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

**222.206 Protection from Subpoena and Public Records Requests**

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

**222.410 Collaborative Agreements with Registries from Other States**

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 **authorized recipients and authorized users** ~~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 access~~es~~ the MIIS.

222.003: Definitions

**Authorized Recipient means an individual or agency the Department may release immunization information to for specified purposes without further express consent of the Immunization Recipient or legally authorized representative of the Immunization Recipient. An authorized recipient may not access the MIIS until the authorized recipient becomes a MIIS site or MIIS user.**

**Data Sharing Objection or Objection to Data Sharing means a patient’s indication of an objection to sharing the patient’s immunization information across MIIS users. A data sharing objection shall not limit the Department’s access to and use of immunization information.**

**Data Sharing Objection Form means a mechanism as determined by the Department by which an Immunization Recipient or legally authorized representative of the Immunization Recipient may indicate a data sharing objection. The indication of an objection to data sharing via a Data Sharing Objection Form shall not limit the Department’s access to and use of immunization information.**

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 graphicaluser interface **as designated by the department for authorized users to access the MIIS**.

Health Care Provider means a **licensed** health care **provider** ~~professional~~ who **is legally authorized to** administer~~s~~ immunizations **in Massachusetts.** ~~and is licensed under M.G.L. c. 112 and pharmacists authorized by 105 CMR 700.004 (B)(6) to dispense vaccine by administration.~~

**Health Plans means commercial health insurers, Blue Cross and Blue Shield of Massachusetts, Inc., health maintenance organizations offering or renewing insured health products in Massachusetts, to Massachusetts residents, and MassHealth.**

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

**Immunization Information means any data contained in the MIIS that relate to an individual immunization recipient or that may, in the determination of the Department, be used to identify an individual immunization recipient.**

**Immunization Recipient means an individual who received or will receive an immunization.**

**Legally Authorized Representative means a parent, guardian, or person or agency legally authorized to act on behalf of the patient in the event the patient is not legally able to act on their own behalf.**

MIIS means the Massachusetts Immunization Information System.

**MIIS User means** **an individual who is an Authorized Recipient and has registered and agreed to comply with all terms and conditions developed and set forth by the Department, which may include but not be limited to user and confidentiality agreements.**

**MIIS Site means a fixed or mobile location with MIIS users that has registered and agreed to comply with all terms and conditions developed and set forth by the Department, which may include but not be limited to user and confidentiality agreements.**

~~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 **U.S.** 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 **and may also include fact sheets or other information required by the CDC or U.S. Food and Drug Administration (FDA).**

VFC means the federal Vaccines For Children Program.

222.100: ~~Health Care Provider~~ Immunization Information Reporting

1. Health care providers shall report all new immunizations either through the GUI or by data exchange within ~~seven days~~ **72 hours** of immunization administration.
	1. **In the event of administration of a birth dose of an immunization to a newborn that is not yet named in the relevant health record, the healthcare provider shall report the immunization administration within 24 hours of the immunization recipient being so named.**
2. ~~Health care provider~~ **MIIS users and MIIS** sites that perform data exchange shall comply with all electronic data exchange specifications required by the Department.
3. ~~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.~~

Data ~~for each individual~~ reported **pursuant to 105 CMR 222.000** ~~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 **Immunization Recipient**, immunization type, and date of immunization administration;
	2. For current immunizations~~,~~**: the Immunization Recipient’s** VFC status, ~~individual’s~~ current home address, **sex, gender, race, ethnicity, preferred language,** 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 **Immunization Recipient or the Immunization Recipient’s legally authorized representative** ~~individual or the individual’s parents/legal representative (if under 18 years of age)~~; and
	3. Any other information as determined by the Department.

**~~(D)~~**

222.105: Duty to Inform

1. **Health care** ~~P~~**p**roviders shall explain to **Immunization Recipients,** ~~individuals,~~ or the **Immunization Recipient’s** ~~parent or~~ legal**ly** **authorized representative** ~~guardian of an individual under 18 years of age~~, the MIIS reporting procedures and requirements for immunization information for all **Immunization Recipients** ~~individuals~~ to the MIIS, including the right to object to data sharing, as described in 105 CMR 222.105(~~C~~ **B**).
2. ~~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.~~

Objection~~/~~ **to or** Withdrawal of Objection **to Data Sharing** Procedures.

* 1. If an **Immunization Recipient** ~~individual~~, or the **Immunization Recipient’s legally authorized representative** ~~parent or guardian of an individual under~~ ~~18 years of age~~, chooses to object to data sharing (or**, in the alternative, to** withdraw **a previously filed** objection to data sharing) in the MIIS, the individual must complete the appropriate form **designated by the Department** ~~Objection Form~~ and submit it either to **the Immunization Recipient’s** ~~his or her~~ health care provider or directly to the Department.
	2. If a~~n~~ ~~Objection F~~ **f**orm **as described in 105 CMR 222.105(B)(1)** is received directly by a **health care** provider, the **health care** provider must fax the form to the Department within 24 hours of receipt. **Health care** ~~P~~**p**roviders must also change the data sharing status of the **Immunization Recipient** ~~individual~~ in the GUI in order to ensure the ~~O~~**o**bjection or ~~W~~**w**ithdrawal of ~~O~~**o**bjection is implemented within the **MIIS** ~~system immediately, as practical~~.
	3. The records of an **Immunization Recipient** ~~individual~~ whose data sharing is changed from “Yes” or “Unknown” to “No” will be accessible **in the MIIS** only by the **MIIS** ~~provider~~ site that entered the immunization information **and the Department**.
	4. An **Immunization Recipient** ~~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.

~~(C) 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: **MIIS Site and MIIS User Registration** ~~Provider Enrollment~~

1. **Authorized Recipients that wish to become MIIS** ~~Health care provider~~ sites shall **register with the Department and agree to comply with all terms and conditions of registration developed and set forth by the Department, which may include but not be limited to site and confidentiality agreements. MIIS sites must be registered prior to registering individual MIIS** ~~review and complete the Provider Site Enrollment Agreement prior to enrolling individual~~ users at their site in the MIIS.
2. ~~Health care providers~~ **Authorized Recipients that wish to become MIIS users** shall **regist**er ~~enroll~~ **with the Department** and agree to comply with all terms and conditions **of registration developed and** set forth **by the Department, which may include but not be limited to user and confidentiality agreements.**  ~~in the MIIS Individual User Agreement and Confidentiality Statement prior to receiving access to the MIIS either through the GUI or electronic data exchange. Signed individual user agreements shall be sent to Department and copies maintained at the provider site~~
3. **MIIS sites and MIIS users registered in accordance with 105 CMR 222.200 and approved by the Department to access the MIIS shall be considered to have been designated by the Department to access only that immunization information and for those purposes described in M.G.L. c111 s. 24M and 105 CMR 222.205. Revocation of MIIS access privileges in accordance with 105 CMR 222.200(D) shall terminate such designation for the period of revocation.**
4. **The**Department may ~~at any time~~ revoke **MIIS** access **privileges**~~to the~~ **from** MIIS **sites** **and or MIIS users for just cause.** ~~from any user who fails to comply with the MIIS Individual User Agreement and Confidentiality Statement.~~   **Just cause shall include the failure to comply with the terms detailed in 105 CMR 222.000. An MIIS site or MIIS user may contest the revocation of access privileges, in writing, and request further review.**

222.205: System Access and Confidentiality

1. **The following individuals and agencies are Authorized Recipients:** ~~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~~ **H**~~h~~ealth 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;
	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~~.~~ **; and**
	6. **Health plans for immunization rate improvement and quality improvement efforts.**
2. I~~n accordance with the MIIS Individual User Agreement and Confidentiality Statement, all users of the~~ **Authorized Recipients,** MIIS **sites, and MIIS users may receive and have access to immunization information solely for the purposes delineated in M.G.L. c111 s. 24M and 105 CMR 222.205(A).** ~~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.~~
3. Access by department staff. ~~Authorized~~ **Designated** Department staff may have access to **immunization information for any purpose authorized by law.** ~~all records in the system including those for which data sharing status is set to “No.”~~
4. Access by researchers. Research requests shall be submitted **in writing and follow any applicable procedure pursuant to M.G.L. c. 111 s, 24A, including** ~~through~~ the **execution of any agreement deemed by the** Department~~’s~~ **to be necessary and which may include confidentiality and** ~~research proposal submission system and reviewed by designated Department staff. Researchers granted approval shall sign the~~ MIIS **user agreements**. ~~Individual User Agreement and Confidentiality Statement.~~
5. **Recipients authorized by 105 CMR 222.205(A)(2) through 105 CMR 222.205(A)(6) who are MIIS sites or MIIS users shall have “view only” and/or report generating privileges only, unless otherwise designated pursuant to 105 CMR 222.205(F).** ~~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.~~
6. **Access by Designated Users. The Department may designate other appropriate MIIS users. Such designation shall specify the terms, limits, and conditions of such access. Users so designated many not access or use immunization information in any manner other than is specified in the Department’s designation.**

**222.206:** 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

1. ~~Incorrect information may be amended by an individual’s~~ **A** health care provider **may update MIIS Information upon the Immunization Recipient’s or, as applicable, Immunization Recipient’s legally authorized representative’s request.** ~~or by any health care provider if the individual has not objected to data sharing in the MIIS.~~
2. Requests for record amendments may also be made directly to the Department in writing in a form and manner determined by the Department.
3. **An Immunization Recipient, or as applicable, an Immunization Recipient’s legally authorized representative, may request copies of the Immunization Recipient’s** ~~Requests for copies of~~ records **from the Immunization Recipient’s** ~~by~~ ~~individuals should be made to their~~ health care provider. **The health care provider fulfilling the** ~~Such~~ request~~s~~ shall **validate the** ~~may be made in person and the health care provider filling the request shall validate the individual’s~~ identity **of the** ~~and in the case of a minor’s record, validate that the~~ individual **receiving the record in a manner consistent with the disclosure of medical records and MGL Chapter 111 section 24M and 105 CMR 222.000.** ~~is the legal guardian or parent of the minor.~~ Requests may also be made directly to the Department in writing in a form and manner determined by the Department.
4. **Individuals may access MIIS Information they are legally entitled to access through a form and manner specified 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.~~

**222.410: Collaborative Agreements with Registries in Other States**

**The Department may enter into agreements with other states to facilitate the exchange of immunization information, provided that such agreements protect the confidentiality of the immunization information under the applicable state law.**

REGULATORY AUTHORITY

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