NATIONAL PHARMACY BENEFITS MANAGEMENT DRUG SAFETY ALERT DISTRIBUTION

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy for the dissemination of drug-related safety information from the Food and Drug Administration (FDA) and other credible sources to providers and, when appropriate, to patients.

2. SUMMARY OF MAJOR CHANGES: Definitions have been added for relevant terminology. Responsibilities have been added for the Under Secretary for Health and the Deputy Under Secretary for Health for Policy and Services. All remaining responsibilities have been updated.

3. RELATED ISSUES: VHA Directive 1068, Recall of Defective Medical Devices and Medical Products, Including Food and Food Products, dated July 22, 2014.

4. RESPONSIBLE OFFICE: Pharmacy Benefits Management (PBM) Services (10P4P) is responsible for the contents of this directive. Questions may be addressed at 202-461-7326.

5. RESCISSIONS: VHA Directive 1069, National Pharmacy Benefits Management (PBM) Drug Safety Alert Distribution, dated November 24, 2014, is rescinded.

6. RECERTIFICATION: This VHA directive is due for recertification on or before the last working day of October 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.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

DISTRIBUTION: Emailed to the VHA Publication Distribution List on October 25, 2019.

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

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1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for the dissemination of drug-related safety information from the Food and Drug Administration (FDA) and other relevant sources to providers and, when appropriate, to patients. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b*). **NOTE:** This policy does not apply to information disseminated through Patient Packaging Inserts as required under 21 Code of Federal Regulations (CFR) 310.501 and 21 CFR 310.515; instructions for use approved by FDA; or, Medication Guides under 21 CFR part 308.*

2. BACKGROUND

Pharmacy Benefits Management (PBM) Services receives drug-related safety information from the FDA, pharmaceutical manufacturers, and wholesalers. Drug-related safety information includes 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-related 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 Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.*

3. DEFINITIONS

a. **Drug-Related Safety Information.** Drug-related safety information includes alerts related to drug recalls, shortages, labeling changes, and new information for providers and patients. This information can come from a variety of sources including the FDA, pharmaceutical manufacturers, and wholesalers.

b. **Drug Safety Alert.** A Drug Safety Alert is a detailed notification written by a VA Pharmacy Benefits Management Services Center for Medication Safety (VA MedSAFE) staff member and distributed through channels outlined in this directive. Drug Safety Alerts disseminate pertinent practitioner and patient information based on correspondence through Drug-Related Safety Information and can consist of a National PBM Bulletin or a National PBM Patient Level Recall Communication.

c. **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), Veterans Integrated Service Network (VISN) Directors, VISN Chief Medical Officers, Chiefs of Staff, Office of Patient Care Services (10P4) representatives, Nurse Executives, Consolidated mail-out Pharmacy (CMOP) Directors, Primary Care Chiefs or

Directors, Medical Advisory Panel (MAP) members, VISN Pharmacist Executives (VPE), VA medical facility Chiefs of Pharmacy (COPs), and representatives from Pharmacy Reengineering (PMO), the National Center for Patient Safety (NCPS), Network Patient Safety, Emergency Preparedness, Public Affairs (10C3), the Office of Research and Development (ORD), and the Office of Research Oversight (ORO).

d. **Medication Safety Newsletter.** A Medication Safety Newsletter is an electronic newsletter published by VA MedSAFE 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 a 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.

e. **National PBM Bulletin.** A National PBM Bulletin is a detailed Drug Safety Alert directed to VA health care providers 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 health care provider due to an identified safety risk. The National PBM Bulletin may include standard sections, e.g., Issue, Background, Recommendations, and References.

f. **National PBM Patient Level Recall Communication.** A National PBM Patient Level Recall Communication is a detailed Drug Safety Alert directed to VA health care providers 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 including specific incidents, general information, actions, and references.

4. POLICY

It is VHA policy that PBM develops and disseminates Drug Safety Alerts within specified time frames and, when appropriate, monitors feedback from specified field representatives to ensure all communications were received and actions have been completed in order to assure that Veterans receive safe and effective medication therapy and minimize safety concerns. ***NOTE:*** *PBM/VAMedSAFE executes this policy in conjunction with the VISN Pharmacist Executive Committee (VPEs), MAP, NCPS, the Office of Research and Development (ORD), and field 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, dated July 22, 2014.*

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 implement 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.

(4) Ensuring that VISN Directors comply with reporting and confirmation requirements associated with Drug Safety Alert documents.

(5) Tracking reports of local VA medical facilities who did not respond that required National PBM Patient Level Recall required actions have been completed as instructed as submitted by PBM services and working with VISN Director to ensure that patient level actions are completed.

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services is responsible for oversight and ensuring that PBM services develops, disseminates, and monitors Drug Safety Alerts in accordance with this directive.

d. **Deputy Chief Consultant, Pharmacy Benefits Management Services.** The Deputy Chief Consultant, Pharmacy Benefits Management Services, is responsible for:

(1) Ensuring that VA MedSAFE leadership, at least one MAP representative, at least one VISN Pharmacist Executive representative, and PBM National Program Manager(s) or field experts, when appropriate, review drug-related safety information and identify the need for a Drug Safety Alert.

(2) Ensuring VA MedSAFE develops Drug Safety Alerts including National PBM Bulletins and National PBM Patient Level Recall Communication.

(3) Ensuring VA MedSAFE drafts patient letters, when warranted.

(4) Ensuring VA MedSAFE disseminates the National PBM Bulletin and the National PBM Patient Level Recall Communication to the Drug Safety Alert Mail Group within 10 business days, or by the assigned completion date as determined by the Deputy Chief Consultant, PBM when the date is different than 10 business days, when required from the FDA or other credible source, once sufficient evidence has been collected.

(5) Ensuring VA MedSAFE disseminates the Medication Safety Newsletter to the Drug Safety Alert Mail Group on a monthly basis.

(6) Monitoring the VHA Alerts and Recalls Web site for the VA medical facility COP to confirm all communications were received and recommended actions have been completed within 10 business days, or the assigned completion date as determined by the Deputy Chief Consultant, PBM when date is different than 10 business days, when required.

(7) Reporting non-responders to the Deputy Under Secretary for Health for Operations and Management for follow-up within 3 weeks of the due date of the action via email message from the Deputy Chief Consultant, PBM.

(8) Ensuring that the assigned PBM pharmacist(s) review all new drug-related safety information.

(9) Ensuring that the Drug Safety Alert and related materials are posted on the PBM Web site (https://www.pbm.va.gov/) and the VAMedSAFE Web site (https://www.pbm.va.gov/PBM/VACenterForMedicationSafetyIndex.asp).

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

e. **VA Pharmacy Benefits Management Services Center for Medication Safety Leadership.** VA MedSAFE is a PBM Center for Medication Safety that is a pharmacovigilance center 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). VA MedSAFE 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. VA MedSAFE leadership is responsible for:

(1) Collaborating with the Deputy Chief Consultant, PBM, at least one MAP representative, at least one VISN Pharmacist Executive representative, and PBM National Program Manager(s) or Field experts as requested, to develop and disseminate Drug Safety Alerts. This includes:

(a) Determining if a Drug Safety Alert is appropriate.

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

(c) Developing Drug Safety Alerts including National PBM Bulletins and National PBM Patient Level Recall Communication. Developing these alerts requires:

1. Gathering input from PBM Clinical Pharmacists or subject matter experts with provider notification.

2. Providing written information to VA health care providers as a part of the alert including pertinent background information.

3. Preparing any supplemental clinical information ensuing from the alert recommendations (e.g., patient letter templates).

4. Consulting with field experts (see paragraph 5.k.) on content development and recommendations.

5. Reviewing all final drafts of Drug Safety Alerts and providing feedback and edits when necessary.

6. Drafting patient letters, when warranted.

7. Creating recommended actions, when appropriate:

a. Recommended Actions for National PBM Bulletins. 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.

b. Recommended Actions for National PBM Patient Level Recall. 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 patient notification actions have been completed by pharmacy is required.

(2) Disseminating the National PBM Bulletin and the National PBM Patient Level Recall Communication 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.

(3) Disseminating the Medication Safety Newsletter to the Drug Safety Alert Mail Group on a monthly basis.

(4) Ensuring that the Drug Safety Alert is posted on the VA MedSAFE Web site.

f. **Veterans Integrated Service Network Director.** Each VISN Director is responsible for:

(1) Ensuring that VA medical facility Directors comply with reporting and confirmation requirements associated with Drug Safety Alert documents.

(2) Working with Deputy Under Secretary for Health for Operations and Management to ensure that patient level actions are completed.

g. **VA Medical Facility Director.** The VA 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 and Medication Safety Newsletter documents to the VA medical facility Chief of Staff (COS) or designee.

(3) Ensuring that the VA medical facility COS or designee complies with reporting and confirmation requirements associated with Drug Safety Alert and Medication Safety Newsletter documents.

(4) Delegating the VA medical facility Director responsibilities to a designee, as appropriate.

h. **VA Medical Facility Chief of Staff.** The VA medical facility COS or designee is responsible for:

(1) Receiving Drug Safety Alert and Medication Safety Newsletter documents from the VA medical facility Director.

(2) Disseminating all Drug Safety Alerts and related materials to all providers and individual designees within their VA medical facility, including the Associate Chief of Staff (ACOS) for Research and Development (R&D).

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

(4) 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.

(5) Ensuring that VA medical facility COPs comply with reporting and confirmation requirements associated with Drug Safety Alert documents.

(6) Receiving communication from the ACOS for R&D confirming timely completion of required notifications.

(7) Delegating the VA medical facility COS responsibilities to a designee, as appropriate.

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

(1) Receiving Drug Safety Alerts and related materials from the VA medical facility COS.

(2) Disseminating Drug Safety Alerts and related materials to all Principal Investigators who have authority to practice at the VA medical facility.

(3) Communicating the Drug Safety Alert information to their respective Institutional Review Board.

(4) Communicating to the VA medical facility COS that all actions required by the Drug Safety Alert were completed within the designated timeframe.

j. **VA Medical Facility Chief of Pharmacy.** The VA medical facility COP is responsible for:

(1) Complying with reporting and confirmation requirements associated with Drug Safety Alert documents; and

(2) Documenting completion of all required actions on the VHA Alerts and Recalls Web site: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html (National Center for Patient Safety). ***NOTE:*** *Responses are required within 10 business days, or the assigned completion date as determined by the Deputy Chief Consultant, PBM when date is different than 10 business days. This is an internal VA Web site that is not available to the public.*

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

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENTS

All records regardless of format (paper, electronic, electronic systems) created by 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 referred to the appropriate Records Manager or Records Liaison.

8. REFERENCES

a. 38 U.S.C. 7301(b).

b. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.

c. VHA Directive 1068, Recall Of Defective Medical Devices and Medical Products, Including Food And Food Products, dated July 22, 2014.

d. PBM Web site (https://www.pbm.va.gov/).

e. VAMedSafe Web site (https://www.pbm.va.gov/PBM/VACenterForMedicationSafetyIndex.asp).

f. VHA Alerts and Recalls Web site: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html. ***NOTE:*** *This is an internal VA Web site that is not available to the public.*