



**James R. Erwin**

Merrill's Wharf  
254 Commercial Street  
Portland, ME 04101

**P** 207.791.1237  
**F** 207.791.1350  
jerwin@pierceatwood.com  
pierceatwood.com

Admitted in: ME

November 19, 2021

Hon. Jon D. Levy  
United States District Court  
Edward T. Gignoux U.S. Courthouse  
156 Federal Street  
Portland, ME 04141

***Re: 1:21-cv-00242-JDL JANE DOES 1-6 et al v. MILLS et al***

Dear Judge Levy:

I am writing on behalf of all the Defendants in this case to provide to the Court the State of Maine's final rule relating to immunization requirements for healthcare workers. This rule became effective on November 10, 2021, and replaces the emergency rule that has been the subject of this litigation.

Sincerely yours,

/s/ James R. Erwin

James R. Erwin

Attachment

cc: Counsel of Record via CM/ECF System

**STATE OF MAINE**

**IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS**

**10-144 CODE OF MAINE RULES  
CHAPTER 264**



Maine Department of Health and Human Services  
Maine Center for Disease Control and Prevention  
11 State House Station  
Augusta, Maine 04333-0011

Date Amended: November 10, 2021

**10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES  
MAINE CENTER FOR DISEASE CONTROL AND PREVENTION**

**Chapter 264: IMMUNIZATION REQUIREMENTS FOR HEALTHCARE WORKERS**

---

**Purpose:** This rule is issued pursuant to the statutory authority of the Department of Health and Human Services to establish procedures for the control and prevention of communicable diseases and to require immunization of the employees of Designated Healthcare Facilities as set forth in 22 MRS §802. The purpose of the immunization requirements set forth in this rule is to reduce the risk of exposure to and transmission of vaccine-preventable diseases among healthcare workers, patients, and other members of the public in Designated Healthcare Facilities. Limiting transmission of vaccine-preventable diseases in Designated Healthcare Facilities also serves to reduce the risk of these diseases spreading throughout the general population. This rule prescribes the dosage for required immunizations; specifies the employees and certain contractors Designated Healthcare Facilities must exclude if the specified immunization requirements are not met; describes conditions under which unimmunized employees and certain contractors may be excluded by order of a Public Health Official, and defines recordkeeping responsibilities and reporting requirements for Designated Healthcare Facilities and their Chief Administrative Officers.

---

**SECTION 1. DEFINITIONS**

- A. **Certificate of Immunization** means a written statement from a physician, nurse, physician assistant or health official who has administered an immunization to an employee, specifying the vaccine administered and the date it was administered. Secondary school or collegiate health records, having been compiled and maintained as an official document based on certificates of immunization, which provide at a minimum the month and year that the immunization was administered and/or which contain copies of laboratory evidence of immunity, may also be accepted as proof of immunization.
- B. **Chief Administrative Officer** means the person designated as the president, chief executive officer, administrator, director or otherwise the senior official of a Designated Healthcare Facility.
- C. **Declination** means a formal process where an individual makes an informed choice declining Hepatitis B vaccination, following standards and procedures established by the federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR §1910.1030(f)(2)(iv) (effective July 6, 1992).
- D. **Department** means the Department of Health and Human Services.
- E. **Designated Healthcare Facility** means a licensed nursing facility, residential care facility, Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), multi-level healthcare facility, hospital, or home health agency subject to licensure by the State of Maine, Department of Health and Human Services Division of Licensing and Certification.

- F. **Disease** means the following conditions which may be preventable by immunization:
1. Rubeola (measles);
  2. Mumps;
  3. Rubella (German measles);
  4. Varicella (chicken pox);
  5. Hepatitis B.;
  6. Influenza; and
  7. COVID-19.
- G. **Employee** means, for purposes of this rule, any person who performs any service for wages or other remuneration for a Designated Healthcare Facility, including independent contractors. Persons who provide ad hoc, non-health care services for a Designated Healthcare Facility and have no potential for direct contact (clinical, hands-on, or face-to-face interaction) with staff, patients, or visitors of a Designated Healthcare Facility are not included in this definition of employee. For illustrative purposes only, these may include, but are not limited to, landscapers, snow plow operators, and delivery persons.
- H. **Exclusively work remotely** means to provide services while outside the physical premises of a Designated Healthcare Facility and have no direct contact (clinical, hands-on, or face-to-face interaction) with patients, visitors, and other employees.
- I. **Exemption** means a formal procedure to procure discharge from requirement to vaccinate.
- J. **Health Official** means, for the purposes of this rule, any person who is authorized to administer immunizations.
- K. **Immunization** means a vaccine, antitoxin, or other substance used to increase an individual's immunity to disease.
- L. **Public Health Official** means a local health officer, the Director of the Maine Center for Disease Control and Prevention (Maine CDC), or a designated employee or agent of the Maine Department of Health and Human Services (Department).
- M. **Public Health Threat** means a condition or behavior that can reasonably be expected to place others at significant risk of exposure to a toxic agent or environmental hazard or infection with a notifiable disease or condition, as defined in 22 MRS §801.

## SECTION 2. IMMUNIZATIONS REQUIRED

- A. Except as otherwise provided by law, each Designated Healthcare Facility in the State of Maine must require for all employees who do not exclusively work remotely a Certificate of Immunization, or Proof of Immunity, subject to Section 4(B) of this rule, against:
1. Rubeola (measles);
  2. Mumps;
  3. Rubella (German measles);
  4. Varicella (chicken pox);
  5. Hepatitis B;
  6. Influenza;
  7. COVID-19.
- B. In accordance with 29 CFR §1910.1030(f)(1)(i) (effective July 6, 1992) of the Occupational Safety and Health Administration (OSHA) regulations, Designated Healthcare Facilities must make available the Hepatitis B vaccine to all healthcare workers with a risk of occupational exposure, provided at no cost to the employee and at a reasonable time and place.
- C. No Chief Administrative Officer may permit any employee who does not exclusively work remotely to be in attendance at work without a Certificate of Immunization for each disease Proof of Immunity as described in Section 4(B) of this rule, or documentation of an authorized exemption or declination in accordance with 22 MRS § 802(4-B).

## SECTION 3. EXEMPTIONS

An employee who does not provide a Certificate of Immunization or Proof of Immunity, as described in Section 4(B) for a vaccine required under this rule may be permitted to attend work if that employee is exempt in accordance with 22 MRS § 802 (4-B), unless otherwise provided by law. Documentation for an employee's immunization exemption must be maintained in the permanent health record for that employee for a minimum of six years after termination.

## SECTION 4. CERTIFICATE of IMMUNIZATION and PROOF OF IMMUNITY

### A. Certificate of Immunization

To demonstrate proper immunization against each disease, an employee must present the Designated Healthcare Facility with a Certificate of Immunization from a physician, nurse or health official who has administered the immunization(s) to the employee. Physicians within their own practice may authorize their own employees to issue a certificate of immunization on behalf of the physician. The certificate must specify the immunization(s), and the date(s), including month and year, on which it was

administered. Physicians, having reviewed official patient records created by another practitioner which indicate that a particular patient has received an immunization on a specified date, demonstrating at a minimum the month and year the immunization was given, may certify that the immunization was given. Adequately prepared secondary and/or collegiate school health records will also be considered acceptable for the purpose of meeting this requirement.

**B. Proof of Immunity**

To demonstrate that an employee is immune to any of the diseases listed in Section 5(A)(1)-(5), the employee may present the hospital/facility Designated Healthcare Facility with laboratory evidence demonstrating immunity, or other acceptable evidence of immunity. (See Section 7(-B) Individual Health Records.) No Proof of Immunity is available for COVID-19 or Influenza.

**SECTION 5. IMMUNIZATION DOSAGE**

A. The following schedule contains the minimally required number of doses for the immunization(s) listed in Section 2(A) of this rule:

1. **Rubeola (Measles):** Two doses of live measles vaccine given after the first birthday, with a minimum of four weeks separating the two doses.
2. **Mumps:** Two doses of live mumps vaccine given after the first birthday.
3. **Rubella (German Measles):** Two doses of live rubella vaccine given after the first birthday.
4. **Varicella (Chickenpox):** Two doses of live varicella vaccine given after the first birthday, with a minimum of four weeks separating the two doses.
5. **Hepatitis B:** Fully completed series of either two or three doses of hepatitis B vaccine. If a two-dose series, then the second dose must be given one month after the first dose. If a three-dose series, the second dose must be given one month after the first dose and five months must separate the second and third doses.
6. **Influenza:** Annual dose of inactivated influenza vaccine or live attenuated influenza vaccine.
7. **COVID-19:** The number of recommended doses must be in accordance with the COVID-19 immunization manufacturer's Emergency Use Authorization or labeling.

B. Any such immunization must meet the standards for biological products which are approved by the United States Public Health Service.

## SECTION 6. EXCLUSIONS FROM THE HEALTHCARE SETTING

### A. Exclusion by order of Public Health Official

A Public Health Official may order a Chief Administrative Officer to exclude from the worksite an employee who has not been immunized when the employee's continued presence poses a clear danger to the health of others. The documented occurrence of a single case of rubeola (measles), mumps, rubella (German measles) varicella (chickenpox), or COVID-19 in a Designated Healthcare Facility or amongst its employees may be interpreted as a clear danger to the health of others.

The Chief Administrative Officer must exclude that employee during the period of danger, unless otherwise ordered by the Public Health Official.

### B. The following periods are defined as the minimum "period of danger:" for each disease listed below:

1. **Measles:** 15 days from the onset of symptoms from the last identified case
2. **Mumps:** 18 days from the onset of symptoms from the last identified case
3. **Rubella:** 23 days from the onset of symptoms from the last identified case
4. **Varicella:** 16 days from the onset of symptoms from the last identified case.

### C. There is no defined minimum period of danger for influenza, Hepatitis B, or COVID-19.

## SECTION 7. RECORD KEEPING, REPORTING, AND ENFORCEMENT

### A. Designated Record Keeping

The Chief Administrative Officer in each Designated Healthcare Facility must be responsible for the maintenance of employee immunization records. The Chief Administrative Officer may designate a person to be responsible for record keeping.

### B. Individual Health Records

Each Designated Healthcare Facility must adopt a uniform, health record for maintaining information regarding the health status of each employee. The immunization status of each employee with regard to each disease must be noted on the employee's health record. The health record of each employee must include, at a minimum, the month and year that each immunization was administered. Health records are to be retained a minimum of six years after the date the employee provided services.

Where an exemption has been granted for a reason authorized by law, the documentation supporting the exemption (including any information regarding the anticipated duration of the exemption) must be on file with the employee health record. Where Proof of Immunity has been accepted, a copy of the documentation must also be on file.

**C. List of Non-Immunized Employees**

The Chief Administrative Officer or his/her designee in each Designated Healthcare Facility must keep a listing for each disease of the employees who are not currently immunized and have not provided Proof of Immunity. This list must include the names of all employees with authorized exemptions from immunization as well as any who are otherwise not known to be immune and must state the reason that the employee is not immune. The purpose of the list is to provide an efficient means to rapidly contact non-immunized employees in the event of disease outbreaks and exclude them from the workplace as necessary.

**D. Required Reports**

The Chief Administrative Officer of each Designated Healthcare Facility is responsible for completing the Maine CDC's annual survey regarding the immunization status of all employees by December 15 of each calendar year. The survey will include the following information at a minimum:

1. Specific contact information identifying the facility;
2. The name of the Chief Administrative Officer;
3. The total number of employees; and
4. The number of employees identified by vaccine type as either being immunized, having demonstrated serological proof of immunity, having an exemption in accordance with law, having declined hepatitis B vaccine, or being out of compliance.

The survey results may be constructed so as to reflect meaningful data by groupings within the facility (e.g., pediatric unit). Each report must be signed by the Chief Administrative Officer as a certification that the information is accurate.

**E. Record Sampling and Review**

The Department will conduct periodic reviews of annual survey results by selecting samples of employee health records to compare against information reported by the Designated Healthcare Facility and to assess for compliance with this rule. The Department will share the results of this review with the Chief Administrative Officer of the Designated Healthcare Facility and/or their designees(s) for the purpose of identifying problems with recordkeeping or other compliance issues.

**F. Compliance Rates**

Compliance rates may also be made available to the public at the Department's discretion in accordance with 22 MRS §824.

**G. Enforcement**

If a Designated Healthcare Facility fails to correct violations identified by the Department or otherwise fails to comply with the requirements of this rule, the Department may take enforcement action pursuant to 22 MRS §804 or as otherwise provided by law.

STATUTORY AUTHORITY:

22 MRS §802

EFFECTIVE DATE:

April 16, 2002 – filing 2002-115 (*New*)

NON-SUBSTANTIVE CORRECTIONS:

May 13, 2002 - corrected the spelling of DEPARTMENT in header, page 1

May 10, 2004 - spacing, capitalization and punctuation only

EFFECTIVE DATE:

October 6, 2009 to January 4, 2010 - filing 2009-531 (EMERGENCY)

December 8, 2009 – filing 2009-644

April 14, 2021 – filing 2021-198 (ROUTINE TECHNICAL)

August 12, 2021 – filing 2021-166 (EMERGENCY ROUTINE TECHNICAL)

November 10, 2021 – filing 2021-226 (ROUTINE TECHNICAL)