STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

January 21, 2014

The Honorable Joan Carter Conway
Senate Education, Health, and Environmental Affairs Committee
2 West Miller Senate Building
Annapolis, MD 21401

The Honorable Peter A. Hammen
House Health and Government Operations Committee
Room 241 House Office Building
Annapolis, MD 21401

RE: HB 179 (Ch. 256 of the Acts of 2013) Pharmacists – Administration of Vaccinations – Expanded Authority and Reporting Requirements

Dear Chair Conway and Chair Hammen:

Pursuant to House Bill 179 (Ch. 256 of the Acts of 2013), the Department of Health and Mental Hygiene has conducted a study on the feasibility and desirability of requiring all health care providers who administer vaccinations in Maryland to report the vaccinations to the ImmuNet Program. This study was conducted in consultation with a workgroup of stakeholders, including representatives of health care providers, pharmacies, health insurance carriers, the State Board of Physicians, the State Board of Nursing, and the State Board of Pharmacy. The attached report details the findings and recommendations of this study.

If you have questions concerning this report, please contact Ms. Christi Megna, Assistant Director, Office of Governmental Affairs, at (410) 767-6509.

Sincerely,

Joshua M. Sharfstein, M.D.
Secretary

Enclosure

cc: Christi Megna, Esq.
Laura Herrera, MD, MPH
Donna Gugel, MHS
Deborah McGruder, MPH, PMP
Sarah Albert, MSAR# 9649

The Department of Health and Mental Hygiene
2013 Feasibility and Desirability of ImmuNet
Reporting Requirement Study

Background

Pursuant to House Bill 179 (Ch. 256 of the Acts of 2013), the Department of Health and Mental Hygiene (DHMH) has conducted a study and is mandated to report its findings and recommendations on the feasibility and desirability of requiring all health care providers who administer vaccinations to report to ImmuNet. Immunization registries are confidential, computerized, population-based systems that record vaccine doses administered by providers in a given state or other jurisdiction. At the point of clinical care, an immunization registry can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations; and at the *population level*, an immunization registry provides aggregate data on vaccinations for use in surveillance and program operations and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease.[1] As of 2013, all 50 US states and some large local jurisdictions have an immunization registry.

ImmuNet, the Maryland statewide Internet-based immunization registry, is authorized by the Annotated Code of Maryland, Health-General Article §18-109. ImmuNet was fully implemented in 2004 and substantially upgraded in 2011. The upgrade led to enhancements to a number of ImmuNet functions, including client reminder and recall capacities, vaccine management and accountability monitoring, and, perhaps most importantly, the ability for ImmuNet to incorporate and exchange vaccination records directly from a healthcare provider's existing clinical electronic health record (EHR) system without duplicate entry by the provider. All health care providers and all health care professionals who administer vaccines are authorized to participate in ImmuNet. As of December 2013, there were approximately 7,000 providers or provider groups registered with secure access to ImmuNet. More than 18 million vaccination records are recorded in ImmuNet, with approximately 12,000 - 80,000 new vaccination records being added per month. More than 700 of sites reporting vaccinations regularly do so automatically through electronic file transfers from existing systems directly into ImmuNet, including more than 500 that do so through HL7-formated message transfer.

In 2013, House Bill 179 (Ch. 256) Pharmacists – Administration of Vaccinations – Expanded Authority and Reporting Requirements was enacted. This legislation expanded the authority of pharmacists to administer vaccinations. As part of that law, the DHMH was charged with conducting a study of the feasibility and desirability of requiring all Maryland health care providers who administer vaccinations to report to ImmuNet. The following report summarizes existing literature and the input of Maryland stakeholders, and addresses the costs and benefits of mandating reporting as well as the timeframe in which ImmuNet could be accessible to all health care providers.

---

[1] Centers for Disease Control and Prevention. About Immunization Information Systems: http://www.cdc.gov/vaccines/programs/iis/about.html . Accessed December 2013.

Feasibility and Desirability Study Process

In conducting this study, DHMH reviewed published medical and immunization literature for information about the costs and benefits of immunization registry use and mandated immunization reporting. Input was also solicited from a range of stakeholders (See Appendix A), including representatives of pediatric and adult healthcare providers, pharmacies, health insurance carriers, local health departments, as well as the State Boards of Physicians, Nursing, and Pharmacy.

Stakeholder Workgroup

In October of 2013, DHMH convened a workgroup of stakeholders. Workgroup members were provided with background information on ImmuNet and immunization registries in general. DHMH asked members of the group to respond to a series of questions (See Appendix B) related to the feasibility and desirability of requiring all Maryland health care providers who administer vaccinations to report to ImmuNet. Written comments were received from 15 stakeholders. Additionally, one in-person/teleconference meeting was held on Friday, November 15, 2013 to give stakeholders another opportunity to provide input to DHMH on this issue. Ten stakeholders participated in this meeting with DHMH staff. The summary findings of the literature review and stakeholder input follows.

Findings

How Maryland Compares Nationally

Despite the current level of provider participation, the technical upgrades to ImmuNet, and the increasing submission of records to ImmuNet directly from provider electronic health record (EHR) systems – in part supported by the federal Centers for Medicare and Medicaid Services (CMS) EHR "meaningful use" incentive program – many Maryland vaccinations are not recorded in ImmuNet. Only about 50 percent of Maryland children under age six have at least two vaccinations recorded in ImmuNet, while nationwide 84 percent of children in this age group have two or more recorded vaccinations in immunization registries.[2] Maryland's young child participation is well short of the national Healthy People 2020 goal of 95 percent coverage and is lower than at least 31 other states and the District of Columbia. An even lower percentage of adult vaccinations are currently recorded in the system.

While all Maryland health care providers are authorized to participate in ImmuNet, reporting is currently mandated only for Maryland pharmacists administering vaccines – not for other Maryland vaccination providers. However, some states do mandate reporting of at least some vaccinations by all health care professionals who administer vaccines. According to a survey of states, by the Public Health Informatics Institute, as of mid-2012, at least 16 states and the District of Columbia mandated reporting of either all vaccinations or all vaccinations of children

[2] Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report January 25, 2013. Progress in Immunization Information Systems- United States, 2011. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a2.htm (Accessed December 2013).

to their respective immunization registries.[3] Not surprisingly, provider mandates increase the percentage of the population with records in immunization registries. At least 10 of the jurisdictions with provider mandates have met the Healthy People 2020 goal [4] of at least 95 percent of children under age 6 having at least two vaccinations in their registry, and all but two of the jurisdictions that mandated vaccination reporting had higher inclusion rates than Maryland.[5]

Costs/Concerns/Barriers

There are at least two sets of costs associated with mandated vaccination reporting to ImmuNet: the costs to the health care providers; and the costs to the ImmuNet program.

Costs to Providers

Little published data exists on the actual costs to health care providers of mandated reporting to an immunization registry. Surveys have documented at least some potential costs that providers have raised as concerns. These include the following:

- Costs and time associated with dual data entry if that is necessary;
- Costs and time associated with accessing and retrieving data from the registry;
- Costs associated with integrating registry-related procedures into existing business practices and work flow;
- Costs of training staff on use of a registry; and
- Costs associated with clinic IT staff and/or EHR vendor implementing direct electronic reporting from EHR into registry.[6]

Stakeholders also identified the foregoing concerns as potential costs to Maryland providers.

A 2006 summary policy statement report published in the journal Pediatrics[7] documented one study which suggested that costs at a private sector practice increased by $0.56 per vaccination after implementation of an immunization registry, with nurses spending about 3.4 minutes more per shot than before the registry was implemented. Another study noted in the Pediatrics report suggested that the costs varied by whether a practice entered the information into the registry manually or in an automated fashion, with manual entry costs approximately $3.24 per vaccination but automated entry costing only $0.24 per vaccination. Another study described in the Pediatrics report noted the savings for not having to manually pull a chart to search for

[3] http://www2a.cdc.gov/vaccines/iis/iissurvey/legislation-survey.asp
[4] http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/Immunization.pdf
[5] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a2.htm
[6] American Immunization Registry Association, December 2005, Turning Barriers Into Opportunities. Available online at: http://www.immregistries.org/resources/Provider_Participation_Final_2005.pdf (Accessed December 2013).
[7] PEDIATRICS Vol. 118 No. 3 September 1, 2006 pp. 1293-1295. Available online at: http://pediatrics.aappublications.org/content/118/3/1293.full.pdf (Accessed December 2013).

immunization records at $14.70 per chart. Health care providers have also apparently suggested that these costs are of particular concern if the timeliness, quality, and completeness of the data in the immunization registry are not adequate for clinical care and decision making. No studies to quantify these costs were identified.

Costs to the ImmuNet Program

Through existing federal funding, the ImmuNet program already maintains staff and the technical capacity to enroll providers into ImmuNet, provide on-line user training, maintain a user help desk, operate the system 24/7, incorporate electronic records directly from provider EHRs into ImmuNet, de-duplicate records, assess data timeliness, quality, and completeness, and support vaccine inventory ordering and management. While the system hardware, software, and message transport capacity is currently sufficient to handle mandated reporting by all Maryland health care providers, it is estimated that if all health care providers who administer vaccinations were reporting into ImmuNet, registry support staff at DHMH would need to be increased by at least three full-time equivalent workers (FTEs).

Other Barriers

Several other barriers were identified by stakeholders. First, it was noted that while Maryland's ImmuNet system is now easier to use and has greater functionality than before, many Maryland providers are not aware of the updates, including providers whose practices already successfully submit immunization records to ImmuNet directly through their clinical EHR system. Another noted barrier was that a large number of adult vaccinations are given in occupational settings that might not be recording the vaccinations in an electronic health record system that reports to ImmuNet. Healthcare facilities in particular provide large numbers of vaccinations to employees; however, those vaccinations are not generally recorded in the healthcare facilities' EHR systems but in separate occupational health data systems that do not currently report directly to ImmuNet.

Benefits

While there are ongoing costs for operating ImmuNet, the costs of a registry are likely to be offset by overall savings. The 2006 Pediatrics journal article summarized a study that suggested that the projected annual cost of a nationwide network of immunization registries containing records for children under age 6 would be approximately $78 million, but that these costs would be offset by annual savings of approximately $280 million from improved access to information at schools, reduced access of manual records, reduced duplicated immunizations, more efficient Healthcare Effectiveness Data and Information Set (HEDIS) reporting, and reduced need for national immunization coverage surveys. [8] Moreover, immunization registries can reduce unnecessary vaccinations. According to a report from the American Academy of Pediatrics, about 1 in 5 children in the United States have received at least one unnecessary vaccine due to incomplete records, which wastes approximately $26.5 million per year in health care costs.[9]

[8] PEDIATRICS Vol. 118 No. 3 September 1, 2006 pp. 1293-1295. Available online at: http://pediatrics.aappublications.org/content/118/3/1293.full.pdf (Accessed December 2013).
[9] American Academy of Pediatrics factsheet, Immunization Information Systems. Available online at: http://www2.aap.org/immunization/pediatricians/pdf/RegistriesFactSheet.pdf (Accessed December 2013).

The benefit of immunization registries overall is well established. After a review of published literature and other scientific presentations, the U.S. Community Preventive Services Task Force concluded that there was "strong evidence of effectiveness" for immunization registries increasing vaccination rates and reducing vaccine-preventable diseases through their capabilities to:

1. Support client reminder and recall notices, provider assessment and feedback, and provider reminders;
2. Generate and evaluate public health responses to outbreaks of vaccine-preventable disease;
3. Facilitate vaccine management and accountability;
4. Determine client vaccination status for decision making by clinicians, health departments and schools; and
5. Aid surveillance and investigations on vaccination rates, missed vaccination opportunities, invalid dose administration, and disparities in vaccination coverage.[10]

Immunization registries like ImmuNet have helped providers avoid redundant vaccinations, find immunization histories, and track immunization rates for both children and, increasingly, for adults. Immunization registries like ImmuNet also provide benefits by allowing for the rapid generation of official vaccination records for use by schools and colleges, health departments, and other health care providers. Furthermore, immunization registries, including ImmuNet, are being incorporated into developing Health Information Exchanges (HIEs), like the Chesapeake Regional Information System for our Patients (CRISP), the Maryland state-designated statewide HIE. For these benefits to be maximized in Maryland provider participation in ImmuNet must be high.

Other General Input from Maryland Stakeholders

Stakeholders unanimously expressed support for the use and usefulness of a statewide immunization registry. Stakeholders also strongly endorsed the benefits of having all vaccinations administered in Maryland, pediatric and adult, recorded in ImmuNet. Most, though not all, stakeholders supported mandatory reporting of vaccinations to ImmuNet. There was a general consensus among stakeholders that if reporting were to be mandated, ImmuNet should have the technical capacity and the staff necessary to support the recording of all vaccinations administered and the capacity to accept records electronically directly from provider electronic health records systems so that duplicate record entry was not necessary.

Conclusions

There are likely real costs – not well-defined – to requiring all healthcare providers who administer vaccinations to report those vaccinations to ImmuNet. Those costs are likely greatest to providers who are not using electronic health records or who are using electronic health record

---

[10] U.S. Community Preventive Services Task Force, Community Guide – Increasing Appropriate Vaccination: Immunization Information Systems. Available at: http://www.thecommunityguide.org/vaccines/RRimminfosystems.html (Accessed December 2013).

systems that are not currently capable of achieving the meaningful use requirements. Other incentives might be necessary for such providers to successfully report to ImmuNet. However, the benefit of immunization registries like ImmuNet has been established. Though the benefits of an immunization registry can be accrued even without required reporting, a high proportion of states that have successful registries – as evidenced by already meeting the Healthy People 2020 goal of 95% of young children with at least two vaccinations in the registry – require reporting. Finally, the elements that need to be in place to make required reporting successful (see below) are mostly in place currently and should all be in place by late-2014. It should be clear, however, that required reporting by itself will not be sufficient to achieve the benefits of ImmuNet and what a robust immunization registry program can accomplish. To achieve these benefits – especially as ImmuNet use increases – will require ongoing effort and resources from throughout Maryland, including DHMH, the federal government, Maryland healthcare providers and institutions, Maryland parents, and the legislature.

Issues Related to Timeframe

Pursuant to HB 179 (Ch. 256 of the Acts of 2013), DHMH must recommend a timeframe in which ImmuNet would be available to all Maryland health care providers who administer vaccinations. Health-General §18-109 currently authorizes all Maryland health care providers to use and report vaccinations to ImmuNet. DHMH already has the technical capacity to enroll all Maryland licensed health care providers into the ImmuNet program and provide them with secure access to the system. DHMH is working to also ensure adequate staff support for ImmuNet and should by mid- to late-2014 have in place the human resources to handle a large volume of new providers enrolling and implementing reporting to ImmuNet over a short period of time. Furthermore, DHMH has already developed the capacity to incorporate electronic files, including HL7-formated messages, directly from provider EHRs into ImmuNet using a variety of methods, including those required for the Stage 1 and Stage 2 of the CMS EHR incentive program.[11] Therefore, providers who already record immunizations in their EHRs need not enter the same information separately into ImmuNet.

What Elements Should Be in Place for a Mandate To Be Successful

For mandated reporting of vaccinations by health care providers to be successful, at least the following should be in place:

1. At least half of Maryland office practices and all hospitals should be using electronic health records;
2. ImmuNet should be capable of receiving and processing HL7-formatted messages in accordance with national Meaningful Use Stage 1 and Stage 2 requirements;[12]
3. ImmuNet should be able to record the CDC recommended immunization registry core data elements;[13]

[11] Centers for Disease Control and Prevention: Meaningful Use and Immunization Information Systems Factsheet. Available at: http://www.cdc.gov/vaccines/programs/iis/meaningful-use/index.html (Accessed December 2013).
[12] Ibid.

4. ImmuNet should be able to achieve the CDC recommended "Immunization Information System Functional Standards, 2013-2017";[14] and
5. DHMH should have the capacity – technical and human resources – to support all providers reporting into ImmuNet.

As of July 2013, items 1-2 have already been achieved. ImmuNet is already capable of recording 51 of the 59 CDC recommended immunization registry core data elements and is expected to have the capacity to record the remaining eight by early 2014. Similarly, ImmuNet already meets 24 of the 27 CDC recommended functional standards, and is expected to meet the remaining three standards by mid- to late-2014. Finally, it is expected that at least three additional ImmuNet support staff should be in place by mid- to late-2014, achieving item 5.

Recommendations

Based on the literature review conducted, the experiences of other states with reporting mandates, conclusions and timeframe detailed above, and the input of the stakeholders consulted, DHMH makes the following recommendation:

DHMH recommends that by October 2015, all Maryland healthcare providers who administer vaccinations should be required to report those vaccinations to ImmuNet.

DHMH appreciates the Maryland General Assembly's attention to this important public health issue. As the General Assembly deliberates this matter, DHMH looks forward to continuing to provide input as requested.

[13] Centers for Disease Control and Prevention: IIS Core Data Elements. Available at: http://www.cdc.gov/vaccines/programs/iis/func-stds-appxB.pdf (Accessed December 2013).
[14] Centers for Disease Control and Prevention: Immunization Information Systems Functional Standards, 2013-2017. Available at: http://www.cdc.gov/vaccines/programs/iis/func-stds.pdf (Accessed December 2013).

Appendix A

ImmuNet Feasibility and Desirability Workgroup Stakeholder Participants

Name	Organization
Matthew Burke	MD American Academy of Family Physicians
Shirley Devaris	Board of Nursing
Jacqueline Douge	Frederick County Health Department/ MD Statewide Advisory Commission on Immunizations - Chair
Ethel Famundam	Board of Pharmacy
Scott Feeser	Johns Hopkins Community Physicians
Lee Harrison	Provider/ CDC Advisory Commission on Immunization Practices Member
Marion Hayes	Pediatric and Adolescent Care of Silver Spring
Xiaxuam Hu	Board of Pharmacy
Anna Jeffers	Board of Pharmacy
Pam Kasemeyer	MedChi/American Academy of Pediatrics/MidAtlantic Association of Community Health Centers
Jennifer Maehr	Department of Juvenile Services
Andrea Mathias	Board of Physicians
Aaron Millstone	Johns Hopkins
Paula Minsk	MD American Academy of Pediatrics
J. Crossan O'Donovan	Dundalk Pediatrics
Stacie Sango	CVS Corporate Headquarters
Arethusa Stevens Kirk	Total Health Care
Jennifer Thomas	Pharmacist/ MD Statewide Advisory Commission on Immunizations Member
Duy Tran	Sinai Hospital/ MD American Academy of Pediatrics
5 anonymous providers	MD American Academy of Pediatrics

Note: The Workgroup questions were also sent to the following stakeholders for input, but no responses were provided to DHMH.

Name	Organization
Jennifer Bailey	Johns Hopkins Community Physicians
Patricia Czapp	Annapolis Primary Care
Neal Halsey	Johns Hopkins Bloomberg School of Public Health
Carolyn Heir	Ellicott City Pediatrics
John Lamourex	Baltimore City Health Department
Cherokee Layson-Wolf	UMD School of Pharmacy
Lynnette Mackay	Family Health Centers of Baltimore
Maria McColgan	Office of Smita Mengers, MD
Gene Ransome	MedChi
Debbie Rivkin	CareFirst
Kimberly Robinson	League of Life and Health Insurers
Danielle Weber	Somerset County Health Department

Appendix B

Questions for Workgroup

As the workgroup assesses the "feasibility and desirability of requiring certain health care providers who administer vaccinations to report the vaccinations to the ImmuNet Program," DHMH would like the workgroup of stakeholders to answer the following questions:

1. Why don't Maryland healthcare providers use an immunization registry as much as providers in neighboring states and in other states throughout the US?

2. What capacities should ImmuNet have to be of benefit healthcare providers?

3. What are the costs to providers of using an immunization registry?

4. What are the benefits to providers of using an immunization registry?

5. How can Maryland achieve the Healthy People 2020 objective of having 95% of children under 6 years old with at least two vaccinations recorded in ImmuNet?

6. Why are adolescent and adult vaccination coverage rates so much worse than childhood vaccination rates, and how could an immunization registry help improve vaccinations in these groups?

7. Should any Maryland providers be considered for exemption from a reporting requirement, and if so, which providers and why?