Department of Veterans Affairs **VHA DIRECTIVE 1108.21**
Veterans Health Administration **Transmittal Sheet**
Washington, DC 20420 **June 22, 2023**

PHARMACY CLINICAL INFORMATICS

1. SUMMARY OF CONTENT: This is a new Veterans Health Administration (VHA) directive that:

a. Provides the standards for decision-making and program development related to pharmacy informatics.

b. Standardizes policy for pharmacy system maintenance activities including but not limited to system maintenance activities for the pharmacy aspects of the Veterans Health Information Systems and Technology Architecture (VistA) electronic health record (EHR) and its interfaces with automated pharmacy medication dispensing equipment in multiple pharmacy care delivery settings.

c. Defines staffing standards for pharmacy informatics services.

d. Describes responsibilities related to pharmacy informatics as organizationally aligned under the Department of Veterans Affairs (VA) medical facility Chief of Pharmacy Services.

2. RELATED ISSUES: VHA Directive 1108.07, General Pharmacy Service Requirements, dated November 28, 2022.

3. POLICY OWNER: The Executive Director, Pharmacy Benefits Management Services (12PBM) is responsible for the contents of this directive. Questions may be addressed to 202-461-6938.

4. RESCISSIONS: None.

5. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of June 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: 6 months after publication date to allow for VISNs and VA medical facilities to make necessary changes to comply with the policy.

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

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

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 June 23, 2023.

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PHARMACY CLINICAL INFORMATICS

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1. POLICY

It is Veterans Health Administration (VHA) policy that all Department of Veterans (VA) medical facilities have Pharmacy Clinical Informatics processes and standard operating procedures (SOPs) that align and are consistently applied across the enterprise. This standardization is the foundation for best practices in the electronic health record (EHR) and transition to the Cerner Millennium system. **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.** The Assistant Under Secretary for Health for Patient Care Services is responsible for supporting the implementation and oversight of this directive across VHA.

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 Services Networks (VISNs).

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

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

(4) Ensuring that each VISN Director provides the pharmacy resources necessary to implement this directive in all VA medical facilities within the VISN.

d. **Executive Director, Pharmacy Benefits Management Services.** The Executive Director, Pharmacy Benefits Management (PBM) Services is responsible for:

(1) Serving as an advisor to the Under Secretary for Health, Assistant Deputy Under Secretaries, VHA Central Office (VHACO) program offices, VA medical facilities and other Federal agencies on issues related to pharmacy informatics.

(2) Providing national leadership for the mission, vision, policies and strategic goals of pharmacy informatics. Materials on these subjects can be found at https://dvagov.sharepoint.com/sites/VHAPBM/Clinical_Informatics. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(3) Developing guidance to support and standardize pharmacy informatics services in VHA.

(4) Establishing VA medical facility pharmacy informatics priorities.

(5) Collaborating with VISN Pharmacist Executives on establishing best practices for pharmacy informatics.

(6) Providing business ownership and stewardship of pharmacy-related EHR development and sustainment.

(7) Generating and delivering reports to the VISN Pharmacist Executives which are used to ensure that the processing of controlled substance prescriptions is restricted to licensed pharmacists.

e. **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) Providing the resources necessary to implement this directive in all VA medical facilities within the VISN.

f. **Veterans Integrated Service Network Pharmacist Executive.** The VISN Pharmacy Executive is responsible for:

(1) Facilitating coordination and standardization of pharmacy informatics activities and practices within their assigned VISN.

(2) Serving as an advisor to VA medical facility Chiefs of Pharmacy Services regarding pharmacy informatics.

(3) Developing and coordinating discussion and dissemination of pharmacy informatics issues within the VISN, as appropriate. ***NOTE:*** *This coordination may be done in conjunction with the VISN Chief Health Informatics Officer (CHIO).*

(4) Coordinating communication and required actions by the VA medical facility Chiefs of Pharmacy, regarding pharmacy informatics issues identified at the VA medical facility- or VISN-level to PBM Services.

(5) Reviewing reports used to ensure that the processing of controlled substance prescriptions is restricted to licensed pharmacists and taking action to remove inappropriate system access if identified by such reports.

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

(1) Providing oversight to ensure VA medical facility compliance with this directive and taking corrective action when non-compliance is identified.

(2) Appointing at least one Pharmacy Informaticist to be organizationally aligned under the VA medical facility Chief of Pharmacy Services. ***NOTE:*** *Larger and more complex VA medical facilities may need more than one individual in this role to support the pharmacy informatics responsibilities. Integrated multidivisional facilities may assign an informaticist to support more than one division.*

(3) Ensuring that the VA medical facility Chief of Pharmacy Services or designee (e.g., VA medical facility Pharmacy Informaticist) has access to edit and update the Person Class file taxonomy for pharmacists in pharmacies using Veterans Health Information Systems and Technology Architecture (VistA).

(4) Ensuring that a Pharmacy Informaticist or equivalent subject matter expert is included on all VA medical facility committees and programs that involve any national decisions and planning which affects pharmacy informatics, technologies or related operations.

h. **VA Medical Facility Chief of Pharmacy Services.** The VA medical facility Chief of Pharmacy Services is responsible for:

(1) Ensuring coordination by the VA medical facility Pharmacy Informaticist with the PBM Pharmacy Product System – National (PPS-N) team on the addition of new drug entries into the National Drug File (NDF). ***NOTE:*** *Items for Consolidated Mail Outpatient Pharmacy (CMOP) dispensing must have a monthly utilization of 50 fills per month across the VA to implement a new item request.*

(2) Ensuring that responsibilities assigned to the VA medical facility Pharmacy Informaticist position as described in this directive are not assigned as collateral duty to responsibilities of another primary role.

(3) Ensuring establishment of a position separate from that of the Pharmacy Informaticist that is dedicated to the oversight of inventory management. This role must not be assigned as collateral duty to responsibilities of another primary role.

(4) Ensuring that the VA medical facility Pharmacy Informaticist has appropriate system access necessary to perform their duties. This includes but is not limited to Security keys, FileMan access, authority to use the Corporate Data Warehouse (CDW) via access granted by National Data Services (NDS) and access to VistA option ‘Person Class Edit [XU-PERSON CLASS EDIT]’ for pharmacies using VistA EHR. ***NOTE:*** *Person Class File Taxonomy requires that each health care provider be assigned a code from the Person Classification file. Should the Pharmacy Informaticist have any of this access revoked from a security incident, a full review of their responsibilities is warranted by the VA medical facility Chief of Pharmacy Services.*

(5) Ensuring that the Person Class file taxonomy is reviewed and updated by the VA medical facility Pharmacy Informaticist at least annually for clinical pharmacists, pharmacy technicians and other individuals in their service.

(6) Ensuring that procedures are defined to assess workflow and standardize the use of medication storage and dispensing equipment to include minimum competency requirements for all personnel who have access to and operate the equipment.

(7) Ensuring collaboration by the VA medical facility Pharmacy Informaticist with the VA medical facility Chief of Biomedical Engineering or designee within the Biomedical Engineering service to establish performance requirements for the manufacturer during installation and the automated pharmacy system after implementation. The requirements are to include workflow assessment, installation, staff training and equipment maintenance.

(8) Developing an SOP for automated pharmacy systems and ensuring the safe and efficacious use of the system(s) by VA health care providers and pharmacy personnel with a focus on patient safety. The SOP should:

(a) Include minimum guidelines for routine assessment through an established monitoring and quality assurance program and encourage patient safety reporting as outlined by VHA Directive 1050.01, VHA Quality and Patient Safety Programs, dated March 24, 2023.

(b) Encourage patient safety reporting as outlined by VHA Directive 1050.01.

(c) Address high alert and hazardous drugs, look-alike sound-alike medications, and any potential for medication errors and controlled substance discrepancies.

(d) Define the procedures for the removal, security, re-stock to pharmacy inventory and accountability of medications when a system is removed from a patient care area.

(9) Establishing performance requirements for the manufacturer, pharmacy service personnel and the automated pharmacy system during and after implementation, including installation, workflow assessment, maintenance and training.

(10) Establishing SOPs that define maintenance, troubleshooting techniques, performance and standardization of the equipment, filling and restocking procedures, and device operations. These procedures must be in place prior to the use of medication storage or dispensing equipment to ensure safety, accuracy, security, patient confidentiality, and to define access and limits to equipment and medications. At a minimum, these SOPs should include:

(a) Minimum competency requirements for all personnel who have access to and operate the equipment.

(b) Procedures on how drugs can be safely delivered from the automated pharmacy distribution machine to the patient (the main area of concern is when multiple drugs are being delivered to multiple patients and the potential for errors).

(11) Ensuring that a contingency plan is defined in the event of an equipment, power or process failure and is established in each pharmacy service. This plan must include who needs to be contacted and how medications stored are to be secured and obtained. ***NOTE:*** *It is recommended that a process be established to determine how to recognize when a system failure occurs or is imminent, how to compensate to protect patient safety when failures occur, and how to get failures corrected expeditiously.*

(12) Notifying any State Prescription Drug Monitoring Program (PDMP) that receives data shared by the VA Pharmacy Service, either by telephone or email, in the event of a disaster or other contingency that disrupts normal operations for greater than 3 business days.

(13) Collaborating with the VA medical facility Chief Health Informatics Officer and VA medical facility Pharmacy Informaticist on the creation and maintenance of medication-related components within the facility-specific instance of the EHR, especially prescription and medication ordering tools.

(14) Ensuring that appropriately trained and qualified pharmacy staff (preferably pharmacy technicians) are assigned all activities associated with equipment assessment and routine maintenance.

(15) Ensuring that job-specific competencies related to the care and operation of the automated pharmacy system(s) are part of the pharmacy technician's performance plan and review.

i. **VA Medical Facility Chief Health Informatics Officer.** The VA medical facility CHIO is responsible for:

(1) Collaborating with the VA medical facility Chief of Pharmacy Services and VA medical facility Pharmacy Informaticist on the creation and maintenance of medication-related components within the facility-specific instance of the EHR, especially prescription and medication ordering tools.

(2) Supporting testing and training environments used by the VA medical facility Pharmacy Informaticist for patch testing and user education.

j. **VA Medical Facility Chief of Biomedical Engineering.** The VA medical facility Chief of Biomedical Engineering is responsible for collaborating with the VA medical facility Pharmacy Informaticist, or designee to establish performance requirements for the manufacturer during installation and after implementation of the automated pharmacy system. The performance requirements must include workflow assessment, installation, staff training and equipment maintenance.

k. **VA Medical Facility Pharmacy Informaticist.** The VA medical facility Pharmacy Informaticist is responsible for:

(1) Representing the Pharmacy Service as the subject matter expert in pharmacy informatics on local committees that are involved in technologies and informatics which impact pharmacy operations and clinical pharmacy services.

(2) Completing training to support the creation and maintenance of medication-related components within the facility-specific instance of EHR including testing and implementation, pharmacy automation systems, data analytics, and system monitoring and reporting.

(3) Maintaining the VA medical facility-level Drug File and its supporting VistA files and parameters at VA medical facilities using VistA EHR. This includes processing the NDF updates timely and managing the Pharmacy Orderable Item file in conjunction with the VA medical facility Clinical Application Coordinators (CACs) or Health Information Specialists (HISs). See paragraph 4 “Participation In State Prescription Drug Monitoring Programs” below for additional details.

(4) Managing user access requests for personnel within the VA medical facility Pharmacy Service systems through tools such as Electronic Permission Access System (ePAS).

(5) Generating standardized and ad hoc reports to support pharmacoeconomic analysis, quality assurance, operational workload, productivity tracking, formulary conversions and product recalls.

(6) Managing formulary controls using quick order restrictions for Orderable Items of non-formulary medications at VA medical facilities using VistA EHR.

(7) Providing informational text to health care providers via use of the Drug Text feature as displayed in Computerized Patient Record System (CPRS) during medication ordering at VA medical facilities using VistA EHR.

(8) Creating medication-related CPRS Quick Orders (which may include pharmacy supply items) at VA medical facilities using VistA EHR.

(9) Directing training for new pharmacy users (e.g., VA medical facility pharmacists and pharmacy technicians) and participating in new health care provider training to provide education about Pharmacy Service workflows and processes such as prescription and medication order entry.

(10) Establishing and supporting system interfaces to pharmacy automation (e.g., Pharmacy Automated Dispensing Equipment (PADE) for Omnicell/Pyxis and Outpatient Pharmacy Automation Interface (OPAI) for ScriptPro/OptiFill).

(11) Performing a systematic access review of menus twice a year.

(12) Participating in testing of pharmacy software patch and enhancement releases to ensure proper functionality of the system.

(13) Assist pharmacy staff with troubleshooting of item scanning failures for Bar Code Medication Administration (BCMA).

(14) Overseeing the process by which the pharmacy procurement staff uses EHR to receive drug accountability invoices.

(15) Supporting the drug recall process by generating reports, patient letters, etc.

(16) Managing system parameters and settings for daily prescription transmissions to CMOP, intravenous (IV) room and Outpatient Site configurations.

(17) Coordinating Electronic Prescriptions of Controlled Substances (EPCS) settings with the credentialing, informatics, Office of Information and Technology (OI&T) and health care provider services.

(18) Establishing and maintaining the appropriate settings for receipt of electronic prescriptions (eRxs) from community care providers at VA medical facilities using VistA EHR.

(19) Serving as liaison between pharmacy EHR support staff and external application technical support entities for help desk tickets.

(20) Collaborating with the VA medical facility Chief of Pharmacy Services and VA medical facility CHIO on the creation and maintenance of medication-related components within the facility-specific instance of the EHR, especially prescription and medication ordering tools.

(21) Establishing an account to represent the pharmacy as a dispenser of controlled substance prescriptions with the appropriate state (or other jurisdiction, as appropriate) prescription drug monitoring program. See paragraph 4 below (“Participation In State Prescription Drug Monitoring Programs”) for additional details.

(22) Overseeing automated pharmacy systems and VistA programs that directly support pharmacy operations. This includes:

(a) Communicating with OI&T specialists at the VA medical facility when problems or concerns arise. System downtimes or malfunctions must be reported through the IT help desk ticket process. The PBM Clinical Informatics Office may be contacted through Outlook email for assistance.

(b) Coordinating the installation and maintenance of VistA software and software patches with OI&T. These patches are required to effectively maintain the VistA system and ensure optimal performance and safety.

(c) Maintaining and updating the local VistA Drug Files, including mapping to the NDF, and its supporting VistA files and parameters. It also includes processing the NDF updates (every 2 weeks as of the time of this directive) and managing the Pharmacy Orderable Item file in conjunction with the VA medical facility Pharmacist CACs or HISs and reviewing the local VistA Drug file following installation of the data updates to identify corrective actions resulting from any NDF updates.

(d) Coordinating with the Drug File managers from all stations impacted by additions and edits at VA medical facilities that share a VistA Drug File (i.e., integrated sites or integrated VISNs).

(e) Submitting requests for new product additions or problems with the Medication Order Check Healthcare Application (MOCHA) or other clinical content systems to the PBM NDF team.

NOTE: *Access requirements for the above-listed responsibilities are defined in a VA memorandum between VHA and OI&T (see the Pharmacy Informaticists Automated Data Processing Application Coordinator (ADPAC) Minimum Access Requirements memo at: https://dvagov.sharepoint.com/:b:/r/sites/VHAPBM/Shared%20Documents/Pharmacy%20Informaticists%20ADPAC%20Minimum%20Access%20Requirements.pdf?csf=1&web=1&e=Q20rov). This is an internal VA website that is not available to the public.*

(f) Collaborating with the VA medical facility Chief of Biomedical Engineering or designee within the Biomedical Engineering service to establish performance requirements for the manufacturer during installation and after implementation of the automated pharmacy system. The performance requirements must include workflow assessment, installation, staff training and equipment maintenance.

l. **VA Medical Facility Pharmacist Clinical Application Coordinator or Health Information Specialist.** Pharmacist CACs and HISs are pharmacists who serve in a clinical informatics service. These positions are independent of the Pharmacy Informaticist and may not necessarily report to the VA medical facility Chief of Pharmacy Services. Depending on the VA medical facility structure, the VA medical facility Pharmacist CAC or HIS is responsible for managing the Pharmacy Orderable Item file in conjunction with the VA medical facility Pharmacy Informaticist.

m. **VA Medical Facility Pharmacy Technician.** The VA medical facility Pharmacy Technician is responsible for all activities associated with equipment assessment and routine maintenance if assigned by the VA medical facility Chief of Pharmacy Services or Pharmacy Informaticist.

n. **VA Medical Facility Clinical Application Coordinators/Health Information Specialists, Credentialing and Privileging Specialists, and/or the Designated Education Officer.** These personnel are responsible for the verification of permissions and granting of access for authorized health care providers to electronically prescribe controlled substances. This practice is governed by the Drug Enforcement

Administration (DEA) regulations published at 21 C.F.R. § 1311 and requires two separate individuals to perform the tasks. In the VistA EHR, verification of permissions is recorded using the EPCS Data Entry for Prescriber tool (also referred to as EPCS GUI) and granting of access is performed using VistA option 'EPCS User Enable/Disable' [OR EPCS USERS PARAMETER]. Further detail is provided in SOP: "Management of Access for Electronic Prescriptions of Controlled Substances in the VistA Electronic Health Record," available online at https://dvagov.sharepoint.com/sites/VHAPBM/Cerner%20SOP%20repository/Forms/AllItems.aspx?id=%2Fsites%2FVHAPBM%2FCerner%20SOP%20repository%2FSOP%20EPCS%20Nomination%5FApproval%20in%20VistA%20%28002%29%2Epdf&parent=%2Fsites%2FVHAPBM%2FCerner%20SOP%20repository. ***NOTE:*** *This is an internal VA website that is not available to the public.*

3. AUTOMATED PHARMACY SYSTEMS

a. Automated pharmacy systems, also referred to as automated medication management systems, are utilized in pharmacies to improve medication safety and the efficiency and accuracy of the dispensing process. They include but are not limited to mechanical systems that perform operations or activities (other than compounding or administration) relative to the storage, packaging, dispensing or distribution of medications. These devices may collect, control and maintain all transaction information.

b. Automated pharmacy systems that are interfaced to EHR must utilize a standardized Health Level 7 (HL7) or Fast Healthcare Interoperability Resources (FHIR) interface to the EHR system in use at the VA medical facility.

c. Patient confidentiality must be ensured and maintained in all pharmacy service environments in accordance with HIPAA and VHA privacy standards.

d. All activities associated with equipment assessment, routine maintenance and oversight are assigned to appropriately trained and qualified pharmacy staff (preferably pharmacy technicians) and under the programmatic guidance of the VA medical facility Pharmacy Informaticist. Job-specific competencies, related to the care and operation of the automated pharmacy system(s), must be part of the pharmacy technician's performance plan and review.

4. PARTICIPATION IN STATE PRESCRIPTION DRUG MONITORING PROGRAMS

a. VA pharmacies must participate in sharing data to active State PDMPs. Although State PDMP laws vary, VA will transmit the same information, as described below, to all States' PDMPs.

b. VA pharmacies must comply with the following:

(1) VA pharmacies must enroll in the state program where the VA medical facility is geographically located.

(2) VA pharmacies must only transmit the data outlined in paragraphs 4.b.(3) to 4.b.(5) for substances identified in 21 C.F.R. part 1308 as schedules II through V controlled substances. In states where other agents have been added to the expected transmissions, such as medications that are controlled at the state level but not the federal level, the VA is not authorized to share this information.

(3) VA pharmacies must transmit prescriber information, such as name and DEA number.

(4) VA pharmacies must transmit patient demographic information, such as name, permanent address, date of birth and patient identification number.

(5) VA pharmacies will transmit the following prescription data:

(a) The prescription number,

(b) The date of origin (i.e., issuance) of the prescription,

(c) The date of dispensing (i.e., release date),

(d) The number of authorized refills,

(e) The prescription's origin code,

(f) The NDC for the drug dispensed,

(g) The quantity of drug units dispensed,

(h) The generic or brand name, when the formulation contains multiple agents, of the drug dispensed,

(i) The drug dosage; and

(j) Whether the substances were dispensed as a new or refill of a prescription.
NOTE: *At VistA VA pharmacies, this will be accomplished by using VistA option 'View/Edit SPMP State Parameters' [PSO SPMP STATE PARAMETRS] to establish the parameters for each respective state name, the corresponding version of the American Society for Automation in Pharmacy standard used to transmit data, the frequency of transmissions, and the State's recipient IP address to which the transmission will be directed.*

c. VA pharmacies are prohibited from marking non-controlled medications as controlled substances in the VistA "DEA, SPECIAL HDLG" field solely for the purpose of inventory tracking (e.g., high-cost medications).

d. VA pharmacies are prohibited from changing the controlled substance schedule of a drug in VistA from the federal definition.

e. VA pharmacies must not transmit prescription information about prescriptions dispensed by non-VA entities, even if VA has a record of those prescriptions.

f. VA pharmacies must transmit prescription data to PDMPs daily.

g. VA pharmacies must receive rejected prescription data from the State PDMP.

h. VA pharmacies must reconcile rejected prescription data within 3 business days (or as soon as feasible), if the information is readily available from VA sources.

i. CMOPs are not required to transmit prescription data to a State's PDMP. ***NOTE:*** *Data pertaining to VA controlled substance prescription dispensing from the CMOP will be transmitted to State PDMPs by the originating VA medical facility.*

j. The VA medical facility Chief of Pharmacy Services or designee must notify the PDMP, either by telephone or email, in the event of a disaster or other contingency that disrupts the normal operations for greater than 3 business days. Documentation should be maintained by the Pharmacy Service noting when the PDMP was notified, how long the disruption lasted, and when transmission was re-started.

k. VA health care providers are subject to the requirements of VHA Directive 1306(1), Querying State Prescription Drug Monitoring Programs (PDMP), dated October 19, 2016 regarding requirements for querying the State PDMP databases prior to issuing a prescription for a controlled substance.

5. PHARMACY BENEFITS MANAGEMENT COMMUNICATION TO THE FIELD

a. PBM field guidance is intended to clarify current VA policy, educate field staff and provide direction prior to or at the time of formal VA policy implementation. It is important that VA medical facility pharmacy supervisors review and incorporate these guidance documents into local VA medical facility procedures. Each of the websites referenced below may be accessed from the PBM Home Page at https://dvagov.sharepoint.com/sites/VHAPBM/SitePages/Home.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

b. Guidance issued by the Pharmacy Benefits Management Clinical Informatics (PBM CI) program office may be distributed in several formats:

(1) **Electronic Mail.** The PBM CI program office may distribute updates to the email distribution lists representing VA medical facility Chiefs of Pharmacy Services, pharmacy supervisors and Pharmacy Informaticists. The mail group **VHA PBM Pharmacy Informaticists** (pharmacyinformaticists@va.gov) is the primary distribution list for such topics.

(2) **RxAPID Briefing.** The RxAPID Briefing format is a newsletter-style document intended to respond to Frequently Asked Questions (FAQs) by the pharmacy informatics community. RxAPID Briefings are stored for later reference in a SharePoint document library at:

https://dvagov.sharepoint.com/sites/VHAPBM/PBMRapidBriefings/Forms/AllItems.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(3) **PBM Notice.** A PBM Notice is a formal distribution of policy guidance or direction, frequently in response to an identified patient safety issue or incident. PBM Notices are jointly reviewed by the Informatics Patient Safety office, the National Center for Patient Safety and OI&T before release. PBM Notices are available online at https://dvagov.sharepoint.com/sites/VHAPBM/PBM_Advisories/. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(4) In cases where the actions recommended or required by a guidance document affect users outside the pharmacy service, the content may be referred to the National Center for Patient Safety to be issued as a Notice (information only), Advisory (recommendations) or Alert (required actions with a follow-up reporting mechanism). Alerts and Advisories are available online at: https://dvagov.sharepoint.com/sites/vhancps/Lists/AlertsAdvisoriesandNoticesTracker/AllItems.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

6. TRAINING

There are no formal training requirements associated with this directive.

7. 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 Officer.

8. BACKGROUND

a. The practice of Pharmacy Informatics represents the intersection of clinical pharmacy practice and medication distribution with EHR information technology. Roles and responsibilities within pharmacy informatics include file maintenance, automation interfaces, data analytics, system testing and ongoing staff education.

b. The VA medical facility Pharmacy Informaticist is a VA employee and program manager who is organizationally aligned under the Chief of Pharmacy Services and assigned responsibility for those activities in the intersection of clinical care and information technology. This position is commonly held by a licensed pharmacist although that is not a requirement of the role. Previous names for this position included Pharmacy ADPAC; however, this term is retired and no longer represents the functions and responsibilities of a modern specialist in pharmacy informatics. ***NOTE:*** *There are also VISN Pharmacy Informaticists organizationally aligned to the VISN Pharmacist Executive. They do not fall under this directive's expectation of at least one Pharmacy Informaticist at each VA medical facility that is organizationally aligned under the VA medical facility Chief of Pharmacy Services.*

c. Automated pharmacy systems are used across the health care environment and physically located in multiple clinical settings. These systems promote medication safety and improve operational efficiencies related to the overall management use process. Pharmacy-managed systems typically include technologies and robotic systems related to medication storage, packaging, dispensing and distribution. These systems may be used solely to support pharmacy operational drug dispensing (e.g., ScriptPro outpatient dispensing equipment) or other health care professional activities outside of Pharmacy Service such as nursing (e.g., OmniCell automated dispensing cabinets). Additional automated pharmacy systems related to the medication use process may require a shared governance approach as is the case with BCMA technology and infusion pumps with integrated drug database safeguards.

d. The Pharmacy Informatics Program describes the comprehensive collection of clinical pharmacy informatics services provided by a VA medical facility, VISN or national program office. The scope of services delivered and the optimal staffing requirements may vary depending on the clinical and technical needs of the organizational unit.

9. DEFINITIONS

a. **Automated Pharmacy Systems.** Automated pharmacy systems mean a system that is controlled by a machine or computer that manages (1) distribution of medication to and from the patient care area, (2) distribution of medication directly to the patient, (3) inventory control, (4) storage and packaging and (5) management of controlled substances.

b. **Consolidated Mail Outpatient Pharmacy.** CMOP is a centralized dispensing and fulfillment service for outpatient prescriptions mailed to patients. Unlike private sector mail order pharmacies, the ownership of a prescription filled by CMOP remains at the VA medical facility.

c. **Electronic Health Record.** EHR is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including CPRS, VistA and Cerner platforms. ***NOTE:*** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

d. **Pharmacy Informatics.** Pharmacy informatics is the scientific field that focuses on medication-related data and knowledge within the continuum of healthcare systems – including its acquisition, storage, analysis, use and dissemination – in the delivery of optimal medication-related patient care and health outcomes.

e. **State Prescription Drug Monitoring Program.** A State PDMP is a statewide electronic database which collects designated data on controlled substances dispensed in the State. The PDMP is administered by a specified statewide regulatory,

administrative or law enforcement agency. The authorized agency distributes data from the database to individuals who are permitted under State law to receive the information for purposes of their profession.

10. REFERENCES

a. 38 U.S.C. § 7301(b).

b. 21 C.F.R. § 1308, 1311.

c. VHA Directive 1050.01, VHA Quality and Patient Safety Programs, dated March 24, 2023.

d. VHA Directive 1069, National Pharmacy Benefits Management Drug Safety Alert Distribution, dated October 24, 2019.

e. VHA Directive 1108.07, General Pharmacy Service Requirements, dated November 28, 2022.

f. VHA Directive 1306(1), Querying State Prescription Drug Monitoring Programs (PDMP), dated October 19, 2016.

g. VHA SOP: "Management of Access for Electronic Prescriptions of Controlled Substances" – https://dvagov.sharepoint.com/sites/VHAPBM/Cerner%20SOP%20repository/Forms/AllItems.aspx?id=%2Fsites%2FVHAPBM%2FCerner%20SOP%20repository%2FSOP%20EPCS%20Nomination%5FApproval%20in%20VistA%20%28002%29%2Epdf&parent=%2Fsites%2FVHAPBM%2FCerner%20SOP%20repository. ***NOTE:*** *This is an internal VA website that is not available to the public.*