

Steve Sisolak
Governor

Richard Whitley, MS
Director



DEPARTMENT OF
HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
Helping people. It's who we are and what we do.



Lisa Sherych
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical Officer

Technical Bulletin

Date: May 4, 2021
Topic: Adverse Event Reporting Following COVID-19 Vaccination
Contact: Pamela Forest, MD, Vaccine Safety Coordinator
To: All Health Care Providers and Facilities, Local Health Districts, and Pharmacists

The United States currently has three (3) COVID-19 vaccinations available under an Emergency Use Authorization (EUA). The Centers for Disease Control and Prevention (CDC) use the Vaccine Adverse Event Reporting System (VAERS) as an early warning and safety monitoring system that monitors health problems or events that occur after a vaccination. VAERS continuously monitors the safety of vaccines to help ensure the benefits of vaccination continue to outweigh the risks. VAERS is dependent upon healthcare professionals reporting any potentially significant clinical health problem or adverse event that occurs after vaccination. Healthcare providers are required by law, under the National Childhood Vaccination Injury Act, to report any adverse event listed in the VAERS Table of Reportable Events for COVID-19 Vaccines, without determining causality.

Additionally, a severe reaction to any vaccination is a reportable event by a healthcare provider to the local health authority per Nevada Administrative Code (NAC). Therefore, an adverse event should be reported by a Nevada healthcare provider to both VAERS and their local health authority.

Pursuant to the VAERS Table of Reportable Events Following COVID-19 Vaccination: Healthcare providers are **required** to report the following adverse events after COVID-19 vaccination to VAERS. This is a current list, as of April 20, 2021, and is subject to revision by the CDC.

- Vaccine administration errors, whether associated with an adverse event or not
- Serious adverse events, regardless of causality. Serious adverse events per the U.S. Food and Drug Administration (FDA) are defined as:
 1. Death
 2. A life-threatening adverse event
 3. Inpatient hospitalization or prolongation of existing hospitalization
 4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
 5. A congenital anomaly/birth defect
 6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS)
- Cases of COVID-19 disease following vaccination that result in hospitalization or death

To Report an Adverse Event in VAERS:

Option 1: The preferred method: Submit a VAERS Report by visiting <https://vaers.hhs.gov/esub/index.jsp>. The report must be completed and submitted in the same 20-minute session and cannot be saved to complete later.

Option 2: Download a fillable PDF at <https://vaers.hhs.gov/uploadFile/index.jsp> and upload the completed form back to the site.

Additionally, a severe reaction to a vaccination is a reportable event by a Nevada healthcare provider to the local health authority per [NAC 441A.685](#).

NAC 441A.685 Severe reaction to immunization. ([NRS 441A.120](#))

1. The health authority shall investigate each report of a case having a severe reaction to immunization to confirm the diagnosis and to document the circumstances pertaining to the reported reaction. The health authority shall transmit such information to the Division.
2. As used in this section, a “severe reaction to immunization” means a severe or unusual event related either directly or indirectly to the receipt of a vaccine, which occurred within 30 days after the receipt of a vaccine and resulted in the death of the person vaccinated or the need for the person vaccinated to consult a health care provider.

(Added to NAC by Bd. of Health, eff. 1-24-92)

Based on this code, the Nevada State Immunization Program has developed the following protocol:

1. Healthcare providers should report a severe reaction to an immunization to their local health authority as required by NAC 441A.685 and NRS 441A.120.
 - a. If the event is reported directly to the Nevada Division of Public and Behavioral Health, then it will be forwarded to the appropriate local health authority for further action.
2. The local health authority is responsible for determining whether the investigation should be conducted by their Epidemiology Division or Immunization Division.
3. The local health authority will conduct the investigation and will ensure a VAERS report has been submitted.

In addition to reporting serious adverse events to VAERS and local health authorities, healthcare providers are encouraged to report to VAERS any other clinically significant adverse events that occur within 30 days following COVID-19 vaccination, even if unsure of causality. Throughout the duration of any COVID-19 vaccine being authorized under an EUA, continue to report any additional select adverse event(s) and/or any revised safety reporting requirements per FDA’s conditions of authorized use of the vaccine.

Local Health Authority Contacts

Carson City Health and Human Services:	Veronica Galas (775) 283-7620
Southern Nevada Health Department:	JoAnn Rupiper (702) 759-0815
Washoe County Health Department:	Nicole Mertz (775) 328-6167
Division of Public and Behavioral Health:	Tammy Ritter (775) 684-5031

Questions: For updated guidance, please review the DPBH Technical Bulletin website and Nevada’s COVID-19 response website regularly. ^{1,2} If you have other questions regarding adverse event reporting following COVID-19 vaccination, please email dpbhcovid19vax@health.nv.gov.



Lisa Sherych, Administrator
Division of Public and Behavioral Health



Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

¹ http://dpbh.nv.gov/Resources/Technical_Bulletins-New/

² <https://nvhealthresponse.nv.gov/>