

Informational Briefing on Proposed Regulations at 105 CMR 222.000: Massachusetts Immunization Information System (MIIS)



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Introduction

- M.G.L. c. 111, §24M (2010) authorizes a computerized immunization registry
- Statute directs the Department to develop a system of mandatory reporting to a computerized immunization registry by all healthcare providers who administer immunizations, as well as a vital records data feed to capture immunization information on newborns.
- *“The department shall promulgate rules and regulations to implement the immunization registry.”*
- The Massachusetts Immunization Information System (MIIS) is a confidential, web-based system that collects and stores vaccination records for Massachusetts residents of all ages. The MIIS also serves as the state vaccine ordering and inventory management system that coordinates with the Centers for Disease Control and Prevention’s (CDC’s) centralized vaccine procurement and distribution system.

Background

- The concept of immunization registries has been in circulation for over 30 years
- In the US development of systems did not begin until the early 1990s
- The *All Kids Count (AKC)* program of the Robert Wood Johnson Foundation (1991) was established in response to national concerns over low immunization levels of preschool children
- *AKC* recognized the need to develop model programs for immunization registry systems which eventually lead to the establishment of 16 operational immunization registries by 2000
- Immunization registries continued to grow and expand throughout the country over the past two decades
- The CDC monitors progress on immunization registries through an annual survey, the Immunization Information Systems (IIS) Annual Report (IISAR). Results from the 2012 IISAR,, indicate that 86% (19.5 million) of U.S. children aged <6 years, and 25% (57.8 million) of U.S. adults participated in an IIS

Benefits of an Immunization Registry

- **Shared immunization records:** Records will be available across multiple sites and locations to help identify under-immunized children and pockets of unmet need. MIIS is designed to serve the needs of electronic health record (EHR) users through electronic data exchange, and can also support the needs of non-EHR users through direct data entry
- **Better decision making:** Health care practices, schools, and EHR systems will be able to increase on-time delivery and reduce inappropriate immunizations by using advanced immunization forecasting decision support
- **Reduced waste and increased efficiency:** Vaccine administration will be monitored and assessed on an ongoing basis to optimize distribution and use
- **Enhanced disease control:** MIIS will be integrated with the Department's infectious disease monitoring systems to allow the linkage of disease surveillance with the immunizations designed to prevent them
- **Improved disaster preparedness:** MIIS will provide an essential infrastructure for responding to natural disasters, bioterrorism events, influenza pandemics and other emergencies.

Development

- System development lead the Commissioner's Office, Legal Office, Bureau of Infectious Disease, and EOHHS IT
- **2009** - development of system began:
 - Initial collaboration and information seeking with stakeholders
 - communication with federal funders and existing state registries
 - validation of confidentiality protections
- **2010** - the system was reviewed, modified, and given custom enhancements to meet the needs of providers and allow the MIIS to be in compliance with the CDC's and other national standards. Funds from federal CDC grants, including the federal Immunization and Vaccine for Children and the American Recovery and Reinvestment Act, were used during this time

Development

- **2011** – Additional federal resources allowed further development of the MIIS, including an expansion to enhance interoperability with electronic health records (EHRs).
- Throughout the development process, the MIIS Policy Statement (located on the Immunization Program's website) served as a guide to pilot providers testing the system, providers interested in learning more about MIIS and as a general framework for the development of the regulations and final system components
- Immunization Program staff created web-based video training modules, an online help system, a user manual, and quick user guides
- Clinical integration protocols were developed and tailored for sites with EHRs and sites with paper-based records
- Confidentiality protocols were strictly adhered to during this time of development and were clearly documented in the MIIS Policy Statement

MIIS

- February **2011** - The system went live
- Utilization of the system was first piloted by sites that did not have electronic health records, who entered data through a conventional user interface.
- August **2012** - interface was established for provider sites with EHRs to exchange data with the MIIS.
- Currently, the majority of providers use EHRs, and therefore will be submitting data to the MIIS using electronic data exchange. However, there are still a significant number of end users (predominantly local health departments and schools that administer vaccines) who will be entering data using the user interface.
- **The proposed regulations, based on the MIIS Policy Statement, represent language, policies and procedures that have been in place and followed by health care providers for the past several years.**

Current Status of MIIS

- Over 400 vaccine administration sites (includes individual health care provider practices, provider groups, pharmacies, hospitals, and local health departments) are reporting data to the MIIS
- Over 1.7 million patient records and over 10 million administered vaccine doses have been entered into the system
- Several hundred additional health care sites that administer vaccines are enrolled, but only using the MIIS for online vaccine ordering (not yet reporting data)
- Access to MIIS is through the EOHHS hosting environment (Virtual Gateway)
- Process is evolving with the advent of the Mass Hlway. Mass Hlway is a secure statewide network that facilitates the transmission of healthcare data and health information among providers, hospitals and other healthcare entities. Eventually all providers that submit data via electronic data exchange will do so through this state-run secure network (www.mass.gov/hhs/masshlway)

Proposed Regulations

M.G.L. c. 111, §24M allows the Department, through the promulgation of these regulations, to determine provider enrollment practice, type of immunization information entered into the MIIS, manner in which it is entered, and to determine a compliance schedule and designate authorized system users within the Department.

Mandated System Users:

- All health care providers licensed in the Commonwealth who administer immunizations in MA to any person, whether or not that person is a resident, pharmacists authorized by 105 CMR 700.004 (6) to dispense vaccine by administration, and any entity that accesses the MIIS

Enrollment:

- Health care provider sites shall review and complete the Provider Site Enrollment Agreement (as developed by the Department) prior to enrolling individual users at their site.

Reporting:

- All new immunizations must be reported within seven days of immunization administration (if necessary, a one-time historical upload of records into the MIIS may be performed)
- Newborn immunizations - Birth hospitals/facilities shall report to MIIS through electronic data submission to the Massachusetts Registry of Vital Records and Statistics (MRVRS) which in turn provides a data feed to the MIIS

Proposed Regulations

Type of Information/Data:

- Current and historical immunization data requirements: Vaccines For Children Program (VFC) status, home address, immunization manufacturer/lot number, name, address/title of the vaccinator, edition date on Vaccine Information Statements (VIS), date the VIS was given to the individual/parents/legal representative; and any other information as determined by the Department

Duty to Inform:

- Providers shall explain MIIS reporting procedures and requirements, including right to object to data sharing (information must be entered into the MIIS, but individuals may object to the sharing) Applies also to information obtained from birth hospitals/facilities

Confidentiality Protections:

- Users must sign agreements to access immunization information solely for the purposes of ensuring up to date immunization schedules, compliance with school entry requirements, disease control and prevention, improvement of immunization rates
- MIIS information may be released without consent to certain entities unless there is an objection to data sharing
- Department staff have access to all records regardless of data sharing status
- Research requests submitted through MDPH's research proposal submission system (pursuant to M.G.L. c. 111, §24A)
- MIIS data do not constitute public records, and are not subject to subpoena/court order

Public Hearing

- A public hearing to be held in October, 2014
- Comments from the public hearing and any written remarks will be reviewed, summarized, and incorporated into the proposed regulatory language as appropriate
- Revised regulations to be presented back to the Public Health Council