

**NATIONAL PHARMACY BENEFITS MANAGEMENT DRUG SAFETY ALERT
DISTRIBUTION**

1. SUMMARY OF MAJOR CHANGES: This directive updates:

a. Paragraph 3: Moves programmatic information on Drug Safety Alerts, the National Pharmacy Benefits Management (PBM) Bulletin and National PBM Patient Level Recall Communication to new paragraph 3, Drug Safety Alerts.

b. Paragraph 2: Responsibilities have been added for the Executive Director, PBM Services; Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer; and the Department of Veterans Affairs (VA) medical facility Associate Director for Patient Care Services.

2. RELATED ISSUES: VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020.

3. POLICY OWNER: PBM Services (12PBM) is responsible for the contents of this directive. Questions may be addressed to VHA12PBMPCSActions@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: There are no local document requirements in this directive.

5. RESCISSIONS: VHA Directive 1069, National Pharmacy Benefits Management Drug Safety Alert Distribution, dated October 24, 2019, is rescinded.

6. RECERTIFICATION: This Veterans Health Administration (VHA) directive is due for recertification on or before the last working day of March 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

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

/s/ M. Christopher Saslo
DNS, APRN-BC, FAANP
Assistant Under Secretary for Health
for Patient Care Services/CNO

NOTE: All references herein to VA and VHA documents incorporate by reference

March 21, 2024

VHA DIRECTIVE 1069

subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publication Distribution List on March 26, 2024.

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NATIONAL PHARMACY BENEFITS MANAGEMENT DRUG SAFETY ALERT DISTRIBUTION

1. POLICY

It is Veterans Health Administration (VHA) policy that Pharmacy Benefits Management (PBM) Services develop and disseminate Drug Safety Alerts and drug-related safety information from the Food and Drug Administration (FDA) and other relevant sources to Department of Veterans Affairs (VA) health care providers and, when appropriate, to patients within timeframes specified by the Deputy Chief Consultant, PBM Services and, when appropriate, monitors feedback from specified VA subject matter experts to ensure all communications are received and actions have been completed. This provides Veterans with safe and effective medication therapy and minimizes safety concerns. **NOTE:** *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 the National Center for Patient Safety (NCPS) per VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020. This policy does not apply to information disseminated through Patient Packaging Inserts as required under 21 C.F.R. §§ 310.501 and 310.515; instructions for use approved by FDA; or Medication Guides under 21 C.F.R. part 208. AUTHORITY:* 38 U.S.C. § 7301(b).

2. RESPONSIBILITIES

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

b. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer (CNO) is responsible for:

(1) Supporting PBM Services with implementation and oversight of this directive.

(2) Ensuring that PBM Services develop, disseminate, and monitor Drug Safety Alerts in accordance with this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Overseeing VISNs to ensure compliance with this directive and its effectiveness.

(4) Ensuring that VISN Directors comply with reporting and confirmation

requirements as dictated by Drug Safety Alert documents (e.g., patient lists, manufacturer documents) that are distributed with each Drug Safety Alert.

(5) Tracking VA medical facilities that do not complete National PBM Patient Level Recall Communication required actions and taking corrective action as appropriate.

d. **Executive Director, Pharmacy Benefits Management Services.** The Executive Director, PBM Services is responsible for providing oversight for the VISN and VA medical facility compliance with this directive and ensuring corrective action is taken when non-compliance is identified.

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

(1) Collaborating with the VHA PBM Services Center for Medication Safety (VHA MedSAFE) Director, at least one Medical Advisory Panel (MAP) representative, at least one VISN Pharmacist Executive representative, and PBM National Program Manager(s) or VA subject matter experts, when appropriate, to review drug-related safety information and identify the need for a Drug Safety Alert. ***NOTE: Selection of MAP, VISN Pharmacist Executive, PBM National Program Managers, and subject matter experts representation is at the discretion of the Deputy Chief Consultant, PBM Services. In the event that the MAP, VISN Pharmacist Executive, PBM National Program Manager or VA subject matter expert representatives are not available, the Deputy Chief Consultant, PBM Services may select other representatives to complete this responsibility based on urgency and severity of the Drug Safety Alert.***

(2) Ensuring that the VHA MedSAFE Director fulfills all responsibilities as required by this directive. See paragraph 2.f. for more information.

(3) Monitoring the VHA Alerts and Recalls website to ensure the VA medical facility Chief of Pharmacy (COP) confirms all communications were received and required actions have been completed within 10 business days or by the assigned completion date as determined by the Deputy Chief Consultant, PBM Services (e.g., when required action is needed before 10 business days).

(4) Reporting VA medical facilities that have not confirmed communications or completed required actions by the appropriate due date to the Assistant Under Secretary for Health for Operations within 3 weeks of the required action due date. ***NOTE: Required action due date is determined by the Deputy Chief Consultant, PBM and is communicated to VA medical facility COP via email.***

(5) Determining the due date for Drug Safety Alert required actions and communicating due dates to the VA medical facility COP via email. ***NOTE: If the Deputy Chief Consultant, PBM Services does not assign a due date, the default due date is 10 business days.***

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

(7) Maintaining confirmation records of Drug Safety Alert document dissemination and completed required actions from each VA medical facility COP.

f. **VHA Pharmacy Benefits Management Services Center for Medication Safety Director.** The VHA MedSAFE Director is responsible for:

(1) Collaborating with the Deputy Chief Consultant, PBM Services; at least one MAP representative; at least one VISN Pharmacist Executive representative; and PBM National Program Manager(s) or VA subject matter experts as requested, to review drug-related safety information, identify the need for a Drug Safety Alert, and develop and disseminate Drug Safety Alerts. This includes:

(a) Determining whether 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). See paragraph 3 for additional information on the types of Drug Safety Alerts.

(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 National Program Managers or VA subject matter experts (see paragraph 2.1.) on content development, recommendations, and VA health care providers notifications.

2. Reviewing all Drug Safety Alerts drafts and providing feedback and edits.

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

4. Providing written information to VA health care providers as a part of the Drug Safety Alert including pertinent background information.

5. Issuing required actions, when appropriate. For more information on required actions, see paragraph 3.

(2) Disseminating the National PBM Bulletin and the National PBM Patient Level Recall Communications to the Drug Safety Alert Mail Group (DrugSafetyAlert@va.gov) within 10 business days of receipt of notification from the FDA or other credible source, once sufficient evidence has been collected as determined by the VHA MedSAFE Director.

(3) Disseminating the Medication Safety Newsletter to the Drug Safety Alert Mail Group (DrugSafetyAlert@va.gov) quarterly at minimum.

(4) Ensuring that the Drug Safety Alert is posted on the VHA MedSAFE website (<https://www.pbm.va.gov/PBM/VACenterForMedicationSafetyIndex.asp>).

g. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Ensuring that VA medical facility Directors comply with reporting and confirmation requirements associated with Drug Safety Alert documents (e.g., patient lists, manufacturer documents).

(3) Ensuring that required actions involving patient contact are completed as required by the Drug Safety Alert.

(4) Complying with all assigned reporting and confirmation requirements as dictated by Drug Safety Alert documents (e.g., patient lists, manufacturer documents) that are distributed with each Drug Safety Alert.

h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and that appropriate corrective action is taken if non-compliance is identified.

(2) Ensuring that VA medical facility medical staff processes are in place to ensure compliance with this directive, including procedures on how to complete required actions (e.g., whether to remove the drug) and associated documentation.

(3) Ensuring that the Drug Safety Alert and Medication Safety Newsletters are disseminated to the VA medical facility Chief of Staff (CoS), Associate Director for Patient Care Services (ADPCS), and Associate Chief of Staff for Research and Development (ACoS for R&D).

(4) Ensuring that the VA medical facility CoS and ADPCS comply with reporting and confirmation requirements associated with the Drug Safety Alert and Medication Safety Newsletter.

(5) Complying with all assigned reporting and confirmation requirements as dictated by Drug Safety Alert documents (e.g., patient lists, manufacturer documents) that are distributed with each Drug Safety Alert.

i. **VA Medical Facility Chief of Staff and Associate Director for Patient Care Services.** The VA medical facility CoS and ADPCS are responsible for:

(1) Reviewing Drug Safety Alert and Medication Safety Newsletter and all related documents disseminated by the VA medical facility Director and ensuring all reporting and confirmation requirements are fulfilled.

(2) Disseminating all Drug Safety Alerts and related Drug Safety Alert documents to all VA health care providers within their VA medical facility, including the VA medical

facility ACoS for R&D.

(3) Ensuring that the VA medical facility Chief of Pharmacy completes all required actions, including mailing patient letters when included in Drug Safety Alert required actions.

(4) Ensuring that there is a process for timely dissemination of Drug Safety Alerts to appropriate VA health care providers at the VA medical facility.

(5) Organizing and maintaining records (either paper or electronic) of:

(a) Individuals designated to contact patients (when required); and

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

(6) Ensuring that the VA medical facility COP confirms all communications were received and required actions have been completed within 10 business days or by the assigned completion date as determined by the Deputy Chief Consultant, PBM Services.

(7) Ensuring that the VA medical facility ACoS for R&D confirms all actions required by the Drug Safety Alert are completed within the designated timeframe.

j. **VA Medical Facility Associate Chief of Staff for Research and Development.**

The VA medical facility ACoS for R&D is responsible for:

(1) Reviewing Drug Safety Alerts and related Drug Safety Alert documents disseminated by the VA medical facility CoS and ADPCS, forwarding to all appropriate VA medical facility staff under their supervision, including Principal Investigators who have authority to practice at the VA medical facility, and communicating the Drug Safety Alert information to their respective Institutional Review Board.

(2) Completing all actions required by the Drug Safety Alert within the designated timeframe for patients under their supervision, including mailing patient letters when dictated by Drug Safety Alert required actions, and notifying the VA medical facility CoS and ADPCS.

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

(1) Complying with reporting and confirmation requirements associated as dictated by Drug Safety Alert documents (e.g., patient lists, manufacturer documents) that are distributed with each Drug Safety Alert.

(2) Confirming all communications received regarding Drug Safety Alerts and documenting completion of all required actions on the VHA Alerts and Recalls website:

<https://vha-gov.lightning.force.com/lightning/page/home>. **NOTE:** Responses are required within 10 business days of action assignment or within the assigned completion date as determined by the Deputy Chief Consultant, PBM Services; shortest timeframe takes precedence. This is an internal VA website that is not available to the public and access is granted by permission only.

I. **VA Subject Matter Experts.** VA subject matter 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 by the VHA MedSAFE Director and providing feedback and edits where necessary (e.g., correcting typos, clarifying content).

3. DRUG SAFETY ALERTS

A Drug Safety Alert is a detailed notification written by VHA MedSAFE and distributed through channels outlined in this directive. Drug Safety Alerts disseminate pertinent VA health care provider and patient information based on correspondence through drug-related safety information. Each Drug Safety Alert is distributed with related documents called Drug Safety Alert documents which could include but are not limited to patient lists and manufacturer documents. The types of Drug Safety Alert Documents vary based on the requirements of the Drug Safety Alert and are determined by the VHA MedSAFE Director. Drug Safety Alerts can consist of a National PBM Bulletin or a National PBM Patient Level Recall Communication.

a. **National Pharmacy Benefits Management 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 VA health care provider due to an identified safety risk. The required actions in a National PBM Bulletin must include VA health care provider notification and may include additional actions to be carried out by the VA health care provider such as patient notifications by phone call, in person, or by letter. When warranted, confirmation that actions have been completed may be required. The National PBM Bulletin may include issue, background, recommendations, and references. PBM Medication Safety Alerts and Newsletters can be found at:

<https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/Policies%20directives%20and%20info%20letters/Forms/AllItems.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

b. **National Pharmacy Benefits Management 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 required actions. The required actions in a National PBM Patient Level Recall include VA health care provider notification and patient notifications by phone call, in person, or by letter. Confirmation that patient

notification actions have been completed by the VA medical facility COP is required. Standard sections include specific incidents, general information, actions, and references.

4. TRAINING

There are no formal training requirements associated with this directive.

5. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Manager.

6. BACKGROUND

a. 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 VA health care providers and patients.

b. In instances where a closed-loop confirmation is required due to the gravity of the alert (e.g., reports of potential patient harm from using a drug), confirmation that the communications were received and that actions were completed is required and are dictated as such in the National PBM Patient Level Recall Communication. **NOTE:** *Disclosure of adverse events to patients is addressed in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.*

c. VHA 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 in the VA health care system with the primary focus on preventing adverse drug reactions. VHA 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.

7. DEFINITIONS

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

b. **Drug Safety Alert Mail Group.** The Drug Safety Alert Mail Group (DrugSafetyAlert@va.gov) is a mail group consisting at a minimum of the Assistant Under Secretary for Health for Operations; Assistant Under Secretary for Health Clinical

Services/Chief Medical Officer; the Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer; the Office of Research and Development; the Office of Research Oversight; the Network Patient Safety, Emergency Preparedness, Public Affairs; VISN Directors, Chief Medical Officers, Chief Nursing Officers, and Pharmacist Executives; VA medical facility Directors, CoS and ADPCS, Office of Patient Care Services representatives, COPs, Consolidated Mail-Outpatient Pharmacy Directors, Primary Care Chiefs or Directors, MAP members, VA medical facility COPs, representatives from Pharmacy Reengineering, NCPS, ACoS for R&D, and Institutional Review Board Administrators.

c. **Medication Safety Newsletter.** A Medication Safety Newsletter is an electronic newsletter published by VA MedSAFE in conjunction with PBM Services to communicate pertinent but non-urgent safety information that does not require immediate action or response from VA health care providers. The Medication Safety Newsletter is not considered a Drug Safety Alert; it is a separate information notification tool. The purpose of a newsletter is to:

(1) Disseminate new drug safety information to the VA health care provider-level 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.

8. REFERENCES

a. 38 U.S.C. § 7301(b).

b. 21 C.F.R. part 208 and §§ 310.501 and 310.515.

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

d. VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020.

e. VHA MedSAFE website.

<https://www.pbm.va.gov/PBM/VACenterForMedicationSafetyIndex.asp>.

f. VHA Alerts and Recalls website. <https://vha.gov/lightning.force.com/lightning/page/home>. **NOTE:** This is an internal VA website that is not available to the public and access is granted by permission only.

g. VHA. PBM Medication Safety Alerts and Newsletters can be found at: <https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/Policies%20directives%20and%20info%20letters/Forms/AllItems.aspx>. **NOTE:** This is an internal VA website that is not available to the public.