaintiffs’ argument, reiterated in the instant motion, that the economic harms they have sustained from losing their employment and professional status constitute irreparable harm. Also, Plaintiffs cannot rely on an alleged infringement of their First Amendment rights to establish irreparable harm because they fail to demonstrate a likelihood of success on their Free Exercise Clause claim.

Finally, Plaintiffs do not establish that the balance of the equities weighs in their favor, or that the requested injunction is in the public interest. The requested injunction would gravely undermine the State’s ongoing efforts to protect public health by controlling the COVID-19 pandemic. The State’s efforts to promote widespread vaccination, especially of healthcare workers, is in the public interest. Accordingly, Plaintiffs’ renewed motion for a preliminary injunction should be denied.

STATEMENT OF FACTS

A. COVID-19 Continues to Present a Grave Threat to Public Health and Safety

Despite the gains that New York has made, the COVID-19 pandemic is not over. The COVID-19 variants discovered in New York and around the world create an increased risk for transmission and as expected, the winter surges of these variants caused COVID-19 case numbers and hospitalizations to rise. Declaration of Dr. Emily Lutterloh (“Lutterloh Decl.”) at ¶ 4. In particular, the emergence of the highly transmissible Omicron variant made implementation of the layered mitigation strategies of vaccination, masking, and testing, even more urgent. *Id.* at ¶ 11.

A study recently published in the Centers for Disease Control and Prevention (“CDC”) Morbidity and Mortality Weekly Report (“MMWR”) reiterates the importance of COVID-19 vaccination and booster doses. *Id.* at ¶ 15. This study examined COVID-19 incidence and hospitalization rates among adults over the age of 18 in Los Angeles County during the Omicron surge from November 7, 2021 to January 8, 2022. *Id.* The study found that for the period dominated by the Omicron surge (between mid- December to January 8, 2022), unvaccinated persons had infection and hospitalization rates of 3.6 and 23.0 times, respectively, of those of fully vaccinated individuals with a booster. *Id.* Additionally, during the entire period of study, incidence and hospitalization rates were consistently lowest for fully vaccinated persons with a booster. *Id.* The study concluded that the risk for infection and COVID-19 associated hospitalization are lower among fully vaccinated individuals, and the “reduction is even more pronounced among those who have received additional or booster doses.” *Id.* at ¶ 16.

Another study published in the CDC’s MMWR examined COVID-19 case and death rates and incidence rate ratios among unvaccinated and fully vaccinated adults during pre-Delta, Delta emergence, Delta predominance, and Omicron emergence periods in 25 U.S. jurisdictions. *Id.* at ¶ 16. Ultimately, the study showed that booster doses provided additional protection against infection and death during the Delta predominant period and against infection during the Omicron emergence, especially among those aged 60-64 and those over the age of 65. *Id.*

On January 19, 2022, a study co-authored by the New York State Department of Health was published in the CDC’s MMWR report. *Id.* at ¶ 17. The study, evaluating COVID-19 cases and hospitalizations from May to November 2021 (prior to the emergence of the Omicron variant) found that both vaccination and prior infection provided protection against future infection and hospitalization. *Id.* Although prior infection may protect against reinfection, initial infection

among unvaccinated individuals increases the risk of serious illness, hospitalization, and death. *Id.* Therefore, the Department of Health continues to recommend vaccination as “the most effective and *only recommended* way to gain immunity to COVID-19,” and the safest way “to prevent SARS-CoV-2 infections, associated complications, and onward transmission.” *Id.*

Recent data from the Department, for the week of beginning January 31, 2022, show that vaccine effectiveness for those 18 and older was 78.7%, meaning that fully vaccinated New Yorkers had nearly 79% lower chance of becoming a COVID-19 case as compared to unvaccinated New Yorkers. *Id.* at ¶ 18. Recent data from the Department for the past few weeks show between 90.8% -91.0% vaccine effectiveness against COVID-19 hospitalizations for fully vaccinated New Yorkers, as compared to an unvaccinated New Yorkers (for those 18 and older). *Id.* at ¶ 19.

Reducing the number of unvaccinated healthcare personnel is critically important. As of February 9, 2022, the CDC reported that there were a total of 913,075 COVID-19 cases among healthcare personnel and 3,530 recorded healthcare personnel deaths associated with COVID-19 to date. *Id.* at ¶ 35. A study published in the CDC’s MMWR found that the rapid rise of Omicron cases in December 2021 “has resulted in the highest number of COVID-19 associated [emergency department] visits and hospital admissions since the beginning of the pandemic, straining the health care system.” *Id.* at ¶ 46. The study reiterated the importance of, among other things, “the ability to adequately staff local health care systems . . . [and] being up to date on vaccination and following other recommended prevention strategies.” *Id.*

Another study published in the MMWR reiterated that “a rapid increase in infections during Omicron predominance has resulted in a relatively substantial volume of hospitalizations” and this high volume “can compound the effects of staffing shortages and staff member burnout, which puts a strain on the health care sector.” *Id.* at ¶ 47. The study concluded that the rise in

hospitalization rates in this specific study was most pronounced among unvaccinated individuals and lower among those who are fully vaccinated and lowest among those who had received a booster. *Id.* Essentially, “[b]eing up to date with COVID-19 vaccinations is a critical component of reducing the strain on health care facilities.” *Id.*

B. New York’s Emergency Regulation

On August 26, 2021, the Department of Health’s Public Health and Health Planning Council (“PHHPC”) adopted an Emergency Regulation under which hospitals, nursing homes, and other “covered entities” must require their personnel to be fully vaccinated against COVID-19. *Prevention of COVID-19 Transmission by Covered Entities*, N.Y. Comp. Codes R. & Regs. tit. 10, § 2.61 (2021).² The Emergency Regulation was effective for ninety days.

On November 24, 2021, the Department filed a new Notice of Emergency Adoption for Section 2.61. The November 24, 2021 Notice of Emergency Adoption amended the language of Section 2.61 to update the dates for receiving the vaccination, and added a physician assistant as an individual who could certify a medical exemption.³

On January 21, 2022, the Department filed another Notice of Emergency Adoption for Section 2.61. Under the January 21st Notice of Emergency Adoption, the Department added a requirement for personnel in covered entities to receive the booster or supplemental dose of the COVID-19 vaccine, as recommended by the CDC. Accordingly, Section 2.61 now states that,

² Public Health Law §§ 225(5), 2800, 2803(2), 3612, and 4010(4) and Social Services Law § 461 authorize the Department (through the PHHPC) to issue and amend regulations 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.

³ On November 24, 2022, a Notice of Proposed Rulemaking to move the Emergency Regulation to be permanently adopted was filed with the Department of State. Lutterloh Dec., ¶ 32. It was published in the State Register on December 15, 2021, with public comment set to expire on February 14, 2022. *Id.*

“[c]overed entities shall continuously require personnel to be fully vaccinated against COVID-19, and to have received any booster or supplemental dose as recommended by the CDC, absent receipt of an exemption” 10 N.Y.C.R.R. § 2.61(c)(underline in original). The regulation provides that personnel are exempt from these requirements “[i]f any licensed physician, physician assistant, or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of a member of a covered entity’s personnel, based upon a pre-existing health condition, the requirements of [Section 2.61] 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.” *Id.* at § 2.61(d)(1). Section 2.61 does not contain a religious exemption from the vaccine requirement.

C. The CMS Mandate

On November 5, 2021, the United States Secretary of Health and Human Services issued an interim final rule, known as the “CMS Mandate,” requiring facilities that participate in the Medicare and Medicaid programs to ensure that their staff are vaccinated against COVID-19. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555 – 61627 (November 5, 2021). The CMS Mandate and Section 2.61 share a common goal to reduce COVID-19’s potential burden on the healthcare system because “[w]hen health care staff cannot work because of illness or exposure to COVID-9, the strain on the health care system becomes more severe and further limits patient access to safe and essential care.” Lutterloh Decl., ¶ 55.

The CMS Mandate requires that covered facilities “establish and implement a process by which staff may request an exemption from COVID-19 vaccination requirements based on an applicable Federal law.” 86 Fed. Reg. 61572. The rule explains that “[u]nder Federal law,

including the ADA and Title VII of the Civil Rights Act of 1964 . . . workers who cannot be vaccinated or tested because of an ADA disability, medical condition, or sincerely held religious beliefs, practice, or observance may in some circumstances be granted an exemption from their employer. In granting such exemptions or accommodations, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients.” *Id.*

The rule also defines the scope of its intended preemption of State and local laws. *Id.* at 61613. Specifically, the rule states that only “State and local laws that *forbid* employers in the State or locality from imposing vaccine requirements on employees,” are preempted because any such State or local rules forbidding vaccine mandates “directly conflict with this exercise of our statutory health and safety authority to *require* vaccinations for staff of the providers and suppliers subject to this rule.” *Id.* The rule goes on to explain that “to the extent that State-run facilities that receive Medicare and Medicaid funding are prohibited by State or local law from imposing vaccine mandates on their employees, there is direct conflict between the provisions of this rule (requiring such mandates) and the State or local law (forbidding them).” *Id.* Thus, the rule “preempts the applicability of any State or local law providing for exemptions to the extent such law provides *broad*er grounds for exemptions than provided for by Federal law and are inconsistent with this [rule].” *Id.* (emphasis added).

PROCEDURAL HISTORY AND THE INSTANT MOTION

A. The Second Circuit Vacates the Preliminary Injunction and the Supreme Court Denies Plaintiffs’ Application for an Emergency Injunction

On October 12, 2021, this Court issued a Memorandum-Decision and Order granting Plaintiffs’ request for a preliminary injunction. ECF No. 22. Under the preliminary injunction, Defendants were enjoined from enforcing Section 2.61 to the extent that they were barred from

enforcing any requirement that employers deny religious exemptions from the COVID-19 vaccine requirement, from otherwise interfering with the granting of such religious exemptions, and from taking any disciplinary or other action against the professional licensure or status of any of the plaintiffs on account of their having obtained a religious exemption. *Id.*

Defendants appealed the October 12, 2021 Memorandum-Decision and Order. ECF No. 23. On October 29, 2021, the Second Circuit issued an Order vacating the preliminary injunction. ECF No. 26. On November 4, 2021, the Second Circuit issued an Opinion explaining the basis for the October 29, 2021 Order. ECF No. 27. The Second Circuit held that Plaintiffs had not demonstrated a likelihood of success on any of the causes of action raised in the Complaint. *Id.* As relevant to the instant motion, the Second Circuit found that Plaintiffs had not demonstrated a likelihood of success on their claim that Title VII preempts Section 2.61. *Id.* The Court rejected Plaintiffs’ preemption argument, concluding that “Section 2.61 does not require employers to violate Title VII because, although it bars an employer from granting a religious *exemption* from the vaccination requirement, it does not prevent employees from granting a religious *accommodation* allowing them to continue working consistent with [Section 2.61], while avoiding the vaccination requirement.” *Id.* at 38 (emphasis in original). The Court went on to explain that “Title VII does not require covered entities to provide the accommodation that Plaintiffs prefer – in this case, a blanket religious exemption allowing them to continue working at their current positions unvaccinated Instead, an employer must officer a *reasonable* accommodation that does not cause the employer undue hardship.” *Id.* Accordingly, the Court held that “[b]ecause Section 2.61’s text does not foreclose the opportunity for Plaintiffs to secure a reasonable accommodation under Title VII, [Section 2.61] does not conflict with federal law.” *Id.*

Further, the Court held that Plaintiffs failed to demonstrate irreparable harm, explaining that “because they have failed to demonstrate a likelihood of success on their First Amendment or other constitutional claims, their asserted harm is not of a constitutional dimension.” *Id.* at 42. The Court also rejected Plaintiffs’ argument that loss of employment or professional standing constitute irreparable harm because “adverse employment consequences are not the type of harm that usually warrants injunctive relief because economic harm resulting from employment actions is typically compensable with money damages.” *Id.*

Finally, the Second Circuit held that Plaintiffs failed to demonstrate that the public interest weighs in their favor. The Court found that the State’s “indisputably compelling interest in ensuring that employees who care for hospital patients, nursing home residents, and other medically vulnerable people are vaccinated against COVID-19” outweighed any alleged hardships faced by Plaintiffs. *Id.* at 44.

In response to the Second Circuit’s decision, Plaintiffs filed an emergency application in the Supreme Court, in which they sought an injunction prohibiting enforcement of Section 2.61. *Dr. A., et al. v. Hochul, et al.*, No. 21A145, Emergency Application for Writ of Injunction or, in the Alternative, Petition for Writ of Certiorari and Stay Pending Resolution (November 12, 2021). Plaintiffs also filed a petition for re-hearing *en banc* in the Second Circuit. *Dr. A., et al. v. Hochul, et al.*, No. 21-2566, Petition for Panel Rehearing or Rehearing En Banc (December 2, 2021). On December 13, 2021, the Supreme Court denied the emergency application. On January 11, 2022, the Second Circuit issued denied Plaintiffs’ petition for re-hearing *en banc*.

B. Plaintiffs File an Amended Complaint and a Renewed Motion for a Temporary Restraining Order and Preliminary Injunction

On January 30, 2022, plaintiffs filed an Amended Complaint. ECF No. 40. The Amended Complaint rehashes Plaintiffs’ claims under the First Amendment, Fourteenth Amendment, and

Supremacy Clause, and adds two new claims. *Id.* First, the Amended Complaint adds a claim that the Section 2.61 is preempted by the recently issued CMS Mandate. *Id.* Second, the Amended Complaint adds a claim that the denial of unemployment insurance benefits to Plaintiffs as a result of their termination for refusal of the COVID-19 vaccine violates the Free Exercise Clause. *Id.*

Simultaneously with the filing of the Amended Complaint, Plaintiffs moved, pursuant to Federal Rule of Civil Procedure 65, for a temporary restraining order and preliminary injunction pending the resolution of their request for a permanent injunction. ECF No. 41. By Text Order dated January 31, 2022, the Court denied Plaintiffs' request for a temporary restraining order. Order, ECF No. 44.

STANDARD OF REVIEW

Injunctive relief, such as the preliminary injunction sought by plaintiffs here, is “an extraordinary remedy *never* awarded as of right.” *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008) (emphasis added). Specifically, the movant bears the burden of establishing, by clear and convincing evidence, that (a) it is likely to succeed on the merits; (b) it is likely to suffer irreparable harm in the absence of preliminary relief; (c) the balance of equities tips in its favor; and (d) an injunction is in the public interest. *See Winter*, 555 U.S. at 20. The final two factors—the balance of equities and the public interest—“merge when the Government is the opposing party.” *L&M Bus Corp. v. Bd. of Educ. of the City Sch. Dist. N.Y.*, 2018 WL 2390125, *13 (E.D.N.Y. May 25, 2018) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

In addition, the Second Circuit has “held the movant to a heightened standard” where (i) an injunction is “mandatory” (i.e., altering the status quo, rather than maintaining it), or (ii) the injunction “will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits.” *New York v. Actavis PLC*, 787

F.3d 638, 650 (2d Cir. 2015). In such cases, the movant must show a “clear” or “substantial” likelihood of success on the merits and make a “strong showing” of irreparable harm, in addition to showing that the preliminary injunction is in the public interest. *See id.* (quoting *Beal v. Stern*, 184 F.3d 117, 123 (2d Cir. 1999) and *Doe v. New York University*, 666 F.2d 761, 773 (2d Cir. 1981)).

ARGUMENT

POINT I

PLAINTIFFS FAIL TO ESTABLISH THAT THEY ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS

A. Plaintiffs Fail to Demonstrate a Likelihood of Success on their CMS Mandate Claim.

Plaintiffs renew their request for a preliminary injunction on two grounds. First, Plaintiffs argue that the CMS Mandate, issued after the Second Circuit reviewed the prior preliminary injunction, preempts Section 2.61. ECF No. 41-1 at 11-27. Second, Plaintiffs argue that the denial of unemployment benefits following their termination for refusing to receive the COVID-19 vaccine on religious grounds violates the Free Exercise Clause. *Id.* at 27 – 29. Plaintiffs’ renewed request for a preliminary injunction should be denied because they fail to demonstrate a likelihood of success on either of these new claims.

1. The CMS Mandate does not conflict with Section 2.61.

Federal law preempts state law (1) where Congress “preempt[s] state law by so stating in express terms”; (2) where “the scheme of federal regulation is sufficiently comprehensive to make the reasonable inference that Congress ‘left no room’ for supplementary state regulation”; and (3) only where there is an actual conflict between the two because compliance with both is “a physical impossibility” or because state law 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, 280 (1987). “Pre-emption is not to be lightly presumed.” *Id.* (citing *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Moreover, it is presumed that the State’s regulation “of matters related to health and safety” are valid under the Supremacy Clause. *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985).

There is no actual conflict between the CMS Mandate and Section 2.61. Plaintiffs entirely misconstrue the CMS Mandate as containing a requirement that States provide religious “exemptions” to COVID-19 vaccine requirements. However, the language of the CMS Mandate contains no such requirement. The CMS Mandate requires that covered “providers and suppliers . . . establish and implement a process by which staff may request an exemption from COVID-19 vaccination requirements *based on an applicable federal law.*” 86 Fed. Reg. 61572 (emphasis added). The CMS Mandate, therefore, requires that covered employers establish a *process* by which employees may “request an exemption from . . . COVID-19 vaccination requirements based on an applicable federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964.” *Id.* The CMS Mandate observes that there “some circumstances” where an employer “*may* be required by law to offer accommodations for some individual staff members,” but does not impose any requirement that an employer actually provide any “exemption” or accommodation beyond what is required by federal law. *Id.* (emphasis added).

Under Section 2.61, covered personnel have the opportunity to request that their employers provide accommodations under applicable federal law. Section 2.61 does not require employers to violate the CMS Mandate, nor does Section 2.61 stand as an obstacle to the objectives of the CMS Mandate. Under both provisions, employers must comply with federal law, including Title VII. The Second Circuit rejected Plaintiffs’ argument that Title VII conflicts with Section 2.61,

holding that “Section 2.61 does not require employers to violate Title VII because, although it bars an employer from granting a religious *exemption* from the vaccination requirement, it does not prevent employees from seeking a religious *accommodation* allowing them to continue working consistent with the Rule, while avoiding the vaccination requirement.” The Second Circuit further explained that “Title VII does not require covered entities to provide the accommodation that Plaintiffs prefer – in this case, a blanket exemption allowing them to continue working at their current positions unvaccinated.” ECF No. 27 at 38. While the CMS Mandate uses both the words “exemption” and “accommodation,” it instructs covered employers to follow applicable federal law in evaluating whether an “exemption” or “accommodation” is required. There is no logical interpretation of the CMS Mandate that would require employers to provide the sort of blanket “exemption” Plaintiffs seek because federal law does not require it.

Under Section 2.61, employers must similarly follow federal law in evaluating accommodation requests. As the Second Circuit has already held in this case, “Section 2.61’s text does not foreclose all opportunity for Plaintiffs to secure a reasonable accommodation under Title VII.” *Id.* Under Title VII, an employer “must offer a *reasonable* accommodation that does not cause the employer an undue hardship.” *Id.* Such a reasonable accommodation may include assigning an employee to remote work, but Section 2.61 does not foreclose other forms of reasonable accommodation, so long as accommodation does not involve activities that could potentially expose others to COVID-19. *See* 10 N.Y.C.R.R. § 2.61(a)(2).

Further, Section 2.61 does not fall within the scope of the State and local laws that the CMS Mandate intends to preempt. Under the CMS Mandate, “State and local laws that *forbid* employers in the State or locality from imposing vaccine requirements on employees directly conflict with this exercise of our statutory health and safety authority to *require* vaccinations for staff of the

providers and suppliers subject to this rule.” 86 Fed. Reg. 61613 (emphasis added). The CMS Mandate goes on to explain that “to the extent that State-run facilities that receive Medicare and Medicaid funding are *prohibited* by State or local law from imposing vaccine mandates on their employees, there is direct conflict between the provisions of this rule (requiring such mandates) and the State or local law (forbidding them).” *Id.* Thus, the CMS Mandate “preempts the applicability of any State or local law providing for exemptions to the extent such law provides *broad*er grounds for exemptions than provided for by Federal law and are inconsistent with this [rule].” *Id.*

Section 2.61 does not provide *broad*er grounds for exemption from the vaccine requirement than the CMS Mandate. The CMS Mandate’s preemption scheme is directed toward those State and local laws which would either prohibit vaccine mandates altogether, or would broaden the pool of individuals who are exempt from their requirements beyond what is permitted by the Mandate. Section 2.61 does not fall within that scheme.

2. *The CMS Mandate does not “occupy the field” of regulation encompassed by Section 2.61.*

The CMS Mandate does not “occupy the field” of regulation encompassed by Section 2.61. “Field preemption occurs ‘where Congress has legislated so comprehensively that federal law occupies an entire field of regulation and leaves no room for state law.’” *New York City Health & Hosps. Corp. v. Wellcare of N.Y.*, 801 F. Supp. 2d 126, 141 (S.D.N.Y. May 10, 2011) (quoting *New York SMSA Ltd. P’ship v. Town of Clarkstown*, 612 F.3d 97, 104 (2d Cir. 2010)).

First, as Plaintiffs concede, “[t]here is a strong presumption against preemption when states and localities ‘exercise[] their police powers to protect the health and safety of their citizens.’” *Steel Inst. of N.Y. v. City of New York*, 716 F.3d 31, 36 (2d Cir. 2013) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); see also *Medical Society of New York v. Cuomo*, 976 F.2d 812,

816 (2d Cir. 1992) (“The regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state.”). Section 2.61 is unquestionably an exercise of New York’s police power to protect the health and safety of its citizens. Therefore, there is a strong presumption that the CMS Mandate does not preempt Section 2.61.

Moreover, the presumption against preemption is particularly strong in the context of Medicaid and Medicare, which are jointly administered by the state and federal governments through a “cooperative program of shared financial responsibility.” *Rebaldo v. Cuomo*, 749 F.2d 133, 139 (2d Cir. 1984).

Further, nothing in the language of the CMS Mandate implies an intent to “occupy the field” of regulation pertaining vaccine requirements for healthcare workers. To the contrary, the CMS Mandate expressly contemplates the continued existence of State and local laws that impose vaccine requirements for healthcare workers. 86 Fed. Reg. 61556 (“We note that entities not covered by this rule may still be subject to *other State* or Federal COVID-19 vaccination requirements”) (emphasis added). The Supreme Court’s recent decision upholding the CMS Mandate similarly recognizes that state laws requiring vaccination are “a common feature of the provision of healthcare in America.” *Biden v. Missouri*, 142 S. Ct. 647, 653 (2022).

The CMS Mandate preempts only those State or local laws that afford broader exemptions from the vaccine requirement than are permitted under federal law. *See id.* at 61613 (“This rule would pre-empt *some* State laws that prohibit employers from requiring their employees to be vaccinated for COVID-19.”) (emphasis added). The CMS Mandate applies only to an enumerated list of “Medicare and Medicaid-certified providers.” *Id.* at 61556. By contrast, Section 2.61 is not limited to such Medicare or Medicaid-certified facilities and applies to a wider group of “covered

entities” within New York as defined by the New York Public Health Law. *See* N.Y. Public Health Law §§ 2801, 3602, 4002. The CMS Mandate does not foreclose New York from regulating those entities.

The Supreme Court’s holding in *Gade v. National Solid Wastes Management Association* does not support Plaintiffs’ argument here. In *Gade*, the Supreme Court considered whether the Occupational Safety and Health Act of 1970 (“OSHA”) preempted an Illinois occupational safety statute. *Gade v. National Solid Wastes Management Ass’n*, 505 U.S. 88, 91 (1992). The Court concluded that OSHA preempted Illinois’ statute because the OSHA required States to obtain prior approval from the Secretary of Labor if it wished to regulate an issue of worker safety for which a federal standard already existed. *Id.* at 99. Here, there is no such requirement that a State obtain prior approval from CMS, or any other federal authority, to impose vaccine requirements. In fact, it is just the opposite, as the regulation of public health and safety are traditionally within the police powers of the State and there is a presumption *against* preemption by federal law.

3. Title VII does not preempt Section 2.61 under the Chevron Doctrine

Plaintiffs argue that Title VII preempts Section 2.61 under the *Chevron* deference standard. Courts apply the *Chevron* deference framework to evaluate judicial challenges to “an agency’s construction of a statute which it administers.” *Chevron, U.S.A. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984). The *Chevron* analysis involves two steps. First, the Court determines “whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.* at 842-43. Second, if the statutory language is “silent or ambiguous,” the Court proceeds to “step two” where “the question for the court is whether the agency’s answer is based on a permissible construction of the statute” at issue. *Id.* at 843.

Here, Plaintiffs’ argument that Title VII preempts Section 2.61 under the *Chevron* framework is meritless. First, the CMS Mandate does not contain any sort of “interpretation” of Title VII that would be subject to review under the *Chevron* framework. The CMS Mandate references Title VII only to note that it is among the federal laws that employers must comply with when considering accommodation requests. Nothing in the language of the CMS Mandate purports to offer an interpretation of Title VII. The CMS Mandate refers to the existence of certain requirements under Title VII, but it does not interpret, modify, or supplement them in any way.

Moreover, this action does not involve a challenge to the administering agency’s interpretation of Title VII. CMS is not the federal agency that administers Title VII. Rather, Title VII is administered by the Equal Employment Opportunity Commission (“EEOC”). *See* 42 U.S.C. §§ 2000e-4, 2000e-5(a). In fact, the CMS Mandate explicitly refers employers to the EEOC Compliance Manual on Religious Discrimination for guidance on how to evaluate and response to requests for religious accommodations to the COVID-19 vaccination requirement. The Compliance Manual refers to religious “accommodations,” not exemptions, and explains that an employer need not provide a religious accommodation when doing so would pose an undue hardship.

B. Plaintiffs Fail to Demonstrate a Likelihood of Success on Their Free Exercise Clause Claim.

Plaintiffs are not likely to succeed on the merits of their claim that the denial of unemployment insurance benefits for employees terminated following their refusal to obtain the COVID-19 vaccine on religious grounds violates the Free Exercise Clause.

1. *The Defendants do not administer New York’s unemployment insurance program.*

As an initial matter, Plaintiffs’ claim is not likely to succeed because none of the Defendants are responsible for the administration of unemployment insurance benefits. Determinations of the validity of a claim for an unemployment insurance (“UI”) benefits are made by the Commissioner of Labor, not by the Defendants. See N.Y. Labor Law § 597. The Commissioner of Labor’s determination is reviewable before an independent Referee. *Id.* at § 620. Decisions by the referee can then be appealed to the Unemployment Insurance Appeal Board (“UIAB”). *Id.* at § 621. Decisions by the UIAB can then be appealed to the New York State Supreme Court, Appellate Division, Third Department. *Id.* at § 624. Pursuant to N.Y. Labor Law § 626, this is the exclusive procedure for challenging determinations related to UI.

2. *Denial of claims for unemployment insurance benefits does not violate the Free Exercise Clause.*

In support of their contention that New York has a “rule” which categorically denies unemployment insurance benefits on the basis of religion, Plaintiffs cite the “Unemployment Insurance Top Frequently Asked Questions” page of the Department of Labor’s (“DOL”) website. New York State Department of Labor, *Unemployment Insurance Frequently Asked Questions* (February 11, 2022), <https://dol.ny.gov/unemployment-insurance-top-frequently-asked-questions>.⁴ Question 6 on this page asks: “If a worker refuses to get vaccinated, will they be eligible for UI benefits?” *Id.* In response to that question, DOL offers the following guidance:

Like all UI claims, eligibility will depend on the circumstances as each claim is unique and reviewed on a case-by-case basis. Workers in a healthcare facility, nursing home, or school who voluntarily quit or are terminated for refusing an

⁴ Plaintiffs previously raised their claim about UI benefits in their application for an emergency stay to the Supreme Court. *Dr. A., et al. v. Hochul, et al.*, No. 21A145, Emergency Application for Writ of Injunction or, in the Alternative, Petition for Writ of Certiorari and Stay Pending Resolution (November 12, 2021). Plaintiffs’ application was denied.

employer-mandated vaccination will be ineligible for UI absent a valid request for accommodation because these are workplaces where an employer has a compelling interest in such a mandate, especially if they already require other immunizations. Similarly, a public employee who works in a public setting and is subject to a local government mandate to submit proof of vaccination or negative testing may be disqualified from the receipt of UI if they refuse to get vaccinated or tested. In contrast, a worker who refuses an employer's directive to get vaccinated may be eligible for UI in some cases, if that person's work has no public exposure and the worker has a compelling reason for refusing to comply with the directive.

Id.

Nothing in DOL's guidance suggests that religious objectors to the vaccine are uniquely or categorically targeted for the denial unemployment insurance benefits. *Employment Div., Dept. of Human Resources of Ore. v. Smith*, 494 U.S. 872, 878 (1990) (where an alleged limitation on the exercise of religion "is not the object . . . but merely the incidental effect of a generally applicable and otherwise valid provision, the First Amendment has not been offended"). To the contrary, DOL's guidance applies to all employees who resign or are terminated for refusing vaccination, whether that refusal was based upon a religious objection or for any other reason.

DOL's guidance also states that eligibility is reviewed on a case-by-case basis. DOL's guidance acknowledges that there are employees who may remain eligible for UI benefits despite refusing vaccination if their "work has no public exposure and the worker has a compelling reason for refusing to comply with the directive."

POINT II

PLAINTIFFS FAIL TO ESTABLISH THEY WILL SUFFER IRREPARABLE HARM

Plaintiffs have not established that they will suffer irreparable harm in the absence of injunctive relief, which is "[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) (per curiam) (alteration in original) (quoting *Bell & Howell: Mamiya Co. v. Masel Supply Co.*, 719 F.2d 42, 45 (2d Cir. 1983)). To meet their burden, plaintiffs "must demonstrate that absent a preliminary

injunction they will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm.” *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009) (citation omitted).

Plaintiffs reiterate the argument, previously rejected in this case by the Second Circuit, that they will suffer irreparable harm because of monetary losses sustained on account of their termination or suspension of their admitting privileges. The Second Circuit squarely rejected this argument, holding that the economic harm alleged by Plaintiffs does not constitute irreparable harm because it can be remedied by money damages, or by reinstatement of their employment. ECF No. 27 at 43 Further, the Second Circuit, did “not place any weight” at the preliminary injunction stage on the issue of how Plaintiffs’ alleged financial losses would ultimately be remediated should they prevail in this action. *Id.*

Further, Plaintiffs cannot rely on the mere fact they have alleged a loss of First Amendment freedoms to establish irreparable harm. “Although ‘the loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury,’” courts “have not consistently presumed irreparable harm in cases involving allegations of the abridgement of First Amendment rights[.]” *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 349 (2d Cir. 2003) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)); see also *CompassCare v. Cuomo*, 2020 U.S. Dist. LEXIS 98930, *30 (N.D.N.Y. June 5, 2020). A movant is entitled to the presumption that a loss of First Amendment freedoms constituted irreparable harm only when he or she “alleges injury from a rule or regulation that *directly limits*” a First Amendment right. *Bronx Household of Faith*, 331 F.3d at 349 (emphasis added).

As discussed above, Plaintiffs have not established a likelihood of success on their claim that the denial of unemployment insurance benefits violates the Free Exercise Clause.

Accordingly, Plaintiffs “fail to meet the irreparable harm element simply by alleging an impairment of their Free Exercise right.” ECF No. 27 at 42.

POINT III

THE EQUITIES BALANCE IN FAVOR OF THE STATE’S EFFORTS TO PROTECT THE PUBLIC HEALTH DURING THE EXISTING PANDEMIC, AND ISSUANCE OF A PRELIMINARY INJUNCTION IS NOT IN THE PUBLIC INTEREST

Because Plaintiffs cannot establish the likelihood of success on the merits of their claims, or irreparable harm, the court need not consider “the public’s interests in a temporary restraining order or the balance of the equities.” *Amato v. Elicker*, 2020 U.S. Dist. LEXIS 87758, at **38-39 (D. Conn. May 19, 2020).

However, should the Court consider this prong of the test, Plaintiffs’ request for a preliminary injunction must be denied because the equities balance in favor of continuing the State’s vaccination requirement under Section 2.61. It is well-established that a “preliminary injunction may not issue unless the movant clearly shows that the balance of equities favors the movant.” *Litwin v. OceanFreight, Inc.*, 865 F. Supp. 2d 385, 401–02 (S.D.N.Y. 2011) (citation omitted). As discussed above, Plaintiffs have not established that they will suffer irreparable harm if the Court denies the requested injunction. In light of Plaintiffs’ failure to show irreparable harm, the balance of the equities weigh in favor of denying interim equitable relief.

Likewise, the public interest favors the continuation of the State’s vaccination requirement under Section 2.61 without a religious exemption. As the Second Circuit held, “the State has an indisputably compelling interest in ensuring that the employees who care for hospital patients, nursing home residents, and other medically vulnerable people in its healthcare facilities are vaccinated against COVID-19, not just to protect them and those with whom they come into

contact from infection, but also to prevent an overburdening of the healthcare system.” ECF No. 27 at 44.

Section 2.61 was promulgated as part of the State’s ongoing efforts to curb the spread of the deadly COVID-19 virus, which continues to pose a significant public health threat. Increasing the number of people, particularly health care workers, who receive the vaccine undoubtedly serves that vital objective. A study published in the CDC’s MMWR found that the rapid rise of Omicron cases in December 2021 “has resulted in the highest number of COVID-19 associated [emergency department] visits and hospital admissions since the beginning of the pandemic, straining the health care system” despite that disease severity has been lower than during the Delta surge (likely attributed to the increase in vaccination coverage and use of vaccine boosters, which reduces disease severity). The study reiterated the important of, among other things, “the ability to adequately staff local health care systems . . . [and] being up to date on vaccination and following other recommended prevention strategies.” Lutterloh Decl., ¶ 46.

Another recent CDC study observed that “a rapid increase in infections during Omicron predominance has resulted in a relatively substantial volume of hospitalizations” and this high volume “can compound the effects of staffing shortages and staff member burnout, which puts a strain on the health care sector.” *Id.* at ¶ 47. The study concluded that the rise in hospitalization rates in this specific study was most pronounced among unvaccinated individuals and lower among those who are fully vaccinated and lowest among those who had received a booster. Essentially, “[b]eing up to date with COVID-19 vaccinations is a critical component of reducing the strain on health care facilities.” *Id.*

In short, “[s]temming the spread of COVID-19 is unquestionably a compelling interest,” *Hopkins Hawley LLC v. Cuomo*, 518 F. Supp. 3d 705, 717 (S.D.N.Y. 2021) (quoting *Roman*

Catholic Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 67 (2020)); *see also Garcia v. New York City Dep't of Health & Mental Hygiene*, 31 N.Y. 3d 601, 612 (2018) (“Undisputedly,” there is a “very direct connection” between vaccination rules and “the preservation of health and safety.”); *F.F. ex rel. Y.F. v. State*, 65 Misc. 3d 616, 633 (Sup. Ct. Albany Cty. 2019) (“Protecting public health” through the use of vaccines “has long been recognized as the gold standard for preventing the spread of contagious diseases” and “is unquestionably a compelling [public] interest”), *aff'd*, 194 A.D.3d 80 (3d Dep't 2021).

CONCLUSION

For the reasons discussed above, Plaintiffs’ motion for preliminary injunctive relief should be denied in its entirety.

Dated: Albany, New York
February 11, 2022

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