Department of Veterans Affairs **VHA DIRECTIVE 2008-059**
Veterans Health Administration
Washington, DC 20420 **September 29, 2008**

ADVERSE DRUG EVENT REPORTING AND MONITORING

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes national policy and procedures for reporting, monitoring, and surveillance of adverse drug events (ADEs) entered into the VHA's spontaneous ADE reporting system for observed and new ADEs at VHA medical centers.

2. BACKGROUND: ADEs must be reported to the national VA Adverse Drug Event Reporting System (VA ADERS), the newly formed VA ADERS Advisory Committee, and the Food and Drug Administration (FDA) MedWatch system (can be found at: http://www.fda.gov/medwatch/safety/FDA-3500A_Fillable.pdf). ***NOTE:*** *Disclosure of adverse events to patients is not addressed in this Directive. Consult current VHA policy for disclosure of adverse events to patients, as it is a related but separate policy.*

a. The VHA intranet spontaneous ADE reporting system known as the VA Adverse Drug Event Reporting System (VA ADERS) standardizes reporting at the facility level, centralizes ADE data analysis, and improves efficiency of ADE report coding used to categorize and classify symptoms associated with the event.

b. VA ADERS is able to:

(1) Report, track and electronically submit serious adverse drug events to the FDA's MedWatch system;

(2) Assess information on adverse drug events that are potentially preventable and report to the personnel involved in ADE monitoring;

(3) Trend ADE data at local, regional and national levels; and

(4) Track ADEs associated with newer drugs (e.g., drugs that have been on the market in the United States for 3 years or less).

c. The primary goal of VA ADERS is to improve ADE reporting as well as to provide ADE trending reports and an intranet portal for VHA medical centers 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 local medical centers have data to track, trend, and compare information throughout the organization. This enhanced ADE reporting and tracking system will enable VHA to take prompt action to ensure the safety of pharmaceutical drug product use.

THIS VHA DIRECTIVE EXPIRES SEPTEMBER 30, 2013

d. **Definitions**

(1) **Adverse Drug Event (ADE).** 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). Severity levels are:

(a) Mild ADE. A mild ADE is an event that requires no intervention or minimal therapeutic intervention such as discontinuation of drug(s).

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

(c) Serious ADE. An ADE is serious when the patient outcome is: death, life-threatening, hospitalization-initial or prolonged, disability or permanent damage, congenital anomaly or birth defect, required intervention to prevent permanent impairment or damage, other serious important medical events.

(2) **Adverse Drug Reaction (ADR).** An ADR is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. ***NOTE:*** *There should be a causal or suspected link between a drug and adverse drug reaction. However, a causality assessment or association of the drug to the adverse drug reaction does not have to be established in order to report an adverse drug reaction or adverse drug event.*

(a) Historical ADR. A historical ADR is a past event (i.e., more than 3 months old) or an event that reportedly occurred in the past at another healthcare setting. It is defined in the CPRS system as "reported by the patient as occurring in the past; no longer requires intervention."

(b) Observed ADR. An observed ADR is defined in the Computerized Patient Record System (CPRS) 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, typically within the past 3 months. Although the term implies that the provider of record made the diagnosis, the fact that a provider may not have visually "observed" an adverse drug reaction does not preclude reporting as "Observed."*

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

(4) **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.

(5) **Medication Error.** A medication error is a mishap that occurs during prescribing, transcribing, dispensing, administering, adherence, or monitoring a drug. ***NOTE:*** *Not all prescribing errors lead to adverse outcomes.*

(6) **Pharmacovigilance.** Pharmacovigilance is a clinical science whose objectives are the surveillance, evaluation, and signal detection of the undesirable effects of pharmaceutical products (drugs, biologics, medicines) used for medical therapy or diagnosis..

(7) **Reporter.** A reporter is the person who first notifies the responsible person caring for the patient following recognition of the ADE (whether mild, moderate, or serious) and can be the patient, family member or health care personnel. The responsible person would be the health care clinician (VA health care clinician, provider, nurse, research investigator team member) who is involved in the patient's direct care and who observed the occurrence of the ADE. Following identification of the observed ADE or suspect drug(s) associated with the ADE, the health care clinician must document the ADE into CPRS to be subsequently identified for entry into VA ADERS by health care personnel designated by the medical center as the VA ADERS reporter.

(8) **Side Effect.** A side effect is an expected and known effect of a drug that is not the intended therapeutic outcome. Since the term "side effect" tends to nominalize the concept of injury from drug, it is recommended that this term be avoided and be reported and monitored as an ADR.

(9) **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.

(10) **VA ADERS Advisory Committee.** The VA ADERS Advisory Committee is comprised of key stakeholders involved in ADE monitoring and surveillance in the VHA. It is comprised of representatives from PBM Services, VA MedSAFE, VA ADERS, National Center for Patient Safety, Office of Research and Development, VISN Formulary Leader, Medical Advisory Panel member, and physician and pharmacist end-users of VA ADERS.

(11) **VA ADERS ProClarity^{R} Data Cube.** The VA ADERS ProClarity^{R} Data Cube is a multidimensional database that stores the ADE data. The cube allows different views of the data to be quickly displayed.

(12) **VA ADERS Reporters.** VA ADERS reporters are health care personnel who enter ADEE reports in VA ADERS as designated by the medical center. These health care personnel must have the ability to read progress notes in CPRS and to log into VA ADERS.

3. POLICY: It is VHA policy that all ADEs that meet the definition of observed ADRs (see subpars. 2d(1) and 2d(2)) must be reported into VA ADERS, this includes ADRs observed in subjects participating in VA research protocols.

4. ACTION

a. **Pharmacy Benefits Management (PBM) Services** The PBM is responsible for the administration and maintenance of the intranet spontaneous ADE reporting system, known as VA ADERS.

b. **Chief Consultant, PBM Service.** The Chief Consultant, PBM, or designee, is responsible for ensuring that:

(1) VA MedSAFE and VA ADERS staff aggregate and analyze data nationally to identify potential signals of ADEs. ***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).*

(2) VA ADERS generates a quarterly (or if feasible, monthly) trending report. ***NOTE:*** *These reports must be shared with the VHA ADE Advisory Committee for review. Medical centers can also use VA ADERS reporting tools to build customized or ad hoc reports as needed.*

(3) An VA ADERS Advisory Committee is established with representative members appointed from the: PBM Clinical Pharmacy Section, Medical Advisory Panel, VA MedSAFE, VA ADERS, the National Center for Patient Safety, Office of Research and Development, VISN Formulary Leaders, VA ADERS end users, and PBM Pharmacy Re-engineering staff.

c. **VA ADERS Advisory Committee.** The VA ADERS Advisory Committee provides oversight of the VA ADERS system and is responsible for:

(1) Ensuring a mechanism is in place to communicate that further analysis is required by the Veterans Integrated Service Networks (VISNs) to assess and intervene upon preventable ADE trends that have been identified by VA ADERS staff and confirmed by the committee; and

(2) Reviewing process and system improvements reported by VISNs or medical centers to evaluate and determine national applicability.

(3) Ensuring access to the to the VA ADERS ProClarity® cube briefing books; ***NOTE:*** *The committee members will define trending reports that will be contained in the VA ADERS ProClarity® cube briefing books. Relevant committee members (e.g., representatives from The National Center for Patient Safety and Office for Research and Development committee members will communicate these reports from the briefing books, as needed, to their respective departments monthly.*

(4) Meeting quarterly and reviewing the ADE data in VA ADERS. ***NOTE:*** *The National Center for Patient Safety and Office for Research and Development committee members must communicate the relevant data reviewed at the meetings to their respective departments and inform the VA ADERS Advisory Committee of any follow up. Ad-hoc meetings and data requests are scheduled as needed by the VA ADERS Advisory Committee in response to significant ADE or an unusual cluster of ADEs reported by VISNs or medical centers.*

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

(6) Ensuring a mechanism is in place to communicate to VISNs preventable ADE trends analysis.

(7) Assisting in identifying quality assurance projects (such as medication use evaluations) for review and consideration by VA MedSAFE.

d. **Facility Director.** The facility Director is responsible for ensuring that:

(1) The facility has a local ADE reporting policy that includes:

(a) Written procedures that describe the operation of the facility ADE reporting system through VA ADERS that meet or exceed requirements mandated by The Joint Commission (TJC) in ADE reporting in accordance with the 2008 TJC standards PI.2.20. ***NOTE:*** *This standard requires analysis of serious ADEs and appropriate action based on the analysis.*

(b) Instructions or education to all health care providers involved in direct patient care on how to enter ADEs into CPRS.

(c) Procedures for reporting all ADEs meeting the definition of observed ADRs into VA ADERS.

(d) Documentation by all research investigators of all drug or biologic-associated ADEs for FDA-approved drugs in CPRS and entry into VA ADERS, if appropriate.

(e) A description of the ADE that is associated with the suspect drug as determined by the clinical judgment of the reporter. Clinicians should not have to obtain approval by any other person or committee before submitting an ADE report and the causality does not have to be absolutely established before submitting a report.

(f) Training provided to designated health care personnel on how to submit and retrieve reports from VA ADERS.

(g) A system for sharing information from ADE reports and coordinating action from analysis of information with appropriate groups, such as: Associate Chief of Staff (ACOS) for Research and Development (R&D), Pharmacy &Therapeutics (P&T) Committee and Pharmacy

Service, and, if applicable, Quality Management, Risk Managers, Patient Safety Managers, or if the ADE was identified as preventable as a result of a medication error, the Safety Committee Officers.

(h) A procedure for tracking, reviewing, and providing ADE reports monthly to the local medical center P&T Committee. In the event that the local P&T Committee only meets bi-monthly or quarterly, the reports must be submitted to a designated person who has the ability to call an adhoc meeting if the need arises.

(i) A system whereby ADEs identified as "preventable" are reviewed and analyzed. Any action taken is to be reported to the local P&T Committee, the VISN PBM or Formulary Committee, and the VA ADERS Advisory Committee.

(j) A requirement that each local P&T Committee include ADE report reviews as a standing agenda item at meetings and each VISN PBM or Formulary Committee review VA ADERS reports during their meetings.

(k) The requirement that any process or system improvements made at local medical centers or at the VISN level is shared with the VA ADERS Advisory Committee.

(2) A request that sufficient health care personnel are designated for ADE reporting into VA ADERS.

5. REFERENCES

a. VA VHA, Manual M-2, Part I, Chapter 3.

b. VHA Handbook 1058.01.

c. VHA Handbook 1050.01

d. Nebeker JR, Barach P, Samore MH. "Clarifying adverse drug events: A clinical guide to terminology, documentation, and reporting," Annals of Internal Medicine. 2004; 140:795-801.

e. World Health Organization. International drug monitoring. The role of the hospital. World Health Organization Technical Report Series. 1969; 425:5-24.

f. Food and Drug Administration. "What Is A Serious Adverse Event?" Available at: http://www.fda.gov/medwatch/report/DESK/advevnt.htm. Accessed August 29, 2008.

g. World Health Organization. Requirements for adverse reaction reporting. Geneva: Author, 1975.

h. The Joint Commission Standard PI.2.20; The Improving Organization Performance, 2008.

6. FOLLOW-UP RESPONSIBILITY: The Chief Consultant for Pharmacy Benefits Management (PBM) Services (119), in the office of Patient Care Services, is responsible for the contents of this Directive. Questions may be directed to 202-461-7326.

7. RESCISSIONS: None. This VHA Directive expires on September 30, 2013.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 9/29/08
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed9/29/08