Maryland
Board of Pharmacy
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary
Jennifer L. Hardesty, Board President – Deena Speights-Napata, Executive Director

March 14, 2022

The Honorable Shane Pendergrass
Chair, House Health and Government Operations Committee
Room 241, House Office Building
Annapolis, MD 21401

RE: House Bill 1189 – Public Health – Vaccines Administered Under Emergency Use Authorization – Reporting of Adverse Events

Dear Chair Pendergrass and Committee Members:

The Maryland Board of Pharmacy (the Board) is submitting this Letter of Information for House Bill (HB) 1189 – Public Health – Vaccines Administered Under Emergency Use Authorization – Reporting of Adverse Events.

HB 1189 will require a health care provider to report any adverse event observed in a patient after the administration of a vaccine administered under an emergency use authorization (EUA) to the National Vaccine Adverse Event Reporting System (VAERS). HB 1189 defines an "adverse event" as any "illness, disability, incapacity, hospitalization, death, or impairment of mental, emotional, behavioral, or physical functioning or development, the first manifestation of which appears after the date of administration of a vaccine."

The Board notes that federal reporting requirements for a vaccine authorized under an EUA are: (1) vaccine administration error, (2) death, (3) life threatening adverse event, (4) inpatient hospitalization or prolongation of existing hospitalization, (5) persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, (6) congenital anomaly or birth defect, (7) important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above, and (8) multisystem inflammatory syndrome.[1]

The Board recommends that State VAERS reporting requirements remain consistent with federal VAERS reporting requirements. Deviation from the standard reporting requirements may cause confusion among healthcare practitioners, result in unreliable reporting, and undermine the credibility of the VAERS system.

[1] https://vaers.hhs.gov/reportevent.html; 21 C.F.R. § 312.32.

I hope this information is useful. If you would like to discuss this further, please do not hesitate to contact me at deena.speights-napata@maryland.gov or (410) 764-4753.

Sincerely,

Deena Speights-Napata, MA
Executive Director

Jennifer L. Hardesty,
PharmD, FASCP
President

The opinion of the Board expressed in this document does not necessarily reflect that of the Maryland Department of Health or the Administration.