Massachusetts Department of Public Health
Massachusetts Immunization Information System
Policy Statement

Version 3.0
January 2013

Purpose:
The purpose of this policy statement is to facilitate and promote the use of the Massachusetts Immunization Information System (MIIS) by health care providers, schools, public health and other agencies to help improve immunization coverage among all individuals in the Commonwealth.

Please note: This document is under development. Updated versions will be posted at http://www.mass.gov/dph/miis and made available to all actively enrolled sites.

Authority:
This policy statement is authorized by M.G.L. Chapter 111, Section 24M:

- The department shall establish, maintain and operate a computerized immunization registry. The immunization registry shall record immunizations and immunization history with identifying information and shall include appropriate controls to protect the security of the system and the privacy of the information. The department shall promulgate rules and regulations to implement the immunization registry.

Scope:
This policy statement applies to all health care institutions licensed by the MDPH and 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. The policy also applies to any agency that accesses the MIIS in accordance with the guidelines set forth below.

Definitions:

- “EHR” shall mean an electronic health record.

- “GUI” shall mean a web-based graphical user interface.

- “Health care provider” shall mean a health care professional who administers immunizations and is licensed under M.G.L. Chapter 112.

- “Immunization” shall mean a vaccine or immunoglobulin, identified on a list maintained by the Department, which introduces active or passive immunity to a specific disease or group of diseases.

- “MDPH” shall mean the Massachusetts Department of Public Health.
“MIIS” shall mean the Massachusetts Immunization Information System.

“MIIS Fact Sheet” shall mean the MIIS Fact Sheet for Parents and Patients

“MRVRS” shall mean the Massachusetts Registry of Vital Records and Statistics.

“Objection Form” shall mean the Sharing Your Immunization Information Objection (or Withdrawal of Objection) Form

VFC shall mean the federal Vaccines For Children Program

Overview: Access to Information and Data Sharing

By law, immunization information for all patients must be reported to the MIIS.

Providers must explain to patients that the law requires the reporting of all immunization information for all patients to the MIIS.

Providers must then tell patients that their information (data) will be shared with other providers who may need access to it.

Patients must then have the option to object to data sharing, i.e., they may restrict access to their information to only MIIS staff and the reporting physician.

Birth Record Reporting:

MRVRS provides a daily data feed of all new births from the birth registry to the MIIS.

Data feeds include all fields in the “open” part of the birth record along with all information associated with the administration of any vaccines or immunoglobulins given at birth.

If someone objects to data sharing at birth, the MIIS will still receive the information from MRVRS but it will not be made visible within the system to external users (only MIIS staff) except for the minimum information that would appear in the search screen results.

Birth hospitals and other birthing facilities shall provide the Fact Sheet to all new parents. If parents choose to object to data sharing at birth the birth hospital must provide the parent with an Objection Form and fax completed forms to MDPH within 24 hours of receipt.

Reporting of Immunization Information:

Reporting of new immunizations shall be made either thru the GUI or by data exchange and must occur within 7 days of vaccine administration.

Newly enrolled providers sites (both GUI-users and those doing data exchange) will be expected to report all new shots to the MIIS.

Reporting of immunization data thru data exchange must follow the standards for HL7 data exchange as outlined in the MIIS HL7 Transfer Specifications.

The following items must be included in the reporting of data for each vaccine recipient thru the GUI:

- For both current and historical immunizations: the full first and last name and date of birth of the vaccine recipient, vaccine and date of vaccine administration.
For current immunizations: VFC status; current home address; vaccine manufacturer and lot number; name, address and title of person administering the vaccine; edition date printed on the appropriate VIS; and date the VIS was given to the vaccine recipient, or the parents/legal representative are required.

- Immunization data may also include: the vaccine type, dose, site and route of administration.

- For sites performing HL7 data exchange, complete immunization records should be sent with all new shots 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 as outlined in the MIIS Flat File Transfer Specifications.

- MDPH is working on regulations that will outline in more detail a phased approach for enforcement of this requirement. However, providers who are reporting to the MIIS must comply with the minimum data elements listed above.

**Duty to Inform Procedures:**

- M.G.L. Chapter 111, Section 24M requires that health care providers “must discuss the reporting procedures of the immunization registry…” with patients who are receiving immunizations. Please note this applies to all health care providers (and/or their affiliated institutions) who have enrolled with the MIIS, either for HL7 data exchange and/or access to the web-based graphical user interface (GUI). The MDPH has developed multiple tools to facilitate health care providers’ compliance with the duty to inform requirements, including: MIIS Fact Sheet, posters, sample language for new patient registration forms, and sample provider email or template letters for informing patients. These materials are available to all providers and can be downloaded at [http://www.mass.gov/dph/miis](http://www.mass.gov/dph/miis).

- The best way to comply with the requirement to inform as described in the law is to provide all patients with a copy of the MIIS Fact Sheet as outlined below:
  - Provide the MIIS Fact Sheet at least once to all new patients upon joining the practice and all existing patients prior to having their first immunization entered into the registry. For sites performing data exchange, provide the MIIS Fact Sheet for all new patients and all patients having their first immunization encounter after the site’s go-live date with the MIIS.
  - Either a paper or electronic copy of the MIIS Fact Sheet should be available to read in the office. A paper copy may also be offered to the patients to take home.
  - Providers are responsible for downloading the latest version of the MIIS Fact Sheet from the MDPH website ([http://www.mass.gov/dph/miis](http://www.mass.gov/dph/miis)) and making their own copies.

- Please Note: as long as the provider has a system to provide information about the MIIS (as outlined above) and the provider (or someone else who is equally knowledgeable) is available to answer questions, provision of written information about the registry will meet the statutory requirement to “discuss the reporting procedures of the immunization registry.”

- All birth hospitals/facilities must also comply with the duty to inform requirements due to the daily data feed the MIIS receives from MRVRS as outlined above.
Data Sharing Status:
- As stated above, providers are required to report immunization data to the MIIS. Patients have a right to limit access to their data to the provider that administered the immunization and MDPH. The data sharing status of an individual in the system determines this.
- All patients in the MIIS have a data sharing status of either Yes, No, or Unknown.
- The default value for data sharing is ‘Yes’.
- A ‘Yes’ or ‘No’ status means that the patient has been made aware of the MIIS and understands their right to limit other provider access to their information.
- A ‘Yes’ status indicates the patient’s immunization record may be shared with Massachusetts health care providers, schools, and other agencies as described in M.G.L. c. 111, s.24M.
- A ‘No’ status limits access to the patient’s immunization information to only the health care provider site that entered the information into the system and MDPH.
- An ‘Unknown’ status is reserved for historical immunization information where the MIIS has not yet been discussed with the patient.
- For historical data uploads, patient’s data sharing status is initially set to ‘Unknown.’ However, once new shots are entered into the system, the status will be switched to ‘Yes’.
- For patients whose data sharing status is Unknown (due to historical data uploads or entry) their record will not be visible by a new provider until the provider informs the individual about the registry and then their data sharing status is updated to ‘Yes’. No signature or form is required for this situation.
- All out of state residents seen by MA providers will be treated the same as MA residents and will have their data sharing status default to ‘Yes’ (unless an Objection Form is received by the provider/MDPH).

Objection/Withdrawal of Objection Procedures:
- Providers must have available paper copies of the Objection Form. They must provide their patients or their parents/guardians if a child is younger than 18 years of age, a copy of this form upon request.
- If patients or their parents/guardians choose to object to data sharing (or withdraw their objection to data sharing) in the MIIS, they must complete the Objection Form and submit it to their health care provider or directly to MDPH.
- If an Objection Form is received directly by a provider, they must fax the form to MDPH within 24 hours of receipt. Providers are strongly encouraged to change the data sharing status of the patient in the GUI in order to ensure the Objection or Withdrawal of Objection is implemented within the system immediately; however even in this situation, the form must still be faxed to MDPH for confirmatory processing.
- Individuals can send completed Objection Forms directly to MDPH for processing.
- MDPH will process all forms upon receipt.
- Records of individuals where data sharing is switched from ‘Yes’ or ‘Unknown’ to ‘No’ will only be accessible by the provider site that changed their status. If the Objection Form is received from a birth hospital or directly from an individual then no provider will have access to the record except for MDPH.
• Individuals who have objected to data sharing but whose names are not yet in the MIIS will be added to the system and will have their data sharing set to ‘No’ by MDPH.

System Access and Confidentiality:
• All health care provider sites must review and complete the Provider Site Enrollment Agreement prior to enrolling individual users at their site in the MIIS.
• Prior to receiving access to the MIIS either thru the GUI or HL7 data exchange, all users must enroll and agree to comply with all terms and conditions set forth in the MIIS Individual User Agreement and Confidentiality Statement including limiting access to the system to authorized users and maintaining the confidentiality of the data entered into the system. Signed individual user agreements must be sent to MDPH and copies maintained at the provider site. All users are also strongly encouraged to complete a recommended training.
• Sites that will perform data exchange must:
  o Comply with the specifications outlined in the MIIS HL7 Transfer Specifications
  o Demonstrate their capability to perform data exchange by sending HL7 test messages that can be successfully mapped into the MIIS.
  o Perform data quality checks as outlined by MDPH to ensure data they have sent to the MIIS matches data that is in the EHR.
• All non-health care providers who may be granted access to the system for “view only” and/or report generating privileges must complete a site and an individual agreement and agree to comply by the same terms and conditions that apply to health care providers including completion of a recommended training session.
• All users of the system must agree to use the system solely for the purpose of ensuring 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.
• MDPH may at any time revoke access to the MIIS from any user who fails to comply with the MIIS User Agreement.

Requests to Amend Records and Access Records by Individuals:
• 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.
• Requests for copies of records by individuals should be made to their health care provider, local board of health or any health care provider if the individual has not objected to data sharing in the MIIS. Such requests can be made in person and the health care provider or local board of health filling the request must 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 MDPH by completing the Immunization Record Request Form. MDPH will process these requests within 10 business days.
• Requests for record amendments may be made directly to MDPH. These requests must be made in writing and accompanied by the name, current address and date of birth of the patient/individual in the system and name, address, and relationship to the patient/individual of the requestor. The requestor must also submit a photocopy of their
driver’s license or other state-issued ID with their license number redacted; MDPH will redact the license number if received. MDPH will process these requests within 10 business days.

Requests for List of Those Who Have Accessed Records:
- Requests for a record of all individuals and agencies that have accessed an individual’s information must be made in writing to the MIIS at the MDPH of Public Health.
- MDPH will reply to such requests within 10 business days upon receipt of the written request.

Access by MDPH Staff:
- Internal DPH users who perform surveillance and disease control may have access to all records in the system including those where data sharing status is set to No.

Access by Researchers:
- All research requests must be reviewed by either the Immunization Program Medical Director, the Director of the Division of Epidemiology and Immunization, or their designee.
- Research requests must be submitted through IRBNet at: http://www.mass.gov/dph/research
- Researchers granted approval will only be given “read only” access and must sign the MIIS User Agreement.

Collaborative Agreements with Other States:
- All collaborative agreements entered into with other state registries will be approved by the MDPH Commissioner and General Counsel.

Protection from Subpoena:
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. If a provider receives a subpoena or court order for immunization related information, the provider should consult with legal counsel.