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March 4, 2021

To: The Honorable Shane E. Pendergrass  
Chair, Health and Government Operations Committee

From: The Office of the Attorney General, Health Education and Advocacy Unit

Re: House Bill 1040 (Health Occupations- Pharmacists- Administration of Vaccinations):  
Oppose

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) submits the following written testimony in opposition to House Bill 1040. For the duration of the pandemic, no statutory changes are required to authorize pharmacists and pharmacist interns to administer adult Covid-19 vaccines and childhood vaccines approved by the U.S. Food and Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention (CDC) for children 3-18 years old, without prescriptions, because those services are expressly authorized by federal orders issued by the Secretary of the U.S. Department of Health and Human Services and state orders issued by the Secretary of Health (attached). The temporary orders supersede current § 12-508 of the Health Occupations Article which only allows pharmacist-administration of a childhood vaccination approved by the FDA and recommended by the CDC to children 11-18 years old, if prescribed by an authorized prescriber, and adult vaccination of CDC recommended prevention and travel immunizations.

The federal order's expanded childhood vaccine authority is directly linked to the pandemic-induced decline in national vaccination rates resulting from stay-at-home orders, provider practice restrictions, and urgent concerns about outbreaks of preventable diseases secondary to the pandemic:

A May 2020 [CDC] report found a troubling drop in routine childhood immunizations as a result of families staying at home. While families

followed public health warnings about going out, an unfortunate result was many missed routine vaccinations. This decrease in childhood-vaccination rates is a public health threat and a collateral harm caused by the COVID-19 pandemic.

“As a pediatric critical care physician who has treated critically ill children suffering from vaccine preventable diseases, I know first-hand the devastation to the child – and to the family and community – of a death or severe brain damage that could have been avoided by a safe and effective vaccine,” said HHS Assistant Secretary for Health Brett P. Giroir, M.D. “The cornerstone of public health, vaccines, makes these dreaded diseases preventable. **As we expand options during the COVID-19 response, we are also reminding parents, grandparents, and caretakers that there is no substitute for a critically important well-child visit with a pediatrician or other licensed primary care provider when available.**”

HHS is expanding access to childhood vaccines to avoid preventable diseases in children, additional strains on the healthcare system, and any further increase in avoidable adverse health consequences—particularly if such complications coincide with an additional resurgence of COVID-19.

<https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html> (August 19, 2020 press release from HHS, emphasis added).

These changes were never intended to be permanent and should remain temporary until after proper study and analysis of the pandemic data has been conducted by subject matter experts in pediatric medicine and pediatric vaccines with oversight by the Department of Health, home to the state’s Vaccination Program, occupational health boards and the Maryland Health Care Commission.

The federal order’s expanded authority to administer FDA authorized or approved vaccinations is also directly linked to the urgency to vaccinate for COVID-19 and likewise is not intended to be permanent.

The HEAU has long advocated for accessible, affordable health care for families in Maryland, many of whom now have improved access to pediatricians and preventive care. We urge the General Assembly to not make these pandemic-induced changes permanent without full consideration of the consequences, including insurance coverage related issues.

This bill does not conform to the provisions of the federal and state orders currently in effect, and if enacted now could cause confusion and thus patient harm for the remainder

of the pandemic. For instance, without prescriptions, pharmacists could administer to children or adults any vaccines “approved or authorized by the [FDA].” (p. 2, l. 7-8; 17-18) Exhibit A is a list of FDA approved vaccines, including vaccines to protect against rabies, dengue fever, ebola, anthrax and HPV.

We would not oppose the bill if it is amended to mirror federal and state orders currently in effect and includes a December 31, 2022 sunset date. Otherwise, we urge an unfavorable report on the bill.

cc: Sponsor

## EXHIBIT A

- Adenovirus Type 4 and Type 7 Vaccine, Live, Oral
- Anthrax Vaccine Absorbed (Trade name: Biothrax)
- BCG Live (Trade name: BCG Vaccine or TICE BCG)
- Cholera Vaccine Live Oral (Trade name: Vaxchora)
- Dengue Tetravalent Vaccine, Live (Trade name: DENGIVAXIA)
- Ebola Zaire Vaccine, Live (Trade name: ERVEBO)
- Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant (Trade name: Gardasil)
  - **Note: Gardasil 9 is on both lists**
- Human Papillomavirus Bivalent (Types 16, 18) Vaccine, Recombinant (Trade: Cervarix)
- Japanese Encephalitis Virus Vaccine, Inactivated, Absorbed (Trade name: Ixiaro)
- Meningococcal Polysaccharide Vaccine, Groups A, C, Y, and W-135 Combined (Trade name: Menomune-A/C/Y/W-135)
- Plague Vaccine
- Poliovirus Vaccine Inactivated (Human Diploid Cell) (Trade name: Poliovax)
  - **Note: IPOL, the more commonly used poliovirus vaccine is on both lists**
- Rabies Vaccine (Trade name: Imovax and RabAvert)
- Smallpox and Monkeypox Vaccine, Live, Non-Replicating (Trade name: JYNNEOS)
- Smallpox (Vaccinia) Vaccine, Live (Trade name: ACAM2000)
- Typhoid Vaccine Live Oral Ty21a (Trade name: Vivotif)
- Typhoid Vi Polysaccharide Vaccine (Trade name: Typhim Vi)
- Yellow Fever Vaccine (Trade name: YF-Vax)

**FOR IMMEDIATE RELEASE****August 19, 2020****Contact: HHS Press Office****202-690-6343****[media@hhs.gov](mailto:media@hhs.gov)**

## HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic

The U.S. Department of Health and Human Services (HHS) [issued a third amendment - PDF\\*](#) to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.

"Today's action means easier access to lifesaving vaccines for our children, as we seek to ensure immunization rates remain high during the COVID-19 pandemic," said HHS Secretary Alex Azar. "The Trump Administration has worked to allow pharmacists—alongside all of America's heroic healthcare workers—to practice at the top of their license, empowering the public with more options to protect their health and well-being."

The amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through 18 years, subject to several requirements:

- The vaccine must be approved or licensed by the Food and Drug Administration (FDA).
- The vaccination must be ordered and administered according to the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

The above requirements are consistent with many States that already permit licensed pharmacists to order and administer vaccines to children.

A May 2020 Centers for Disease Control and Prevention (CDC) report found a troubling drop in routine childhood immunizations as a result of families staying at home. While families followed public health warnings about going out, an unfortunate result was many missed routine vaccinations. This decrease in childhood-vaccination rates is a public health threat and a collateral harm caused by the COVID-19 pandemic.

“As a pediatric critical care physician who has treated critically ill children suffering from vaccine preventable diseases, I know first-hand the devastation to the child – and to the family and community – of a death or severe brain damage that could have been avoided by a safe and effective vaccine,” said HHS Assistant Secretary for Health Brett P. Giroir, M.D. “The cornerstone of public health, vaccines, makes these dreaded diseases preventable. As we expand options during the COVID-19 response, we are also reminding parents, grandparents, and caretakers that there is no substitute for a critically important well-child visit with a pediatrician or other licensed primary care provider when available.”

HHS is expanding access to childhood vaccines to avoid preventable diseases in children, additional strains on the healthcare system, and any further increase in avoidable adverse health consequences—particularly if such complications coincide with an additional resurgence of COVID-19.

For CDC guidance on Routine Vaccination during the COVID-19 Outbreak, click [here](#).

For more information on National Immunization Awareness Month, click [here](#).

For the latest CDC Immunization Schedule, click [here](#).

For clinical resources on vaccines, including continuing education training on best practices, click [here](#).

To view the Notice of Amendment, click [here - PDF](#).\*

\* This content is in the process of Section 508 review. If you need immediate assistance accessing this content, please submit a request to [digital@hhs.gov](mailto:digital@hhs.gov). Content will be updated pending the outcome of the Section 508 review.

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Note: All HHS press releases, fact sheets and other news materials are available at <https://www.hhs.gov/news>.

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Last revised: August 19, 2020

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## **DIRECTIVE AND ORDER REGARDING VARIOUS VACCINATION MATTERS**

### **Pursuant to the Governor’s Executive Order Relating to Various Healthcare Matters**

**No. MDH 2020-12-08-01**

I, Dennis R. Schrader, Acting Secretary of Health, finding it necessary for the prevention and control of 2019 Novel Coronavirus (“SARS-CoV-2” or “2019-NCoV” or “COVID-19”), and for the protection of the health and safety of patients, staff, and other individuals in Maryland, hereby authorize and order the following actions for the prevention and control of this infectious and contagious disease under the Governor’s Declaration of Catastrophic Health Emergency.

#### **1. Definitions**

- A. “Vaccination Site” means any location at which COVID-19 vaccinations are offered to the public in accordance with the State of Maryland’s Vaccination Plan and includes, but is not limited to, facilities as defined in the Order of the Governor of the State of Maryland No. 20-11-17-02 Establishing Alternate Care Sites and Authorizing Regulation of Patient Care space in Health Care Facilities, the offices of health care practitioners, local health departments, pharmacies, urgent care centers, and any event at which vaccinations are offered in accordance with the State of Maryland’s Vaccination Plan.
- B. “COVID-19 Vaccine(s)” means any COVID-19 vaccine that has U.S. Food and Drug Administration (FDA) approval or has been granted an Emergency Use Authorization from the FDA.

#### **Administration of COVID-19 Vaccines**

#### **2. Personnel Who May Administer Vaccines**

The following individuals may administer COVID-19 vaccines at vaccination sites:

- A. Health care practitioners licensed, certified, or registered under the provisions of the Health Occupations Article whose scope of practice includes the administration of vaccines;
- B. Health care practitioners licensed, certified, or registered under the provisions of the Health Occupations Article whose scope of practice does not include the administration of vaccines provided that:



- i. The health care practitioner has successfully completed training on the administration of COVID-19 vaccines;
  - ii. Qualified supervisory personnel at the vaccination site reasonably determine that said health care practitioner is able to administer COVID-19 vaccines under appropriate supervision; and
  - iii. The health care practitioner administers the COVID-19 vaccine at the vaccination site under reasonable supervision of qualified supervisory personnel.
- C. Paramedics as authorized by the Emergency Medical Services (EMS) Board under [EMS Board Public Order #6](#); and
- D. Other individuals provided that:
  - i. Each individual has successfully completed training on the administration of COVID-19 vaccines;
  - ii. Qualified supervisory personnel at the vaccination site reasonably determine that each individual is able to administer COVID-19 vaccines under appropriate supervision; and
  - iii. The individual administers the COVID-19 vaccine at the vaccination site under the reasonable supervision of qualified supervisory personnel.

3. **Personnel Who May Prepare Vaccines for Administration**

The following individuals may prepare, as necessary when directed by the manufacturer, COVID-19 vaccines for administration at vaccination sites:

- i. Health care practitioners licensed, certified, or registered under the provisions of the Health Occupations Article who have received appropriate training in the preparation and dilution of COVID-19 vaccines.

4. **Penalties**

Persons who violate this Order and Directive may face administrative and criminal sanctions to include imprisonment not exceeding one year or a fine not exceeding \$5,000 or both.

5. **Severability**

If any provision of this Directive and Order or its application to any person, entity, or circumstance is held invalid by any court of competent jurisdiction, all other provisions or applications of this Directive and Order shall remain in effect to the extent possible without the invalid provision or application. To achieve this purpose, the provisions of this Directive and Order are severable.

THESE DIRECTIVES AND ORDERS ARE ISSUED UNDER MY HAND THIS 8TH DAY OF  
DECEMBER 2020 AND ARE EFFECTIVE IMMEDIATELY.

A handwritten signature in black ink, reading "Dennis R. Schrader". The signature is written in a cursive style with a large initial "D".

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Dennis R. Schrader  
Secretary (Acting)