UNITED STATES DISTRICT COURT WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel., Deborah Conrad,

Relator,

DECLARATION OF JAMES E. PEACOCK, ESQ.

-against-

Case No: 1:23-cv-00438-JLS

ROCHESTER REGIONAL HEALTH and UNITED MEMORIAL MEDICAL CENTER,

Defendants.

James E. Peacock, pursuant to 28 U.S.C. § 1746, declares under penalty of perjury that the following is true and correct:

- 1. I am a shareholder of the law firm Greenberg Traurig, LLP, counsel to Defendants Rochester Regional Health ("RRH") and United Memorial Medical Center ("UMMC," and together with RRH, "Defendants") in this action, am admitted to this Court *pro hac vice* in connection with this action, and, as such, am familiar with the pleadings and proceedings herein.
- 2. I submit this Declaration in support of Defendants' motion, pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), seeking dismissal of Relator Deborah Conrad's ("Relator") Amended Complaint in its entirety, with prejudice (the "Motion").
- 3. Specifically, this Declaration sets forth procedural background pertinent to this Motion, and attaches certain pertinent, publicly available, documents that Defendants request this Court take judicial notice of in its determination of the Motion.
- 4. Attached hereto as **Exhibit A** is a copy of the United States Center for Disease Control's published Vaccine Adverse Event Reporting System (VAERS) guidance for the COVID-19 vaccine.

- 5. Attached hereto as **Exhibit B** is a copy of Section 2.61 of Chapter 10 of the New York State Rules and Regulations (10 NYCRR § 2.61), which is the New York State regulation adopted in August 2021 that required qualifying healthcare workers to be "fully vaccinated" against COVID-19.
- 6. Attached hereto as **Exhibit** C is a copy of a New York Times article by Anne Barnard et al., dated September 26, 2021, titled *These Health Care Workers Would Rather Get Fired Than Get Vaccinated*, which featured the Relator.
- 7. Attached hereto as **Exhibit D** is a copy of an affidavit of Relator, sworn to on September 21, 2021, filed in the Albany County Clerk's office in connection with a proceeding commenced pursuant to Article 78 of the New York Civil Practice and Rules in New York State Supreme Court, Albany County (*Serafin et al. v. New York State Dept. of Health et al.*, Albany County Index No. 908296-21).
- 8. Relator's affidavit, which appears at Docket 11 on the *Serafin* New York State Courts Electronic Filing system docket, is also available at the following link: https://iapps.courts.state.ny.us/nyscef/ViewDocument?docIndex=INPA9w0gVM0sEcPfOH3FJA
 =. The complete docket in the *Serafin* proceeding is available on the at the following link: https://iapps.courts.state.ny.us/nyscef/DocumentList?docketId=dCMiKKg3sD5WUoaRLTVnD
 A=&display=all&courtType=Albany%20County%20Supreme%20Court&resultsPageNum=1.
- 9. Defendants respectfully request that the Court take judicial notice of the foregoing Exhibits, as well as the docket in the *Serafin* proceeding, pursuant to Federal Rule of Evidence 201.

WHEREFORE, Defendants respectfully request that the Court enter an order dismissing Relator's Amended Complaint in its entirety, with prejudice, take judicial notice of the Exhibits

attached hereto, and grant such other and further relief, whether in law or equity, as the Court deems just and proper.

Dated: December 20, 2024

/s/ James E. Peacock
JAMES E. PEACOCK

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EXHIBIT A

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en Español (faqSpanish.html)



VAERS Home (../index.html)

VAERS (../index.html)

/ en Español (faqSpanish.html)

Frequently Asked Questions (FAQs)

What is VAERS?	>
Which government agencies manage VAERS?	>
Who can report to VAERS?	>
What are healthcare providers required to report to VAERS?	>
What is a serious adverse event?	>
What adverse events should healthcare providers report to VAERS after Monkeypox vaccination?	>
What adverse events should healthcare providers report to VAERS after COVID-19 vaccination?	~

For licensed COVID-19 vaccines (Moderna and Pfizer-BioNTech in people ages 12 years and older), healthcare providers are strongly encouraged to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

For COVID-19 vaccines given under an Emergency Use Authorization (EUA), vaccination providers are required to report to VAERS:

- Vaccine administration errors, whether or not associated with an adverse event
- Serious adverse events regardless of causality. Serious adverse events per FDA are defined as:
 - Death
 - o A life-threatening adverse event
 - Inpatient hospitalization or prolongation of existing hospitalization
 - · A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
 - A congenital anomaly/birth defect
 - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- · Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov (reportevent.html#submitReport) or by calling 1-800-822-7967.

Why should I report to VAERS?	>
Are VAERS reports kept confidential?	>
How do I report to VAERS?	>
What adverse events should I report to VAERS?	>
Will I receive confirmation that the report I filed was received?	>
How can I get a copy of my report?	>
How do I provide follow-up information for a case?	>
What are the strengths and limitations of VAERS?	>

Case 1:23-cv-00438-JLS Document 38-1 Filed 12/20/24 Page 7 of 42 Are all adverse events reported to VAERS caused by vaccines? How do I find out what adverse events have been reported to VAERS? Does VAERS provide medical advice? Is VAERS involved in the Vaccine Injury Compensation Program?

FAQs (faq.html) | Contact Us (contact.html) | Privacy (privacy.html) | info@vaers.org (mailto:info@vaers.org) |

Vulnerability Disclosure Policy - HHS.gov (https://urldefense.us/v3/_https:/www.hhs.gov/vulnerability-disclosurepolicy/index.html_;!!JRQnnSFuzw7wjAKq6ti6!gyBeT_HGREEd5t14KdwlRf5ZQVFqyRtp14miSwyxziZwqdmRMEA3YjGiHz5gU4Q\$)

USA.gov (http://www.usa.gov) | Centers for Disease Control and Prevention (https://www.cdc.gov/) | Food and Drug Administration (http://www.fda.gov/) |

U.S. Department of Health & Human Services (https://www.hhs.gov/)

VAERS is co-sponsored by the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), agencies of the U.S. Department of Health and Human Services (HHS).

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EXHIBIT B

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.

Contact Person:

Ms. Katherine E. Ceroalo

NYS Department of Health

Bureau of Program Counsel, Regulatory Affairs Unit

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REGSQNA@health.ny.gov

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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.

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The New Hork Times https://www.nytimes.com/2021/09/26/nyregion/health-workers-vaccination.html

These Health Care Workers Would Rather Get Fired Than Get Vaccinated

Monday is the vaccination deadline for New York State health care workers. Thousands of refusers have failed to meet it.

By Anne Barnard, Grace Ashford and Neil Vigdor

Published Sept. 26, 2021 Updated Oct. 18, 2021

Update: As the mandate deadline approached, thousands of resistant health care workers got vaccinated.

Deborah Conrad, a physician assistant in western New York, and Simmone Leslie, a hospital switchboard operator in Queens, have both worked long, risky hours during the pandemic. But now, both are prepared to lose their jobs rather than meet Monday's state deadline for health care workers to get vaccinated.

In defying the order, they are resisting a step that public-health experts say is critical to save lives and end the pandemic. While they each cite differing reasons for their decisions — Ms. Leslie said her employer rejected her request for a medical exemption; Ms. Conrad referenced vaccine side effects she claimed to have seen but that veer from the scientific consensus — their recalcitrance embodies a conundrum facing New York.

Experts have called the mandate a clear-cut way for health care workers to prevent new waves of the virus from spreading, and to persuade doubters to get vaccinated. And health systems say the plan is crucial to keeping patients and staff safe.

Westchester Medical Center Health Network, where 94 percent of the system's 12,000 workers are vaccinated, called the mandate "a critical part of upholding our mission" in a statement on Sunday.

But a vocal minority working within the health care system are themselves skeptics — and some, like Ms. Conrad, have imperiled the plan, even fighting the mandate in court.

They see their work as a badge of credibility, and the order from their bosses and the state to make a choice — get vaccinated or get fired — as a betrayal.



Deborah Conrad is among medical staff that has felt hesitant to take the Covid-19 vaccine. Malik Rainey for The New York Times

"We were all traumatized, vaccinated and unvaccinated," said Ms. Conrad, who works at United Memorial, a hospital in Batavia, a small city midway between Rochester and Buffalo, and felt respected by colleagues there. "It's very hard that the same people who elevated me to this level now look at me as a dangerous person."

The dispute is dividing hospitals, where most workers are vaccinated and want their colleagues to be. The nurses' union supports the mandate — some 95 percent of members are already vaccinated — even as some members complain its rollout was too rushed. But unions representing support workers, including nurses' aides, orderlies, cafeteria workers

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and others, have opposed it. If many of those workers leave or are fired, their duties could fall to already taxed nurses.

The disagreement is also testing government's power to mandate compliance with public-health measures; New York's mandate and the state's refusal to allow religious exemptions are the subject of at least two lawsuits, including one by Ms. Conrad and five other plaintiffs.

Still, staff members choosing to exit their jobs because of the mandate could also create immediate practical challenges: Many nurses and other health workers are burned out or traumatized from the pandemic's strain; others have been lured by high salaries to become "travel nurses," crisscrossing the country to fill emergency staffing gaps.

On Sunday at the Christian Cultural Center in Brooklyn, Gov. Kathy Hochul pushed back hard against the idea of religious exemptions to vaccination, urging worshipers to be "apostles" for the vaccine in order to "keep more people alive."

"God did answer our prayers," she told the congregation. "He made the smartest men and women — the scientists, the doctors, the researchers — he made them come up with a vaccine. That is from God to us and we must say, 'Thank you, God, thank you!"

"There are a lot of people out there who aren't listening to God and what God wants," she said as a gold necklace spelling "Vaxed" glinted from her chest.



Gov. Kathy Hochul, wearing a "Vaxed" necklace, told worshipers at Christian Cultural Center in Brooklyn on Sunday that they should thank God for the vaccine. Dave Sanders for The New York Times

A federal judge last week gave a reprieve to 17 health care workers, including doctors, nurses, therapists and medical residents who sued the state, extending a temporary restraining order for enforcing the mandate against them until Oct. 12. Their lawyer, Stephen Crampton, said the delay should apply to all health workers, but the state does not agree.

"There's this coercive element that is hard to ignore in all of this urgency," Mr. Crampton, a senior counsel for the Thomas More Society, a conservative law firm that handles religious freedom cases, said. He would not identify the plaintiffs but said many are Catholic and some Protestant.

Pope Francis and the leaders of many major religions have endorsed vaccine mandates.

The plaintiffs, like other health care workers opposing the mandate, contend that the state is not taking into account that some of them have already had Covid-19 and believe they have a natural immunity.

But scientists say that prior infection does not fully protect people, and available data shows that while breakthrough infections in vaccinated people are rising, vaccines still greatly reduce the risk of infection, hospitalization and death.

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State vaccination figures show that, as of Wednesday, 16 percent of the state's roughly 450,000 hospital workers, or about 70,000 people, were not fully vaccinated. The data show that 15 percent of staff at skilled nursing facilities and 14 percent of workers at adult care facilities are also not fully vaccinated, representing another 25,000 or so workers.

There are no clear data on how many of those have absorbed unfounded anti-vaccination ideas through word of mouth, social media or politically inflected cable news; how many have not managed to take time off to get vaccinated; and how many have concerns about their personal health.

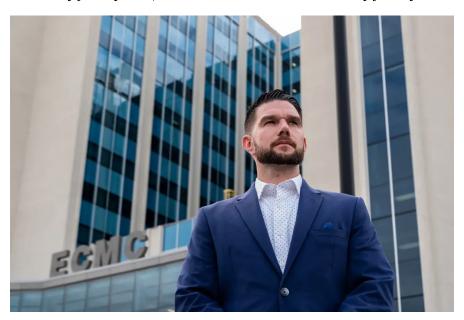
But what it adds up to is angst on all sides.

"Nobody should be put in these types of positions," Ms. Leslie said on Sunday.

She has gotten other vaccines, she said, but she believes the Covid-19 shot would be risky for her, even though the Crohn's and Colitis Foundation, an advocacy group, broadly recommends vaccination for people with her condition. With her medical exemption rejected, she asked for a religious one.

Ms. Conrad, a physician assistant for 18 years, said she did not understand why the protective equipment she has always used to protect patients and herself — including before the vaccine was available — would not be enough now. But she also said that she wouldn't get weekly tests unless vaccinated workers also had to: She would sooner sell her house and move.

"It's not that I don't want to do my job anymore," she said. "I'm not allowed to do my job anymore."



Greg Serafin, a registered nurse at Erie County Medical Center in Buffalo, is suing the state Health Department over the mandate. Malik Rainey for The New York Times

Greg Serafin, a registered nurse at Erie County Medical Center in Buffalo who has sued the state Health Department in state court over the mandate, said Sunday that he expects to lose his job. He said he anticipates being placed on unpaid administrative leave for 30 days and then being fired for cause.

Regardless, he said, "I'm not taking the vaccine."

New York's experience with the mandate and its enforcement could inform how other states proceed. So far, neighboring states have instituted less stringent requirements.

New Jersey and Connecticut have stopped short of conditioning employment on vaccination in most health care settings. In New Jersey, workers at state and private health care facilities have the option of getting tested at least once or twice a week if they are not vaccinated under an order that went into effect on Sept. 7.

In Connecticut, nursing homes and other long-term care facilities face fines of up to \$40,000 a day if their workers do not

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get at least one dose of the coronavirus vaccine by Monday. There are no civil penalties for hospitals, but many already require vaccines for employees.

Dave Sanders and Sharon Otterman contributed reporting.

A correction was made on Sept. 27, 2021: An earlier version of this article mischaracterized a vaccination requirement for some health care workers in Connecticut. The deadline for workers at nursing homes and long-term care facilities to get one dose of a coronavirus vaccine was extended to Sept. 27. It did not go into effect on Sept. 7.

When we learn of a mistake, we acknowledge it with a correction. If you spot an error, please let us know at nytnews@nytimes.com. Learn more

Anne Barnard covers climate and environment for the Metro desk. She was Beirut bureau chief from 2012 to 2018. She joined The Times in 2007 after covering the Middle East and the Iraq war for The Boston Globe. More about Anne Barnard

Grace Ashford is a reporter on the Metro desk covering New York State politics and government from the Albany bureau. She previously worked on the Investigations team. More about Grace Ashford

Neil Vigdor covers political news for The Times. More about Neil Vigdor

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EXHIBIT D

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NYSCEF DOC. NO. CASE 1:23-CV-00438-JLS DOCUMENT 38-1 Filed 12/20/24

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RECTIVED NYSCEF: 09/21/2021

STATE OF NEW YORK SUPREME COURT : COUNTY OF ALBANY

GREGORY SERAFIN, et al., each on behalf of themselves and on behalf of all others similarly situated, and DAVID DIPIETRO, MEMBER OF THE ASSEMBLY FOR NEW YORK'S 147TH ASSEMBLY DISTRICT, on his own behalf in his official capacity and on behalf of all similarly situated members of the

Petitioners/Plaintiffs,

For Judgment Pursuant to Article 78 of the CPLR And The New York Constitution, Art. I, § 6

New York State Legislature,

Index No.

v

NEW YORK STATE DEPARTMENT OF HEALTH; NEW YORK STATE PUBLIC HEALTH AND HEALTH PLANNING COUNCIL; HOWARD ZUCKER, NEW YORK STATE COMMISSIONER OF HEALTH,

Respondents/Defendants.

STATE OF NEW YORK) | ss.:

COUNTY OF GCOLSER)

DEBORAH CONRAD, being duly sworn, deposes and says:

- I am over the age of eighteen and make this Affidavit on my own personal knowledge, except as to those allegations asserted upon information and belief, and as to those allegations, I believe them to be true.
 - 2 I am a Petitioner/Plaintiff in the above-captioned action.

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3. This Affidavit is submitted in support of the Petition and Complaint in this matter, as well as the Order to Show Cause seeking a Temporary Restraining Order and a Preliminary Injunction to restrain and enjoin Respondents/Defendants from applying and/or enforcing 10 NYCRR § 2.61, and seeking to stay the date when vaccination become mandatory for workers at certain health care facilities as set forth in 10 NYCRR § 2.61(c) until a hearing on this matter can be had.

- I have been employed by Rochester Regional Health, United Memorial Medical
 Center as a Hospitalist Physician Assistant, for 14 years.
- 5. I worked the front lines when COVID-19 first started, frequently with insufficient PPE.
- 6. I personally reported more than 125 possible adverse vaccine reactions of hospitalized patients to the Vaccine Adverse Event Reporting System ("VAERS").
 - 7. I am working on completing approximately 20 more reports to VAERS.
- 8. I am personally aware of approximately 100 additional incidents of possible adverse vaccine reactions that occurred at my place of employment but were not reported to VAERS.
- 9. I am unwilling to get vaccinated because of the significant number of adverse vaccine reactions I have reported and am aware of. I am terrified of the unknown side-effects of vaccination.
- 10. I am unwilling to compromise my medical autonomy to comply with the requirements of 10 NYCRR § 2.61.
 - 11. Accordingly, I face termination of my employment on September 27, 2021.

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12. Moreover, under 10 NYCRR § 2.61 I will be precluded from working in any similar healthcare setting after this date.

13. This will constitute a major interruption of my career. I have developed experience and technical competence in working in a hospital setting, but 10 NYCRR § 2.61 will prevent me from continuing to practice my profession.

14. I have also been informed by my employer that if I refuse to be vaccinated I will not be eligible for unemployment.

15. Accordingly, in just one week I face unemployment, and unemployability in my chosen profession, without any safety net whatsoever.

16. Upon information and belief, there are hundreds similarly situated unvaccinated employees at my place of work.

17. Based upon the foregoing, I respectfully request that this Court grant the relief requested in the accompanying Petition and Complaint, as well as grant Petitioners' request for a Temporary Restraining Order and Preliminary Injunction restraining and enjoining Respondents from applying or enforcing the vaccine requirement.

DEBORAH CONRAD

Subscribed and sworn to before me this <u>Z</u>1 day of September 2021.

Notary Public

TIMOTHY R CLARK
Notary Public - State of New York
No. 01CL6095641
Qualified in Genesee County
My Commission Expires Jul. 14, 2023