

**NATIONAL PHARMACY BENEFITS MANAGEMENT (PBM)
DRUG SAFETY ALERT DISTRIBUTION**

- 1. PURPOSE:** This Veterans Health Administration (VHA) Directive establishes policy for the dissemination of drug-related safety communications from the Food and Drug Administration (FDA) and other credible sources to providers and, when appropriate, to patients.
- 2. SUMMARY OF MAJOR CHANGES:** The major change with this recertification is that the Chief of Pharmacy has responsibility for documenting completion of all required actions on the VHA Alerts and Recalls Website (National Center for Patient Safety).
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBLE OFFICE:** Pharmacy Benefits Management Services (10P4P) is responsible for the contents of this Directive. Questions may be addressed at 202-461-7326.
- 5. RESCISSION:** VHA Directive 2008-078, dated November 17, 2008, is rescinded.
- 6. RECERTIFICATION:** This VHA Directive is due for recertification on or before the last working day of November, 2019.

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Interim Under Secretary for Health

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**NATIONAL PHARMACY BENEFITS MANAGEMENT (PBM)
DRUG SAFETY ALERT DISTRIBUTION**

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy for the dissemination of drug-related safety communications from the Food and Drug Administration (FDA) and other relevant sources to providers and, when appropriate, to patients.

AUTHORITY: 38 U.S.C. 7301(b).

2. BACKGROUND: Pharmacy Benefits Management (PBM) Services receives drug-related safety information from a variety of sources including the FDA, manufacturers, and wholesalers that include a number of different alerts, such as drug recalls, shortages, labeling changes, and new information for providers and patients. This Directive establishes a consistent method for the dissemination of drug-safety information in the form of a Drug Safety Alert (National PBM Bulletin or National PBM Patient Level Recall Communication) or a Medication Safety Newsletter. In instances where a closed-loop confirmation is required due to the gravity of the alert, assurance that the communications were received and that actions were completed is required. *NOTE: Disclosure of adverse events to patients is not addressed in this Directive. See VHA Handbook 1004.08, Disclosure of Adverse Events to Patients.*

3. POLICY: It is VHA policy that PBM develop and disseminate Drug Safety Alerts within specified time frames and, when appropriate, monitor feedback from specified field representatives to ensure all communications were received and actions have been completed. *NOTE: PBM/VAMedSAFE executes this policy in cooperation with the Medical Advisory Panel (MAP), National Center for Patient Safety (NCPS), Office of Research and Development (ORD), and field-based experts. Drug recalls apply to this Directive only to the extent that patient notification is warranted as a result of a drug recall; recalls (including drugs and devices) are the responsibility of NCPS per VHA Directive 1068, Recall Of Defective Medical Devices and Medical Products, Including Food And Food Products.*

4. RESPONSIBILITIES:

a. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for ensuring that Veterans Integrated Service Network (VISN) Directors comply with reporting and confirmation requirements associated with Drug Safety Alert documents (see Appendix A).

b. **Veterans Integrated Service Network Director.** Each Veterans Integrated Service Network (VISN) Director is responsible for ensuring that medical facility Directors comply with reporting and confirmation requirements associated with Drug Safety Alert documents (see Appendix A).

c. **Medical Facility Director.** The medical facility Director, or physician designee, is responsible for:

(1) Ensuring that a facility medical staff process is in place to ensure compliance with this Directive;

(2) Disseminating Drug Safety Alert documents to facility Chief of Staff (COS) (see Appendix A); and

(3) Ensuring that the COS complies with reporting and confirmation requirements associated with Drug Safety Alert documents (see Appendix A).

d. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff (COS) is responsible for:

(1) Disseminating all Drug Safety Alerts and related materials to all providers and individual designees within their facility, including the Associate Chief of Staff (ACOS) for Research and Development (R&D) (see Appendix A);

(2) Ensuring that all required actions are completed, including mailing patient letters when directed by PBM Services;

(3) Organizing and maintaining records of:

(a) VA medical facility providers and other designees to whom Drug Safety Alerts are sent (including date and time),

(b) Individuals designated to contact patients (when required), and

(c) A list of patients who were notified of the Drug Safety Alert by their providers, or designees, where applicable. The method, date, and time of notification must be included.

(4) Ensuring that facility Chiefs of Pharmacy comply with reporting and confirmation requirements associated with Drug Safety Alert documents (see Appendix A).

e. **Facility Chief of Pharmacy.** The VA medical facility Chief of Pharmacy (COP) is responsible for:

(1) Coordinating with the medical facility COS to ensure completion of all required actions by the ACOS for R&D;

(2) Complying with reporting and confirmation requirements associated with Drug Safety Alert documents (see Appendix A); and

(3) Documenting completion of all required actions on the VHA Alerts and Recalls Website (National Center for Patient Safety). *NOTE: Responses are required within 10 business days of receipt.*

f. **Associate Chief of Staff for Research and Development.** The ACOS for R&D is responsible for:

(1) Disseminating Drug Safety Alerts and related materials to all Principal Investigators (PIs) who have authority to practice at the VA medical facility (see Appendix A);

(2) Communicating the Drug Safety Alert information to their respective Institutional Review Board (IRB); and

(3) Communicating to the facility COS that all required actions were completed within the designated timeframe.

g. **Pharmacy Benefits Management Services.** PBM in collaboration with VAMedSAFE (see paragraph 5.e.) is responsible for developing Drug Safety Alerts (with input from PBM Clinical Pharmacists and/or subject matter experts) with provider notification, recommended actions (when appropriate) and, when warranted, patient letters. When required, confirmation from the medical facility COP through the VHA Alerts and Recalls website is monitored by PBM and VAMedSAFE to ensure all communications were received and recommended actions have been completed within 10 business days. Non-responders are reported to the Deputy Under Secretary for Health for Operations and Management for follow-up.

h. **Deputy Chief Consultant, PBM Services.** The Deputy Chief Consultant, PBM Services, or designee, is responsible for:

(1) Ensuring that the PBM FDA Liaison Pharmacist reviews all new drug safety information;

(2) Ensuring that VAMedSAFE, PBM Clinical Pharmacists, a MAP representative, a VISN Pharmacist Executive representative, and field experts review drug safety information and identify the need for dissemination to the Drug Safety Alert Mail Group. This includes:

(a) Determining if a Drug Safety Alert is appropriate; and

(b) Determining the type of Drug Safety Alert (e.g., National PBM Bulletin, National PBM Patient Level Recall Communication).

(3) Ensuring that VAMedSAFE, PBM Clinical Pharmacists, a MAP representative, a VISN Pharmacist Executive representative, and Field experts develop Drug Safety Alerts, as deemed appropriate, with recommended actions (e.g., patient letters when warranted). VAMedSAFE in collaboration with the PBM Clinical Pharmacist responsible for the disease state or the Drug Class must:

(a) Provide written information in response to the alert including pertinent background information;

(b) Prepare any supplemental clinical information ensuing from the alert recommendations (e.g., patient letter templates);

(c) Consult with field experts (see paragraph 4.i.) on content development and recommendations; and

(d) Review all final drafts and provide feedback and edits when necessary.

(4) Ensuring the dissemination of Drug Safety Alerts to the Drug Safety Alert Mail Group within 10 business days, once sufficient evidence has been collected;

(5) Ensuring that the Drug Safety Alert and related materials are posted on the PBM website and the VAMedSAFE web page; and

(6) Ensuring the maintenance of all records confirming the completed dissemination of documents and actions from each medical facility COP.

i. **Field Experts.** Field experts (e.g., Field Advisory Committees, Technical Advisory Groups, Clinical Advisory Groups, Chiefs of Services, etc.) are responsible for reviewing drafts, when consulted, and providing feedback and edits where necessary.

j. **Original Author.** The original author of the Safety Alert is the owner of the Safety Alert and, as such, incorporates all edits, changes, and revisions. In addition, the original author of the Safety Alert is responsible for:

(1) E-mailing the finalized Safety Alert and related materials to the Deputy Chief Consultant PBM, or designee, for electronic distribution to the Drug Safety Alert Mail Group; and

(2) Posting the finalized Safety Alert and related materials on the PBM website and the VAMedSAFE web page.

5. DEFINITIONS:

a. **Drug Safety Alert Mail Group.** The Drug Safety Alert Mail Group is a mail group consisting of the Deputy Under Secretary for Health for Operations and Management (10N), Assistant Deputy Under Secretary for Health Clinical Operations (10NC), VISN Directors, VISN Chief Medical Officers, Chiefs of Staff, Patient Care Services (10P4) representatives, Nurse Executives, Consolidated mail-out Pharmacy (CMOP) Directors, Primary Care Chiefs or Directors, MAP members, VISN Pharmacist Executives (VPE), COPs, and representatives from Pharmacy Reengineering (PMO), the NCPS, Network Patient Safety, Emergency Preparedness, Public Affairs (10C3), the Office of Research and Development (ORD), and the Office of Research Oversight (ORO).

b. **Medication Safety Newsletter.** An electronic newsletter published by the VA Center for Medication Safety (VAMedSAFE) in conjunction with the PBM to communicate pertinent but non-urgent safety information that does not require immediate action or response from VA health care providers. The purpose of the newsletter is to: (1) disseminate new drug safety information to the provider-level in an effort to decrease preventable adverse drug events and (2) reduce the number of Drug Safety Alerts sent to the field by compiling them into a single circulation. It is disseminated by PBM to the Drug Safety Alert Mail Group on a monthly basis.

c. **National PBM Bulletin.** A National PBM Bulletin is a detailed Drug Safety Alert that addresses urgent medication safety issues with specific recommendations for action or intervention from the field, such as additional monitoring, change in therapy, or an enhanced assessment by a healthcare provider due to an identified safety risk. The National PBM Bulletin may include standard sections, e.g., Issue, Background, Recommendations, and References. It is disseminated by PBM to the Drug Safety Alert Mail Group within 10 business days of receipt of notification from the FDA or other credible source, once sufficient evidence has been collected. The recommended actions in a National PBM Bulletin include provider notification and may

include actions to be carried out by the provider. Recommended actions may include patient notifications by phone call, in person, or by letter. When warranted, confirmation that actions have been completed may be required.

d. **National PBM Patient Level Recall Communication.** A National PBM Patient Level Recall Communication is a detailed Drug Safety Alert that addresses urgent product recalls (e.g., one with the potential for serious harm to the patient) and includes specific recommendations for product sequestering, patient notification, and feedback actions from the field to confirm completion of recommended actions. It includes standard sections and is disseminated by PBM to the Drug Safety Alert Mail Group within 10 business days of receipt of notification from the FDA or other credible source, once sufficient evidence has been collected. The recommended actions in a National PBM Patient Level Recall include provider notification and patient notifications by phone call, in person, or by letter. Confirmation that actions have been completed is required.

e. **VAMedSAFE.** VAMedSAFE is a PBM Center for Medication Safety with a mission to identify, track, and address preventable adverse drug events (ADEs) in the VA health care system with the primary focus on preventing adverse drug reactions (ADRs). As a pharmacovigilance center, VAMedSAFE undertakes quality improvement and safety initiatives that ultimately assess, monitor, and improve the safe and appropriate use of medications, promote risk reduction efforts, and enhance education and communication of adverse events (AE) as well as potential AEs on a national level.

NATIONAL PBM DRUG SAFETY ALERT DISTRIBUTION ALGORITHM

