

Department of Legislative Services  
Maryland General Assembly  
2022 Session

FISCAL AND POLICY NOTE  
First Reader

House Bill 1189 (Delegate M. Fisher, *et al.*)  
Health and Government Operations

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Public Health - Vaccines Administered Under Emergency Use Authorization -  
Reporting of Adverse Events

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This bill requires a health care provider to promptly report to the national Vaccine Adverse Event Reporting System (VAERS) any “adverse event” observed in a patient after the administration of a vaccine, including a COVID-19 vaccine or booster, administered under an emergency use authorization (EUA). “Adverse event” means *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, including a COVID-19 vaccine or booster.

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**Fiscal Summary**

**State Effect:** While the bill generally codifies existing practice/procedure for COVID-19 vaccines, it broadens the situations required to be reported and extends the reporting requirement to other EUA vaccines. Any such impact does not materially affect State operations or finances.

**Local Effect:** While the bill generally codifies existing practice/procedure for COVID-19 vaccines, it broadens the situations required to be reported and extends the reporting requirement to other EUA vaccines. Any such impact does not materially affect operations or finances of local health departments.

**Small Business Effect:** Minimal.

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**Analysis**

**Current Law:** VAERS is a national program managed by the U.S. Centers for Disease Control and Prevention and the U.S. Food and Drug Administration to monitor the safety

of all vaccines *licensed* in the United States. VAERS collects and reviews reports of adverse events that occur after vaccination. VAERS cannot determine if a vaccine caused an adverse event but can determine if further investigation is needed.

Under the National Childhood Vaccine Injury Act, health care providers are required by law to report to VAERS any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccinations or an adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

Health care providers are strongly *encouraged* to report any adverse event that occurs after the administration of a vaccine *licensed* in the United States, regardless of whether it is clear a vaccine caused the adverse event, and vaccine administration errors.

However, health care providers who administer COVID-19 vaccines, including those under EUA, are *required* by law to [report](#) the following to VAERS: (1) vaccine administration errors, whether or not associated with an adverse event, if the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a two-dose series or if a different product from the primary series is inadvertently administered for the additional or booster (third dose) and (2) serious adverse events regardless of whether the reporter thinks the vaccine caused the adverse event (*e.g.*, death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly/birth defect, or an important medical event that may jeopardize the individual and may require medical or surgical intervention); (3) cases of multisystem inflammatory syndrome; and (4) cases of COVID-19 that result in hospitalization or death.

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## Additional Information

**Prior Introductions:** None.

**Designated Cross File:** None.

**Information Source(s):** U.S. Centers for Disease Control and Prevention; Maryland Association of County Health Officers; Maryland Institute for Emergency Medical Services Systems; Maryland Department of Health; Department of Legislative Services

**Fiscal Note History:** First Reader - March 13, 2022  
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