

Please be advised that the following does not constitute the official version of this regulation. As is the case with all state regulations, official versions are available from the Secretary of the Commonwealth's State Publications and Regulations Division, through the State Bookstore. For the official version, contact the State Bookstore in Boston at (617) 727-2834.

105 CMR: Department of Public Health

105 CMR 222.000: Massachusetts Immunization Information System

222.001: Purpose

222.002: Scope

222.003: Definitions

222.100: Health Care Provider Immunization Information Reporting

222.105: Duty to Inform

222.200: Provider Enrollment

222.205: System Access and Confidentiality

222.300: Requests to Amend Records and Access Records by Individuals

222.305: Requests for List of Those Who Have Accessed Records

222.400: Compliance Schedule

222.001: Purpose

The purpose of 105 CMR 222.000 is to facilitate and promote the use of the Massachusetts Immunization Information System (MIIS) to help improve immunization coverage among all individuals in the Commonwealth.

222.002: Scope

105 CMR 222.000 applies to all health care providers licensed in the Commonwealth who administer immunizations in Massachusetts to any person, whether or not that person is a resident of the Commonwealth, and any entity that accesses the MIIS.

222.003: Definitions

Department means the Massachusetts Department of Public Health.

Electronic Data Exchange means the electronic interchange of information or data using a standardized format that allows one entity to send information to another electronically rather than with paper.

EHR means an electronic health record.

GUI means a web-based graphical user interface.

Health Care Provider means a health care professional who administers immunizations and is licensed under M.G.L. c. 112 and pharmacists authorized by 105 CMR 700.004 (B)(6) to dispense vaccine by administration.

Immunization means a vaccine or immunoglobulin, identified on a list maintained by the Department that introduces active or passive immunity to a specific disease or group of diseases.

MIIS means the Massachusetts Immunization Information System.

MIIS Fact Sheet means the MIIS Fact Sheet for Parents and Parents

MRVRS means the Massachusetts Registry of Vital Records and Statistics.

Objection to Data Sharing means an individual's immunization information will be accessible only to Department staff and the provider that entered the immunization information.

Objection Form means a mechanism as determined by the Department by which an individual may indicate an objection to sharing immunization information across providers that access the MIIS.

VIS means Vaccine Information Statements, which are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives the risks and benefits of a vaccine.

VFC means the federal Vaccines For Children Program.

222.100: Health Care Provider Immunization Information Reporting

- (A) Health care providers shall report all new immunizations either through the GUI or by data exchange within seven days of immunization administration.
- (B) Health care provider sites that perform data exchange shall comply with all electronic data exchange specifications required by the Department.
- (C) Health care provider sites performing electronic data exchange shall send complete immunization records with all new immunizations being reported to the system. If sites are unable to send complete records, they may perform a one-time historical upload of records into the MIIS in a form and manner determined by the Department.
- (D) Data for each individual reported through the GUI shall include at a minimum:
 - (1) For both current and historical immunizations, the full first and last name and date of birth of the individual, immunization type, and date of immunization administration;
 - (2) For current immunizations, VFC status, individual's current home address, immunization manufacturer and lot number, name, address, and title of the person administering the immunization, edition date printed on the appropriate VIS, and date the VIS was given to the individual or the individual's parents/legal representative (if under 18 years of age); and

- (3) Any other information as determined by the Department.

222.105: Duty to Inform

- (A) Providers shall explain to individuals, or the parent or legal guardian of an individual under 18 years of age, the MIIS reporting procedures and requirements for immunization information for all individuals to the MIIS, including the right to object to data sharing, as described in 105 CMR 222.105(C).
- (B) Written materials developed by the Department for this purpose may include: MIIS Fact Sheet, posters, sample language for individual registration forms, sample provider email or template letters for informing individuals, MIIS Objection (or Withdrawal of Objection) Form. These materials will be maintained and updated by the Department.
- (C) Objection/Withdrawal of Objection Procedures.
- (1) If an individual, or the parent or guardian of an individual under 18 years of age, chooses to object to data sharing (or withdraw objection to data sharing) in the MIIS, the individual must complete the Objection Form and submit it either to his or her health care provider or directly to the Department.
 - (2) If an Objection Form is received directly by a provider, the provider must fax the form to the Department within 24 hours of receipt. Providers must also change the data sharing status of the individual in the GUI in order to ensure the Objection or Withdrawal of Objection is implemented within the system immediately, as practical.
 - (3) The records of an individual whose data sharing is changed from “Yes” or “Unknown” to “No” will be accessible only by the provider site that entered the immunization information.
 - (4) An individual who has objected to data sharing, but whose name is not yet in the MIIS, will be added to the system and will have data sharing status set to “No” by the Department.
- (D) All birth hospitals/facilities shall also inform the individual’s parent or guardian of the electronic data transmission of all immunizations provided to newborns from MRVRS to MIIS.

222.200: Provider Enrollment

- (A) Health care provider sites shall review and complete the Provider Site Enrollment Agreement prior to enrolling individual users at their site in the MIIS.
- (B) Health care providers shall enroll and agree to comply with all terms and conditions set forth in the MIIS Individual User Agreement and Confidentiality Statement prior to receiving access to the MIIS either thru the GUI or electronic data exchange. Signed individual user agreements shall be sent to Department and copies maintained at the provider site.
- (C) Department may at any time revoke access to the MIIS from any user who fails to comply with the MIIS Individual User Agreement and Confidentiality Statement.

222.205: System Access and Confidentiality

- (A) Immunization information shall be released from the MIIS only to the following individuals and agencies without further expressed consent of the individual or the

individual's parent or guardian unless the individual or the individual's parent or guardian has objected to data sharing:

- (1) Licensed health care providers and their staff providing direct care to the individual patient;
 - (2) Elementary and secondary school nurses and registration officials who require proof of immunization for school enrollment and disease control;
 - (3) Local boards of health for disease prevention and control;
 - (4) Women Infants and Children (WIC) nutrition program staff who administer WIC benefits to eligible infants and children; and
 - (5) Staff of state agencies or state programs whose duties include education and outreach related to the improvement of immunization coverage rates among their clients.
- (B) In accordance with the MIIS Individual User Agreement and Confidentiality Statement, all users of the MIIS must agree to access immunization information solely for the purpose of ensuring that individuals are up to date on the recommended immunization schedule, in compliance with school entry immunization requirements, for disease control and prevention, or for the improvement of immunization coverage rates of their clients or the public.
- (C) Access by department staff. Authorized Department staff may have access to all records in the system including those for which data sharing status is set to "No."
- (D) Access by researchers. Research requests shall be submitted through the Department's research proposal submission system and reviewed by designated Department staff. Researchers granted approval shall sign the MIIS Individual User Agreement and Confidentiality Statement.
- (E) Access by non-health care providers. Non-health care providers who may be granted access to the system for "view only" and/or report generating privileges shall complete a site and an individual agreement and agree to comply by the same terms and conditions that apply to health care providers.
- (F) Protection from subpoena and public record requests. Information contained in the MIIS does not constitute a public record, is not subject to subpoena or court order, and is not admissible as evidence in any action of any kind before a court, tribunal, agency, board, or person.

222.300: Requests to Amend Records and Access Records by Individuals

- (A) Incorrect information maybe amended by an individual's health care provider or by any health care provider if the individual has not objected to data sharing in the MIIS.
- (B) Requests for record amendments may also be made directly to the Department in writing in a form and manner determined by the Department.
- (C) Requests for copies of records by individuals should be made to their health care provider. Such requests can be made in person and the health care provider filling the request shall validate the individual's identity, and in the case of a minor's record, validate that the individual is the legal guardian or parent of the minor. Requests can also be made directly to the Department in writing in a form and manner determined by the Department.

222.305: Requests for List of Those Who Have Accessed Records

Requests for a record of all MIIS users that have accessed an individual's immunization information shall be made in writing in a form and manner determined by the Department.

222.400: Compliance Schedule

All health care providers licensed in the Commonwealth who administer immunizations in Massachusetts to any person, whether or not that person is a resident of the Commonwealth, shall be in compliance with 105 CMR 222.000 according to a schedule to be determined and distributed by the Department.

REGULATORY AUTHORITY

105 CMR 222.000: M.G.L. c. 111, ss. 3, 24M.