

# Request for Final Approval of Proposed Regulations at 105 CMR 222.000: Massachusetts Immunization Information System (MIIS)



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**December 10, 2014**

# Introduction

- Informational briefing presented to the Public Health Council on September 17, 2014 on proposed regulations at 105 CMR 222.000: Massachusetts Immunization Information System (MIIS)
- M.G.L. c. 111, §24M, which was enacted in 2010, requires the Department to establish, maintain, and operate a computerized immunization registry.
- The MIIS is a confidential, web-based system that collects and stores vaccination records for Massachusetts residents of all ages. The statute requires reporting to a computerized immunization registry by all healthcare providers who administer immunizations and also includes a vital records data feed to capture immunization information on newborns.
- In addition to serving as the central vaccine registry, the MIIS also serves as the state vaccine ordering and inventory system that coordinates with the Centers for Disease Control and Prevention (CDC) centralized vaccine procurement and distribution system.

# Review: Development and Benefits

- System development began in 2009 and went live February 2011 with ongoing development and system enhancements
- The proposed MIIS regulations, based on the currently operative MIIS Policy Statement, represent language, policies, and procedures that have been in place and utilized by health care providers for the past several years
- Benefits of the MIIS include: improved immunization record and documentation access, better clinical decision making, reduced vaccine waste, improved vaccine order processing and inventory control, enhanced vaccine-preventable disease outbreak control, and improved disaster preparedness
- The CDC monitors progress on state immunization registries through an annual national survey

# Current Status of MIIS

- Over 500 vaccine administration sites (includes individual health care provider practices, provider groups, pharmacies, hospitals, and local health departments) are reporting data to the MIIS (*20% increase in sites since the informational briefing in September*)
- Over 2.2 million patient records and over 12.6 million administered vaccine doses have been entered into the system (*23% increase in patient records and 16% increase in doses since the informational briefing in September*)
- Several hundred additional health care sites that administer vaccines are enrolled, but are only using the MIIS for online vaccine ordering
- Access to MIIS is through the EOHHS hosting environment (Virtual Gateway)
- Process is evolving with the advent of the Mass HIway. Mass HIway 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 submitting data via electronic data exchange will do so through this state-run secure network ([www.mass.gov/hhs/masshiway](http://www.mass.gov/hhs/masshiway) )

# Public Hearing

- Public hearing held on Wednesday October 29, 2014
- Comment period was open until October 31, 2014.
- One individual testified in person.
- Written testimony was submitted by the MA Chapter of the American Academy of Pediatrics, the MA Association of Public Health Nurses, the MA Chain Pharmacy Council, and several local public health nurses from across the Commonwealth.
- Notification of the public hearing was published in the Boston Herald on 9/28/14 and in the Massachusetts Register on 10/10/14, in accordance with state requirements.
- Comments and responses summarized in following table:

# Public Hearing Comments

Comment	Response
<p>Request extension of seven-day requirement for new immunizations to be reported to MIIS. Feel the time frame presents a burden on annual flu clinics with limited staff; many requested an extension of three months.</p>	<p>Ultimately, the purpose of all immunization activities, including the MIIS, is to ensure the appropriate delivery of immunization services to all members of a population. Quality of care in immunization services requires age-appropriate administration of vaccines to the individual patient in a clinical setting. To accomplish this, the MIIS must provide access to quality, complete immunization data and clinical decision support information in a location and at a time where it can affect patient care.</p> <p>Information regarding administered immunizations must be submitted to the MIIS in a timely fashion in order to prevent over-immunization, provide accurate immunization histories and appropriate clinical decision support at the point of care, assure effective disease control in an outbreak, and optimize vaccine distribution. Reporting vaccine administration to the MIIS is an essential element to ensure clinical quality, particularly as vaccines are offered in multiple venues (local health departments, pharmacies, etc). The Immunization Program reviewed standards for Immunization Information Systems from other jurisdictions in setting this requirement. Rhode Island and Vermont operate under the same seven-day requirement (<a href="https://kidsnet.health.ri.gov/llr-practice-osm-prod/pdf/Terms-&amp;-Conditions-SSV.pdf">https://kidsnet.health.ri.gov/llr-practice-osm-prod/pdf/Terms-&amp;-Conditions-SSV.pdf</a>); <a href="http://www.leg.state.vt.us/statutes/fullsection.cfm?Title=18&amp;Chapter=021&amp;Section=01129">http://www.leg.state.vt.us/statutes/fullsection.cfm?Title=18&amp;Chapter=021&amp;Section=01129</a>)</p> <p>Michigan's time frame is more limited at 72 hours (<a href="http://www7.dleg.state.mi.us/orr/Files/AdminCode/976_2011-013CH_AdminCode.pdf">http://www7.dleg.state.mi.us/orr/Files/AdminCode/976_2011-013CH_AdminCode.pdf</a>).</p> <p>DPH recommends maintaining the seven-day requirement.</p>
<p>Unfair for DPH to make local BOH abide by regulations until all providers are equally held to the regulations.</p>	<p>M.G.L. c. 111, §24M, which requires the promulgation of 105 CMR 222.000 mandates that all licensed health care providers who administer immunizations must report to the registry. 105 CMR 222.400 specifies the development of a compliance schedule, which the Immunization Program is developing.</p>

# Public Hearing Comments: cont.

Comment	Response
Request that sorting requirement of MIIS should match that of Commonwealth Medicine (CM requires that vaccine records submitted for reimbursement be sorted by insurance company; MIIS rosters used for flu clinics sort by vaccine lot number).	The MIIS team consulted local public health in developing the requirements for roster entry, and this issue was not raised. The team regularly receives feedback about the specific screens and functions within the MIIS to make the system more user-friendly, and will consider these recommended changes for a subsequent system release.
Oppose MIIS staff etc. being able to look at data even when parent/guardian does not want data to be shared	The language in c 111 §24M mandates DPH's access to all submitted data.
Felt as though health nurses were not included in the development of the regulations.	Several local boards of health were included in the early pilot phase of the MIIS and have been participating in its use under the current policy statement for several years; this policy statement is the basis of the proposed regulations and local boards of health have had the opportunity to weigh in on our policies and procedures during pilot implementation and roll-out.
System can be slow and tends to freeze without saving data entry	System operation will vary by site and capacity of the end user's computer systems, and is not a issue of the MIIS's core functionality.
Request the DPH to develop an alternative registration mechanism for pharmacists who administer vaccinations upon reviewing/re-registering for their professional licensure.	Registration for the MIIS is a one-time requirement, and is not particularly burdensome. The Department cannot justify developing a separate registration system just for pharmacists tied to their professional licensure requirements.
Request regulations clearly state that the enrollment is not required for those pharmacists that do not administer vaccinations.	The proposed regulatory language is clear that all providers (including pharmacists) who administer immunizations must enroll in MIIS (conversely those who do not administer do not need to enroll). This can be clarified via other communications and does not need to be added to the regulations themselves.

# Conclusion

- DPH concludes that no changes to the proposed regulations are indicated, as summarized above
- The DPH requests that the Public Health Council approve the regulations as proposed.