CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-20-15-7

RULE TITLE: Immunization, Testing and Health Screening of Health Care Workers

REASON FOR RULEMAKING: This regulation is being promulgated to: add definitions for the terms advance practice registered nurse, healthcare facility, period in which flu is widespread, and up to date; revise the definitions of healthcare worker, physician, physician assistant and practitioner; remove superfluous language; require healthcare workers be up to date with a SARS-CoV-2 vaccine or wear a medical grade N95 mask when the prevalence rate is substantial or higher; require healthcare facilities to document COVID-19 immunization status of their healthcare workers; simplify the requirements for influenza; and create a "Violations" section.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS:

Public comment was received opposing the inclusion of assisted living residences (ALRs) in the definition of healthcare facility, as ALRs do not provide healthcare but rather board and care. These comments were further stated at a meeting with the Rhode Island Assisted Living Association in which the members expressed objection of the inclusion of ALRs for requiring all non-COVID-19 vaccines. The Department has revised the regulation to remove ALRs from the definition of healthcare facility and instead provide a stand-alone definition of ALR and ALR workers. The Department further clarified that ALRs are only required to comply with rules regarding COVID-19 vaccination at this time and until the new regulations are final.

Public comment was received requesting that religious exemptions be included in the regulation and permitted as a reason to refuse a COVID-19 vaccine. Pursuant to federal case law, the right of a person to refuse a vaccine for a sincerely held religious belief is constitutionally protected; however, it is up to a person's employer to determine when a reasonable accommodation for a sincerely held religious belief is necessary. *This comment will not be accepted at this time.*

Public comment was received requesting that additional medical exemptions be included in the regulation and permitted as a reason to refuse a COVID-19 vaccine. A person is allowed to refuse a vaccine for a medical exemption. The Centers for Disease

Control and Prevention (CDC) provides the criteria for acceptable medical exemptions for the COVID-19 vaccine. *This comment will not be accepted at this time.*

Public comment was received stating the definition of “up to date” is misleading and should be defined as fully vaccinated or fully boosted. The definition “up to date” is an evergreen definition used by the CDC to account for any future recommended doses.

Public comment was received stating that the proposed rule should have all healthcare workers wear masks or no healthcare workers wear masks. Healthcare workers who are unvaccinated pose a higher health risk to patients and are required to wear masks during periods of substantial (or higher) transmission (greater than or equal to 50 cases per 100,000 people per week) in order to protect the health and safety of patients. *This comment will not be accepted at this time.*

Public comment was received in support of the proposed regulations. *The Department thanks you for the support.*

Public comment was received demanding that unvaccinated healthcare workers be sent back to work and with retroactive pay if they were previously dismissed. This is beyond the scope and authority of the Department. *This comment will not be accepted at this time.*

Public comment was received opposing the proposed regulation as there should be no COVID-19 vaccine mandate. This regulation does not mandate the COVID-19 vaccine and provides a healthcare worker with the option to wear an N95 mask if not up to date. *This comment will not be accepted at this time.*

Public comment was received demanding that the COVID-19 vaccine mandate be dropped. The proposed regulation provides healthcare workers to be either up to date on their COVID-19 vaccine or wear an N95 mask if not up to date. The proposed regulation does not mandate the COVID-19 vaccine. *This comment will not be accepted at this time.*

Public comment was received opposing a vaccine mandate as the vaccine does not prevent the spread of COVID-19. Vaccination is the best way to protect oneself and others, and while a vaccinated person can spread COVID-19 to others, they are less likely to spread COVID-19 when compared to unvaccinated people. *This comment will not be accepted at this time.*

Public comment was received requesting that the Department recognize “natural immunity.” Currently, there are no approved measures or titers to determine the COVID-19 antibody levels of an individual. Additionally, it is unknown how long prior infection can prevent future infection, and there is no standardization of these periods for a population. The Department may consider recognizing natural immunity when more information is available. *This comment will not be accepted at this time.*

Public comment was received stating that the matter of COVID-19 vaccination should be determined by the legislature and that the Department has no authority to regulate in this area. The regulations were promulgated under R.I. Gen. Laws §§ 23-17-10, 23-17-36, 23-17.7.1-3, 23-17.7.1-10, and 23-17.7.1-19. The Department also has additional authority to regulate in this area under R.I. Gen. Laws §§ 23-1-1 and 23-1-18. Public health departments have had long-standing legal authority to regulate immunization. *This comment will not be accepted at this time.*

Public comment was received stating that travel contracts are dangerous, burden local economies, and are unfair to the people deserving higher wages for the skilled work performed in areas in which they reside and pay taxes. This is beyond the scope and authority of the Department. *This comment will not be accepted at this time*.

Public comment was received stating that the proposed regulation should have been in place from the beginning and that there should have never been a vaccine mandate. Rhode Island was in a very different place back in early fall 2021 than it is now; based on the experience of foreign countries whose cycles preceded ours, extensive scientific modeling that we reviewed and calculated, and feedback that we were receiving from our colleagues practicing on the front lines in Rhode Island healthcare networks, fall 2021 necessitated more stringent requirements for the Department to fulfill its mission: protecting the health, welfare, and well-being of Rhode Islanders. By contrast, COVID-19 is now, in April 2022, becoming endemic, or constantly present, and as such the Department is updating regulations to be reflective of the new COVID-19 direction.

Public comment was received stating support for healthcare workers getting back to work. The Department is also in support of healthcare workers working.

Public comment was received stating healthcare workers should have choice on how to protect themselves. The regulation permits healthcare workers to be either up to date with a COVID-19 vaccine or only requires N95 masks to be worn when there is substantial transmission.

Public comment was received stating that organizations should not be allowed to make their own policy requiring boosters and any organizations that do should be heavily fined. Private organizations are able to require more stringent requirements than the regulations. Furthermore, it is beyond the scope and authority of the Department to implement such a requirement. *This comment will not be accepted at this time.*

Public comment was received objecting to the requirement for healthcare workers to receive vaccines that have not been fully approved by the Food and Drug Administration (FDA), and indicating that the vaccines' failure to receive FDA approval means that they are not safe. Safety is a top priority for the FDA in the regulation of vaccines. The COVID-19 vaccines underwent rigorous safety testing and had large clinical trials with people of different ages, races, and ethnicities, as well as people with different underlying health conditions. No safety steps have been skipped and COVID-19 vaccines are being held to the same standards as other vaccines. The Pfizer

and Moderna COVID-19 vaccines have been granted full FDA approval and are safe. The Johnson & Johnson COVID-19 vaccine is still under emergency use authorization and the CDC recommends it for use when a person cannot or does not want to get an mRNA vaccine (e.g., Pfizer and Moderna).

Public comment was received stating that the COVID-19 vaccine should be treated like the annual influenza (flu) vaccine. The Department modeled the rule for COVID-19 vaccine in the proposed regulation after the existing rule for flu vaccine: healthcare workers are required to either be up to date with the COVID-19 vaccine or wear a mask when there is substantial transmission. Similarly with respect to the flu, healthcare workers are required to either be up to date with the flu vaccine or wear a mask when the transmission of influenza has been declared "Widespread." *This comment will not be accepted at this time.*

Public comment was received stating the COVID-19 vaccine should not be a condition of employment or to attend school. The Department does not have authority to determine conditions of employment for private businesses. This regulation also does not cover schools. *This comment will not be accepted at this time.*

Public comment was received stating the vaccines will further cripple the healthcare system and that there are dangerous adverse reactions to the vaccine. The COVID-19 vaccines are safe and were rigorously tested. Often, vaccines can cause our immune systems to respond in a way that shows they are working. The likelihood of severe adverse effects from the vaccines is relatively small. Finally, the regulation permits individuals to be either up to date on their COVID-19 vaccines or wear an N95 mask when there is substantial (or higher) transmission.

Public comment was received stating it is blatant overreach for the Department to impose 'administrative action' on those who do not comply with the regulation. The Department licenses both healthcare facilities and healthcare providers. As a condition of licensure, both healthcare facilities and healthcare providers must agree to comply with all state and federal statutes and regulations. The Department does not take licensure actions lightly. Violations go through a systematic process and include administrative appeals which can be found in the Department's regulation, Practices and Procedures Before the Rhode Island Department of Health (216-RICR-10-05-4). *This comment will not be accepted at this time.*

Public comment was received stating the CDC is not a governing body and as such Rhode Island should not rely on them to set policy. The CDC is a governing body and has the authority to implement regulations to protect America from health and safety threats. This authority was granted to the CDC by the federal government. As they are the leading federal agency in public health, the Department follows and implements their policy and guidance.

Public comment was received stating the Department has way too much power and that these regulations require public input or legislative oversight. The Rhode Island General

Assembly granted the Department authority to regulate in certain areas. These regulations are promulgated under the authority granted in R.I. Gen. Laws Chapters 23-17 and 23-17.7(.1) by the Rhode Island General Assembly to the Department. Furthermore, these regulations went out for public comment to solicit feedback from the public on the proposal, and the Department held a public hearing as an additional venue for any concerned person to provide comments or thoughts in writing, verbally, or both.

Public comment was received stating that the Department is taking too much power by expanding the definition of "Director" to include a "designee"; expand the definition of "healthcare facility" to give the Department more control over other entities; and expand "widespread flu periods." As is customary, the Director of the Department delegates certain duties to senior administrators in the Department, all of which is detailed in the "delegation of authority" document that is filed and recognized by the State legislature. The expansion of the definition of "healthcare facility" includes entities that are not included in the statutory definition but are entities which the Department has the authority to regulate. Furthermore, there are separate regulations for each additional facility included in the definition of healthcare facility (see 216-RICR-40-10-2, Licensing of Assisted Living Residences; 216-RICR-40-10-7, Licensing of Adult Day Care Centers; and 216-RICR-60-05-4, Clinical Laboratories and Stations). The definition of "widespread flu periods" is not a new definition and was previously included in the regulation but not in the definition section. The Department reorganized the regulation and moved the definition to the definition section. Additionally, the definition is based on data metrics that are set by the CDC, a national, expert, third-party organization.

Public comment was received stating that it was an infringement of privacy and medical records to collect medical information from healthcare workers. Healthcare facilities are considered covered entities under the Health Information Portability and Accountability Act (HIPAA) and are knowledgeable about how to protect their employees' health information. *This comment will not be accepted at this time.*

Public comment was received that companies who deny religious or medical exemptions should be fined. The CDC provides the list of acceptable medical exemptions, and it is up to the employer to find a reasonable accommodation for a sincerely held religious belief. *This comment is beyond the scope and authority of the Department and will not be accepted at this time.*

Public comment was received stating that people need to have a right to determine what happens to and what goes into their bodies. The proposed regulation requires a healthcare worker to either be up to date with his or her COVID-19 vaccine or wear an N95 mask when there is substantial (or higher) transmission. Healthcare workers have a choice of how they must protect patients. *This comment will not be accepted at this time.*

Public comment was received questioning if there would be a distinction among healthcare facilities regarding masking and vaccination; and noted that a physical

therapy or chiropractic clinic is treating very different types of patients than a hospital. There are no exceptions for healthcare facilities, and they must comply with the regulation as written. However, private physical therapy offices and chiropractic clinics do not fall under the definition of “healthcare facility,” so those offices and clinics would likely not be subject to this new regulation, as proposed.

Public comment was received stating that CDC recommendations and guidelines should not be included as they are a “captured” agency beholden to big pharma, acting against the public interest and approving unsafe vaccines like COVID-19 and influenza. The CDC is an independent government agency and does not approve vaccines. The FDA approves all medications for the United States and the CDC makes recommendations on the vaccine schedule based on all the data available at the time of its opinion. *This comment will not be accepted at this time.*

Public comment was received to remove the COVID-19 booster mandate stating that the primary series should be sufficient. Evidence has shown waning immunity after six months from completion of the primary series. Boosters are strongly recommended, for people who are eligible, by the CDC. However, a healthcare worker is not required to receive a booster and can instead wear an N95 mask when there is substantial (or higher) transmission. *This comment will not be accepted at this time.*

Public comment was received that graduate or professional students who have medical or religious objections to vaccines be exempted from vaccine policies set forth by the Department. It would be inequitable and unfair for students placed in healthcare facilities to not be subject to the same vaccine requirements as their colleagues. Furthermore, it places those vulnerable to severe disease, especially people who may not be able to be vaccinated, at higher risk in the very place they have come seeking medical help – their healthcare facility. It is a person’s choice whether to be vaccinated or not; it is through the Department’s authority that vaccines are required to protect workers, patrons, and students alike. If a post-graduate student is interested in working in the healthcare industry, he or she must comply with all policies of the employing institution – today, those policies happen to include vaccine policies. *This comment will not be accepted at this time.*

Public comment was received stating that all healthcare workers should be vaccinated and there should be no masking option unless a medical or religious exemption applies. Rhode Island is in a very different stage of the COVID-19 pandemic than we were when we identified our first case or even several months ago. COVID-19 is becoming more endemic and there are ample ways for the public to protect themselves (vaccine, masks) and treatment is widely available. The Department maintains that getting vaccinated is the best way to protect oneself and others and that healthcare workers have a duty to protect the patients they serve; however, there are other ways to protect patients such as wearing N95 masks. *This comment will not be accepted at this time.*

Public comment was received opposing the vaccine mandate being lifted; these commenters stated that lifting the COVID-19 vaccine requirement for healthcare workers amounted to rewarding employees who had shown blatant disregard for their patients. Furthermore, the State should use the National Guard to fill staffing shortages if necessary. Rhode Island is in a very different place with the pandemic and there are numerous ways to control COVID-19 infection now. There are widely available treatments. Additionally, only a small subset of National Guard members are medical professionals who could assist with the staff shortage. *This comment will not be accepted at this time.*

Public comment was received that vaccines do not prevent infection or transmission, and everyone should have to mask during an outbreak. Additionally, the vaccines do not protect against hospitalization, and they should not be seen as the ‘miracle cure’ all for COVID-19. While no vaccine is 100% effective against transmission or infection, they do dramatically reduce transmission. Data also show that the COVID-19 vaccines do substantially protect against severe illness and death. During an outbreak, vaccinated healthcare workers can choose to wear a mask to further protect themselves and patients. *This comment will not be accepted at this time.*

Public comment was received questioning the six percent of healthcare workers who are not accounted for in an article that quoted the Department’s spokesperson, Joseph Wendelken, that said, “roughly 94 percent of Rhode Island’s healthcare workforce is vaccinated.” As healthcare workers can include both licensed and unlicensed individuals it is difficult to determine the exact vaccination rate of Rhode Island healthcare workforce. These numbers came from comprehensive surveys sent out to healthcare facilities and healthcare workers. Furthermore, the six percent could include healthcare workers with medical exemptions, religious exemptions, or those who only provide telehealth.

Public comment was received questioning why unvaccinated and vaccinated healthcare workers are being treated differently when evidence shows both can transmit the virus. Vaccinated healthcare workers could transmit the virus, but at much lower rates than unvaccinated healthcare workers. Furthermore, the proposed regulations will become permanent minimum standards. In the event of an outbreak or rise in transmission rates, the Department has the authority to issue emergency regulations to require masking of everyone.

Public comment was received demanding that any healthcare worker who was fired due to not receiving the COVID-19 vaccine be reinstated with backpay. This is beyond the scope and authority of the Department. *This comment will not be accepted at this time.*

Public comment was received that masking only unvaccinated nurses makes zero sense as even with 100% vaccination there are still COVID-19 outbreaks. This proposed regulation is not the sole regulation for masking, just in relation to vaccination

status. In the event of high transmission or high hospitalization rates or periods, the Department can issue additional regulations.

Public comment was received that there should be a vaccine mandate and that there is no guarantee unvaccinated healthcare workers will wear a mask when required. Reports and complaints of non-compliance can be sent to the Department's complaint line.

Public comment was received asking to have these regulations apply to all Department licensed providers, including massage therapists, as they are in close contact with patients. The scope of the regulation is to cover healthcare workers in healthcare facilities. If a massage therapist works in a healthcare facility, he or she is required to follow this regulation. *This comment will not be accepted at this time.*

Public comment was received stating that the new proposed regulations are an admission by the Department that the emergency COVID-19 vaccine mandate was a failure. The COVID-19 vaccine mandate for healthcare workers and healthcare providers was not a failure. Through auditing, the Department was able to determine there was 100% compliance among healthcare workers and 94% compliance among healthcare providers. Additionally, Rhode Island is in a different position than when the emergency regulations were first issued: cases have fallen; vaccine administration is high; and hospitalizations are down. The new regulation is demonstrating the shift from a pandemic to an endemic.

Public comment was received stating that the new regulation would result in new costs for healthcare facilities via an unfunded mandate that requires "an adequate supply of medical masks or higher grade N95 masks" be provided at no charge to healthcare workers. Healthcare facilities are already required to provide personal protective equipment (PPE) to their employees, and PPE cost is accepted as a general cost of doing business. While this requirement will cost healthcare facilities some marginal amount of expense, facilities concerned about these costs have the capability to adopt policies that would affect the total volume of such charges.

Public comment was received providing a summary of a presentation titled "Nuremburg 2.0 in America – It Is Time" by Ohio Attorney Tom Renz. The summary of the presentation includes data regarding deaths of Medicare patients but does not include data sources. RIDOH's subject matter experts disagree with the conclusions presented in the presentation.

Public comment was received opposing the requirement of having healthcare workers receive a COVID-19 vaccine because they are "bioweapons." The COVID-19 vaccine is not a bioweapon.

Public comment was received asking to see the report that has been sent to the CDC from the Department. Public comment is for commenting on the proposed regulations. Public information requests are handled in a separate process.

Public comment was received stating that COVID-19 has a 99.997% survival rate. This statement is inaccurate. The survival rate of COVID-19 is based upon several factors such as age, race, sex, and underlying health conditions. Additionally, COVID-19 can cause lasting health conditions, known as long COVID.

Public comment was received asking why cases rose after COVID-19 vaccines were available. Vaccines are the best way to protect oneself and others, however no vaccine is 100% effective. The more people who receive a COVID-19 vaccine, the harder it becomes for the virus to spread; vaccines become more effective once herd immunity, meaning when a large portion of the population is immune to a specific disease, is reached. Cases were rising at the same time that COVID-19 vaccines became available in Rhode Island. Initially, supply was limited and this impacted the speed of the vaccine roll-out. In addition, variants of COVID-19 can occur that evade the currently available COVID-19 vaccines. Data shows that booster doses provide additional protection against severe illness and hospitalization. As such booster doses have been recommended.

Public comment was received asking why PCR (polymerase chain reaction) tests are still being used when the “CDC stated on July 26, 2021, they would no longer be valid and recognized method for testing.” This is false information; the CDC issued no such statement. PCR testing is the accepted method for confirming COVID-19.

Public comment was received stating that the FDA’s 2017 guidance on emergency use authorization (EUA) products indicate that individuals can refuse ‘the shots.’ An individual can refuse medication for any reason; however, a refusal of medication can come with consequences.

Public comment was received stating that the vaccine breaks all of the ethics of the Nuremburg Code. All available COVID-19 vaccines were developed and tested under strict research requirements. There is no evidence to suggest, nor did the commenter provide, any evidence to demonstrate that vaccines violated research ethics codes.

Public comment was received stating that the exclusion criteria in each of the clinical trials should also be considered for taking the shots. This statement is misleading. Clinical trials are conducted in various stages. Clinical trials start in small and homogenous groups at first; as long as the results are relatively positive, the sample pool is expanded to more diverse groups. The most vulnerable groups, such as pregnant individuals and children, are some of the last groups to be tested. There are multiple safeguards that occur during clinical trials and the evidence is clear that all of the COVID-19 vaccines are safe.

Public comment was received stating there is no danger with COVID-19 but there is ‘proven’ danger from the COVID-19 shots. COVID-19 is the cause of nearly 1 million deaths in the past two years and 11,000 hospitalizations. COVID-19 can also have lasting negative health effects, known as long COVID. Meanwhile, the COVID-19

vaccine has been extensively proven to be safe and effective; and no one has died or been hospitalized solely due to receiving a COVID-19 vaccine.

Public comment was received stating that the Department should adopt the Centers for Medicare and Medicaid Services (CMS) mandate. The CMS mandate requires that all CMS-certified facility employees must have received the primary series of a COVID-19 vaccine (i.e., two doses of Moderna or Pfizer, or one dose of Johnson & Johnson). CMS-certified facilities are still required to comply with the CMS requirement. The proposed regulation provides two options for healthcare workers and facilities to comply. Furthermore, the final regulation is the minimum standard and a healthcare facility can choose to implement a more stringent policy regarding COVID-19 vaccine requirements.

Public comment was received stating the definition of "up to date" was unclear and appears to necessitate multiple boosters through the use of the plural 'dose(s).' The definition used is the term used by the CDC and accounts for the likelihood of the COVID-19 vaccine requiring additional boosters, or perhaps become an annual vaccine requirement.

Public comment was received stating that by requiring boosters, the proposed regulation will impact facilities' ability to recruit and retain staff for critical care positions. The regulation only requires healthcare workers to wear an N95 mask when the transmission rate is substantial (or higher) if they are not up to date with a COVID-19 vaccine. The Department believes this is a reasonable alternative.

Public comment disagrees that the N95 masking alternative is the proper alternative to a booster. The Department has determined that public understanding, acceptance, and compliance is best served with this approach.

Public comment was received stating that facilities should have flexibility in their masking policy and that the Department should approve individual facility or industry-based masking criteria. RIDOH has developed FAQs for nursing homes and assisted living residences that contain information on masking. See: NH FAQ_En_04122022_FINAL.pdf (ri.gov) Smaller facilities do not have the resources to develop and document evidence of robust masking policies. Furthermore, public understanding, acceptance, and compliance is best served with this approach.

Public comment was received stating that the penalties should be revised to be similar to CMS with opportunities to correct the action before revoking a license. The severity of the action will determine the severity of the consequence and the likelihood of revoking licensure based on a first offense is incredibly rare. Furthermore, there are opportunities to appeal a Department decision which are detailed in the Department regulation, Practices and Procedures before the Rhode Island Department of Health (216-RICR-10-05-4).

Public comment was received stating the definition of “up to date” conflicts with the CMS final rule on COVID-19 vaccination and requests alignment. The CMS final rule (CMS 3415) uses the term “vaccinated” which only includes the primary series. The term “up to date” comes from the CDC and is an evergreen definition that accounts for boosters and potential annual vaccination requirement. The CDC is the nation's top public health agency and is considered the subject matter expert for vaccines; as the Department is a public health agency, the Department aligns itself with the CDC. *This comment will not be accepted at this time.*

Public comment was received stating that the N95 masking requirements do not consider Occupational Safety and Health Administration (OSHA) respiratory fit testing standards required for healthcare facilities and fail to provide alternative masking options. 29 C.F.R. § 1910.134 Appendix A (OSHA Fit Testing Procedures) states “[T]he test subject shall be allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.” The proposed regulations require healthcare workers who are not up to date to wear an N95 mask when the transmission rate is substantial. For individuals who choose to wear an N95 mask, OSHA requires the employer to provide a selection of options for the individual to choose from that is suitable to his or her needs.

Public comment was received stating that the regulation lacks specificity regarding to whom and when masking is mandated. As stated in the regulation, masking is required for any individual who is not up to date with their COVID-19 vaccine and only when transmission rates are substantial or higher.

Public comment was received stating the regulation does not address N95 masking supplies. The Department is unaware of any supply chain issues that would prevent a healthcare facility from ordering N95 masks. Furthermore, in the event there are supply chain issues or there is difficulty for a healthcare facility to get N95 masks, the healthcare facility should contact the Department.

Public comment was received stating that the implementation of seven days is not sufficient time for fit testing all affected employees. As there is an existing emergency regulation with an identical requirement, healthcare facilities should already be complying with the regulation. Furthermore, the regulation becomes effective 20 days after signing; factoring in that the regulation cannot be enforced until seven days after the effective date, healthcare facilities will have almost 30 days to implement the regulation from the time that the Department submits its final version of the regulation. *This comment will not be accepted at this time.*

Public comment was received stating that the regulation does not address or provide alternatives for healthcare workers who fail medical clearance to undergo fit testing or fail fit respiratory testing. It is highly unlikely that an individual would fail medical clearance, and, furthermore, that determination would be made by a physician. Per 29 C.F.R. § 1910.134, an individual must undergo a medical evaluation prior to fit testing.

During the medical evaluation, the physician will determine the type of respirator the individual will wear and if any activity is restricted while wearing a respirator (e.g., break intervals, duration). If an individual is medically approved to wear an N95 but does not properly fit during the fit test, then the employer is only obligated to offer a different N95 model or size.

Public comment was received stating the definition of healthcare worker is too broad and requires staff who are not directly involved in patient care to wear an N95 mask. The comment further states that the masking requirement does not include any patient contact-specific language, nor does it address when during the day the N95 mask can be removed by staff (e.g., eating, drinking, etc.). The Department acknowledges this comment and has added clarifying language to § 7.6.1(B)(2).

Public comment was received stating that the Department should be aware that the reversal of a COVID-19 vaccine mandate puts health centers at a disadvantage in recruiting and retaining staff as individuals who do not want to be vaccinated can instead go into private practice. The regulation is not a reversal; but rather provides more options for healthcare workers. Additionally, individuals who do not want to be vaccinated can be employed by a healthcare facility, provided that an N95 mask is worn during a period of substantial transmission; in this way, the regulation re-aligns opportunities offered at health centers and private practices.

Public comment was received asking for clarification if private practices are bound by the proposed regulations. The current regulations apply to healthcare facilities and healthcare workers. They do not apply to private practice offices.

Public comment was received asking if healthcare workers with two doses but not the booster will be required to mask. It depends. If the healthcare worker has recently received his or her second shot, then he or she would be considered up to date. After six months from the second shot, the healthcare worker would need a booster dose or would not be considered up to date. If the healthcare worker were not up to date and the transmission rate were substantial or higher, the healthcare worker would be required to mask until the booster dose was received (unless the transmission rate dipped below substantial).

Public comment was received asking for confirmation that no mask is required when COVID-19 is not widespread regardless of vaccination status. An N95 mask is required when COVID-19 transmission is substantial (50 cases per 100,000 people per week) or higher and a healthcare worker is unvaccinated. If there are COVID-19 fewer than 50 cases per 100,000 people over the most recent seven-day period, then an N95 mask is not required.

Public comment was received asking if unvaccinated individuals, such as those with medical exemptions, will now be subject to higher level of masking. The regulation requires all healthcare workers who are not up to date to wear an N95 mask during a period of substantial or higher transmission.

Public comment was received asking if those with medical exemptions would need to mask when there are periods of widespread COVID-19. Healthcare workers with medical exemptions would be required to wear an N95 mask when the COVID-19 transmission rate is substantial or higher, just as all healthcare workers who are not up to date would be required to do.

Public comment was received noting substantial transmission seems quite low, resulting in healthcare workers being nearly perpetually masked. The CDC recommends that healthcare workers in healthcare facilities wear masks during this transmission period to provide source control and protect patients. Additionally, it may be difficult for us to recall what it was like when Rhode Island was routinely less than substantial, but that standard will certainly be achieved soon.

Public comment was received there is no mention of testing requirements for COVID-19. Testing for COVID-19 is still required for certain healthcare facility types, and the public is directed to the specific regulations of the healthcare facility types in order to understand the rules applying to that type. Testing guidance for nursing homes and assisted living residences is available here: Overview of Point-of-Care COVID-19 Testing Guidance for Nursing Homes and Assisted Living Facilities (ri.gov).

Public comment was received stating there is no mention how medical exemptions will be handled. No healthcare worker with a medical exemption is required to receive the COVID-19 vaccine (or any other vaccine) and as such they would be required to wear an N95 mask when the COVID-19 transmission rate is substantial.

Public comment was received stating that "during the original mandate, individual healthcare facilities were allowed to develop their own policies in relation to COVID-19." The comment further asks if the Department's regulations supersede individual facilities' policies. The Department's regulations are minimum standards that must be followed by all licensed healthcare facilities. A healthcare facility is permitted to be more stringent than the Department's regulations.

Public comment was received asking "if there is another severe wave [of COVID-19] will individuals [be] allowed to return to work with masking then be subject to loss of their employment again." *The Department is not able to opine on hypothetical circumstances.*

Public comment was received requesting that home care, home nursing care, and hospice providers be exempted from the definition of "healthcare facility." The Rhode Island General Assembly has designated home care, home nursing care, and hospice as healthcare facilities by statute (R.I. Gen. Laws Chapter 23-17), which the Department has no authority to affect. Furthermore, even if the Department could somehow exempt home care, home nursing care, and hospice from the definition of "healthcare facility," they are still bound by CMS's requirements, which include healthcare workers to have received a primary series of COVID-19 vaccinations. *This comment will not be accepted at this time.*

Public comment was received requesting regulatory exemptions for operational staff as they do not interact with patients. The regulation does exempt staff who do not interact with patients from its requirements.

Public comment was received questioning the authority the Department's Director that would supersede the authority of the Governor to determine a "declaration of widespread flu" without an executive order by the Governor declaring an emergency. The declaration of widespread flu is not a declaration of an emergency, in a statutory sense. In order to declare widespread flu, the Director looks at data and metrics from the CDC and, if they meet certain thresholds, flu is considered widespread and masks are required for unvaccinated healthcare staff. The Director's authority to issue a statement that declares when flu is widespread is derived from R.I. Gen. Laws § 23-1-1, which authorizes the Department to "mak[e] investigations into the causes of disease, the prevalence of epidemics and endemics among the people…and do all in its power to ascertain the causes and the best means for the prevention and control of diseases or conditions detrimental to the public health and adopt proper and expedient measures to prevent and control diseases and conditions detrimental to the public health in the state." Note that the capacity in question is rather narrow: (i) at a certain time (or times) during the year, the Director issues a public statement about the prevalence of influenza; (ii) if the Director makes such a statement, healthcare workers treating patients must be vaccinated against the flu to continue working maskless; and (iii) if unvaccinated and/or not getting vaccinated, these workers must mask in the presence of patients to remain in good standing as a licensed professional. Note also that the declaration of a gubernatorial state of emergency has the power to affect each and every person in the State of Rhode Island for up to six months at a time.

Public comment was received stating that the definition of "up to date" is vague as it relates to a schedule of vaccination against COVID-19 and if the Department intended to include a schedule or defer to a federal authority with said schedule, then the Department should have published that schedule. The definition of up to date is from the CDC and the CDC provides the COVID-19 vaccine schedule, which can be found here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

Public comment was received inquiring if the Department intends to review and revise the definition of up to date to include a timeline of post-recovery natural immunity or defer to a federal authority with a natural immunity schedule. There are currently no approved methods for determining titers for natural immunity or a timeline for how long natural immunity lasts. *The Department will consider such revisions when the data to substantiate findings become available.*

Public comment was received questioning if the Department anticipates that providers will have the resources to freely distribute higher grade masks and if the Department will maintain its stockpile to give to healthcare facilities. The Department's stockpile was intended to help the industry with the supply chain issues and is currently available for healthcare facilities to utilize. The Department does not anticipate keeping the stockpile

forever as N95 masks are able to be ordered and there are no current supply chain issues. If a healthcare facility has issues ordering N95 masks, the healthcare facility should reach out to the Department.

Public comment was received stating that by allowing healthcare workers to be vaccinated or wear a mask that the Department has conceded that it “maliciously, capriciously and inappropriately” enacted emergency regulations. The Department does not concede to having conducted itself in any such way. However, the Department does recognize that Rhode Island is moving out of a pandemic phase and into an endemic stage, and regulations and policies must be revised and updated appropriately to signal that the world is the process of adopting a new normal.

Public comment was received asking if the regulation allows for healthcare workers and employees of healthcare facilities who are not vaccinated at all or are not fully vaccinated to return to work or seek employment with a healthcare facility regardless of the employee’s intention to seek full vaccination. Healthcare facilities can hire healthcare workers who are not up to date on their COVID-19 vaccinations (i.e., unvaccinated and/or unwilling to secure vaccinations) provided that the healthcare worker wears a mask when the transmission rate is substantial or higher. Please be advised that CMS still requires employees of CMS-certified facilities to have the COVID-19 primary series.

Public comment was received that the Department is better equipped to determine vaccination status of healthcare employees than the healthcare facility and as such should take on the administrative responsibility of determining the vaccination status of all healthcare facilities’ employees instead of the facilities themselves. The Department does not license all healthcare workers and as such the Department would not be able to verify a significant portion of healthcare workers – these are individuals over whom the Department has jurisdiction because of where they work, not because of what they do. Furthermore, licensure cycles will not always match up with the up-to-date vaccine schedule, making it difficult for the Department to determine compliance. *This comment will not be accepted at this time.*

Public comment was received asking if the Department would request the Executive Office of Health and Human Services to promulgate similar regulations for personal care attendants and individual providers. The Department does not have legal authority to license or regulate personal care attendants (PCAs) or individual providers (IPs). EOHHS has regulations related to client self-directed long-term home care (210-RICR-50-10-2) that discuss both PCAs and IPs. While these regulations require PCAs/IPs to have both a criminal background check and a driver’s license, no immunization requirements currently exist. Per R.I. Gen. Laws § 42-35-6, the author of this comment may petition EOHHS to promulgate rules and regulations regarding this subject matter.

Public comment was received requesting that the regulation include emergency medical technicians (EMTs), EMT-Cardiacs, and Paramedics into the regulation. The scope of the regulation is to provide vaccination requirements for those professionals defined as healthcare workers. EMTs, EMT-Cardiacs, and Paramedics are not covered under the regulation unless they meet the definition of healthcare worker—that is, unless they are employed by healthcare facilities. However, a town/city may adopt more stringent rules and regulations for its own workforce than the State has; any municipality has the authority to require its own EMTs, EMT-Cardiacs, and Paramedics to be vaccinated.

Public comment was received requesting that the regulation be updated to require all healthcare workers be up to date with the COVID-19 vaccine series. The Department has determined that, given all of the attendant circumstances related to the COVID-19 pandemic, it will proceed with final promulgation of these regulations as written.

CHANGES TO THE TEXT OF THE RULE:

§ 7.4(A)(3) created definition of "assisted living residences"

§ 7.4(A)(4) created definition of "assisted living residence worker"

§ 7.4(A)(6) removed "assisted living residences" from the definition of health care facility.

§ 7.6.1(B)(2) permitted N95 masks to only be worn when in direct patient contact or in a patient care area.

§ 7.6.1(B)(3) added in reference to federal requirement for COVID-19 vaccination.

§ 7.9(A)(1) remove reference to testing requirements.

§ 7.9(A)(2) and (3) remove assisted living residences.

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

1) Alternative approaches;

2) Overlap or duplication with other statutory and regulatory provisions; and

3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.