216-RICR-20-15-7

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 20 – COMMUNITY HEALTH

SUBCHAPTER 15 – INFORMATION FOR HEALTH CARE PROFESSIONALS

PART 7 - Immunization, Testing, and Health Screening for Health Care Workers

7.1 Purpose

These Regulations establish requirements for adopting standards for immunization and communicable disease screening and testing for health care workers prior to employment in Rhode Island-licensed health care facilities.

7.2 Authority

These Regulations are promulgated pursuant to the authority conferred under Chapters 23-17 and 23-17.7.1 of the General Laws of Rhode Island.

7.3 Incorporated Materials

- A. These Regulations hereby adopt and incorporate the Centers for Disease Control and Prevention (CDC) General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR, Recommendations and Reports (January 2011) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations. https://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf.
- B. These Regulations hereby adopt and incorporate the CDC Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (November 2011) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations. https://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf.
- C. These Regulations hereby adopt and incorporate the CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings MMWR, Recommendations and Reports (December 2005) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm

D. These Regulations hereby adopt and incorporate the Occupational Safety and Health Administration (OSHA) Blood Borne Pathogens Standard (29 C.F.R Parts 1910 - 1030), (April 2012) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

7.4 Definitions

- A. Wherever used in these Regulations, the following terms shall be construed as follows:
 - 1. "Advance practice registered nurse" or "APRN" means an individual licensed in accordance with R.I. Gen. Laws § 5-34-45.
 - 2. "Advisory Committee on Immunization Practices (ACIP) recommendations", as used in these Regulations, means official Federal recommendations for the use of vaccines in the United States and as published by the Centers for Disease Control and Prevention. ACIP recommendations represent the standard of care for immunization practice in the United States.
 - 3. "Assisted living residence" means as defined in R.I. Gen. Laws § 23-17.4-2(4).
 - 4. "Assisted living residence worker" means any person who is temporarily or permanently employed by the assisted living residence, or who serves as a volunteer in an assisted living residence, or any person who is compensated by a third (3rd) party that has an agreement with the assisted living residence to provide staffing services and has or may have direct contact with a patient in that assisted living residence. This may include. but not be limited to students and trainees, contractual staff not employed by the assisted living residence; other health care providers, including those who have privileges at, but are not employed by, the assisted living residence; and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted from person to person. This term shall not apply to a residence's family member or friend who visits or otherwise assists in the care of that patient in an assisted living residence.
 - 5. "Department" means the Rhode Island Department of Health.
 - 6. "Direct patient contact" means any routinely anticipated face-to-face interaction with patients in a health care facility.

- 7. "Director" means the Director of the Rhode Island Department of Health or his or her designee.
- 8. "Healthcare facility", as used herein, means a facility as defined in R.I. Gen. Laws § 23-17-2(9), as well as adult daycare programs, as defined in R.I. Gen. Laws § 23-1-52 and stations, as defined in R.I. Gen. Laws § 23-16.2-2.
- 9. "Healthcare worker" means any person who is temporarily or permanently employed by a health care facility, or who serves as a volunteer in a health care facility, or any person who is compensated by a third (3rd) party that has an agreement with the health care facility to provide staffing services, and has or may have direct contact with a patient in that health care facility. This may include, but not be limited to, a physician, physician assistant, nurse, nursing assistant, therapist, technician, clinician, behavioral analyst, social worker, occupational, physical or speech therapist, phlebotomist, emergency medical service personnel, dental personnel, pharmacist, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility; other health care providers, including those who have privileges at, but are not employed by, the health care facility; and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted from person to person. This term shall not apply to a patient's family member or friend who visits or otherwise assists in the care of that patient in a health care facility.
- 10. "Nurse" means an individual licensed in this State to practice nursing pursuant to the provisions of R.I. Gen. Laws Chapter 5-34.
- 11. "Period in which flu is widespread" means a period that commences when the Director declares that there is an outbreak of influenza that is widespread within a facility, or within a defined geographic area in which the facility is located, or throughout Rhode Island; and that ends when the Director declares to such a health care facility or facilities that the outbreak is no longer widespread.
- 12. "Physician" means an individual licensed under the provisions of R.I. Gen. Laws Chapter 5-37.
- 13. "Physician assistant" means an individual licensed in this State to practice as a physician assistant pursuant to the provisions of R.I. Gen. Laws Chapter 5-54.
- 14. "Practitioner" means a physician, advance practice registered nurse, registered nurse, licensed practical nurse, or a physician assistant.

- 15. "Pre-employment health screening" means the review of health records, pertinent laboratory results, and other documentation of a health care worker performed by a licensed practitioner in order to determine that the health care worker is free of the communicable diseases cited in these Regulations, and is also appropriately immunized, tested, and counseled prior to employment.
- 16. "Up to date" means a person has received all recommended doses of a COVID-19 vaccine, including any booster dose(s), when eligible.

7.5 General Requirements

- A. Healthcare facilities shall adopt, at a minimum, the standards of immunization and communicable disease testing and standards for health screening contained herein.
- B. It shall be the responsibility of the administrative head, or his or her designee, of any healthcare facility to secure compliance with these Regulations.
- C. Each healthcare facility shall develop policies, procedures, and/or protocols for compliance with the requirements described in these Regulations.
- D. Transient employees or outside contractors who are not involved in direct patient contact and are not potentially exposed in the course of employment to infectious agents that can be transmitted from person to person, are exempt from the requirements stated in these Regulations.
- E. Healthcare facilities and healthcare workers shall comply with additional immunization and screening requirements that the Director may prescribe from time to time to control communicable diseases.
- F. Persons discovering communicable diseases (e.g., physicians, physician assistants, registered nurse practitioners), in the process of screening health care workers shall comply with the reporting requirements contained in Part 30-05-1 of this Title.
- G. In accordance with ACIP recommendations, for all vaccines discussed in these Regulations, vaccine doses administered less than or equal to four (4) days before the minimum interval or age shall be counted as valid. Doses administered five (5) or more days earlier than the minimum interval or age shall not be counted as valid doses and shall be repeated as age-appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval as provided in § 7.3(A) of this Part.
- H. Healthcare workers who receive the first (1st) dose of a multi-dose vaccine series may begin to work after this first (1st) dose is received.

I. Each healthcare facility shall provide, at no financial charge, an adequate supply of medical masks or higher-grade masks (e.g., N95) to any health care worker.

7.6 Minimum Standards for Immunization and Communicable Disease Testing for Health Care Workers

- A. A pre-employment health screening shall be required for each healthcare worker involved in direct patient contact. Acceptable evidence shall be provided by the healthcare worker that testing and/or immunization for the communicable diseases listed in these Regulations for pre-employment health screening have been completed.
- B. The healthcare facility shall document, in written or electronic form, that said acceptable evidence has been provided by the healthcare worker and validated by the practitioner as being acceptable in accordance with § 7.7 of this Part. Copies of said acceptable evidence shall be maintained in the healthcare worker's file.
- C. A practitioner shall have responsibility for performance of the pre-employment health screening. Such a practitioner may be an employee of the facility where employment is sought or may be an independent non-employee, contracted practitioner.
- D. A healthcare worker who is not in compliance with these requirements shall be excluded from attending patients in a healthcare facility until the requirements are met.

7.6.1 Immunization and Testing Requirements

- A. In accordance with the guidelines set forth in § 7.3(B) of this Part, evidence of immunity is required for all healthcare workers (except for healthcare workers who receive a medical exemption) against:
 - 1. Measles, Mumps and Rubella
 - a. Pre Employment: Two (2) doses of MMR (measles-mumps-rubella) vaccine. Alternatively, two (2) doses of a live measles-containing vaccine, two (2) doses of a live mumps-containing vaccine and one (1) dose of a rubella vaccine. The first (1st) dose of vaccine must have been administered on or after the first (1st) birthday. The second (2nd) dose of a measles or mumps containing vaccine must be administered at least four (4) weeks after the first (1st) dose. or
 - b. Laboratory evidence of immunity or laboratory confirmation of disease (i.e., laboratory report of positive lgG titers for measles, and mumps and rubella). An equivocal laboratory result for

- measles, mumps and/or rubella are considered negative and vaccination is required.
- c. Current Healthcare Workers. For unvaccinated health care workers born before 1957 who lack laboratory evidence of measles immunity or laboratory confirmation of disease, two (2) doses of MMR vaccine is recommended.
- d. Outbreak Control. For unvaccinated healthcare workers born before 1957 who lack laboratory evidence of measles immunity or laboratory confirmation of disease, health-care facilities shall require two (2) doses of MMR vaccine during an outbreak of measles.

2. Varicella (Chickenpox)

- a. Two (2) doses of varicella vaccine. The second (2nd) dose of varicella vaccine must be administered at least four (4) weeks after the first (1st) dose; or
- b. Laboratory evidence of immunity or laboratory confirmation of disease; or
- c. A healthcare provider diagnosis of varicella or healthcare provider verification of history of varicella disease; or
- d. History of herpes zoster based on healthcare provider diagnosis.
- 3. Tetanus, Diphtheria and Pertussis (Whooping Cough)
 - a. Pre-employment: One (1) single dose of Tdap (tetanus-diphtheriapertussis) vaccine is required for all healthcare workers who have not previously received a dose of Tdap vaccine.
 - b. Effective 1 January 2014: This requirement shall apply to current employees, as well as new employees.

4. Annual Seasonal Influenza

- a. Annual influenza vaccination is required for all healthcare workers, subject to § 7.8(F) of this Part.
- b. Each healthcare facility shall develop a specific plan to require annual influenza vaccination of all health care workers in a timely manner in keeping with ACIP guidelines, and at no cost to the health care worker.

- c. Each healthcare facility shall maintain an active surveillance program to track and record influenza vaccination levels among healthcare workers, including vaccinations obtained outside of the formal healthcare facility program.
- d. Each healthcare facility shall be responsible for reporting to the Department:
 - (1) The number of healthcare workers who are eligible for vaccination:
 - (2) The number of healthcare workers who received vaccination; and
 - (3) The number of healthcare workers who decline annual influenza vaccination for medical or personal reasons, reported by each of the two (2) categories.
 - (4) Such reporting shall occur according to procedures and format required by the Department.

5. Tuberculosis (TB)

- a. Pre-employment: Evidence that the healthcare worker is free of active tuberculosis based upon the results of a negative two (2) step tuberculin skin test shall be required.
 - (1) If documented evidence is provided by the healthcare worker that a two (2) step tuberculin skin test, performed within the most recent twelve (12) months prior to hire, was negative, the requirements of this section shall be met. For healthcare workers who can present documentation of serial tuberculin testing with negative results in the prior two (2) years (or more), a single baseline negative tuberculin test result is sufficient evidence of absence of TB infection.
 - (2) A negative U.S. Food and Drug Administration (FDA)-approved blood assay for Mycobacterium tuberculosis (BAMT) may be used instead of a two (2) step tuberculin skin test. If the baseline BAMT is positive, screening should proceed as indicated below for positive PPD.
 - (3) Documentation shall include date and result of the tuberculin skin test (PPD), and reaction size in millimeters or an actual copy of the laboratory test result from a BAMT.
 - (4) If the PPD test or BAMT is positive, consistent with the most current CDC guidance, or a previous one is known to have

been positive, a physician's or other licensed practitioner's (acting within his or her scope of practice) certification that the health care worker is free of active disease shall be required. Such certification shall be based on documentation of adequate chemotherapy for TB disease or chemoprophylaxis for latent TB infection in the past, and a current history of freedom from signs and symptoms of TB. In the absence of documentation of chemotherapy or chemoprophylaxis, a negative chest x-ray shall be required for certification. The chest x-ray shall have been performed at any time after the most recent positive PPD test result.

(5) A physician, certified registered nurse practitioner, or a physician assistant may certify that the healthcare worker is currently free of TB based on his or her clinical judgment for complex cases or unusual circumstances that do not fit the above criteria.

b. Current Healthcare Workers

- (1) Periodic follow up testing of all healthcare workers must be based on the CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings incorporated above at § 7.3(C) of this Part.
- (2) Effective 1 January 2013, healthcare workers with newly detected latent TB infection (LTBI) at initial or periodic testing are required to be referred for care with intent to obtain treatment for latent TB infection. Referral of previously (prior to 1 January 2013) known LTBI for care is recommended.
- (3) Effective 1 January 2013, LTBI cases detected in healthcare workers must also be reported to the RI TB Program on standard reporting forms.

6. Hepatitis B Vaccination and Testing

- a. Healthcare facilities shall abide by the OSHA Blood Borne
 Pathogens Standard, incorporated above at § 7.3(D) of this Part
 including the offering of hepatitis B vaccination along with all
 recommendations for infection control training and provision of
 protective equipment to those healthcare workers at risk.
- An exposure control plan shall be in place in all healthcare facilities licensed by the Department, pursuant to the provisions of R.I. Gen. Laws Chapter 23-17.

- c. Employees at risk of exposure to blood-borne pathogens shall be offered hepatitis B vaccine within ten (10) days of employment.
 - (1) The hepatitis B vaccination series consists of three (3) doses of vaccine given as two (2) doses four (4) weeks apart followed by a third (3rd) dose five (5) months after the second (2nd) dose.
 - (2) It is recommended that testing for anti-HBs be performed one (1) to two (2) months after the last dose.
 - (3) Persons failing to develop a titer shall be offered a repeat three (3) dose series with follow up titers.
 - (4) Employees have the option of signing a standard OSHA declination form if they choose not to be vaccinated and should be counseled regarding risk.
- d. If the healthcare worker, upon hire, has written documentation of a full hepatitis B vaccine series administered in accordance with ACIP guidelines, testing for anti-HBs shall not be necessary. If the healthcare worker has a subsequent exposure to HBV, hepatitis B immunoprophylaxis should be administered following ACIP guidelines for a person who has been vaccinated, but the immune response is not known.
- B. In accordance with the guidelines set forth in § 7.3(B) of this Part, with respect to SARS-CoV-2 (COVID-19) vaccination, a healthcare worker or assisted living residence worker shall:
 - 1. Be up to date with all CDC recommended doses of FDA approved or authorized COVID-19 vaccine (e.g., Moderna, Pfizer, or Johnson & Johnson) or have received all recommended dose(s) of another COVID-19 vaccine approved by the Department (e.g., Novavax); or
 - 2. Wear an N95 mask at each healthcare facility or assisted living residence during where he or she is employed or volunteering, or with which he or she is compensated by a third (3rd) party which has an agreement with the healthcare facility to provide staffing services during each direct patient contact or while in a patient care area in the performance of his or her duties when a period in which the COVID-19 prevalence rate in the State is greater than or equal to fifty (50) cases per one hundred thousand (100,000) people per week, as reported by the Department.
 - 3. In accordance with the Center for Medicaid and Medicare Services (CMS) 86 FR 61555, all Medicare and Medicaid certified providers, suppliers, and healthcare workers are required to receive the primary series (e.g., two (2))

doses of Pfizer or Moderna, or one (1) dose of Johnson & Johnson) of a COVID-19 vaccine.

7.7 Documentation of Immunity and Testing (Immunization Records)

- A. Acceptable documentation of completion of immunizations shall include the day, month, year and type/name of each dose of vaccine administered. The record of such evidence shall be signed by a practitioner (the signature of the healthcare worker is not acceptable).
 - 1. Acceptable documentation of completion of immunization consists of:
 - a. An official immunization record card, school immunization record, medical passport, World Health Organization immunization record, a copy of a medical record indicating administration of vaccine; or other official immunization records acceptable to the Director; or
 - b. An electronically stored and/or transmitted documentary record (facsimile transmission, computerized record, including, but not limited to, a record on magnetic media or similar record) as may be utilized by a school; or
 - c. Presentation of laboratory evidence of immunity is made in the case of measles, mumps, rubella, varicella, or hepatitis B.
- B. Each healthcare facility shall ensure the documentation in its internal records of the COVID-19 immunization status of its healthcare workers. With such documentation, each healthcare facility shall additionally maintain documentary proof of COVID-19 vaccination. Documentation of status and proof of vaccination, including month, day and year of vaccine administration shall be made available to the Department upon request.
- C. A healthcare facility and/or healthcare worker must provide documentation of immunization to the Department upon request.

7.8 Influenza Vaccination Refusal

A. Any healthcare worker may refuse the annual seasonal influenza vaccination requirements described in these Regulations; provided, however, that he or she provides proper annual written notice of such refusal prior to December 15 of each year to each healthcare facility in or at which he or she is employed or volunteering, or with which he or she has an employment contract; and provided, however, that he or she who so refuses shall be required during any declared period in which flu is widespread to wear a procedure mask or higher-grade mask (e.g., KN95 or N95) during each direct patient contact or while in a patient care area in the performance of his or her duties at any healthcare facility. For

healthcare workers licensed by RIDOH, compliance with this provision is part of his or her professional licensing obligations.

- 1. No healthcare worker shall be required to explain his or her refusal to obtain an annual seasonal influenza vaccination, nor shall any healthcare facility inquire into the basis of such refusal.
- B. Whenever the Director declares a period in which flu is widespread in a healthcare facility, within a defined geographic area, or throughout Rhode Island, the requirements in § 7.8 of this Part for wearing surgical face masks shall apply only to those nonimmunized healthcare workers at facilities or in geographic areas for which the period is declared.
- C. If the Director declares that a shortage exists for annual seasonal influenza vaccine, the Director shall be permitted to modify and/or suspend any requirement for some or all healthcare workers to obtain an annual seasonal influenza vaccination and/or any requirement for healthcare workers to wear surgical face masks in any healthcare facility; and shall be permitted to extend the deadlines in § 7.8(A) of this Part.

7.9 Violations

- A. Healthcare facilities, assisted living residences and healthcare workers and assisted living residence workers that violate any provisions of this Part are subject to administrative action by the Department, and any other action provided for under applicable law and Regulations, including R.I. Gen. Laws § 23-1-25, in addition to any action against the professional and/or facility license, as applicable.
 - 1. Healthcare facilities and assisted living residences shall have seven (7) days from the promulgation of this Part to implement measures necessary to ensure compliance with this Part.
 - 2. Healthcare facilities now covered by this Part (i.e., Adult Day Cares and Stations) shall have three (3) months from the promulgation of this Part to implement measures necessary to ensure compliance with vaccination documentation.
 - 3. Healthcare workers who are employed at newly covered healthcare facilities (i.e., Adult Day Cares and Stations) shall have three (3) months from the promulgation of this Part to receive all required vaccinations.

7.10 Severability

If any provision of these Regulations or the application thereof to any person or circumstances shall be held invalid, such invalidity shall not affect the provisions

or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.

216-RICR-20-15-7 TITLE 216 - DEPARTMENT OF HEALTH CHAPTER 20 - COMMUNITY HEALTH SUBCHAPTER 15 - INFORMATION FOR HEALTH CARE PROFESSIONALS PART 7 - IMMUNIZATION, TESTING, AND HEALTH SCREENING FOR HEALTH CARE WORKERS (216-RICR-20-15-7)

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