

## ADVERSE DRUG EVENT REPORTING AND MONITORING

**1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive establishes national policy for the reporting, monitoring, and surveillance of adverse drug events (ADEs) entered into VHA's voluntary ADE reporting system for observed adverse drug reactions (ADRs) and new ADEs at Department of Veterans Affairs (VA) medical facilities. **NOTE:** *This directive also maintains national policy, which is co-managed by the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) on the reporting requirements of ADEs due to vaccines.*

### 2. SUMMARY OF MAJOR CHANGES:

a. The links to the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) vaccine adverse event reporting system have been updated.

b. Oversight responsibilities have been added for the Under Secretary of Health, Deputy Under Secretary for Health for Operations and Management, and the Deputy Under Secretary for Health for Policy and Services (see paragraph 5).

c. Responsibilities for the Chief Consultant, Pharmacy Benefits Management (PBM), Director of VA PBM Center for Medication Safety, VA medical facility Pharmacy and Therapeutics Committee, VA medical facility VA Adverse Drug Event Reporting System (ADERS) point of contact, VA health care providers that report to VA ADERS, VA health care providers, and VA medical facility investigators have been added (see paragraph 5).

d. Existing responsibilities of VA ADERS Advisory Committee, the Veterans Integrated Services Network Director, and the VA medical facility Director have been updated (see paragraph 5).

e. Requirement for written procedures that describe the operation of the VA medical facility ADE reporting system has been removed (see paragraph 5).

f. Requirements for reporting ADEs have been added (see paragraph 7).

g. Requirements for monitoring ADEs have been added (see paragraph 8).

**3. RELATED ISSUES:** VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018; VHA Directive 1069, National Pharmacy Benefits Management Drug Safety Alert Distribution, dated October 24, 2019; and VHA Handbook 1108.04, Investigational Drugs and Supplies, dated February 2012.

**4. RESPONSIBLE OFFICE:** The Chief Consultant for Pharmacy Benefits Management (PBM) Services (10P4P) is responsible for the contents of this directive. Questions may be directed to 202-461-7326.

**5. RESCISSIONS:** VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated September 12, 2014, is rescinded.

**6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working date of May 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF  
THE UNDER SECRETARY FOR HEALTH:**

/s/ Lucille B. Beck, Ph.D.  
Deputy Under Secretary for Health  
for Policy and Services

**NOTE:** *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

**DISTRIBUTION:** Emailed to the VHA Publications Distribution List on May 20, 2020.

**CONTENTS**

**ADVERSE DRUG EVENT REPORTING AND MONITORING**

1. PURPOSE ..... 1

2. BACKGROUND ..... 1

3. DEFINITIONS ..... 2

4. POLICY ..... 4

5. RESPONSIBILITIES ..... 4

6. VA APPROVED RESEARCH STUDIES ..... 9

7. REQUIREMENTS FOR REPORTING ADVERSE DRUG EVENTS ..... 10

8. REQUIREMENTS FOR MONITORING ADVERSE DRUG EVENTS ..... 10

9. TRAINING ..... 11

10. RECORDS MANAGEMENT ..... 11

11. REFERENCES ..... 11

APPENDIX A

RECOMMENDED TRAINING .....A-1

## ADVERSE DRUG EVENT REPORTING AND MONITORING

### 1. PURPOSE

This Veterans Health Administration (VHA) directive establishes national policy for the reporting, monitoring, and surveillance of adverse drug events (ADEs) entered into VHA's voluntary ADE reporting system for observed adverse drug reactions (ADRs) and new ADEs at the Department of Veterans Affairs (VA) medical facilities. **NOTE:** *For purposes of this directive, ADE includes events related to medication (drug), vaccination, and immunization products. VA Adverse Drug Event Reporting System (VA ADERS) is a voluntary ADE reporting system and is not mandated by a government regulatory agency.* **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

### 2. BACKGROUND

a. VA ADERS is VHA's national intranet voluntary ADE reporting system, available at: [https://vaww.cmop.med.va.gov/MedSafe\\_Portal/](https://vaww.cmop.med.va.gov/MedSafe_Portal/). **NOTE:** *This is an internal VA Web site that is not available to the public. VA Adverse Drug Event Reporting System (VA ADERS) is not mandated by a government regulatory agency. VA ADERS standardizes reporting at the VA medical facility level, centralizes ADE data analysis, and uses a standardized reporting scheme to categorize and classify symptoms associated with the adverse drug event.*

b. Tracking ADEs is crucial to ensuring Veteran safety. The primary goal of VA ADERS is to sustain quality assurance and process improvement activities related to voluntarily reported adverse drug events with a focus on adverse drug reactions (ADRs). **NOTE:** *See VHA Directive 2011-012, Medication Reconciliation, dated March 9, 2011, for more information about ADRs.*

c. The objectives of VA ADERS are to improve ADE reporting and monitoring, to provide VA ADERS trending reports (aggregate ADE specific reports by year, drug, or event), and to maintain an intranet portal for VA medical facilities to share process improvements as a result of ADE data analysis. VA ADERS achieves these objectives using a central database within VHA where all ADEs are reported uniformly so that surveillance activities can identify safety concerns in Veterans promptly, and VA medical facilities have data to track, trend, and compare information throughout VHA. This ADE reporting and tracking system enables VHA to take prompt action to ensure the safety of pharmaceutical drug product use.

d. In addition to serving as VHA's centralized system to report ADEs, VA ADERS allows health care providers to:

(1) Report, track, and electronically submit ADEs to the Food and Drug Administration (FDA) MedWatch system which is submitted through the VA ADERS system.

(2) Report, track, and electronically submit adverse events due to vaccine and immunization products to the Centers for Disease Control and Prevention (CDC) and

FDA's Vaccine Adverse Event Reporting System (VAERS) program which is submitted through the VA ADERS system.

(3) Assess information on ADEs that are potentially preventable and report to the health care providers involved in ADE monitoring.

(4) Trend ADE data at local, regional, and national levels.

(5) Track ADEs associated with drugs that have been on the market in the United States for 3 years or less.

e. The VA ADERS trending report is generated at least quarterly by the VA ADERS staff and VA ADERS Advisory Committee and communicated to VA medical facility VA ADERS points of contact (POCs). The VA ADERS trending report includes a summary analysis of trends of the ADEs reported, ADE symptoms, and medications that cause ADEs. Other items can also be analyzed, and trends assessed including: age, potential association, and severity.

f. Veterans Integrated Service Networks (VISNs) and VA medical facilities can use the VA ADERS data for customized benchmarking and utilizing report totals. Comparisons for benchmarking can utilize reporting trends from VA medical facilities of similar size and complexity and, where applicable, by drug, drug class, event of interest, or ADE severity.

g. VA ADERS staff and VA ADERS Advisory Committee members evaluate overall trends utilized for benchmarking. VA ADERS staff and VA ADERS Advisory Committee communicate if a safety signal is identified and inform decision makers at the national, VISN, and VA medical facility level. Benchmarking is communicated by VA ADERS staff, when needed, to the VISNs and VA medical facilities for review and sharing at the respective level.

### 3. DEFINITIONS

a. **Adverse Drug Event.** An ADE is an injury resulting from the use of a drug. For the purposes of this directive, this definition includes harm caused by the drug as a result of adverse drug reactions, drug-drug interactions, product quality problems, or drug overdoses (whether accidental or intentional). See reference in paragraph 11.n. for more information. Severity levels are:

(1) **Mild Adverse Drug Event.** A mild ADE is an event that requires no intervention or minimal therapeutic intervention such as discontinuation of drug(s).

(2) **Moderate Adverse Drug Event.** A moderate ADE is an event that requires active treatment of adverse reaction, further testing, or evaluation to assess the extent of the non-serious outcome.

(3) **Serious Adverse Drug Event.** A serious ADE occurs when a patient's condition has one or more of the following outcomes (or requires medical intervention to prevent

one or more of these outcomes): death, a life-threatening experience, inpatient hospitalization (or a prolonged hospitalization), a persistent or significant disability, or a congenital anomaly or birth defect. **NOTE:** Please see FDA definition

<https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event>.

b. **Adverse Drug Reaction.** An adverse drug reaction (ADR) is a response to a drug which is noxious, unintended, and which occurs at doses normally used in individuals for prophylaxis, diagnosis, therapy of disease, or for the modification of physiologic function. **NOTE:** *There should be a causal or suspected link between a drug and ADR. However, a causality assessment or association of the drug to the ADR does not have to be established in order to report an ADR or ADE. Other definitions may exist and are not excluded from the definition in this directive, such as the American Society of Health-System Pharmacists.*

(1) **Allergy.** An allergy is an ADR mediated by an immune response (e.g., rash, hives).

(2) **Historical Adverse Drug Reaction.** A historical ADR is a past event or an event that reportedly occurred in the past at another health care setting that no longer requires intervention.

(3) **Observed Adverse Drug Reaction.** An observed ADR is defined as a reaction that is directly observed or occurring while the patient was on the suspected causative agent. **NOTE:** *“Observed” refers to a newly noted adverse outcome. Although the term implies that the health care provider of record made the diagnosis, the fact that a health care provider may not have visually “observed” an adverse drug reaction does not preclude reporting as “observed.”*

c. **Blinding.** A research methodology in which the investigators do not know a treatment assignment for any subject. Clinical trials are often double-blind (or double-masked), meaning that both subjects and investigators, as well as sponsor-investigator or investigator staff involved in the treatment or clinical evaluation of subjects, are unaware of each subject's assigned treatment. **NOTE:** *Blinding is intended to minimize the potential biases resulting from differences in management, treatment, or assessment of subjects, or interpretation of results that could arise as a result of subject or investigator knowledge of the assigned treatment.*

d. **Causality Assessment.** A causality assessment is a determination whether there is a reasonable possibility that the drug caused or contributed to an adverse event. It includes assessing temporal relationships, de-challenge or re-challenge information, association (or lack of association) with underlying disease, and the presence (or absence) of a more likely cause.

e. **Medication Error.** A medication error is a mishap that occurs during prescribing, transcribing, dispensing, administering, adherence, or monitoring a drug. See [www.nccmerp.org](http://www.nccmerp.org). **NOTE:** *Not all medication errors lead to adverse outcomes and all medication errors regardless of harm or adverse outcome are to be reported in*

accordance with VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011, into the Patient Safety Reporting system. When medication errors result in an adverse outcome, the event should be reported in both VA ADERS and the Patient Safety Reporting system as well as communicated with VA medical facility Patient Safety staff. Likewise, with ADE reports submitted to VA ADERS found to be the result of a medication error, the event is to be entered in both systems and appropriate VA medical facility Patient Safety staff notified.

f. **Pharmacovigilance.** Pharmacovigilance is a clinical science whose objectives are the surveillance, evaluation, and signal detection of the undesirable effects of pharmaceutical products (e.g., drugs, biologics, medicines) used for medical therapy or diagnosis. **NOTE:** For more information, please see *The Importance of Pharmacovigilance - Safety Monitoring of Medicinal Products*, World Health Organization, available at: <https://apps.who.int/iris/handle/10665/42493>. This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.

g. **Suspect Drug.** A suspect drug is a drug product administered before the ADE began and is believed by the reporter, manufacturer, or the health care agency to have contributed to its occurrence. It is “suspected” of being the cause of the ADE, and this suspicion makes the ADE an ADR for reporting purposes. Types of suspect drugs include: drug products or products of biologic origin (vaccines, blood products); non-prescription drugs; replacement drugs (hormones, vitamins, minerals, electrolytes, and fluids); non-active ingredients (excipients); or medical, surgical, and dental devices and their interactions with drugs.

h. **VA Adverse Drug Event Reporting System Data Cube.** The VA ADERS data cube is a multidimensional database that stores the ADE data and can be viewed by any authorized VA health care provider. The VA ADERS data cube allows different views of the data to be quickly displayed and to generate local ADE trending reports.

#### 4. POLICY

It is VHA policy that ADEs voluntarily reported to VA ADERS that meet the criteria of serious adverse drug events must be reported to FDA MedWatch. ADEs due to vaccines must be reported to VAERS. The ADEs and observed ADRs in subjects participating in VA clinical trials or research protocols must be reported into VA ADERS, when appropriate, to enhance Veteran safety. **NOTE:** ADRs are the majority of the ADEs reported to the VA ADERS program, but for clarity, both ADE and ADR are noted here.

#### 5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services is responsible for ensuring that the Chief Consultant of Pharmacy Benefits Management Services complies with the requirements of this directive.

d. **Chief Consultant, Pharmacy Benefits Management Services.** The Chief Consultant, Pharmacy Benefits Management (PBM) Services, is responsible for ensuring that the Director, VA MedSAFE, complies with all requirements in this directive.

e. **Director, VA Center for Medication Safety.** VA Center for Medication Safety (VA MedSAFE) is a PBM Center for Medication Safety with a mission to identify, track, and address preventable ADEs in the VA system with the primary focus on preventing ADRs. As a pharmacovigilance center, VA MedSAFE undertakes quality improvement and safety initiatives that assess, monitor, and improve the safe and appropriate use of medications; promote risk reduction efforts; and enhance education and communication of ADEs as well as potential ADEs on a national level. VA ADERS is a program under VA MedSAFE. The Director, VA MedSAFE, is responsible for:

(1) Administering the VA ADERS program and ensuring the VA ADERS program complies with all requirements of this directive.

(2) Appointing representative members from, but not limited to, PBM Clinical Pharmacy Section; Medical Advisory Panel (MAP); VA MedSAFE; VA ADERS and VA ADERS end users; National Center for Patient Safety (NCPS); Office of Research and Development (ORD); VISN Pharmacist Executive; PBM Clinical Informatics; PBM Clinical Pharmacy Program Office (CPPO); and Consolidated Mail Out Pharmacy (CMOP) staff to the VA ADERS Advisory Committee.

(3) Ensuring VA ADERS staff and VA ADERS Advisory Committee meet at least every 3 months and review ADE data in VA ADERS.

(4) Communicating any variations or unusual trends, as appropriate, to health care providers through medication safety bulletins.

(5) Ensuring VA ADERS staff aggregate and analyze data nationally to identify potential signals of ADEs to support pharmacovigilance activities, determine if certain actions must be taken if a safety signal is identified, and inform decision makers at the national and VISN level. **NOTE:** *All symptoms reported into VA ADERS that are*



associated with the ADE will be coded in accordance with terminology from the Medical Dictionary for Regulatory Activities (MedDRA). See <https://www.meddra.org/>.

(6) Ensuring VA ADERS staff identify any trends in variation in reporting of ADEs (in total and by type).

(7) Ensuring VA ADERS staff evaluate overall trends for benchmarking and communicating benchmarking trends to VA medical facility VA ADERS POCs.

(8) Ensuring VA ADERS staff generate a quarterly VA ADERS trending report at least every 3 months, or more frequently as directed. The quarterly VA ADERS trending report is shared with the VA ADERS Advisory Committee, and designated health care providers, or as directed. The VA ADERS trending report includes a summary analysis of trends of the ADEs reported, ADE symptoms, and medications that cause ADEs. Other items can also be analyzed, and trends assessed including: age, potential association, and severity. **NOTE:** *VA medical facilities can also use VA ADERS reporting tools to build customized or ad hoc ADE trending reports as needed.*

(9) Ensuring access to the VA ADERS data cube for designated health care providers, as determined by the VA medical facility Chief of Pharmacy.

(10) Ensuring VA ADERS staff review process and system improvements reported by VA medical facility VA ADERS POCs to evaluate and determine national applicability with the VA ADERS Advisory Committee.

(11) Ensuring VA ADERS staff identify quality assurance projects, such as medication use evaluations, with the assistance of VA ADERS Advisory Committee.

(12) Ensuring a process is in place to communicate that further analysis is required by VA medical facilities to assess and intervene upon preventable ADE trends that have been identified by VA ADERS staff and confirmed by the VA ADERS Advisory Committee.

f. **Chair, VA Adverse Drug Events Reporting System Advisory Committee.** The Chair, VA ADERS Advisory Committee, is responsible for:

(1) Serving as an advisor to VA ADERS staff.

(2) Meeting at least every 3 months with VA ADERS staff and reviewing ADE data in VA ADERS to identify any potential signals of ADEs to support pharmacovigilance activities. **NOTE:** *Ad hoc meetings and data requests are scheduled, as needed, by VA ADERS staff and VA ADERS Advisory Committee in response to significant ADE or an unusual cluster of ADEs reported by VISNs, VA medical facilities, and ORD or reported through the NCPS safety reports database.*

(3) Reviewing process and system improvements reported by VA medical facilities to evaluate and determine national applicability with VA ADERS staff.

(4) Providing assistance, guidance, and education to VISNs when variation in reporting is identified as a trend by VA ADERS staff.

(5) Assisting VA ADERS staff in identifying quality assurance projects, such as medication use evaluations, for review and consideration by VA ADERS staff.

g. **Veterans Integrated Service Network Director.** The VISN Director, or designee (i.e., VISN Pharmacist Executive), is responsible for:

(1) Ensuring that information from VA MedSAFE and VA ADERS trending reports are reviewed, as necessary.

(2) Coordinating action from VA MedSAFE, if necessary.

(3) Ensuring that all VA medical facilities within the VISN comply with this directive.

h. **VA Medical Facility Director.** The VA medical facility Director can delegate the following responsibilities to the VA medical facility Chief of Pharmacy as needed. The VA medical facility Director, or designee, is responsible for:

(1) Appointing a VA medical facility VA ADERS POC(s) that communicates with VA ADERS staff.

(2) Submitting the name of the appointed VA medical facility VA ADERS POC to VA MedSAFE. **NOTE:** *Submission by Email to VHAPBM MedSAFE Informatics BI Tools at [VHAPBMMedSAFEInformaticsBITools@va.gov](mailto:VHAPBMMedSAFEInformaticsBITools@va.gov) is preferred. Contact VA ADERS staff as soon as possible to notify of VA medical facility VA ADERS POC change.*

(3) Ensuring sufficient health care providers are designated for reporting ADEs into VA ADERS. **NOTE:** *The VA medical facility Director determines the structure for health care providers who report ADEs to VA ADERS. Acceptable variations include appointing a VA ADERS reporter who reports all observed ADRs for the VA medical facility or appointing each pharmacist as a VA ADERS reporter responsible for reporting ADRs they personally observe.*

(4) Providing oversight to ensure that VA medical facility staff comply with this directive.

(5) Ensuring the VA medical facility Chief of Pharmacy requests access from VA ADERS to the VA ADERS data cube for authorized health care providers.

(6) Ensuring that VA ADERS trending reports are reviewed, and any unusual trends as identified by VA MedSAFE are addressed. **NOTE:** *Reports of ADEs are submitted to VA ADERS Web site: [https://vaww.cmop.med.va.gov/MedSafe\\_Portal/](https://vaww.cmop.med.va.gov/MedSafe_Portal/). This is an internal VA Web site that is not available to the public.*

(7) Ensuring all reports of adverse events due to vaccines are submitted to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) through VA ADERS.

(8) Ensuring that all reports of observed ADRs meeting the criteria as serious adverse drug events are submitted to the FDA MedWatch system through VA ADERS.

(9) Coordinating action from a VA MedSAFE notification if the ADE was identified as preventable as a result of a medication error with appropriate groups, such as: VA medical facility Associate Chief of Staff (ACOS) for Research and Development (R&D); VA medical facility P&T Committee, and VA medical facility; if applicable, VA medical facility Quality Management, VA medical facility Risk Managers, and VA medical facility Patient Safety Managers; and VA medical facility Safety Committee Officers.

i. **VA Medical Facility Chief of Pharmacy.** The VA medical facility Chief of Pharmacy is responsible for requesting access to the VA ADERS data cube for authorized health care providers and all responsibilities if assigned as the designee of the VA medical facility Director.

j. **Chair, VA Medical Facility Pharmacy and Therapeutics Committee.** The Chair, VA Medical Facility Pharmacy and Therapeutics (P&T) Committee, or designee (i.e., VA medical facility Chief of Pharmacy), is responsible for evaluating the benchmarking data and assessing reported ADEs.

k. **VA Medical Facility VA ADERS Point(s) of Contact.** The VA medical facility VA ADERS POC(s) is responsible for:

(1) Functioning as a point of contact for communication between the VA medical facility and VA ADERS staff (e.g. VA ADERS pharmacy program manager, VA ADERS pharmacist specialist, and VA ADERS web developer).

(2) Sharing information from VA ADERS staff (e.g., pharmacy program manager, pharmacist specialist, and web developer), as required, with the VA medical facility Director, VA medical facility P&T committee, and health care providers that report to VA ADERS in accordance with the requirements of this directive.

(3) Sharing any process or system improvements made at the local VA medical facility level with VA ADERS staff, (e.g. pharmacy program manager, pharmacist specialist, and web developer). See VHA Handbook 1050.01. The system for identifying process and system improvements varies by VA medical facilities. Communication by VA medical facilities also varies and is done through direct telephone contact and Email.

(4) Communicating benchmarking data from VA ADERS to the VA medical facility Director, or designee, the VA medical facility P&T Committee, or health care providers that report ADEs to VA ADERS.

(5) Communicating to VA ADERS staff any discrepancies between the benchmarking data at the VA medical facility in comparison to the national data.

(6) Communicating action items to improve reporting or address benchmarking comparisons to VA ADERS staff.

(7) Notifying VA ADERS staff of an ADE that was identified as preventable as a result of medication error. See VHA Handbook 1050.01 for additional information.

**I. VA Medical Facility Health Care Providers that Report to VA ADERS.** Health care providers that report to VA ADERS are responsible for:

(1) Submitting all reports of ADEs due to vaccines to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) through VA ADERS. **NOTE:** Reports are submitted to VA ADERS Web site: [https://vaww.cmop.med.va.gov/MedSafe\\_Portal/](https://vaww.cmop.med.va.gov/MedSafe_Portal/). **NOTE:** This is an internal VA Web site that is not available to the public.

(2) Submitting all reports of observed ADRs meeting the criteria as serious adverse drug events to the FDA MedWatch system through VA ADERS. **NOTE:** Reports are submitted to VA ADERS Web site: [https://vaww.cmop.med.va.gov/MedSafe\\_Portal/](https://vaww.cmop.med.va.gov/MedSafe_Portal/). **NOTE:** This is an internal VA Web site that is not available to the public.

**m. VA Medical Facility Health Care Providers and VA Medical Facility Investigators.** If the observed ADR occurred during clinical trial (as described in paragraph 6), VA health care providers and VA medical facility investigators are responsible for:

(1) Reporting observed ADRs into VA ADERS: [https://vaww.cmop.med.va.gov/MedSafe\\_Portal/](https://vaww.cmop.med.va.gov/MedSafe_Portal/). **NOTE:** This is an internal VA Web site that is not available to the public.

(2) Notifying the study Institutional Review Board of record. VA medical facility health care providers and VA medical facility investigators must also notify other specified groups responsible for study oversight or management in accordance with the reporting requirements (see paragraph 7).

## **6. VA APPROVED RESEARCH STUDIES**

a. This directive is applicable to clinical trials if the research protocol requires the use of investigational drugs, comparator drugs, or concurrent drugs, or any combination thereof (see VHA Handbook 1108.04, Investigational Drugs and Supplies, dated February 29, 2012, for definitions of these terms) if the drugs:

(1) Have been approved by the FDA.

(2) Are being used for an FDA approved indication.

(3) Are being used at a dosage and in a patient population that is consistent with the official labeling of the drug.

b. When observed ADRs are identified during research studies, the local VA medical facility investigator is responsible for:

(1) Reporting observed ADRs into VA ADERS.

(2) Notifying the study Institutional Review Board (IRB) of record in accordance with the reporting requirements (see paragraph 7).

(3) Notifying other specified groups responsible for study oversight or management, as required by the research protocol, if the ADE also meets the definition of an adverse event, serious adverse event, or an unanticipated adverse event for which reporting is required. See 21 Code of Federal Regulations (CFR) 56.102(g).

c. Reporting in VA ADERS is not required if the investigational drugs, comparator drugs, concurrent drugs, or any combination thereof, are:

(1) Considered an investigational drug as defined in VHA Handbook 1108.04; or

(2) Used in a clinical trial in which the VA medical facility investigator does not know participants' treatment assignment because of the use of a blinded methodology.

## 7. REQUIREMENTS FOR REPORTING ADVERSE DRUG EVENTS

a. A VA medical facility VA ADERS POC must be appointed by the VA medical facility Director, or designee, who communicates between the VA medical facility and VA ADERS staff. There must be health care providers designated for reporting ADEs to VA ADERS. **NOTE:** For recommended training see Appendix A.

b. At a minimum, the local VA medical facility ADE reporting system must meet or exceed requirements mandated by The Joint Commission. This standard requires analysis of serious ADEs, and appropriate action based on the analysis. **NOTE:** For more information, please see *The Joint Commission. Medication Management Chapter* available at: <https://www.jointcommission.org/>.

c. All reports of adverse events due to vaccines must be submitted to the FDA/CDC VAERS through VA ADERS. All reports of ADRs meeting the criteria as serious adverse drug events must be submitted to the FDA MedWatch system through VA ADERS.

d. Health care providers do not have to obtain approval by any other person or committee before submitting a report of an ADE to VA ADERS, and the causality does not have to be absolutely established before submitting a report of an ADE to VA ADERS.

## 8. REQUIREMENTS FOR MONITORING ADVERSE DRUG EVENTS

a. The VA medical facility VA ADERS POC(s) is the liaison that provides communication between VA ADERS staff and the VA medical facility. The VA medical facility VA ADERS POC(s) must share any process or system improvements made at the VA medical facility level with VA ADERS staff.

b. The VA medical facility VA ADERS POC(s) must communicate benchmarking data from VA ADERS to the VA medical facility to the VA medical facility Director, or

designee, VA medical facility P&T Committee, or health care providers that report ADEs to VA ADERS. The VA medical facility P&T committee evaluate the benchmarking data and assess reported ADEs at the VA medical facility. If the benchmarking data shows a discrepancy at the VA medical facility in comparison to the national data, then this discrepancy must be communicated to VA ADERS staff by the VA medical facility VA ADERS POC(s). The VA medical facility VA ADERS POC(s) must communicate action items to improve reporting or address benchmarking comparisons to VA ADERS staff.

c. The VA medical facility Director must ensure that monitoring of ADEs occurs at the local level. The VA medical facility Director must ensure action is coordinated from a VA MedSAFE notification if the ADE was identified as preventable as a result of a medication error with appropriate groups, such as: VA medical facility Associate Chief of Staff (ACOS) for Research and Development (R&D); VA medical facility P&T Committee and VA medical facility Pharmacy Service; if applicable, VA medical facility Quality Management, VA medical facility Risk Managers, and VA medical facility Patient Safety Managers; and VA medical facility Safety Committee Officers. If an ADE was identified as preventable as a result of a medication error, the VA medical facility VA ADERS POC must notify VA ADERS staff of the ADE.

## 9. TRAINING

There are no formal training requirements associated with this directive. **NOTE:** *For recommended training see Appendix A.*

## 10. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

## 11. REFERENCES

- a. 38 U.S.C. 7301(b).
- b. 21 CFR 56.
- c. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.
- d. VHA Directive 1069, National Pharmacy Benefits Management Drug Safety Alert Distribution, dated November 24, 2014.
- e. VHA Directive 2011-012, Medication Reconciliation, dated March 9, 2011.
- f. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

g. VHA Handbook 1108.04, Investigational Drugs and Supplies, dated February 2012.

h. "About Medication Errors: What is a medication error?" accessed October 18, 2019, available at: <https://www.nccmerp.org>.

i. Centers for Disease Control and Prevention (CDC) and the FDA Vaccine Adverse Event Reporting System (VAERS), available at: <https://vaers.hhs.gov/reportevent.html>.

j. Food and Drug Administration (FDA) MedWatch system, available at: <https://www.fda.gov/Safety/MedWatch/default.htm>.

k. The Importance of Pharmacovigilance - Safety Monitoring of Medicinal Products, World Health Organization, available at: <https://apps.who.int/iris/handle/10665/42493>.  
**NOTE:** *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

l. The Joint Commission. Medication Management Chapter available at: <https://www.jointcommission.org/>.

m. Medical Dictionary for Regulatory Activities, available at: <https://www.meddra.org/>.

n. Nebeker JR, Barach P, Samore MH. Clarifying adverse drug events: A clinical guide to terminology, documentation, and reporting. *Annals of Internal Medicine*. Vol. 140(10), 2004.

o. U.S. Food and Drug Administration. What Is A Serious Adverse Event? February 2016. <https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event>.

p. VA Adverse Drug Event Reporting System (VA ADERS), available at: [https://vaww.cmop.med.va.gov/MedSafe\\_Portal/](https://vaww.cmop.med.va.gov/MedSafe_Portal/). **NOTE:** *This is an internal VA Web site that is not available to the public.*

q. VA National Patient Safety Handbook.  
<https://www.patientsafety.va.gov/professionals/publications/handbook.asp>.

### RECOMMENDED TRAINING

The following training is accessible and recommended once per year for Department of Veterans Affairs (VA) medical facility VA Adverse Drug Event Reporting System (VA ADERS) point of contacts and health care providers that report to VA ADERS:

1. VA ADERS staff conduct yearly training programs on ADE reporting and monitoring via webinar for health care providers. Programs are recorded and accessible from the VA ADERS web application on demand.
2. VA ADERS staff demonstrate the various reports and mechanisms available to authorized users for accessing VA ADERS summary and trending reports and the pyramid analytics VA ADERS data cube.