Maryland
DEPARTMENT OF HEALTH

Health Occupations - Pharmacists - Administration of Children's Vaccines - Study and Temporary Authority

As required by HB 1040/SB 736 (Chapters 792 and 793 of the Acts of 2021)

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Introduction

Chapters 792 and 793 (HB 1040/SB 736) of the Acts of 2021 authorized a licensed pharmacist, from July 1, 2021 to June 30, 2023, to administer a vaccine approved by the U.S. Food and Drug Administration (FDA) to an individual age 3 to 17 if (1) the vaccination is ordered and administered in accordance with the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) immunization schedules and (2) the pharmacist meets additional requirements, as specified in the legislation.

Additionally, the legislation required the Maryland Department of Health (MDH) to report on the following items, which are discussed in this report:

- the capacity of the health care system to administer vaccines to children;
- vaccination rates for children; and
- community access to the administration of vaccines for children.

In completing this report, MDH was required to evaluate data from Maryland and other states that authorize pharmacists to administer vaccines, study the effectiveness and efficiency of ImmuNet, and consider public health models in which pharmacists can support and facilitate families in obtaining well-child visits from pediatric primary care providers. This report also addresses, as required by the legislation, specified implementation recommendations and recommendations regarding if the temporary authority established under the bill should be made permanent and ways to further integrate the use of ImmuNet in electronic health records to facilitate communication between pharmacists and pediatric primary care providers.

Background

The ImmuNet program, established by Health-General Article §18–109, was implemented in 2010 as an immunization information system/registry to capture and record an individual's vaccination records and provide a web-based tool for health care providers and schools to keep their patient and/or student vaccinations up-to-date. Health-General Article §18-109 and Health Occupations Article §12-508 require specified health care providers and pharmacists administering vaccinations in Maryland to report all vaccinations to ImmuNet.

In addition, Health Occupations Article §12–508 authorizes pharmacists in Maryland to administer influenza vaccines to children 9 years and older, and vaccines recommended by the CDC to children ages 11-17 with a prescription and to adults without a prescription. On August 19, 2020, the U.S. Department of Health and Human Services (HHS) issued an amendment to the declaration under the federal Public Readiness and Emergency Preparedness (PREP) Act authorizing state-licensed pharmacists to order and administer COVID-19 and other vaccines to individuals ages 3-18 years without a prescription. This HHS amendment superseded Maryland's law on the authority of pharmacists to administer vaccines to children through the duration of the federal COVID-19 public health emergency (PHE).

Capacity of the Health Care System to Administer Vaccines to Children

The federal PREP Act created an additional avenue within the health care system to administer vaccines to children during the PHE. Table 1 (next page) shows data on pharmacy- and non-pharmacy-provided immunizations for a year before the pandemic (July 2018 to June 2019) and a year following the pandemic when more regular daily life activities had resumed, and more businesses were open (July 2021 to June 2022). This time frame allows for a comparison of access before and after the federal PREP Act amendment allowing pharmacists and pharmacy technicians in Maryland to provide vaccinations to children without a physician's prescription, which went into effect in 2020.

Overall, significantly more vaccines were administered to children in non-pharmacy settings than in pharmacy settings. In addition, the overall numbers of vaccines administered to children decreased during the pandemic period despite the population numbers remaining roughly the same.[1] However, the proportion of vaccines administered to children in pharmacy settings increased for each of the vaccines from the pre-pandemic to the pandemic period. As illustrated in Table 1, the number of human papillomavirus (HPV) vaccines administered in Maryland by pharmacists doubled from 217 in the 2018-2019 timeframe to 486 in the 2021-2022 timeframe, but the number given by non-pharmacy providers decreased from 171,155 in the 2018-2019 timeframe to 141,447 in the 2021-2022 timeframe. Similarly, influenza vaccinations increased from 28,037 in the 2018-2019 timeframe to 73,529 in the 2021-2022 timeframe for pharmacy providers. Pharmacists administered 127 MMR (Measles, Mumps, and Rubella) vaccines in the 2021-2022 timeframe. While the overall numbers of vaccines given by pharmacists are currently lower, providing vaccines at community pharmacies increases the number of physical locations where families can access critical vaccinations.

[1] Childhood vaccination rates have rebounded to pre-pandemic levels. The latest data can be found at:https://health.maryland.gov/phpa/OIDEOR/IMMUN/Pages/Kindergarten_Immunization_Rates_by_County.aspx

Table 1. Maryland Vaccine Doses Administered by Setting, for certain timeframes

YEAR		JULY 2018-JUNE 2019			JULY 2021-JUNE 2022		
SOURCE		Pharmacy	Non-Pharmacy	Total	Pharmacy	Non-Pharmacy	Total
VAX	AGES						
MMR	3-6	0	24,249	24,249	23	14,930	14,953
	7-10	1	2,945	2,946	9	2,216	2,225
	11-15	5	6,158	6,163	26	5,280	5,306
	16-18	31	4,652	4,683	69	5,024	5,093
	Total	37	38,004	38,041	127	27,450	27,577
HPV	3-6	0	58	58	1	18	19
	7-10	1	10,233	10,234	17	11,593	11,610
	11-15	84	132,397	132,481	284	112,209	112,493
	16-18	132	28,467	28,599	184	17,627	17,811
	Total	217	171,155	171,372	486	141,447	141,933
Flu	3-6	29	146,113	146,142	8,961	110,577	119,538
	7-10	3,791	128,265	132,056	15,193	98,208	113,401
	11-15	13,975	130,408	144,383	28,485	105,304	133,789
	16-18	10,242	48,836	59,078	20,890	47,358	68,248
	Total	28,037	453,622	481,659	73,529	361,447	434,976
Inactivated Poliovirus vaccine (IPV)	3-6	0	84,880	84,880	7	73,707	73,714
	7-10	1	6,062	6,063	1	4,712	4,713
	11-15	4	8,145	8,149	5	7,077	7,082
	16-18	3	5,198	5,201	4	5,191	5,195
	Total	8	104,285	104,293	17	90,687	90,704
Tetanus, Diphtheria, Pertussis (Tdap)	3-6	0	86,902	86,902	6	75,544	75,550
	7-10	2	10,830	10,832	14	6,269	6,283
	11-15	102	79,481	79,583	588	76,014	76,602
	16-18	184	10,182	10,366	220	9,649	9,869
	Total	288	187,395	187,683	828	167,476	168,304
Diphtheria, Tetanus, Pertussis (DTaP)	3-6	0	87,017	87,017	6	75,664	75,670
	7-10	3	12,494	12,497	17	7,255	7,272
	11-15	102	82,577	82,679	597	77,982	78,579
	16-18	187	12,728	12,915	233	11,901	12,134
	Total	292	194,816	195,108	853	172,802	173,655
Varicella	3-6	0	86,422	86,422	24	75,413	75,437
	7-10	0	8,049	8,049	19	6,515	6,534
	11-15	10	9,628	9,638	38	8,659	8,697
	16-18	98	6,281	6,379	58	6,593	6,651
	Total	108	110,380	110,488	139	97,180	97,319

Source: Maryland Department of Health, Data reported to ImmuNet retrieved November 2022

Vaccination Rates for Children

The CDC's Childhood Immunization Schedule recommends specified vaccinations throughout childhood to protect children from preventable illnesses such as MMR, tetanus, polio, and hepatitis.[1] Rates for childhood vaccines for kindergarteners are generally 98 percent or higher for DTaP (Diphtheria, Tetanus, Pertussis), Polio, MMR, Varicella, and Hepatitis B in Maryland. In 2020-2021, during the first year of the COVID-19 pandemic, kindergarteners' vaccine rates dropped to 90 percent for DTaP, Polio, and Hepatitis B and dropped even lower (about 88 percent) for MMR and Varicella.[2] The decreased rate in MMR doses equals about 10,000 fewer children vaccinated in 2020-2021. The rates rebounded in 2021-2022.

Per America's Health Rankings, 66.8 percent of adolescents in Maryland ages 13-17 received all recommended doses of the HPV vaccine in 2020.[3] The CDC reports 2021 vaccination coverage in Maryland for adolescents ages 13-17 as follows: Tdap 89.5 percent, HPV 79.1 percent, and MenACWY (Meningococcal conjugate) 93.7 percent.[4]

Community Access to the Administration of Vaccines for Children

Within the Maryland health care system, physicians and pharmacists are among the entities that can administer vaccines to children. Benefits of physicians administering vaccines include the convenience of completing vaccinations during routinely scheduled well child visits, and the established history between the patient and physician. For pharmacists, nearly 90 percent of Americans in 2018 lived within 2 miles of a community pharmacy, which means pharmacists often work directly in the communities they serve.[7] Additionally, the ability of local pharmacists to answer questions and provide free health advice makes them important public health liaisons.

Table 2 summarizes available avenues for children ages 3-18 to receive pediatric immunizations in Maryland. Researchers found that "over 51 percent of children in 2017 did not have a medical home, meaning they do not have a primary care doctor that manages their care."[7, 8] In most jurisdictions, especially on the Eastern Shore and in Western Maryland, there are more pharmacies than pediatricians. This greater community presence by pharmacies allows for increased opportunities for children to stay up-to-date on their vaccinations, offering an additional 1,266 locations where childhood vaccinations could be provided. Community pharmacies also offer flexibility to families by offering evening and weekend hours.

Table 2: Number of Pediatricians, Pharmacies, and Children Ages 3-17 in Maryland by Jurisdiction

Jurisdiction	Pediatricians (2020-2021)	Pharmacy Facilities*	Population Ages 3-17 years
Allegany	5	19	10,599
Anne Arundel	100	106	109,801
Baltimore City	251	184	98,578
Baltimore	180	368	157,225
Calvert	15	18	18,434
Caroline	0	6	6,552
Carroll	19	32	32,063
Cecil	8	18	19,262
Charles	18	31	33,970
Dorchester	4	8	5,679
Frederick	43	60	54,785
Garrett	1	9	4,324
Harford	32	57	49,236
Howard	175	59	68,119
Kent	5	5	2,792
Montgomery	573	164	201,134
Prince George's	127	147	178,429
Queen Anne's	2	7	9,018
Somerset	4	5	4,021
St. Mary's	10	18	23,094
Talbot	11	10	5,684
Washington	20	36	28,044
Wicomico	16	28	20,781
Worcester	3	18	7,728
Total	**1,622**	**1,266**	**~ 1.1 million**

Source: Population data are from the Maryland Department of Planning based on 2021 population estimates
**Pharmacist Facilities as of 11/2022; a facility may have more than one pharmacist.*

Pharmacists' Authority to Administer Vaccines to Children across the United States

When the federal PREP Act amendment is not in effect, pharmacists' authority to administer other vaccines to children varies from state to state. Excluding seasonal influenza and COVID-19 immunization authority, eight states do not allow pharmacists to administer routine childhood vaccines for children ages 7-18. They include: Connecticut, Florida, Maine, New Hampshire, New Jersey, New York, Pennsylvania, and Rhode Island.[9] Data for doses administered by pharmacists vs. non-pharmacists in Maryland are listed in Table 1.

Input from Pediatric Health Care Providers on the Effectiveness and Efficiency of ImmuNet

To allow pharmacists, pediatricians, nurse practitioners, and physician assistants to share feedback about the effectiveness and efficiency of ImmuNet, a survey (Appendix A) was disseminated to members of the: Maryland Pharmacists Association, Maryland Society of Health-System Pharmacists, Maryland Association of Chain Drug Stores, Maryland Chapter of the American Academy of Pediatrics (AAP), Maryland Academy of Family Physicians, and Nurse Practitioner Association of Maryland. The survey was available for two weeks to allow members to respond. In total, 106 pharmacists and 26 providers (23 physicians and 3 nurse practitioners) responded to the survey. Survey findings are summarized below.

- 57 percent of pharmacists and 44 percent of pediatric primary care providers indicated that ImmuNet is very or extremely effective for tracking pediatric vaccines.
- 83 percent of pharmacists and 77 percent of pediatric primary care providers reported using automated file transfer to enter data in ImmuNet.
- 70 percent of pharmacists and 67 percent of pediatric primary care providers found automated file transfer of vaccine records to be accurate.
- 42 percent of responding pharmacists and 45 percent of responding pediatric primary care providers thought that it is somewhat or extremely easy to manually enter data into ImmuNet.
- When pharmacists were asked about what percentage of caregivers with children who received vaccines at their pharmacy site reported having a medical home or assigned primary care provider:
    - 29% of responding pharmacists, said 75%-89% report having a medical home
    - 29% of responding pharmacists, said greater than 90% report having a medical home
    - 25% of responding pharmacists said fewer than 50% report having a medical home
    - 18% of responding pharmacists, said 50-74% report having a medical home.
- 38 percent of responding pharmacists thought it was somewhat difficult or extremely difficult to find a pediatric primary care provider to provide families with a referral.
- 73 percent of responding pharmacists felt a State-maintained pediatric provider registry would be helpful.

Additionally, Table 4 provides data from Immunet on the timeliness of data entry of vaccine information into ImmuNet for pharmacists and non-pharmacists.

Table 4: Timeliness of Data Entered into ImmuNet, 2021-2022

	% Reporting within 24 hours	% Reporting within 2-7 days	% Reporting > 7 days
Pharmacists	88	10	2
Non-Pharmacists	82	4	14

Source: Maryland Department of Health, Data reported to ImmuNet retrieved November 2022

Ways Pharmacists can Support and Facilitate Families in Obtaining Well-Child Visits

Opportunities exist for more collaborative relationships between pharmacies and local health departments, pediatric primary care providers, and school systems, to meet the vaccination needs of children. Pharmacists are required by the PREP Act amendment to remind families of the importance of well-child visits with their pediatric primary care providers, and to refer the patient to a pediatric primary care provider when appropriate.[11]

Implementation Recommendations

Pursuant to Chapters 792 and 793 (HB 1040/SB 736) of the Acts of 2021, MDH is tasked with addressing implementation recommendations for: (1) tracking multidose vaccines; (2) optimal physical space configurations to protect the privacy and safety of patients; (3) staffing requirements; and (4) processes for responding to adverse reactions.

Tracking Multidose Vaccines

ImmuNet was established to, among other purposes, track multidose vaccines. The ImmuNet system currently has the capacity to track multidose vaccines and does so. This includes tracking multidose vaccines where some of the required doses are given in physician offices and other doses are given in pharmacies. Stakeholders surveyed also indicated that they believe ImmuNet is an effective database to track multidose vaccines. Therefore, MDH recommends increased outreach to vaccinators via a variety of media, including communications from the professional boards and professional associations, to ensure that they are aware of the mandatory reporting requirements set forth in Health-General Article §18–109. MDH will reach out via clinician letter and ensure that the boards send the letter to their members. MDH will also communicate to MedChi and various professional organizations, including the Maryland Chapter of AAP, Maryland College of Physicians, and others.

Physical Space Configurations to Protect the Privacy and Safety of Patients

A safe private or semi-private area for patient consultation and immunization increases patient trust and decreases perceived stigma.[12] The Americans with Disabilities Act (ADA) standards require adequate entry and exit points and accessibility for the elderly as well as those with disabilities and mobility issues.[13] The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires pharmacists to make reasonable efforts and have physical safeguards in place to protect the privacy of protected health information in areas where patient-staff communications routinely occur.[14] Several sources suggest approximately 50 square feet per patient as the ideal spacing in consultation or patient-care settings, with flexibility depending on the function and facility.[13]

Based on the current federal standards and safeguards, MDH recommends a designated immunization area where patients can have confidential conversations, and injection and emergency supplies are pre-assembled.[15] Smaller pharmacies without private consultation rooms should use the most private section of the patient waiting area. There are several creative options to further protect the privacy and safety of patients, as well as to increase vaccination capabilities. Recommendations include: asking waiting patients to stand a few feet back from the

counseling area;[14] using permanent or movable barriers (e.g., cubicles, dividers, shields, curtains, screens);[16] using white noise machines;[12] and using non-pharmacy spaces (e.g., offices, break rooms, stockrooms).[17]

Staffing Requirements

Optimal staffing is situational and depends on overall facility capacity, number of patients, type of services, and other criteria. Research indicates that additional staffing is not required for walk-up immunizations, but is required for immunization clinics held both on- or off-site.[15] Therefore, MDH recommends facilities assess their overall capacity and objectives to determine staffing requirements.

Processes for Responding to Adverse Reactions

The process for pharmacists responding to adverse immunization reactions is the same as for any other health care professional. Licensed pharmacists, pharmacy interns, and pharmacy technicians are required by both the federal PREP Act amendment and Maryland statute (Health Occupations Article §12–508) to complete immunization training that includes the recognition and treatment of emergency reactions to vaccines. These pharmacy professionals must have a current certificate in basic cardiopulmonary resuscitation. In addition, they must complete (during the relevant State licensing period(s)) a minimum of two hours of immunization-related continuing pharmacy education approved by the Accreditation Council for Pharmacy Education.[18,19] Furthermore, the pharmacy permit holder is required to maintain documentation in the pharmacy from which the vaccine was administered that includes: the nature and outcome of an adverse reaction, and that the adverse reaction was reported to both the primary care provider and the Vaccine Adverse Event Reporting System (VAERS). This documentation must be maintained for a minimum of five years.[18]

Overall Recommendations

In accordance with Chapters 792 and 793 (HB 1040/SB 736) of the Acts of 2021, MDH is required to make recommendations regarding (1) whether the temporary authority for pharmacists to order and administer vaccinations to children ages 3-18 should be made permanent; and (2) ways to further integrate the use of ImmuNet in electronic health records to facilitate communication between pharmacists and pediatric primary care providers.

Permanency of Temporary Authority

Given the overall benefit of illness prevention, the documentation that vaccinations are one of the most effective public health tools available, the recognition that lack of easy access to preventive services like vaccinations increases health inequities, and the demonstration that Maryland pharmacists can effectively vaccinate children, MDH strongly recommends making permanent the authority for pharmacists to order and administer CDC recommended vaccinations to children ages 3-18. MDH recognizes the importance of a medical home for all children, and recommends that any extension of this authority ensures that pharmacists inform parents of the need for routine well child care through the primary care provider or medical home.

ImmuNet Integration

Substantial progress has been made in recent years to increase the reporting of vaccinations into ImmuNet and to make vaccination information available to Maryland providers, regardless of who provided the vaccination. As an increasing proportion of outpatient practices use certified electronic health records (EHRs), this allows for more integration of care between different providers. To further enhance access and improve communication between pharmacists and providers, MDH recommends communications to the providers that are not currently using EHRs to adopt an EHR system with bidirectional capabilities to integrate ImmuNet data into their health systems. Providers currently using EHRs that do not support bidirectional capability or the ability to integrate ImmuNet data should be encouraged to request their EHR vendor to add on or upgrade their EHR system.Other opportunities to enhance usability by pharmacists and providers include:

- Adding ImmuNet messaging to:
    - Inform users whether the automatic file transfer was successful or whether there were issues during the upload process; and
    - Easily identify records with errors; and
- Simplifying submission templates to ease the manual reporting burden.

In conclusion, MDH remains committed to increasing the use and versatility of ImmuNet, and supporting efforts at making vaccinations more easily available to Maryland residents, ultimately reducing the morbidity and mortality of vaccine-preventable diseases.

Appendix A

Pharmacists' Survey

We are collecting feedback from stakeholders as requested by the Maryland legislature in order to prepare a report on HB1040 / SB736 (Pharmacist - Administration of Childrens' Vaccines).

1. I am a Maryland pharmacist at a site that provides vaccinations to children 3-18 years old and I agree to participate in the survey.
   - o Yes
   - o No

2. Please select which best describes your site.
   - o Independent pharmacy
   - o Retail chain pharmacy
   - o Outpatient clinic
   - o Other

3. I primarily practice in: (insert county)

4. Who at your site regularly administers pediatric vaccines? Select all that apply.
   - o Pharmacist
   - o Pharmacy intern
   - o Pharmacy technician
   - o Other

5. How does your site most often enter data into ImmuNet?
   - o Staff manually enter vaccine data
   - o Our site performs automated file transfer
   - o I don't know
   - o Other

6. How does your site most often enter data into ImmuNet?
   - o Staff manually enter vaccine data
   - o Our site performs automated file transfer
   - o I don't know
   - o Other

7. How easy is it for you or staff to manually enter new vaccine records into ImmuNet?
   - o Extremely difficult
   - o Somewhat difficult
   - o Neither easy nor difficult
   - o Somewhat easy
   - o Extremely easy
   - o Not applicable

8. Have you found the automated file transfer of vaccine records to be accurate?

- o Yes
- o No
- o Unsure
- o Not applicable

9. How effective do you feel ImmuNet is for tracking pediatric vaccines?

- o Not effective at all
- o Slightly effective
- o Moderately effective
- o Very effective
- o Extremely effective

10. Do you have any specific recommendations on how to improve the efficiency or effectiveness of the ImmuNet database?

11. In your experience, what percentage of caregivers with kids 3-18 years old who received vaccines at your site report having a medical home (assigned primary care provider)?

- o Greater than 90%
- o 75-89%.
- o 50-74%
- o Less than half
- o I don't know

12. For kids without a medical home (assigned primary care provider), how easy is it to find pediatric providers when making a referral?

- o Extremely difficult
- o Somewhat difficult
- o Neither easy nor difficult
- o Somewhat easy
- o Extremely easy

13. If the state maintained a pediatrician registry for referrals would you use it as a resource for referrals?

- o Yes
- o No
- o Unsure

14. Does your site have a partnership with a school, pediatrician's office, or health department to provide vaccines to kids 3-18 years old? If yes, please describe your model.

- o Yes
- o No

Health Care Providers' Survey

1. I am a Maryland healthcare worker at a facility/office that regularly sees children 3-18 years old and I agree to participate in the survey.

- o Yes
- o No

2. Please select your credentials.

- o DO
- o MD

- o NP
- o PA
- o RN
- o Other

3. I primarily practice in (insert county)

4. Who at your site regularly administers pediatric vaccines? Select all that apply.
   - o Medical Assistant
   - o Nurse Practitioners
   - o Nurse
   - o Physician Assistant
   - o Physician
   - o Other

5. How does your site most often enter data into Immunet?
   - o Staff manually enter vaccine data
   - o Our site performs automated file transfer
   - o I don't know
   - o Other

6. How easy is it for you or staff to manually enter new vaccine records into ImmuNet?
   - o Extremely difficult
   - o Somewhat difficult
   - o Neither easy nor difficult
   - o Somewhat easy
   - o Extremely easy
   - o Not applicable

7. Have you found the automated file transfer of vaccine records to be accurate?
   - o Yes
   - o No
   - o Unsure
   - o Not applicable

8. How effective do you feel ImmuNet is for tracking pediatric vaccines?
   - o Not effective at all
   - o Slightly effective
   - o Moderately effective
   - o Very effective
   - o Extremely effective

10. Do you have any specific recommendations on how to improve the efficiency or effectiveness of the ImmuNet database?

11. If the state maintained a pediatrician registry for referrals would your site be willing to be listed?
   - o Yes
   - o No
   - o Unsure

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