



# US DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

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## VETERANS HEALTH ADMINISTRATION

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### **Electronic Health Record Modernization Caused Pharmacy- Related Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus**

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## Executive Summary

The VA Office of Inspector General (OIG) conducted a focused inspection at the VA Central Ohio Healthcare System in Columbus (facility) to review an allegation that implementation of the new electronic health record (EHR) led to a prescription backlog at the facility.<sup>1</sup> The OIG determined that a prescription backlog existed following the new EHR's go-live on April 30, 2022; however, facility leaders took timely and sustainable steps to manage the issue. While reviewing the allegation, the OIG identified that implementation of the new EHR led to other facility and national pharmacy-related patient safety concerns. Most significantly, the OIG found unmitigated high-risk patient safety issues, patient medication inaccuracies, unresolved new EHR usability challenges, inaccurate medication data, the creation of numerous workarounds to provide patient care, overwhelming educational materials for pharmacy-related functions, and pharmacy staffing challenges.<sup>2</sup>

### Facility Pharmacy-Related Patient Safety Concerns

In May 2021, after VA's first deployment of the new EHR at the Mann-Grandstaff VA Medical Center, a VA National Center for Patient Safety (NCPS)-led pharmacy team (pharmacy patient safety team) identified pharmacy-related patient safety and usability issues. For example, updates to a patient's active medication list may not be reflected at the patient's next appointment. The OIG found that although aware of ongoing challenges, VA leaders continued to deploy the new EHR at four additional sites, including the facility.

Following deployment of the new EHR to the facility in April 2022, the OIG determined that previously-identified NCPS patient safety issues were a factor in 32 percent of the facility pharmacy-related patient safety reports and EHR usability was a factor in 66 percent.<sup>3</sup> Although Oracle Health has since resolved some of the previously-identified NCPS issues, the OIG is concerned that the new EHR will continue to be deployed at Veterans Health Administration (VHA) sites prior to resolving the remaining issues.<sup>4</sup>

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<sup>1</sup> The allegation detailed that the prescription backlog could lead to a delay in patients receiving medication.

<sup>2</sup> EHR usability refers to "the extent that EHRs support clinicians in achieving their goals in a satisfying, effective and efficient manner." David J. Keene et al., "Electronic Health Record Usability Issues and Potential Contribution to Patient Harm," *Journal of the American Medical Association*, No. 12 (March 27, 2018): 1276–1278.

<sup>3</sup> The OIG analyzed facility-generated pharmacy-related patient safety reports captured in the Joint Patient Safety Reporting system from April 30, 2022, through March 30, 2023, to determine if the NCPS-identified high-risk pharmacy issues occurred after go-live at the facility.

<sup>4</sup> In June 2022 Oracle acquired Cerner, which is now referred to as Oracle Health. "Oracle Health—Reimagine the Future of Health," Oracle, accessed March 6, 2024, <http://www.oracle.com/health/>.

## The New EHR's Negative Effect on Facility Pharmacy Staff

After implementation of the new EHR, facility staff were challenged to provide safe medication management and avoid patient harm due to ongoing identified patient safety and usability issues.

***Implementation of the new EHR resulted in a prescription backlog and a permanent increase in clinical pharmacists.*** The OIG determined that the chief of pharmacy prepared for challenges with the new EHR. However, pharmacy staff's workload increased due to the new EHR's operational inefficiencies.<sup>5</sup> This contributed to the prescription backlog and the need to hire nine full-time clinical pharmacists, which represented a 62 percent increase. The OIG would have expected the new EHR's implementation to result in more efficient pharmacy processes.

***Numerous workarounds and educational materials were needed to complete facility pharmacy work processes and provide patient care following implementation of the new EHR.***<sup>6</sup> A VHA leader told the OIG that challenges with the new EHR's usability led to the development of pharmacy-related workarounds. Workarounds can create and perpetuate pathways for errors, potentially compromising patient safety. The OIG learned that workarounds were developed at the national and facility level to allow pharmacy staff to complete pharmacy work processes.

In May 2021, the NCPS pharmacy patient safety team created 7 workarounds to allow pharmacy staff to provide patient care using the new EHR.<sup>7</sup> Following go-live at the facility, pharmacy leaders created approximately 29 additional workarounds to support pharmacy staff with processing prescription orders to prevent medication delays. Facility pharmacy leaders also identified a need to develop approximately 25 educational materials to serve as further support for pharmacy staff.<sup>8</sup>

Facility and pharmacy leaders expressed frustration to the OIG about challenges with the new EHR's usability and the need for multiple pharmacy workarounds to complete tasks. The OIG recognizes that facility pharmacy leaders' development and use of workarounds and educational materials demonstrated a commitment to patient care while adapting to the new EHR and

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<sup>5</sup> The facility chief of pharmacy told the OIG that preparations started a year before go-live and included discussions about Mann-Grandstaff VA Medical Center's deployment of the new EHR with the National Pharmacy Council and Veterans Integrated Service Network 20 and Mann-Grandstaff representatives. Mann-Grandstaff VA Medical Center was the first medical center to go live with the new EHR.

<sup>6</sup> An EHR workaround is a temporary process developed outside established rules and regulations to allow users to complete tasks; often when time constraint is a factor. Vincent Blijleven et al., "Workarounds Emerging From Electronic Health Record System Usage: Consequences for Patient Safety, Effectiveness of Care, and Efficiency of Care," *JMIR Human Factors* 4, no. 4 (2017), <https://humanfactors.jmir.org/2017/4/e27/PDF>.

<sup>7</sup> This occurred after the first VA medical center's deployment of the new EHR at the Mann-Grandstaff VA Medical Center in Spokane, Washington.

<sup>8</sup> Educational materials included tip sheets, reference guides, and job aids. This was in addition to 123 EHR pharmacy-related educational materials that existed on the VA Pharmacy Benefits Management SharePoint site for pharmacy staff use as of August 2023. "Pharmacy Benefits Management Services," VA, accessed September 6, 2023, <https://vaww.patientcare.va.gov/PCS/PBM.asp>. (This site is not publicly accessible.)

allowed pharmacy staff to complete work processes. However, the OIG is concerned that the numerous workarounds and educational materials are overwhelming for pharmacy staff, which may lead to increased patient safety issues.

***Implementation of the new EHR resulted in facility pharmacy staff reporting an increase in burnout symptoms and job dissatisfaction.*** Facility pharmacy staff, including the chief of pharmacy, told the OIG that new EHR usability issues contributed to concerns about making errors that could result in patient harm and caused pharmacy staff to experience burnout, low morale, and decreased job satisfaction.

As VA acknowledges the importance of monitoring employee burnout and job satisfaction through the All Employee Survey, the OIG reviewed survey responses prior to and following the new EHR's implementation. The OIG found following implementation, burnout symptoms for pharmacy staff increased and the best places to work score for pharmacy staff decreased from the previous fiscal year.<sup>9</sup>

Additionally, facility pharmacy employees, including the chief of pharmacy, told the OIG that challenges with the new EHR negatively affected pharmacy staff morale. The OIG surveyed frontline pharmacy staff to explore their experience and found 77 percent reported decreased morale after the new EHR's implementation. VHA pharmacy and patient safety leaders told the OIG of a need for increased staff vigilance to avoid patient harm, as the new EHR is fundamentally unsafe. Facility leaders also described experiences synonymous with moral injury related to the new EHR.<sup>10</sup>

## National Pharmacy-Related Patient Safety Issues

VHA providers use the EHR to coordinate a patient's care. The communication of EHR information between VA facilities occurs through different channels such as the Health Data

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<sup>9</sup> The OIG compared 2021 and 2022 facility All Employee Survey results. A facility leader informed the OIG that VA launched the 2022 AES on June 6, 2022, 37 days after the new EHR's implementation at the facility. Burnout is measured as a percentage score ranging from 0–100; lower percentages are more favorable. "Best Places to Work" is a summary measure of the group's satisfaction with the job, organization, and likelihood to recommend VA as a good place to work. The score ranges from 0–100 points; higher scores are more favorable. "2022 VA All Employee Survey (AES), Questions by Organizational Health Framework," VA, accessed July 26, 2023, [https://dvagov.sharepoint.com/:w:/r/sites/AESHelpDesk/\\_layouts/15/Doc.aspx?sourcedoc=%7BF6550A11-35BB-42E5-8C0A-CED3A6D18C95%7D&file=2022%20AES%20Instrument-%20Questions%20by%20Theme.docx&action=default&mobileredirect=true](https://dvagov.sharepoint.com/:w:/r/sites/AESHelpDesk/_layouts/15/Doc.aspx?sourcedoc=%7BF6550A11-35BB-42E5-8C0A-CED3A6D18C95%7D&file=2022%20AES%20Instrument-%20Questions%20by%20Theme.docx&action=default&mobileredirect=true). (This site is not publicly accessible); "The federal government's fiscal year runs from October 1 of one calendar year through September 30 of the next." USAgov, "The federal budget process," accessed August 24, 2023, <https://www.usa.gov/federal-budget-process>.

<sup>10</sup> Moral injury is "the strong cognitive and emotional response that can occur following events that violate a person's moral or ethical code"; Victoria Williamson et al., "Moral Injury: The Effect on Mental Health and Implications for Treatment," *The Lancet Psychiatry* 8, no. 6 (June 2021): 453–455, [https://doi.org/10.1016/S2215-0366\(21\)00113-9](https://doi.org/10.1016/S2215-0366(21)00113-9).

Repository (HDR).<sup>11</sup> Every medication in VA is assigned a distinctive number known as a VA Unique Identifier (VUID), and when a patient is prescribed a medication at a site that has implemented the new EHR, the medication's VUID is sent to the HDR. When providers at sites that have not implemented the new EHR (legacy sites) enter a medication order, a software interface, which relies on the accuracy of the information in the HDR, accesses the medication VUID from the HDR to perform a safety check.<sup>12</sup> The check verifies the medication being prescribed is safe and compatible with the medications and allergies previously documented in the patient's EHR.<sup>13</sup> See figure 1 for an overview of how medication data transmission is intended to flow from the new EHR to the HDR.

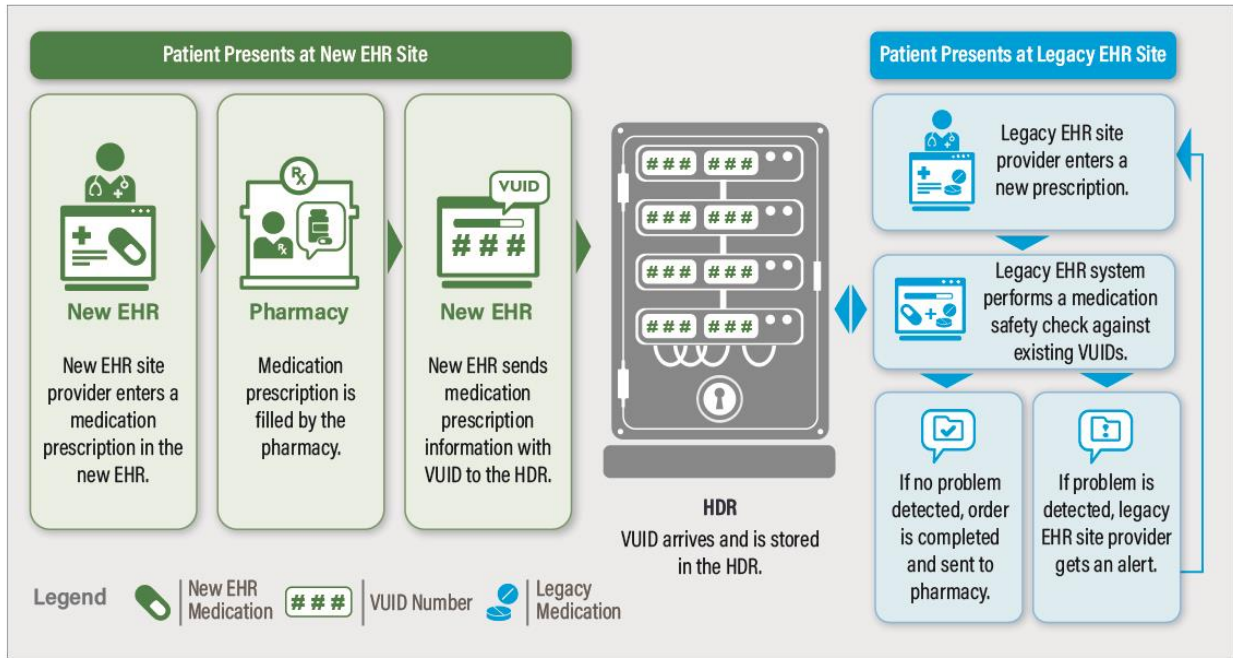
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<sup>11</sup> The HDR is a database that stores patient-specific clinical information, including medication and allergy information from all VA EHRs, including the new EHR. Providers use this information to support treatment decisions.

<sup>12</sup> The OIG uses the term legacy EHR to refer to Veterans Health Information Systems and Technology Architecture (VistA), the EHR used prior to the Oracle Health EHR. For the purposes of this report, sites that have not implemented the new EHR and continue to use VistA will be referred to as legacy sites.

<sup>13</sup> VA Office of Information & Technology, *Computerized Patient Record System (CPRS), Technical Manual: List Manager Version*, October 2023, [https://www.va.gov/vdl/documents/Clinical/Comp\\_Patient\\_Recrd\\_Sys\\_\(CPRS\)/cprslmtm.pdf](https://www.va.gov/vdl/documents/Clinical/Comp_Patient_Recrd_Sys_(CPRS)/cprslmtm.pdf). Medication order checks are a real-time process for evaluating a requested order against existing patient medications and allergy information. The result of the check provides the ordering clinician with information regarding any detected drug-drug interactions, drug-allergy interactions, duplication of medications, or duplications of medication class.





**Summary figure 1.** Intended data transmission process.

Source: OIG analysis.

Note: The figure above shows the basic scenario of medication information data transmission from the new EHR to the HDR and a legacy EHR automated medication safety check.

**Software coding errors created patient safety issues.**

An error in Oracle Health software coding resulted in the widespread transmission of incorrect VUIDs from new EHR sites to legacy EHR sites. VUIDs became inaccurate during transmission to the HDR when prescriptions were processed through the Consolidated Mail Outpatient Pharmacy (CMOP).<sup>14</sup> This error created the potential for medication-related patient safety events.

On March 31, 2023, legacy site staff discovered the incorrect VUID transmission error and sent an issue brief describing the event and the cause to VA, NCPS, and VHA leaders. VA Pharmacy Benefits Management leaders also sent an email to VHA, Veterans Integrated Service Network, and facility leaders alerting them of the event and its potential clinical impact. The email provided specific instructions on how to mitigate the issue and requested recipients to “please share widely.”

<sup>14</sup> CMOP is a centralized automated pharmacy system comprised of seven pharmacies that provide mail order medications to VHA patients. Sherrie L. Aspinall et al., “Pharmacy Benefits Management in the Veterans Health Administration Revisited: A Decade of Advancements, 2004-2014,” *Journal of Managed Care Specialty & Pharmacy* 22, no. 9 (September 2016): 1058–1063, <https://doi.org/10.18553/jmcp.2016.22.9.1058>; Prescriptions filled through CMOP account for approximately 80 percent of all outpatient medications. “Pharmacy Benefits Management Services,” VA, accessed September 16, 2023, [https://www.pbm.va.gov/PBM/CMOP/VA\\_Mail\\_Order\\_Pharmacy.asp](https://www.pbm.va.gov/PBM/CMOP/VA_Mail_Order_Pharmacy.asp).

On April 4, 2023, NCPS notified VHA patient safety managers and officers, and CMOP patient safety managers across VHA that drug-drug interactions, duplicate order, and allergy checks were not functioning as expected. In addition, the communication included recommended actions to offset the risk of patient harm.

Oracle Health applied a successful software patch on April 7, 2023, to ensure accurate VUIDs were applied to all CMOP-processed prescriptions from that date forward. However, the OIG learned the incorrect VUIDs sent from new EHR sites and stored in the HDR from as far back as October 2020 were not corrected. A VHA leader shared that on November 29, 2023, the VHA Pharmacy Council reported withdrawing a request for Oracle Health to resend corrected CMOP-related medication data to the HDR. The council accepted that all remaining inaccurate medication prescription data would expire by April 7, 2024, and would correct at that time.<sup>15</sup>

The OIG is concerned that patient medication data remains inaccurate more than six months after VA and VHA leaders became aware of the issue and data generated from approximately 120,000 new EHR site patients remains incorrect. These patients are at ongoing risk of a medication-related patient safety event should they receive care and medications at a legacy EHR site.<sup>16</sup>

***Additional medication-related data transmission errors resulted in further patient safety issues.*** The OIG learned that research into the cause of the VUID error that occurred when prescriptions were processed through the CMOP led to the further discovery of subsequent transmission issues of medication and allergy information from the new EHR to the HDR.<sup>17</sup> On June 15, 2023, NCPS sent a Patient Safety Notice to VHA patient safety staff providing details concerning the initial and subsequent data transmission issues and errors resulting in inaccurate medication, allergy, and adverse drug reaction information in the HDR. NCPS requested all relevant medical center staff be made aware that legacy EHR site software applications may contain inaccurate medication information for patients who have received care at both legacy and new EHR sites.

When the notice was sent, no resolutions existed for the subsequent transmission issues and there was no clear determination of which patients were affected and who may have experienced harm. As VHA cannot determine which patients were at risk of a patient safety event from the data transmission errors, a VHA leader informed the OIG that all patients who have been prescribed any medications through or have medication allergies documented at a new EHR site are considered “at risk.” The OIG reviewed VHA data reflecting the number of at-risk patients. As of September 2023, approximately 190,000 unique patients had a medication prescribed and

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<sup>15</sup> VA prescriptions are valid up to one year from the date of issue. VHA Directive 1108.07, *General Pharmacy Service Requirements*, November 28, 2022.

<sup>16</sup> Of the 120,000 new EHR site patients, approximately 67,000 have received care and were prescribed medications at legacy EHR sites; VHA remains unaware whether these patients incurred harm.

<sup>17</sup> The issues included transmission of missing, duplicate, or incorrect medication and allergy information.



126,000 unique patients had an allergy documented at a new EHR site. Approximately 68,000 patients were in both groups, for a total of approximately 250,000 affected unique patients.

An Electronic Health Record Modernization Integration Office (EHRM IO) data leader noted that Oracle Health originally tested the software interfaces. The testing plan focused on the transmission of the data from the new EHR to the HDR but failed to verify the accuracy of the data when accessed downstream by legacy EHR users.

The OIG remains concerned for the safety of new EHR site patients who receive care from a legacy EHR site, as the information transmission issues may result in new EHR site patients being prescribed contraindicated medications and legacy site providers making clinical decisions based on inaccurate data. Further, the OIG is not confident in EHRM IO leaders' oversight and control of the new EHR's HDR interface programming.<sup>18</sup>

***Patients who receive care at new EHR sites have not been notified of the risk of harm secondary to data transmission issues.*** Per VHA policy, a disclosure is warranted for harmful or potentially harmful adverse events that “have a potential to affect, or may have already affected multiple patients at one or more VA medical facilities.”<sup>19</sup> VHA leaders convened a Clinical Episode Review Team (CERT) to discuss the issues and errors related to the transmission of inaccurate pharmacy data from the new EHR to the HDR.<sup>20</sup> In early June 2023, a VHA leader involved in the CERT communicated support to the CERT Executive Director for conducting a look-back of patients who may have been harmed, initiating a large-scale disclosure review, and providing instructions to affected patients to mitigate their risk.

On June 21, 2023, the CERT Executive Director sent a memorandum addressed to the VA Under Secretary for Health outlining the CERT review and subsequent recommendations, which included a communication plan to patients who have been seen at and received a prescription through a new EHR site since go-live. Both documents specify that the patient communication was not a disclosure but a “general patient safety/awareness communication” encouraging affected patients to collaborate with their health care providers during the medication reconciliation process.<sup>21</sup> The memorandum also documented that the CERT was still in the process of determining the feasibility of completing a look-back review to identify patient harm.<sup>22</sup>

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<sup>18</sup> These issues occurred in an environment in which they were able to remain undetected for more than two years.

<sup>19</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

<sup>20</sup> VHA Directive 1004.08. The Deputy Under Secretary for Health for Operations and Management convenes a CERT to conduct a “coordinated triage process for review of each potential adverse event that may require large-scale disclosure.” The CERT met between April 13 and May 15, 2023.

<sup>21</sup> The documents included the signed memorandum and the patient communication plan.

<sup>22</sup> Clinical Episode Review Team, “CERT Review and Recommendations Regarding EHRM Medication Checks Pharmacy Issue,” memorandum to the Under Secretary for Health through Clinical Services, June 21, 2023; Clinical Episode Review Team, *EHRM Pharmacy Issue Patient Communication Plan*, August 2, 2023.

A CERT leader emailed the communication plan to VHA, Veterans Integrated Service Network 10 and 20, and facility leaders on August 7, 2023. The communication plan was marked as a draft and did not include a timeline for release or identify responsible parties to disseminate the information. When asked, the CERT Executive Director told the OIG there was no assigned timeline and that it was left to VHA, Veterans Integrated Service Network, and facility leaders to move forward with the plan or request changes. In late October 2023, the OIG asked a facility leader about actions taken in response to the August 7th email. The facility leader responded, “there were no actions taken as it was not clear at the time of the CERT communication. . . that recommended communications were finalized.”

As of September 2023, the approximately 250,000 patients—who either received medication orders or had medication allergies documented in the new EHR site from October 2020—may be unaware of the potential risk for a medication or allergy-related patient safety event should they receive care at a legacy EHR site. Further, a VHA leader told the OIG that as of December 2023, the leader had no knowledge of the development of a comprehensive strategy to conduct a look-back of the care of the growing number of patients who have received and continue to receive services, including medication prescriptions at legacy sites.

The OIG is concerned that the proposed patient communication notification does not include information about the potential risk of harm due to HDR transmission issues. Further, the OIG would have expected VHA leaders to develop a comprehensive strategy to review the care of new EHR site patients who have visited a legacy site and may have sustained harm, and subsequently disclose harm as warranted per VHA policy.

***Patient safety issues remain despite VHA’s recommended actions to mitigate risks created by HDR transmission errors.*** As early as March 31, 2023, VHA leaders sent a series of notifications (described above) about the transmission issues and outlined recommended actions to offset the risk of patient harm. These notifications included instructions for legacy site leaders to have providers perform multistep manual safety checks to replace automated software safety checks when prescribing new medications for patients previously cared for at a new EHR site. These manual safety checks are complex, time consuming, and rely on the vigilance of pharmacists and frontline staff. The OIG is concerned that increased vigilance is unsustainable by pharmacists and frontline staff who are responsible for clinical decision-making and may lead to burnout and medication-related patient safety events.

The OIG recognizes the challenges of modernizing EHR systems and acknowledges the significant work and commitment of facility staff to accomplish this task. The OIG repeatedly heard of the long hours and considerable workload of facility staff dedicated to this mission and recognizes their efforts to ensure safe care for patients.

The OIG has published multiple reports identifying numerous patient safety issues related to the new EHR. While VHA has paused deployments until the new EHR is “highly functioning at

current sites and ready to deliver for Veterans and VA clinicians at future sites,” a planned go-live at the Captain James A. Lovell Federal Healthcare Center is scheduled for March 2024.<sup>23</sup>

The OIG made three recommendations to the Deputy Secretary related to resolution of patient safety and usability issues with the new EHR.

The OIG made six recommendations to the Under Secretary for Health. One recommendation focuses on accurate patient medication data and three recommendations address patient and provider awareness and evaluation of the risk of harm related to the new EHR transmission issues. Another recommendation is related to pharmacy staffing, and one focuses on the underlying technical and functional issues that require workarounds and educational materials to perform pharmacy-related operations in the new EHR.

## **VA Comments and OIG Response**

After reviewing the OIG draft report, VA provided the OIG with technical comments. The OIG reviewed and considered the comments. Based on the review, some changes were made to the report for clarification, but no changes were made to OIG findings.

The Deputy Secretary of Veterans Affairs and Under Secretary for Health concurred with the recommendations and provided acceptable action plans (see appendixes C and D). The OIG will follow up on the planned actions until they are completed.



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<sup>23</sup> Of note, VHA has determined the Captain James A. Lovell Federal Healthcare Center, a joint site with the Department of Defense, will go live in March 2024 “due to the level of integration between VA and DoD [Department of Defense] at this facility.” Undersecretary for Health email message to VHA, April 21, 2023; “VA EHRM Reset Update: Introduction to the Rapid EHRM Baseline Improvement Workstream,” EHRM SharePoint site, July 2023, <https://vaww.ehrm.va.gov/wp-content/uploads/2023/07/BRIEFING-SLIDES-EHRM-Reset-and-Rapid-EHRM-Baseline-Improvement-Workstream-Overview.pdf>. (This site is not publicly accessible.)

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## Abbreviations

AES	All Employee Survey
CERT	Clinical Episode Review Team
CMOP	Consolidated Mail Outpatient Pharmacy
EHR	electronic health record
EHRM	Electronic Health Record Modernization
EHRM IO	Electronic Health Record Modernization Integration Office
HDR	Health Data Repository
JLV	Joint Longitudinal Viewer
JPSR	Joint Patient Safety Reporting
NCPS	National Center for Patient Safety
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture
VUID	VA Unique Identifier



## Introduction

The VA Office of Inspector General (OIG) conducted a focused inspection at the VA Central Ohio Healthcare System (facility) in Columbus to evaluate patient safety and usability issues within the pharmacy domain of the new electronic health record (EHR).<sup>1</sup> There has been significant interest from stakeholders, including members of Congress, on whether the use of the new EHR has resulted in patient harm.

The OIG recognizes the challenges of modernizing EHR systems and acknowledges the significant work and commitment of facility staff to accomplish this task. The OIG repeatedly heard about the long hours and considerable workload of facility staff dedicated to this mission and their efforts to ensure safe care for patients.

## Background

The facility is part of Veterans Integrated Service Network (VISN) 10 and contains one healthcare center, the Chalmers P. Wylie Ambulatory Care Center located in Columbus, Ohio. The healthcare center is a level 2, medium complexity facility and provides outpatient services in primary care, urgent care, mental health, specialty medicine, and ambulatory surgery.<sup>2</sup> The facility has four community-based outpatient clinics in Grove City, Newark, Marion, and Zanesville, Ohio.

## VA Electronic Health Record Modernization

In June 2017, former VA Secretary David Shulkin announced VA's contract with Cerner to develop an interoperable EHR platform across VA and the Department of Defense that would "keep pace with the improvements in health information technology and cybersecurity."<sup>3</sup> As of 2023, five VA sites have implemented the new EHR (see table 1).

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<sup>1</sup> David J. Keene et al., "Electronic Health Record Usability Issues and Potential Contribution to Patient Harm," *Journal of the American Medical Association*, No. 12 (March 27, 2018): 1276–1278. EHR usability refers to "the extent that EHRs support clinicians in achieving their goals in a satisfying, effective and efficient manner."

<sup>2</sup> Veterans Health Administration Office of Productivity, Efficiency and Staffing, "Facility Complexity Model Fact Sheet," January 28, 2021. The Veterans Health Administration Facility Complexity Model categorizes each medical facility by complexity level based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex; level 3 facilities are the least complex.

<sup>3</sup> In June 2022 Oracle acquired Cerner, which is now referred to as Oracle Health. "Oracle Health—Reimagine the Future of Health," Oracle, accessed March 6, 2024, <http://www.oracle.com/health/>.

**Table 1. New EHR Sites**

Site Name	Location	Go-Live Date
Mann-Grandstaff VA Medical Center	Spokane, WA	October 24, 2020
Jonathan M. Wainwright Memorial VA Medical Center	Walla Walla, WA	March 26, 2022
VA Central Ohio Healthcare System	Columbus, OH	April 30, 2022
Roseburg VA Healthcare System	Roseburg, OR	June 11, 2022
VA Southern Oregon Rehabilitation Center and Clinics	White City, OR	June 11, 2022

Source: VA EHR modernization website, accessed March 22, 2023, <https://vaww.ehrm.va.gov/deployment-schedule/>.

Note: The facility is highlighted in blue.

On October 13, 2022, VA issued a press release describing an investigation at new EHR sites that revealed several issues “including challenges with performance, such as latency and slowness, problems with patient scheduling, referrals, medication management, and other types of medical orders.”<sup>4</sup> Within the press release, VA announced implementation at additional sites would be delayed until June 2023 while the Electronic Health Record Modernization (EHRM) program “underwent an aggressive ‘assess & address’ period to diagnose and fix problems.”<sup>5</sup>

After the announcement of the delayed implementation, the Veterans Health Administration (VHA) established an EHRM Sprint Project Team to assess solutions needed to (1) ensure patient safety, (2) accelerate EHR configuration decisions, and (3) plan for future EHR deployments. The EHRM Sprint Project Team provided recommendations to VHA and the Electronic Health Record Modernization Integration Office (EHRM IO).<sup>6</sup>

On April 21, 2023, VHA announced an EHRM program “reset,” which halted all future deployments while issues identified during the previous “assess and address” period were fixed. The announcement further explained that deployments of the new EHR would not resume until

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<sup>4</sup> “VA Extends Delay of Upcoming Electronic Health Record Deployments to June 2023 to Address Technical and Other System Performance Issues,” news release, VA, October 13, 2022, <https://news.va.gov/press-room/va-extends-delay-of-upcoming-electronic-health-record-deployments-to-june-2023-to-address-technical-and-other-system-performance-issues/>.

<sup>5</sup> VHA, *EHRM Sprint Report*, March 2023.

<sup>6</sup> VHA, *EHRM Sprint Report*; “EHRM Program Overview,” VA, accessed September 7, 2023, <https://digital.va.gov/ehr-modernization/resources/fact-sheets/program-overview/>. The VA Office of EHRM revised their governance structure in December 2021 and are now called EHRM IO. The office “provides program management and oversight of the EHRM implementation effort.”



VHA is “confident that the new EHR is highly functioning at current sites and ready to deliver for Veterans and VA clinicians at future sites.”<sup>7</sup>

Prior OIG reports published on VA’s implementation of the new EHR and the status of report recommendations are listed on the [VA OIG website](#).

## VHA Patient Safety Program

VHA established the National Center for Patient Safety (NCPS) in 1999 to provide oversight and guidance about VHA’s approach to facility patient safety programs. NCPS’s goal is to reduce and prevent injury to VA patients throughout the course of their care. NCPS develops policies and strategies to measure and mitigate harm and provides guidance to the field through an intranet site, the distribution of patient safety alerts, and a newsletter.<sup>8</sup>

In May 2023, the NCPS Executive Director released a memorandum that defined the role of NCPS during deployment and sustainment of the new EHR. NCPS would provide “oversight, guidance, and patient safety expertise to EHRM IO to ensure deployments of the new EHR are consistent with VHA patient safety policy.”<sup>9</sup>

In 2018, VHA implemented the electronic Joint Patient Safety Reporting (JPSR) system to capture reports of patient safety incidents at VHA facilities.<sup>10</sup> The JPSR system provides a foundation for VHA to analyze factors that may contribute to patient harm and “take action to prevent future events.”<sup>11</sup> VHA medical center staff are required to enter medication errors as

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<sup>7</sup> Of note, VHA has determined the Captain James A. Lovell Federal Healthcare Center, a joint site with the Department of Defense, will go live in March 2024 “due to the level of integration between VA and DoD [Department of Defense] at this facility.” Undersecretary for Health email message to VHA, April 21, 2023; “VA EHRM Reset Update: Introduction to the Rapid EHRM Baseline Improvement Workstream,” July 2023; EHRM SharePoint site, <https://vaww.ehrm.va.gov/wp-content/uploads/2023/07/BRIEFING-SLIDES-EHRM-Reset-and-Rapid-EHRM-Baseline-Improvement-Workstream-Overview.pdf>. (This site is not publicly accessible.)

<sup>8</sup> VHA Handbook 1050.01; VHA Directive 1050.01. VHA Handbook 1050.01 and VHA Directive 1050.01 contain the same or similar language related to NCPS provides guidance; “National Center for Patient Safety,” VHA Office of Quality and Safety, accessed June 29, 2023, <https://vaww.qps.med.va.gov/divisions/ncps/ncpsDefault.aspx>.

<sup>9</sup> The memorandum of understanding aimed to foster “efficient and effective collaboration, coordination, and consultation among the VA Electronic Health Record Modernization Integration Office (EHRM IO), the VHA National Center for Patient Safety (NCPS) and the VHA Clinical Informatics and Data Management Office (CIDMO) to ensure safe and timely deployment of VHA’s new EHR.” Executive Director, VHA National Center for Patient Safety to Chief Medical Informatics Officer/Executive Director, Clinical Informatics, VHA Office of Health Informatics, Assistant Under Secretary for Health for Quality and Patient Safety, Veterans Health Administration Program Executive Director, VA EHRM Integration Office, May 16, 2023.

<sup>10</sup> “Frequently Asked Questions,” VHA National Center for Patient Safety, accessed November 21, 2023, <https://www.patientsafety.va.gov/about/faqs.asp>.

<sup>11</sup> NCPS, *VHA National Center for Patient Safety: Guidebook for JPSR Business Rules and Guidance*, November 2021. This guidebook was in place during the time of the events discussed in this report. It was replaced by NCPS, *VHA National Center for Patient Safety: JPSR Guidebook*, December 2022. Both contain similar language regarding the purpose of the JPSR system.

patient safety reports in the JPSR system, even if no harm or adverse event occurred.<sup>12</sup> Additionally, NCPS promotes the patient safety concept of “Stop the Line,” which empowers staff to report patient safety issues and stop the provision of care until the concerns are fixed.<sup>13</sup>

## Pharmacy Services

Established in 1995, VA Pharmacy Benefits Management (PBM) provides leadership for pharmacy activities throughout VHA and management of pharmacy-related policies.<sup>14</sup> Per PBM, “pharmacists are essential to health care access and delivery” and “promote wellness, prevent and manage diseases, ensure patient safety and optimize health outcomes in collaboration with the health care team.”<sup>15</sup> PBM also oversees the Consolidated Mail Outpatient Pharmacy (CMOP), which is a centralized automated pharmacy system comprised of seven pharmacies that provide mail order medications to VHA patients.<sup>16</sup>

At the facility, the chief of pharmacy manages the Pharmacy Service and directly supervises three associate service chiefs. Each associate service chief leads one of the following divisions:

- Operations, consisting of clinical pharmacists
- Clinical, consisting of clinical pharmacist practitioners

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<sup>12</sup> VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, May 15, 2020. “A medication error is a mishap that occurs during prescribing, transcribing, dispensing, administering, adherence, or monitoring a drug”; VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. The handbook was in effect at the time of the review until it was rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The two policies contain similar language related to close calls and adverse events. A close call is “an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.” Adverse events are “untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm directly associated with care or services delivered by VA providers.”

<sup>13</sup> “Stop the Line for Patient Safety,” VHA National Center for Patient Safety, accessed July 25, 2023, <https://www.patientsafety.va.gov/professionals/stop-the-line.asp>.

<sup>14</sup> “Pharmacy Benefits Management Services,” VA, accessed September 6, 2023, <https://vaww.patientcare.va.gov/PCS/PBM.asp>. (This site is not publicly accessible); Mariscell Sales et al., “Pharmacy Benefits Management in the Veterans Health Administration: 1995 to 2003,” *American Journal of Managed Care* 11, no. 2 (February 2005): 104–12, <https://www.ajmc.com/view/feb05-1995p104-112>.

<sup>15</sup> “Pharmacy Benefits Management Services,” VA Pharmacy Benefits Management, accessed July 13, 2023, <https://www.pbm.va.gov/PBM/index.asp>.

<sup>16</sup> Sherrie L. Aspinall et al., Pharmacy Benefits Management in the Veterans Health Administration Revisited: A Decade of Advancements, 2004-2014,” *Journal of Managed Care & Specialty Pharmacy* vol. 22, no 9 (September 2016): 1058-1063, <https://doi.org/10.18553/jmcp.2016.22.9.1058>. Prescriptions filled through CMOP account for approximately 80 percent of all outpatient medications. “Pharmacy Benefits Management Services,” VA, accessed September 6, 2023, [https://www.pbm.va.gov/PBM/CMOP/VA\\_Mail\\_Order\\_Pharmacy.asp](https://www.pbm.va.gov/PBM/CMOP/VA_Mail_Order_Pharmacy.asp).

- Electronic medical records, quality, academic affairs, consisting of an informaticist, clinical pharmacist practitioners, pharmacy technicians, and pharmacy residents<sup>17</sup>

Per the chief of pharmacy, the facility's pharmacy service

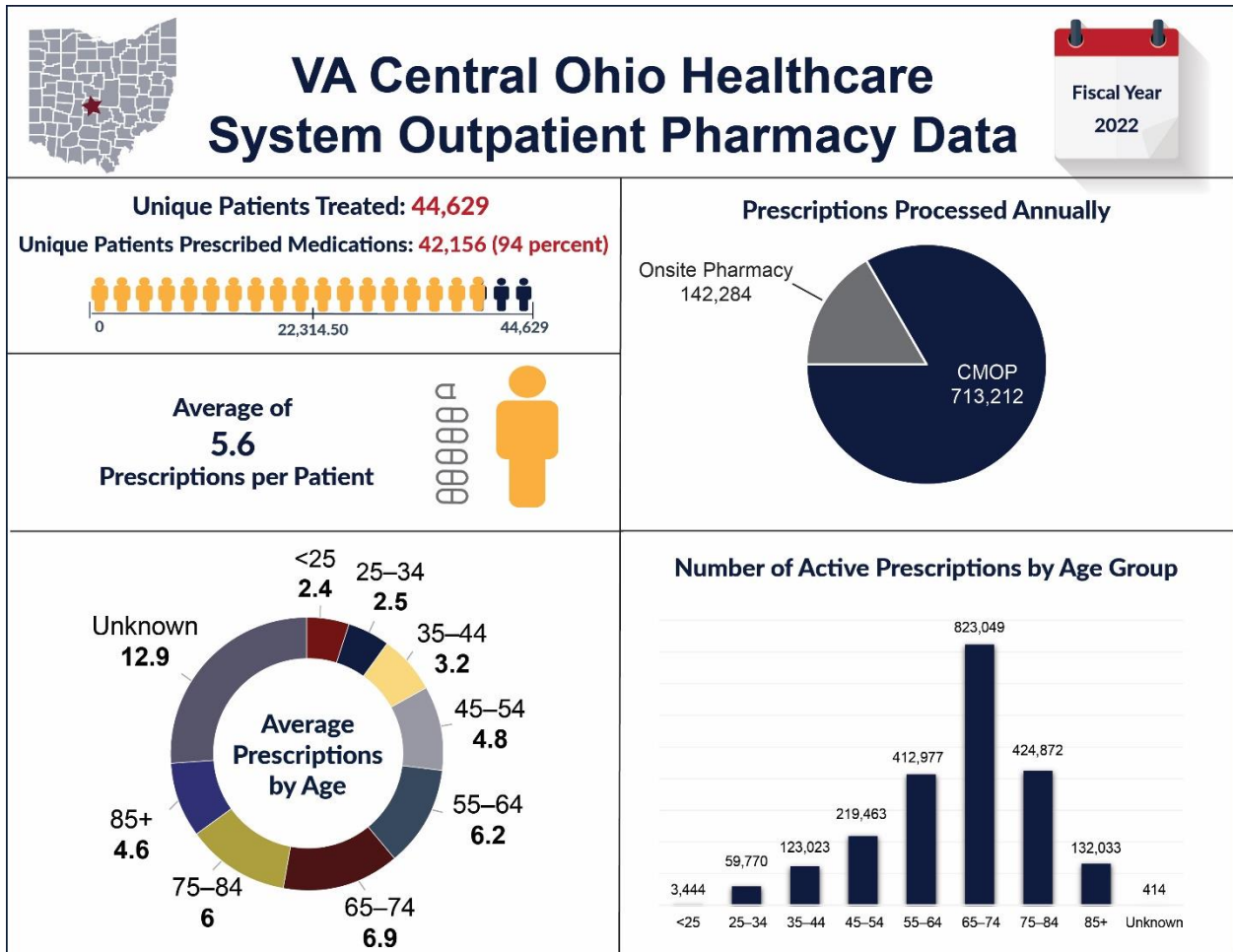
provides comprehensive patient care support through dispensing outpatient medications, distribution of medications to clinic and CBOC [community-based outpatient clinic] locations, compounding of sterile preparations for the infusion and surgery clinics, and provision of comprehensive medication management in primary care and specialty care clinical settings.

Outpatient medication orders are processed at the facility and dispensed through an on-site pharmacy or CMOP. See figure 1 for facility pharmacy data captured in fiscal year 2022.<sup>18</sup>

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<sup>17</sup> Clinical pharmacists are subject matter experts in complex medication management. VHA Handbook 1108.11(2), *Clinical Pharmacy Services*, July 1, 2015, amended June 8, 2023. Clinical pharmacist practitioners possess "a scope of practice which includes medication prescriptive authority serving as a direct care provider." "Clinical Pharmacy Practice Office Resources and Tools," Pharmacy Benefits Management Services, accessed August 21, 2023, [https://www.pbm.va.gov/PBM/CPPO/Clinical\\_Pharmacy\\_Practice\\_Office\\_ResourcesAndTools.asp](https://www.pbm.va.gov/PBM/CPPO/Clinical_Pharmacy_Practice_Office_ResourcesAndTools.asp).

<sup>18</sup> "The federal government's fiscal year runs from October 1 of one calendar year through September 30 of the next." USAgov, "The federal budget process," accessed August 24, 2023, <https://www.usa.gov/federal-budget-process>.



**Figure 1.** Fiscal year 2022 facility pharmacy data.  
Source: VHA Support Service Center Polypharmacy Dashboard, VHA Facility Trip Pack, and the facility chief of pharmacy’s data.

## Allegations and Related Concerns

The OIG received an allegation that implementation of the new EHR led to a prescription backlog at the facility.<sup>19</sup> The OIG determined that while a prescription backlog existed following the new EHR’s go-live on April 30, 2022, facility leaders took timely and sustainable steps to manage it. While reviewing the allegation, the OIG identified other pharmacy-related patient safety issues regarding the new EHR implementation. The OIG evaluated the related concerns and the new EHR’s effect on Columbus facility leaders and pharmacy staff.

<sup>19</sup> The allegation detailed that the prescription backlog could lead to a delay in patients receiving medication. A backlog is an accumulation of unperformed tasks or materials not processed. *Merriam-Webster.com Dictionary*, “backlog,” accessed July 11, 2023, <https://www.merriam-webster.com/dictionary/backlog>.

## Scope and Methodology

The OIG initiated the inspection on March 16, 2023, and conducted a virtual site visit from May 1 through 15, 2023. The OIG conducted additional virtual interviews through August 17, 2023. The OIG interviewed the complainant, VHA leaders from EHRM IO, the Clinical Episode Review Team (CERT), NCPS, and PBM; Office of Information Technology staff; facility executive leaders; relevant leaders and staff from pharmacy and primary care services; and patient safety staff.<sup>20</sup> The OIG also provided written questions to facility pharmacists.

The OIG reviewed relevant VHA directives, handbooks, and guidelines, as well as facility policies and procedures related to pharmacy and patient safety. Other documents reviewed included emails, briefings, and data spreadsheets related to pharmacy-specific patient safety issues in the new EHR. The OIG also reviewed select facility patient EHRs and patient safety reports captured in the JPSR system.

The OIG did not independently verify VHA data for accuracy or completeness.

The OIG uses the term legacy EHR to refer to Veterans Health Information Systems and Technology Architecture (VistA), the EHR used prior to the Oracle Health EHR. For the purposes of this report, sites that have not implemented the new EHR and continue to use VistA will be referred to as legacy sites.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–24. The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

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<sup>20</sup> VHA Directive 1004.08. The Deputy Under Secretary for Health for Operations and Management convenes a CERT to conduct a “coordinated triage process for review of each potential adverse event that may require large-scale disclosure.” Facility executive leaders included the Director, Chief of Staff, and Assistant Director. The patient safety department is referred to as quality, safety, and innovation at the facility.

## Inspection Results

Pharmacy data is considered an essential element in an EHR that directly affects patient safety.<sup>21</sup> EHRs

- provide details about medical history, diagnoses, medications, immunizations, allergies, and test results in a central location;
- increase accuracy of patient information;
- streamline workflow;
- allow staff from different locations to access and manage the same information; and
- deliver safety enhancing capabilities such as drug-drug interaction checks, allergy alerts, and clinical reminders.<sup>22</sup>

The Institute of Medicine notes that a poorly designed EHR

can create new hazards in the already complex delivery of health care, requiring health care professionals to work around brittle software, adding steps needed to accomplish tasks, or presenting data in a nonintuitive format that can introduce risks that may lead to harm.<sup>23</sup>

A core function of pharmacy practice is to ensure medication safety. Pharmacists are trained “to prevent medication errors, drug interactions, and other adverse medication events from reaching patients.”<sup>24</sup> Through this inspection, the OIG found

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<sup>21</sup> “Managing and Analyzing EHR Pharmacy Data in the Hospital Setting,” AHIMA, accessed July 7, 2023, <https://bok.ahima.org/doc?oid=302752>.

<sup>22</sup> “HealthIT.gov, What Are Electronic Health Records (EHRs)?” Office of the National Coordinator for Health Information Technology, accessed June 20, 2023, <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/what-are-electronic-health-records-ehrs>; “HealthIT.gov, Medical Practice Efficiencies & Cost Savings,” Office of the National Coordinator for Health Information Technology, accessed June 29, 2023, <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/medical-practice-efficiencies-cost-savings>; “HealthIT.gov, Improved Patient Care Using EHRs,” Office of the National Coordinator for Health Information Technology, accessed June 29, 2023, <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/improved-patient-care-using-ehrs>; “HealthIT.gov, Improved Diagnostics & Patient Outcomes,” Office of the National Coordinator for Health Information Technology, accessed June 20, 2023, <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/improved-diagnostics-patient-outcomes>.

<sup>23</sup> Institute of Medicine of the National Academies, Committee on Patient Safety and Health Information Technology, *Health IT and Patient Safety: Building Safer Systems for Better Care*, [https://www.ncbi.nlm.nih.gov/books/NBK189661/pdf/Bookshelf\\_NBK189661.pdf](https://www.ncbi.nlm.nih.gov/books/NBK189661/pdf/Bookshelf_NBK189661.pdf).

<sup>24</sup> “Pharmacists’ Impact on Patient Safety,” American Pharmacists Association, accessed April 17, 2023, [https://www.pharmacist.com/Portals/0/PDFS/Practice/PharmacistsImpactonPatientSafety\\_Web.pdf?ver=dYeAzwlN3-PG9eSkMMsV-A%3d%3d](https://www.pharmacist.com/Portals/0/PDFS/Practice/PharmacistsImpactonPatientSafety_Web.pdf?ver=dYeAzwlN3-PG9eSkMMsV-A%3d%3d).



- pharmacy-related patient safety issues and usability challenges within the new EHR contributed to patient safety risks at the facility,
- other patient safety issues as a result of the new EHR’s implementation both at a facility level and across the VA, and
- negative effects from the new EHR on facility leaders and pharmacy staff.

## 1. Implementation of the New EHR Resulted in Pharmacy-Related Patient Safety Issues at the Facility

The OIG determined that following the first deployment of the new EHR, VHA became aware of pharmacy-related high-risk patient safety and usability issues. The OIG found that although aware of ongoing challenges, VA leaders continued to deploy the new EHR at four additional sites, including the facility.

### Findings

The OIG made the following determinations:

***VHA identified pharmacy-related high-risk issues that contributed to facility patient safety issues.***

In May 2021, after the first deployment of the new EHR at the Mann-Grandstaff VA Medical Center, VHA leaders tasked an NCPS-led team, which included a pharmacy patient safety team, to examine patient safety issues.<sup>25</sup> The pharmacy patient safety team identified six high-risk patient safety issues (see table 2).

**Table 2. Identified Pharmacy-Related High-Risk Patient Safety Issues**

Issue	Concern	NCPS-Identified Risk
Need for “virtual viewing”	Healthcare providers can order medications that are not available at the facility.	Prescribing errors and filling delays.
Synchronized discontinuation	Patient records in the new EHR and the pharmacy dispensing software do not match, creating medication information discrepancies.	Prescribing errors.
Consistent renewal process for all prescriptions	Prescriptions automatically transferred from the legacy EHR to the new EHR are missing information and cannot be renewed.	Duplicate medication orders on the patient medication list.

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<sup>25</sup> The teams included staff from VHA program offices, EHRM, VISN 20, and the facility. The NCPS team reviewed patient safety reports captured in the JPSR system and placed them into nine domains (categories). The nine domains of the new EHR are behavioral health and suicide, ambulatory care, referrals and consults, roles/positions/access, pharmacy, identity, orders, medication administration, and unspecified. This report focuses on the pharmacy domain.



Electronic Health Record Modernization Caused Pharmacy-Related Patient Safety Issues Nationally and  
at the VA Central Ohio Healthcare System in Columbus

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Issue	Concern	NCPS-Identified Risk
Consistency of prescription and order status	The prescription and order status are not the same between the new EHR and the pharmacy dispensing software.	Inaccurate medication information and inefficient pharmacy services.
Pharmacy technician refills	Pharmacy technicians cannot initiate prescription refills in the pharmacy dispensing software as they did with the legacy EHR.	Prescription delays.
Refills in the new EHR	Refills cannot be performed in the new EHR for all legacy migration prescriptions.	Over-prescription of medications.

*Source: EHRM Monthly All Hands Call, November 10, 2021.*

To avoid issues at future new EHR sites, in 2021 the NCPS pharmacy patient safety team recommended mitigation of the identified high risks prior to rollout at future VA sites. Additionally, the pharmacy patient safety team identified that until long term issues with functionality in the new EHR were resolved, patient safety remained at risk. The OIG found although VA was aware of the identified pharmacy-related high-risk issues, the new EHR was deployed prior to scheduled software updates in 2023 and 2024 that aimed to resolve them.<sup>26</sup>

Facility and pharmacy leaders told the OIG that facility staff completed required EHR user training and attempted to address known issues with the new EHR prior to go-live at the facility on April 30, 2022. The leaders also expressed that even with this preparation, the new EHR product was not ready for use at the time of go-live and many of the previously identified pharmacy issues continued to occur.

The OIG analyzed facility generated pharmacy-related patient safety reports from April 30, 2022, through March 30, 2023, to determine if the previously identified NCPS high-risk pharmacy issues occurred after go-live at the facility. The OIG determined 182 of 566 (32 percent) of the patient safety reports described previously identified NCPS high-risk pharmacy issues as a contributing factor.<sup>27</sup>

The OIG concluded that VA implemented the new EHR at the facility prior to resolving NCPS-identified pharmacy issues, which resulted in patient safety risks. Although Oracle Health has resolved some of the issues, the OIG is concerned that the new EHR will be deployed at additional VA sites prior to resolution of the remaining problems.

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<sup>26</sup> The new EHR was deployed at the Jonathan M. Wainwright Memorial VA Medical Center in Walla Walla, Washington, on March 26, 2022; at VA Central Ohio Healthcare System in Columbus, Ohio, on April 30, 2022; and at VA Southern Oregon Rehabilitation Center and Clinics in White City and Roseburg VA Healthcare System in Roseburg, Oregon, on June 11, 2022.

<sup>27</sup> The OIG reviewed the related patient safety reports captured in the JPSR system and noted the facility patient safety manager did not classify any as catastrophic or resulting in major harm. NCPS, *VHA National Center for Patient Safety: Guidebook for JPSR Business Rules and Guidance*, November 2021, and NCPS, *VHA National Center for Patient Safety: JPSR Guidebook*, December 2022. Both JPSR guidebooks contain similar language related to classification of harm.

***Challenges with the new EHR's usability contributed to inaccurate medication information and increased patient safety issues at the facility.***

The Agency for Healthcare Research and Quality states poor EHR usability can lead to clinician “errors that compromise patient safety.”<sup>28</sup> Some EHR elements that can affect medication information accuracy include information availability, data entry, alerts, visual display, and system automation and defaults.<sup>29</sup>

VHA requires all medication information displayed to veterans, caregivers, and healthcare professionals to contain “essential medication information” including the name, strength, and dose of the medication, and instructions for use.<sup>30</sup> The absence of medication information “can lead to compromised health care and harm” with potential for information gaps that can be magnified by “rapidly expanding development of digital medication information tools.”<sup>31</sup> VHA identifies medication reconciliation, a review of all medications a patient may be taking, as one of the ways to “maintain and communicate accurate patient medication information.”<sup>32</sup> Accurate medication information is needed to support medication management and ensure “successful, safe, high quality and patient driven medication care.”<sup>33</sup>

As a result of the May 2021 NCPS visit at Mann-Grandstaff VA Medical Center, the pharmacy patient safety team identified usability issues within the new EHR affecting medication refills and medication order accuracy. Usability issues within the new EHR continued and were highlighted in the March 2023 EHRM Sprint Report, “Usability issues within the [new EHR’s] ordering process are contributing to inefficiencies, delays in care, and patient safety concerns.”<sup>34</sup>

VHA and facility leaders and staff’s remarks to the OIG indicated that usability issues made the provision of health care more difficult and less safe.

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<sup>28</sup> “Improving Electronic Health Record Usability for Patient Safety,” Agency for Healthcare Research and Quality, accessed August 10, 2023, <https://digital.ahrq.gov/program-overview/research-stories/improving-electronic-health-record-usability-patient-safety>.

<sup>29</sup> Keene et al., “Electronic Health Record Usability Issues and Potential Contribution to Patient Harm.”

<sup>30</sup> VHA Directive 1164, *Essential Medication Information Standards*, June 26, 2015. This directive was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1164, *Essential Medication Information*, July 13, 2023. The two policies contain similar language related to the elements of essential medication information.

<sup>31</sup> VHA Directive 1164, 2015; VHA Directive 1164 2023. Both directives contain similar language related to the absence of medication information. Essential medication information is the information that the patient, family, caregiver, and healthcare team need for successful medication management.

<sup>32</sup> VHA Directive 1345, *Medication Reconciliation*, March 9, 2022. Medication reconciliation consists of a healthcare provider comparing medications listed in the EHR with the patient’s self-report of their medications. Medication reconciliation is required at every episode of care “where medications will be administered, prescribed, modified, or may influence the care given.”

<sup>33</sup> VHA Directive 1345.

<sup>34</sup> VHA, *EHRM Sprint Report*, March 2023. Pharmacy-related usability issues identified in the EHRM Sprint Report were related to prescription migration, medication ordering, pharmacy formularies, and medication lists.

- “[We] have recognized that there are significant problems with this [new] EHR that make it difficult for providers to function as easily and safely and effectively as they did before.”
- “We used to sort of look to the EHR to prompt us to do the right thing, to make it easiest to do the right thing, and I think now it’s needing to double check to make sure you’re doing the right thing in spite of. . . the electronic health record.”
- “[There was] a significant degradation in both safety, deficiencies of operation, and effectiveness of the electronic health record . . . compared to what we had with VistA and CPRS [legacy system].”<sup>35</sup>

Facility pharmacists also reported similar usability and patient safety issues.

- “The inefficiency and unnecessary complexity of the system create[s] so many opportunities for errors to happen.”
- “It takes a high amount of pharmacist diligence to ensure the system is working appropriately.”
- “[T]he Oracle/Cerner EHR is slow, inefficient, and dangerous.”

The OIG’s analysis determined usability was a factor in 374 of 566 patient safety reports (66 percent); issues included data migration challenges and inaccurate medication lists (see [appendix A](#) for more examples).<sup>36</sup>

Additionally, the OIG examined one particular patient safety report entered in January 2023 that identified an EHR usability issue resulting in facility nurses unintentionally canceling over 1,000 patient medication orders during the medication reconciliation process. The OIG learned this occurred due to confusion surrounding the purpose of a selection button within the new EHR’s medication reconciliation screen that was labeled “complete.”

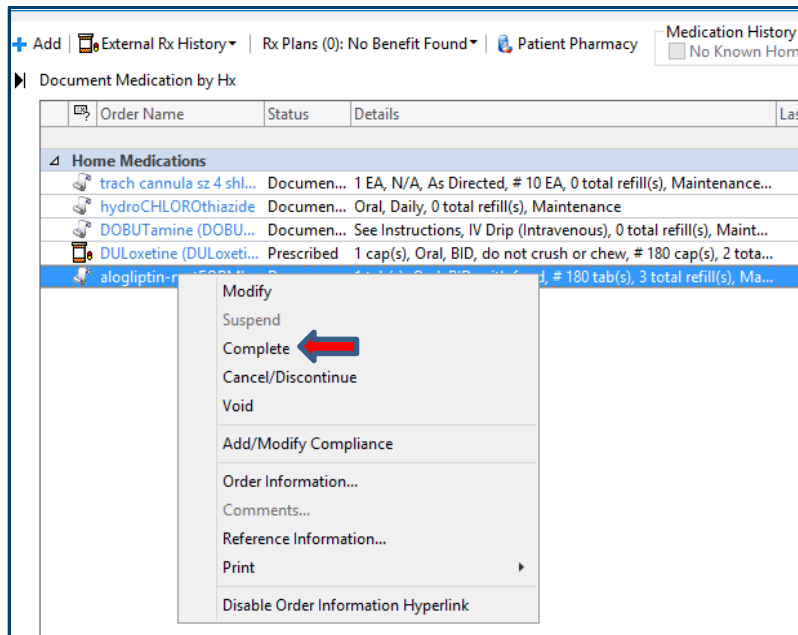
Facility nursing staff believed selecting the “complete button” indicated completion of the medication reconciliation process. However, a VHA leader told the OIG that selection of the “complete button” made a patient’s medication order inactive and healthcare providers were not

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<sup>35</sup> VA.gov, *VistA Monograph*, July 18, 2023, [https://www.va.gov/vdl/documents/Monograph/Monograph/vista\\_monograph\\_0723\\_r.pdf](https://www.va.gov/vdl/documents/Monograph/Monograph/vista_monograph_0723_r.pdf). The Veterans Health Information Systems and Technology Architecture (VistA) is a software platform that includes an EHR record application called a Computerized Patient Record System (CPRS) in which clinical staff enter orders and documentation, perform reviews, and continuously update patient information.

<sup>36</sup> The OIG reviewed usability-related JPSRs and noted the facility patient safety manager did not classify any as catastrophic or resulting in major harm. NCPS, *VHA National Center for Patient Safety: Guidebook for JPSR Business Rules and Guidance*, November 2021; NCPS, *VHA National Center for Patient Safety: JPSR Guidebook*, December 2022. Both guidebooks contain similar language related to classification of harm.

notified of the change.<sup>37</sup> See figure 2 for a visual of the “complete button” option as part of the medication reconciliation process.



**Figure 2.** “Complete button” selected during medication reconciliation.  
Source: Screenshot of new EHR, August 16, 2023.

Following awareness of the usability issue, the Chief of Staff initiated a look-back of over 1,000 canceled medication orders affecting nearly 550 patients.<sup>38</sup> The OIG reviewed a patient safety summary that facility staff developed after completion of the look-back, which included remediation actions:

- Staff submitted an EHR request to disable the “complete button” for nursing staff.
- Staff were re-trained on the function of the “complete button.”
- Pharmacy staff monitored an EHR report to identify issue recurrence.

A VHA leader shared that as of August 2023, this patient safety risk remained. The “complete button” was not disabled and testing needed to be completed to determine if removal affected other work areas. A VHA leader attributed the “complete button” usability error to the new EHR’s design and lack of staff training. One VHA leader stated that due to the nonintuitive design of the new EHR, user errors resulting in patient safety issues can easily occur.

<sup>37</sup> The system patient safety manager reported they first learned of the risk during a regularly occurring NCPS meeting in January 2023.

<sup>38</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. A look-back is “an organized process for identifying patients or staff with exposure to potential risk incurred through past clinical activities, with the explicit intent to notify them and offer care and recourse, as appropriate.”

Additionally, a VHA leader documented that the complete button “system design” contributed to inaccurate medication information:

- Nurses unintentionally removed chronic maintenance medications from patients’ active outpatient medication lists.
- Patients lost access to accurate medication lists and associated medication refills.
- Healthcare providers had to identify and reorder medications that were inadvertently discontinued.

Another VHA leader told the OIG that requested EHR changes intended to increase safety and usability are being submitted at a faster rate than can be delivered and that staff vigilance is protecting patients. Additionally, VHA Essential Medication Information Standards policy defines the components of and need for accurate medication information and “is written with a demanding standard and the EHR does not meet that demanding standard. . . I want the EHR to fit our business practices, not our business practices to fit the EHR we happen to have.”<sup>39</sup>

The OIG concluded usability issues that led to inaccurate medication information in patient EHRs contributed to two-thirds of facility pharmacy-related patient safety reports within the time frame reviewed. Unresolved usability issues in the new EHR will continue to contribute to pharmacy-related patient safety issues.

## 2. Implementation of the New EHR Resulted in Pharmacy-Related Patient Safety Issues Across VA

“Veterans are eligible to receive health care benefits at any facility where Department of Veterans Affairs (VA) services are offered.”<sup>40</sup> Providers use the EHR to coordinate a patient’s care across VA. EHR information is communicated between VA facilities through different channels, including the Joint Longitudinal Viewer (JLV) and the Health Data Repository (HDR). For patients who travel to receive care at any of the 166 medical centers that use the legacy EHR, JLV allows providers to access a “read only” version of a patient’s medical record from both the legacy and new EHR systems.<sup>41</sup>

The HDR is a database that stores patient-specific clinical information, including medications and allergies, from each VA EHR, including the new EHR.<sup>42</sup> Providers use this information to

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<sup>39</sup> VHA Directive 1164.

<sup>40</sup> VHA Handbook 1011.11(4), *Coordinated Care For Traveling Veterans*, April 22, 2015, amended July 20, 2021. Veterans need to register at a facility to be eligible for care.

<sup>41</sup> JLV is a read-only, non-editable, web-based application for viewing patient electronic health records from VA, and community partners through a customizable interface. JLV plays an important role in VA’s transition to the new EHR as it allows users to see EHR data at other sites, regardless of the EHR system in place.

<sup>42</sup> Va.gov, *Vista Monograph*, July 18, 2023. The VA HDR is “a national, clinical data storehouse that supports integrated, computable and/or viewable access to the patient’s longitudinal health record.”

support treatment decisions. Every medication in VA has an assigned distinct number known as a VA Unique Identifier (VUID).<sup>43</sup> When a medication is prescribed at a new EHR site, information regarding the prescription, including the medication’s VUID, is sent from the new EHR to the HDR through a series of digital coding instructions that specify the details of what and how the information is transmitted.<sup>44</sup>

Once in the HDR, this medication information is available to legacy site clinicians providing care to patients previously seen at one of the five sites using the new EHR. When a legacy EHR site provider enters a medication order, a software interface within the legacy EHR accesses the medication VUID data from the HDR to perform a medication safety check. The check verifies the medication being prescribed is safe and compatible with other medications and allergies documented in the patient’s EHR at other VA sites, including sites that use the new EHR.<sup>45</sup> The legacy EHR software interface that performs these medication safety checks relies on the accuracy of the information that resides in the HDR. See figure 3 for an overview of how medication data transmission is intended to flow.

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<sup>43</sup> VA.gov, *VistA Monograph*. VUID’s are “meaningless number[s] which is automatically assigned to concepts, properties, and relationships in a terminology to facilitate their access and manipulation by computers.”

<sup>44</sup> VA.gov, *VistA Monograph*. Health Level Seven (HL7) is a “standard messaging protocol that specifies the set of transactions and encoding rules for electronic data exchange between health care computer systems”; VA EHRM, *VA Health Data Repository/Clinical Health Data Repository (HDR-CHDR) Interface Control Document*, v. 2.0, January 2021. VA’s interface control document describes the content of the required HL7 messages for interactions between the new EHR and the HDR and “identifies the entry points, protocols observed, messages exchanged, and data items in the messages, as well as the timing and sequencing of the interactions.”

<sup>45</sup> VA Office of Information & Technology, *Computerized Patient Record System (CPRS), Technical Manual: List Manager Version*, October 2023, [https://www.va.gov/vdl/documents/Clinical/Comp\\_Patient\\_Recrd\\_Sys\\_\(CPRS\)/cprslmtm.pdf](https://www.va.gov/vdl/documents/Clinical/Comp_Patient_Recrd_Sys_(CPRS)/cprslmtm.pdf). Medication order checks are a real-time process that evaluate a requested order against existing patient medications and allergy information. The result of the check provides the ordering clinician with information regarding any detected drug-drug interactions, drug-allergy interactions, duplication of medications or duplications of medication class; Va.gov, *VistA Monograph*. The Remote Data Interoperability program extends VistA’s existing local drug-drug, and drug-allergy order checks to include data from all VA and Department of Defense facilities at which a patient has been treated.



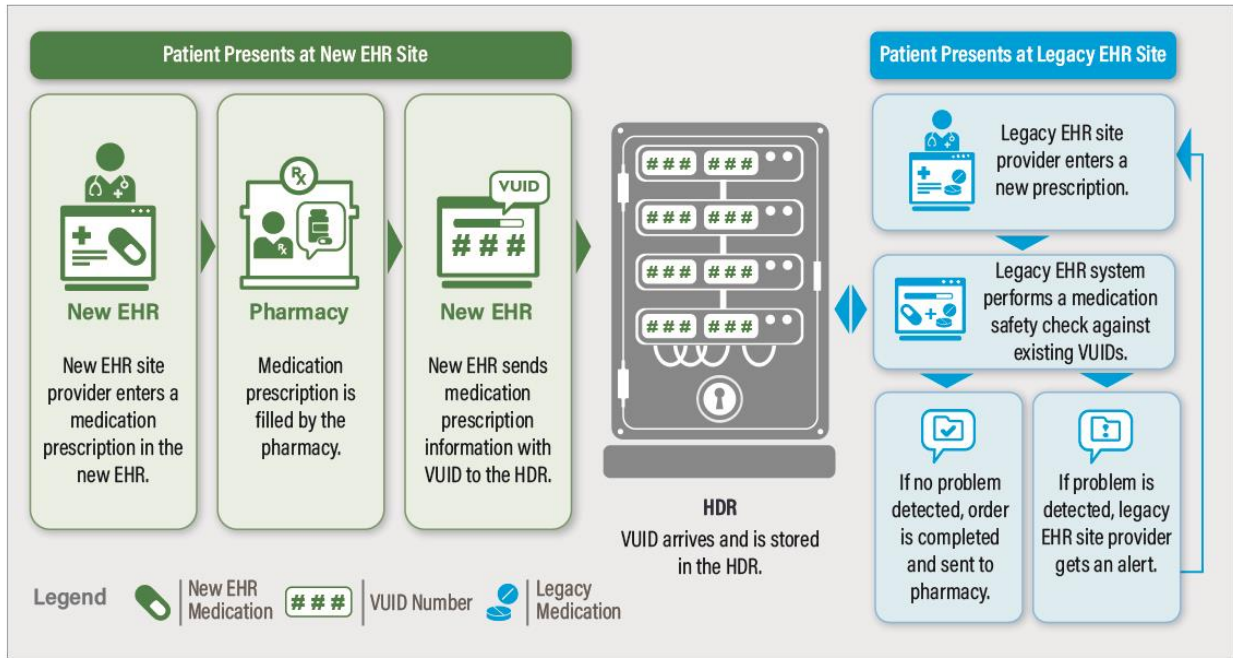


Figure 3. Intended data transmission process.

Source: OIG analysis.

Note: The figure above shows the basic scenario of medication information data transmission from the new EHR to the HDR and a legacy EHR automated medication safety check.

## Findings

The OIG made the following determinations:

***An error in Oracle Health software coding resulted in the widespread transmission of incorrect medication information from new EHR sites to legacy EHR sites. Information stored and communicated within the new EHR system is accurate; however, the information becomes inaccurate during transmission to the HDR. This results in legacy EHR sites accessing incorrect information stored in the HDR.***

On March 31, 2023, a provider at a legacy EHR site prescribed a new outpatient medication for a patient who previously received care at one of the new EHR sites. The provider received an alert from the legacy EHR of a drug-drug interaction between the newly prescribed medication and a medication that the patient had been prescribed at the new EHR site. Facility staff noted there was no drug-drug interaction between the two medications and the EHR software medication safety check was incorrect.

Later that day, PBM informaticists worked with VA Office of Information and Technology HDR staff and identified a transmission error between the new EHR and the HDR resulting in the



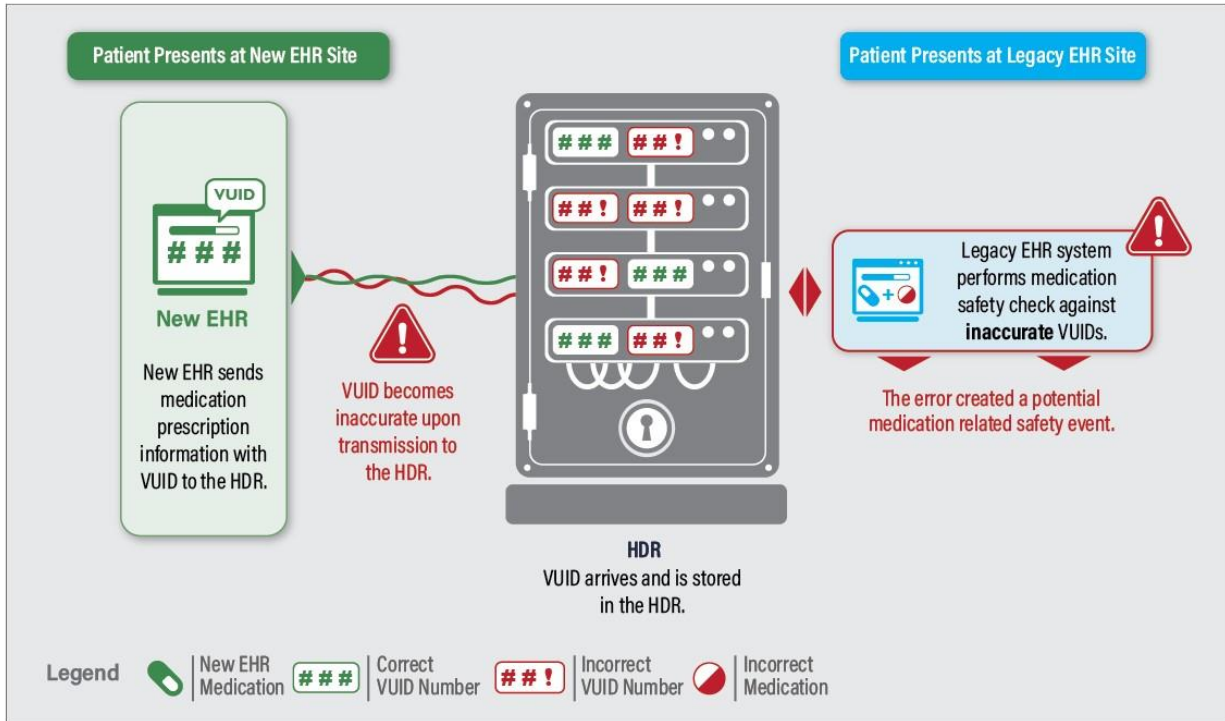
same VUID being assigned to different medications. VA Office of Information and Technology then convened a major incident management call to discuss the VUID error.<sup>46</sup>

An EHRM IO leader told the OIG that call attendees concluded the incorrect VUIDs resulted from an error in the messaging instructions affecting certain medications prescribed at new EHR sites when processed through the CMOP.<sup>47</sup> This led to inaccurate VUIDs being transmitted from the new EHR to the HDR. The incorrect information moved from the HDR to the legacy EHR when a patient from a new EHR site received care at a legacy EHR site. Therefore, the error created the potential for a medication-related safety event when the patient was prescribed a medication at the legacy EHR site. See figure 4 for a visual of the medication data transmission error.

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<sup>46</sup> “A major incident is a high-impact, high urgency incident that affects many users, depriving the business of one or more crucial services, such as patient care, benefits processing, and cemetery operations.” VA Office of Information and Technology, “Major Incident Management Process,” June 25, 2021, version 1.0.

<sup>47</sup> Leaders from the VA Office of Information and Technology, EHRM IO, Oracle Health, and PBM participated in researching why the event occurred. The specific error occurred when CMOP processed a prescription with at least one other prescription prior to sending the medications for delivery to the patient. In each incident, patients received the correct medications.



**Figure 4.** Visual of the medication data transmission error.

Note: The new EHR miscodes the patient’s medication and allergen information as it is transmitted to the HDR, which affects downstream software that uses the HDR data for safety checks. Providers receive inaccurate information from the EHR, potentially impeding the ability to make sound clinical decisions.

Source: OIG analysis.

On the evening of March 31, 2023, staff at the legacy site where the error was identified sent an issue brief describing the event and the cause to VHA, EHRM IO, NCPS, and VISN leaders.<sup>48</sup> PBM leaders also sent an email to VHA, VISN, and facility leaders alerting them of the event and its potential clinical impact. The email provided specific instructions on how to mitigate the issue and requested that recipients “please share widely.”

On April 4, 2023, NCPS sent an email to VHA patient safety managers and officers, and CMOP patient safety managers across VA alerting recipients of the March 31st event, its clinical impact, and mitigation instructions. On April 7, 2023, Oracle Health—who was responsible for coding the digital transmission instructions from the new EHR to the HDR—applied a software patch to ensure an accurate VUID was applied to all CMOP-processed prescriptions from that date forward.<sup>49</sup> Although the issue was discovered on March 31, 2023, the OIG learned that the new

<sup>48</sup> Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017, accessed July 25, 2023. Issue briefs are intended to provide facility, VISN, and VHA leaders clear, concise, and accurate information about an issue that will impact patient care.

<sup>49</sup> The OIG spoke with multiple VHA leaders who confirmed that the patch successfully resolved the issue for new medications prescribed on or after April 7, 2023.

EHR sent incorrect information to the HDR from the time each new EHR site had gone live, as far back as October 2020.

The patch did not correct the data for the patients whose inaccurate prescription information was sent to the HDR prior to April 7, 2023. A VHA leader told the OIG as of December 2023, any active prescription data that was generated from approximately 120,000 new EHR site patients between October 24, 2020, and April 7, 2023, remained incorrect, placing these patients at ongoing risk of a medication-related patient safety event should they receive care and medications at a legacy EHR site.

A VHA leader shared that on November 29, 2023, the VHA Pharmacy Council reported withdrawing a request for Oracle Health to resend corrected CMOP-related medication data to the HDR. The council accepted that all remaining inaccurate medication prescription data would expire by April 7, 2024, and the data would correct at that time.<sup>50</sup> Of the 120,000 new EHR site patients, approximately 67,000 have received care and were prescribed medications at legacy EHR sites; VHA remained unaware whether these patients incurred harm.<sup>51</sup>

The OIG is concerned that although the resolution to correct the inaccurate interface coding was completed within a week of discovery, nearly 120,000 patients' data remains inaccurate more than six months after discovery. This continues to place new EHR site patients who were prescribed medications before April 7, 2023, at risk of a patient safety event when receiving care at a legacy EHR site.

***Additional medication-related data transmission errors resulted in further patient safety issues.***

The OIG learned that research into the cause of the VUID error that occurred when prescriptions were processed through the CMOP led to the discovery of subsequent transmission issues of medication and allergy information from the new EHR to the HDR. These issues included missing, duplicate, or incorrect medication and allergy information being transmitted. The consequences of inaccurate medication information transmission to the HDR include but are not limited to

- discontinued or expired medications in the new EHR displaying as active medications in the legacy EHR;
- allergy warning messages not appearing when intended or inappropriately appearing for the wrong medication;

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<sup>50</sup> VA prescriptions are valid for up to one year from the date of issue. VHA Directive 1108.07, *General Pharmacy Service Requirements*, November 28, 2022.

<sup>51</sup> A VHA Office of Health Informatics statistician provided affected patient data to the OIG.

- duplicate medication order checks not appearing when intended or inappropriately appearing for the wrong drug; and
- the patient’s active medication list showing incomplete or inaccurate information including missing prescriptions, duplicate prescriptions, or erroneous medication order statuses.

On June 15, 2023, NCPS sent a Patient Safety Notice to VHA patient safety staff providing specific details concerning the initial and subsequent issues and errors that resulted in the transmission of inaccurate information to the HDR.<sup>52</sup> NCPS requested all relevant medical center staff be made aware that legacy EHR site software applications may contain inaccurate medication information for patients who have also received care at new EHR sites. Further, as of the date of the notice, (1) no resolutions existed for the subsequent transmission issues, and (2) there was no clear determination of which patients were affected and may have experienced harm. See [appendix B](#) for an example of a patient with adrenal insufficiency whose care was influenced by inaccurate medication data when the patient was not prescribed a critical lifesaving therapy upon admission to a legacy site.

Due to VHA’s inability to determine which patients were at risk of a patient safety event from the data transmission issues and errors, a VHA leader told the OIG all patients who have been prescribed any medication through or have had medication allergies documented at a new EHR site are considered at risk. As of September 2023, the OIG reviewed data reflecting the numbers of patients who VHA classified as at risk. VHA determined that across all new EHR sites, approximately 190,000 unique patients had a medication prescribed and 126,000 unique patients had an allergy documented at a new EHR site. Approximately 68,000 patients were in both groups, for a total of approximately 250,000 affected unique patients.

An EHRM IO data leader noted that Oracle Health originally tested the software interfaces following a plan devised by EHRM IO. The testing plan focused on the transmission of the data from the new EHR to the HDR but failed to verify the accuracy of the data when accessed downstream by legacy EHR users.

The OIG remains concerned for the safety of new EHR site patients who then receive care from a legacy EHR site, as the information transmission issues may result in new EHR site patients being prescribed contraindicated medications and legacy site providers making clinical decisions based on inaccurate data. The OIG is not confident in EHRM IO leaders’ oversight and control of the new EHR’s HDR interface programming.<sup>53</sup>

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<sup>52</sup> VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. In contrast to a Patient Safety Advisory or a Patient Safety Alert, both of which are described as mandates for specific action, a “Patient Safety Notice is prepared by NCPS to provide awareness of patient safety vulnerabilities even where no solutions are immediately evident. Patient Safety Notices may or may not provide recommendations.”

<sup>53</sup> These issues occurred in an environment in which they were able to remain undetected for more than two years.

***Patients who receive care at new EHR sites have not been notified of the risk of harm related to data transmission issues.***

Per VHA policy, a disclosure is warranted for harmful or potentially harmful adverse events that “have a potential to affect, or may have already affected, multiple patients at one or more VA medical facilities.” VHA policy also outlines that the disclosure notification informs patients (or representatives) that “they have been or may have been affected by an adverse event involving actual or potential harm.”<sup>54</sup>

VHA leaders convened a Clinical Episode Review Team (CERT) to review the HDR data transmission issues.<sup>55</sup> Between April 13 and May 15, 2023, the CERT met to discuss the issues and errors related to the transmission of inaccurate pharmacy data from the new EHR to the HDR. In early June 2023, a VHA leader involved in the CERT communicated to the CERT Executive Director their support of

- a look-back of patients who may have been harmed,
- a review to consider a large-scale disclosure to notify all new EHR site patients about their increased risk, and
- sending instructions to affected patients on how to mitigate their risk.<sup>56</sup>

On June 21, 2023, the CERT Executive Director signed a memorandum addressed to the VA Under Secretary for Health outlining the CERT review and subsequent recommendations, which included communication to all VA patients who have been seen at and received a prescription through a new EHR site since go-live.<sup>57</sup>

The OIG reviewed the memorandum and a related communication plan to notify patients of the medication data issues. Both documents specified that the communication to patients was not a disclosure but a “general patient safety/awareness communication” encouraging affected patients to collaborate with their healthcare providers during the medication reconciliation process. The

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<sup>54</sup> VHA Directive 1004.08.

<sup>55</sup> VHA Directive 1004.08. The Deputy Under Secretary for Health for Operations and Management convenes a CERT to conduct a “coordinated triage process for review of each potential adverse event that may require large-scale disclosure.”

<sup>56</sup> VHA Directive 1004.08. A large-scale disclosure “is a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue.” “This process also generally includes public notification and direct communication to key stakeholders.” The public notification can include “an announcement through the media, for example, telephone, mail, newspapers, and electronic media.”

<sup>57</sup> Clinical Episode Review Team, “CERT Review and Recommendations Regarding EHRM Medication Checks Pharmacy Issue,” memorandum to the Under Secretary for Health through Clinical Services, June 21, 2023.

memorandum also documented that the CERT was still in the process of determining the feasibility of completing a look-back review to identify patient harm.<sup>58</sup>

The communication plan included a templated patient letter noting “some issues” with how the EHR systems (new and legacy) “communicate with each other” and that these issues “may affect medications in the system for veterans who use more than one VA medical center.” The letter asks patients to bring their current medications, in their original containers, to all appointments to “help us make sure our medication lists are accurate.”<sup>59</sup> A CERT leader sent the communication plan by email to VHA, VISN 10 and 20, and facility leaders on August 7, 2023. The OIG noted the communication plan was marked as a draft and did not include a timeline for release or identify responsible parties to disseminate the information. When asked, the CERT Executive Director told the OIG that there was no assigned timeline and that VHA, VISN, and facility leaders needed to move forward with the plan or request changes. Further, the CERT Executive Director indicated that the CERT team had no operational authority for oversight. In late October 2023, the OIG asked a facility leader about actions taken in response to the August 7th email. The facility leader responded, “there were no actions taken as it was not clear at the time of the CERT communication. . . that recommended communications were finalized.”

As of September 2023, the approximately 250,000 patients—who either received medication orders or had medication allergies documented at a new EHR site from October 2020—may be unaware of the potential risk for a medication or allergy-related patient safety event should they receive care at a legacy EHR site. Further, a VHA leader told the OIG that as of December 2023, the leader had no knowledge of the development of a comprehensive strategy to conduct a look-back of the care of the growing number of patients who have received and continue to receive services and medication prescriptions at legacy sites.

The communication plan indicated that it was not a disclosure communication. During an OIG interview, a VHA leader involved in the review of the issue expressed concerns about the CERT recommended communication plan. Specifically, the patient notification letter “reads as a Large-Scale Disclosure” and should be treated as such.<sup>60</sup> The VHA leader told the OIG that by expressly avoiding referring to the patient communication as a large-scale disclosure within the disseminated plan, VA can minimize the number of patients who receive the letter and avoid any congressional, media, and staff notifications that may be required.

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<sup>58</sup> Clinical Episode Review Team, “CERT Review and Recommendations Regarding EHRM Medication Checks Pharmacy Issue,” memorandum; Clinical Episode Review Team, *EHRM Pharmacy Issue Patient Communication Plan*, August 2, 2023.

<sup>59</sup> Clinical Episode Review Team, *EHRM Pharmacy Issue Patient Communication Plan*.

<sup>60</sup> The VHA leader provided this commentary after reviewing the CERT developed draft communication plan. The OIG compared the draft communication plan to the final communication plan and noted there were no substantial differences.

The OIG found that, inconsistent with VHA policy, a large group of patients have not received a disclosure. The OIG is concerned that the proposed patient communication letter does not include information about the potential risk of harm due to HDR transmission issues.<sup>61</sup> Further, the OIG would have expected VHA leaders to develop a comprehensive strategy to review the care of new EHR site patients who have visited a legacy site and may have sustained harm, and subsequently disclose harm as warranted per VHA policy.

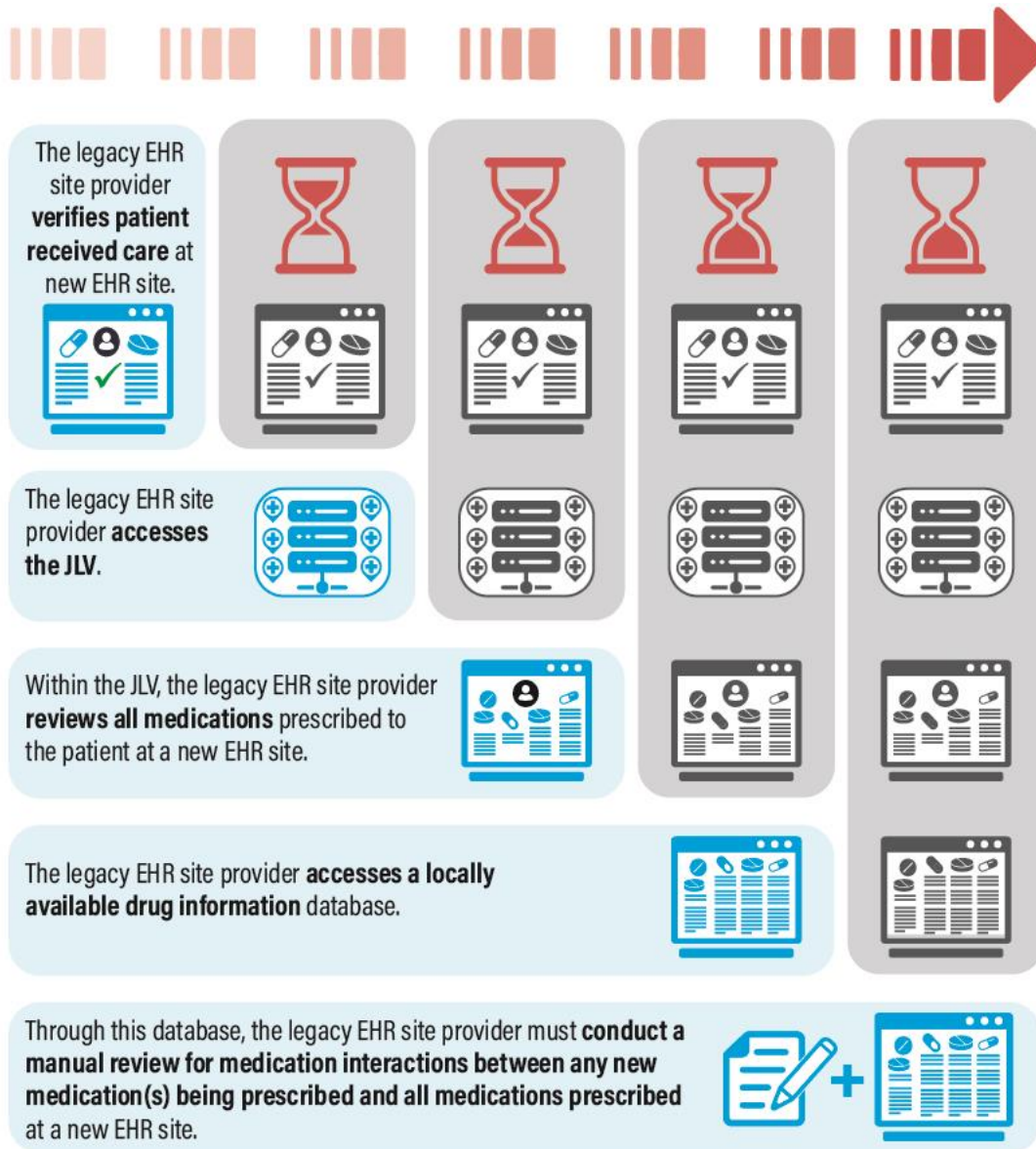
***Risks to Patients from HDR Transmission Issues Remain Despite VHA's Mitigation Actions.***

As early as March 31, 2023, VHA leaders sent a series of notifications (described above) about the transmission issues, outlining recommended actions to offset the risk of patient harm. The notifications included instructions for legacy site leaders to have providers perform multistep manual safety checks when prescribing new medications for patients previously cared for at a new EHR site. VHA leaders did not identify processes to confirm that frontline staff received the notifications or to evaluate whether staff performed the manual safety checks. Figure 5 provides one example of multiple manual processes providers must perform to replace automated software safety checks.

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<sup>61</sup> On June 5, 2023, greater than two months after the initial event had been discovered and its widespread impact understood, the OIG team met with EHRM IO leaders to express concern regarding the lack of notification to the affected patients.





**Figure 5.** Representation of the multistep process for a manual drug interaction safety check.

Source: VHA notification email, March 31, 2023.

Note: A drug information database is a resource that, among other things, can provide clinicians with information regarding adverse drug reactions and drug-drug interactions.

A VHA leader expressed concern regarding the recommended actions in this way:

The dependence on ‘manual’ order checks by providers and pharmacists is complicated in our Veteran population given the large number of prescriptions our patients receive. It is common to encounter Veterans on 10-20+ [sic] medications. The lack of clinical confidence in the EHR order checks and accurate display of medications status and previous refill dates creates a burden on providers and pharmacists to consult pharmaceutical references for complicated medication lists. **In short, providers and**

**pharmacists completing medication reconciliation for this subset of patients will have to do so without the aid of effective EHR technology when caring for complicated patients with multiple comorbidities, medications and health risks** [emphasis in original text].

The OIG is concerned that due to the volume of medications prescribed and allergies documented within the facility’s new EHR alone, the myriad of unresolved HDR transmission issues presents a high risk to patient safety. Further, the responsibility to protect patients from harm rests on legacy site providers’ ability to accurately perform a series of manual, complex, time consuming, and unmonitored mitigations of which they may or may not be aware. Subject matter experts testified before Congress that these manual workaround processes require additional vigilance, beyond what has previously been required by both pharmacy and other frontline clinical staff who prescribe and deliver medications.<sup>62</sup> The need for increased and constant vigilance now extends beyond new EHR site staff to include staff at all 166 legacy EHR sites. The OIG is concerned that increased vigilance is unsustainable by pharmacists and frontline staff responsible for clinical decision-making and may lead to burnout and medication-related patient safety events.

### 3. OIG Review of the New EHR’s Effects on Facility Staff

The OIG determined that implementation of the new EHR challenged pharmacy staff to provide safe medication management and avoid patient harm due to ongoing known usability concerns and patient safety issues.

#### Findings

The OIG made the following determinations:

***Implementation of the new EHR resulted in a prescription backlog and a permanent increase in clinical pharmacists.***

VHA policy states a chief of pharmacy is responsible for pharmacy service operations and is required to evaluate pharmacy staffing annually to “identify the best use of pharmacy resources and staff.”<sup>63</sup> Additionally, pharmacy leaders are responsible for “ensuring that resources allocated to pharmacy service are being utilized in a manner that delivers maximum benefit to the patient and guarantees safety, proper medication use, and the delivery of clinical care that

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<sup>62</sup> [Hearing on Electronic Health Record Modernization Deep Dive Pharmacy](#), Before the Subcommittee on Technology Modernization, House Committee on Veterans’ Affairs, 118th Cong. (May 9, 2023).

<sup>63</sup> VHA Handbook 1108.11(3), *Clinical Pharmacy Services*, July 1, 2015, amended October 2, 2023; VHA Directive 1108.07, *General Pharmacy Service Requirements*, November 28, 2022.

closes gaps in any unmet patient needs.”<sup>64</sup> Per VHA, a chief of pharmacy tracks pharmacy productivity and efficiency through monitoring of pending prescriptions and specifically if prescriptions remain pending for longer than seven days.<sup>65</sup> An increase in the daily average of pending prescriptions can indicate reduced pharmacy productivity and efficiency. The facility chief of pharmacy told the OIG of beginning preparations for go-live over a year before its implementation at the facility. Preparations included discussions with the National Pharmacy Council and representatives from Mann-Grandstaff VA Medical Center and VISN 20 about pharmacy issues at Mann-Grandstaff after the new EHR was implemented. Issues included the need to increase pharmacy staff to support the added workload caused by the new EHR's usability challenges.

In written communication to the OIG, the chief of pharmacy reported a plan to increase pharmacy staff with support from Virtual Pharmacy Services and the National EHRM Supplemental Staffing Unit.<sup>66</sup> The chief of pharmacy also received approval from facility leaders to hire additional pharmacists. However, due to uncertainty about the number of staff needed to accommodate the new workload and VHA's lengthy hiring process, additional pharmacists were not hired prior to the facility's new EHR go-live.<sup>67</sup>

Additionally, the chief of pharmacy reported collecting, tracking, and maintaining independent pharmacy staffing and productivity data following go-live and prior to VHA's creation of data reporting tools.<sup>68</sup> During an OIG interview, the chief of pharmacy described the realization that

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<sup>64</sup> VHA Handbook 1108.05(2), *Outpatient Pharmacy Services*, June 16, 2016, amended February 6, 2020. This handbook was in place at the time the facility implemented the new EHR and was rescinded and replaced by VHA Directive 1108.07, *General Pharmacy Service Requirements*, November 28, 2022. The 2022 directive contains the same or similar language regarding pharmacy leaders being responsible for allocation of resources to deliver safe clinical care as the rescinded 2020 handbook.

<sup>65</sup> VHA Handbook 1108.05(2); VHA Directive 1108.07. This handbook was in place at the time the facility implemented the new EHR and was rescinded and replaced by VHA Directive 1108.07, *General Pharmacy Service Requirements*, November 28, 2022. The 2022 directive contains the same or similar language regarding monitoring of pending prescriptions as the rescinded 2020 handbook. Pending prescriptions are prescription orders awaiting pharmacist action such as reviewing the order and dispensing the medication. VHA PBM Academic Detailing Services, “New Provider Guide An Introduction to Veterans Affairs Pharmacy,” June 2021, accessed July 31, 2023.

<sup>66</sup> PBM oversees VA's Virtual Pharmacy Services Program which provides support to VA medical center pharmacies by virtually processing pending prescriptions. “Pharmacy Benefits Management Virtual Pharmacy Services (VPS) Program FY 2018 Summary,” accessed July 13, 2023. VHA “created the National EHRM Supplemental Staffing Unit (NESSU) to provide in-person and virtual clinical staff, trained on the new EHR system, to further supplement areas of . . . outpatient pharmacy. . . during and after go-live.” Examining the Status of VA's Electronic Health Record Modernization Program, Before the Committee on Veterans' Affairs United States Senate, (July 20, 2022) (statement of Terry Adirim, M.D., Program Executive Director Electronic Health Record Modernization Integration Office Department of Veteran Affairs).

<sup>67</sup> In a written response to the OIG, the chief of pharmacy reported hiring of additional pharmacists began in July 2022.

<sup>68</sup> In a written response to the OIG, the chief of pharmacy reported data collection on May 19, 2022. The data reporting tool now available in the new EHR is the Discern Reporting Portal, which allows users to gather data and run reports.

shortly after go-live, the additional workload created by the new EHR could not be addressed “even [with] what VPS [Virtual Pharmacy Services] was willing to offer.” The OIG reviewed the chief of pharmacy’s data, which showed the number of average daily pending prescriptions and the number of average pending prescriptions older than seven days notably increased following the new EHR’s implementation (see table 3).<sup>69</sup>

**Table 3. Pharmacy Pending Prescription Data**

Time frame	Prior to new EHR	May 2022	June 2022
Average Daily Pending Prescriptions	1,213	3,959	2,557
Average Pending Prescriptions Older Than Seven Days	1	1,005	629

*Source: OIG’s analysis of Pharmacy Service’s average daily pending prescription data.*

On June 15, 2022, after reviewing the prescription data, the chief of pharmacy submitted an issue brief alerting VISN leaders that the Pharmacy Service had experienced

- an increase in pharmacy workload due to the “inefficiencies” of the new EHR,
- a backlog of pending prescriptions as “a significant patient safety risk,” and
- the need for additional pharmacy staff to assist with prescription processing.<sup>70</sup>

On June 21, 2022, the chief of pharmacy reported receiving approval from the facility’s executive leadership team to hire additional clinical pharmacists, equaling a total of nine full-time staff, which represented a 62 percent increase.<sup>71</sup> The OIG also learned that the chief of pharmacy and VISN 10 leaders used multiple strategies to address the increased pharmacist workload required to process pending prescriptions until permanent staff could be hired. Strategies included

- soliciting support from other VISN 10 pharmacists trained on the new EHR,
- offering unlimited overtime and compensatory time to existing facility pharmacists,
- pulling pharmacists from their usual duties to assist with prescription processing, and

<sup>69</sup> The chief of pharmacy averaged the pending prescriptions orders for January, February, and March 2022. The time frame reviewed excluded April 2022 due to pharmacy service preparation for new EHR implementation. The facility had a baseline of 1,213 pending prescriptions prior to go-live. Average daily pending prescription orders were rounded to the nearest whole number.

<sup>70</sup> The OIG reviewed pharmacy backlog related JPSRs and noted the facility patient safety manager did not classify any as catastrophic or resulting in major harm.

<sup>71</sup> In written communication to the OIG, the chief of pharmacy reported the nine additional clinical pharmacists represented the total number of pharmacists hired as a result of the staffing requests prior to implementation of the new EHR and the staffing requests after go-live. The hiring of nine permanent clinical pharmacists occurred between July 2022 and February 2023.

- increasing non-facility pharmacist support from Virtual Pharmacy Services and National EHRM Supplemental Staffing Unit.<sup>72</sup>

The chief of pharmacy told the OIG that because of the new EHR's usability issues, the hiring of nine permanent pharmacists served as a solution to maintain productivity and resulted in a sustained decrease in

- use of overtime,
- pending prescriptions, and
- use of non-facility pharmacist support.

The OIG would have expected the new EHR to make pharmacy processes more efficient; instead, the OIG found the new EHR led to an increase in pharmacy staff workload.

***Numerous workarounds and educational materials were needed to complete facility pharmacy work processes and provide patient care following implementation of the new EHR.***

The Institute of Medicine acknowledged a growing concern that EHRs, “may be creating new paths to failure” and the problems “relate to usability, implementation, and how software fits with clinical workflow.”<sup>73</sup>

In an inadequate or defective EHR system, inconsistencies exist between what the EHR system offers and what the user anticipates needing to complete their work, resulting in workflow mismatches and the creation of workarounds.<sup>74</sup> An EHR workaround is a temporary process developed outside established rules and regulations to allow users to complete tasks; often when time constraint is a factor.<sup>75</sup> Although EHR workarounds provide a temporary solution, they can “negatively influence the safety, effectiveness of care, and efficiency of care” by

- allowing users to bypass built-in patient safety mechanisms,
- masking awareness of EHR deficiencies,

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<sup>72</sup> Compensatory time is “time off with pay in lieu of overtime pay for irregular or occasional overtime work.” US Office of Personnel Management, “Fact Sheet: Compensatory Time Off,” accessed on July 26, 2023, <https://www.opm.gov/policy-data-oversight/pay-leave/pay-administration/fact-sheets/compensatory-time-off/>.

<sup>73</sup> Institute of Medicine of the National Academies, Committee on Patient Safety and Health Information Technology Board on Health Care Services, *Health IT and Patient Safety: Building Safer Systems for Better Care*, 2012.

<sup>74</sup> Workflow mismatches are “discrepancies between the behaviors, intentions, and expectations of the EHR users and the workflows dictated by EHRs.” Vincent Blijleven et al., “Workarounds in Electronic Health Record Systems and the Revised Sociotechnical Electronic Health Record Workaround Analysis Framework: Scoping Review,” *Journal of Medical Internet Research* vol 24, issue 3 (March 15, 2022), <https://www.jmir.org/2022/3/e33046>.

<sup>75</sup> Vincent Blijleven et al., “Workarounds Emerging From Electronic Health Record System Usage: Consequences for Patient Safety, Effectiveness of Care, and Efficiency of Care,” *JMIR Human Factors* vol 4, issue 4 (2017), <https://humanfactors.jmir.org/2017/4/e27/PDF>.

- preventing the creation of permanent solutions, and
- introducing variability to standardized processes.<sup>76</sup>

Implementation of numerous workarounds can lead to the development of “new pathways” for errors, and a decrease in patient safety.<sup>77</sup>

As a result of the May 2021 NCPS site visit to Mann-Grandstaff VA Medical Center, the pharmacy patient safety team created 7 short-term workarounds allowing pharmacy staff to continue providing patient care using the new EHR.<sup>78</sup>

The OIG learned following go-live, facility pharmacy leaders created approximately 29 additional workarounds to support pharmacy staff with processing prescription orders to prevent medication delays.<sup>79</sup> Facility and pharmacy leaders expressed frustration about challenges with the new EHR’s usability and the need for multiple pharmacy workarounds to complete tasks:

- “I tried to track [workarounds] at one point. And honestly, it's been overwhelming. . . there are things that are so nonintuitive about the [new EHR] system that there are eight different ways to do something. I don't know which ones necessarily right.”
- “The [EHR] in my mind is supposed to set ourselves up for success and what we continue to see over and over is that the system is setting us up for failure and its sort of contradictory of what . . . the [EHR] should be doing for us.”

The OIG determined that the use of multiple national and facility-developed workarounds allowed pharmacy staff to complete work processes. However, workarounds can create and perpetuate pathways for errors, potentially compromising patient safety.

Further, the OIG found facility pharmacy leaders identified a need to develop approximately 25 educational guides to serve as additional support for pharmacy staff when completing processes within the new EHR. In addition to facility-developed materials, VHA leaders told the OIG that the National Pharmacy Council contributed to the development of supplemental educational materials (such as tip sheets, reference guides, and job aids) to assist pharmacy staff with navigating the new EHR. Additionally, challenges with the new EHR’s usability led to the development of pharmacy-related workarounds. As of August 2023, the OIG determined that

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<sup>76</sup> Vincent Blijleven et al., “Workarounds Emerging From Electronic Health Record System Usage: Consequences for Patient Safety, Effectiveness of Care, and Efficiency of Care.”

<sup>77</sup> Deborah S Debono et al., “Nurses’ workarounds in acute healthcare settings: a scoping review,” *BMC Health Services Research* vol 13, issue 175 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3663687/>.

<sup>78</sup> NCPS made the determination between short-term and long-term mitigations in addition to classifying the seven short-term mitigations as workarounds. The pharmacy patient safety team workarounds included guidance addressing usability issues related to processing medication orders, completing medication reconciliation, and minimizing medication delays.

<sup>79</sup> The OIG found that Oracle Health released software patches between February and August 2023 that resolved the underlying issues for three of the pharmacy workarounds.



123 new EHR pharmacy-related educational materials existed on the VHA PBM SharePoint site and were available for staff use.<sup>80</sup>

The facility Chief of Staff expressed concern related to the need for pharmacists to use supplemental educational materials to perform general pharmacy processes.

“I think anytime you have to go to a tip sheet to do what should be routine work, I worry that it's a distraction from focusing on that patient in front of you or that prescription in front of you . . . it becomes a risk . . . [you] have to think of it as a patient safety risk.”

The OIG determined as of August 2023 the combined number of national and facility-developed workarounds and educational materials totaled 184.

The OIG recognizes facility pharmacy leaders' development and use of workarounds and educational materials demonstrated a commitment to patient care while adapting to the new EHR. However, the OIG is concerned that the numerous national and facility-developed workarounds and educational materials are overwhelming and time consuming for pharmacy staff. This could lead to employee burnout, care deficiencies, and increased patient safety issues.

***Implementation of the new EHR resulted in facility pharmacy staff reporting an increase in burnout symptoms and job dissatisfaction.***

Implementation of an EHR is considered a change that can have both a positive and negative impact on an organization.<sup>81</sup> When usability challenges within a new EHR exist, change can have a negative impact and “there is a significant increase in stress, anxiety, and resistance.”<sup>82</sup> Usability challenges can result in employees experiencing burnout, an extended response to job stressors that can lead to a decline in productivity, and “poor patient safety outcomes such as medical errors.”<sup>83</sup> Burnout may lead to low morale, which can contribute to negative patient outcomes as staff may

- lose focus of details at work and provide a lower quality of patient care;

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<sup>80</sup> The OIG did not independently review the educational materials to determine if they were duplicative of the facility workarounds.

<sup>81</sup> Theodore B. Feldman, “Understanding the Dynamics of Change and the Impact on Psychiatric Education,” *Academic Psychiatry* 38 (2014): 672–679, <https://doi.org/10.1007/s40596-014-0211-y>.

<sup>82</sup> “Improving Electronic Health Record Usability for Patient Safety,” Agency for Healthcare Research and Quality, accessed August 10, 2023, <https://digital.ahrq.gov/program-overview/research-stories/improving-electronic-health-record-usability-patient-safety>; Theodore B. Feldman, “Understanding the Dynamics of Change and the Impact on Psychiatric Education,” *Academic Psychiatry* 38 (2014): 672–679, <https://doi.org/10.1007/s40596-014-0211-y>.

<sup>83</sup> Christina Maslach and Michael P. Leiter, “Understanding the burnout experience: recent research and its implication for psychiatry,” *World Psychiatry* 15, no 2 (June 2016): 103-111, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4911781/>; Louise Hall et al., “Healthcare Staff Wellbeing, Burnout, and Patient Safety: A Systemic Review,” *PLoS* 11(7) (July 8, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4938539/>.



- miss work more frequently leading to understaffing and an increased need for overtime; and
- trigger low morale among other staff within the department, adversely affecting patients' care.<sup>84</sup>

The VA National Center for Organizational Development recognizes burnout as an individual's "whole relationship with their work and their experience of the usual stresses involved in carrying out their tasks."<sup>85</sup>

Facility pharmacy staff, including the chief of pharmacy, told the OIG that working in the new EHR contributed to concerns about making errors that could result in patient harm. These concerns caused pharmacy staff burnout and job dissatisfaction. A facility quality, safety, and innovations staff member also shared concerns regarding pharmacy staff burnout:

[Pharmacy staff] want to be here, and they want to provide safe, adequate, appropriate care and they are taking all these extra steps continuously, day in and day out. They're working over[time]. They're coming in on the weekends. They're doing those triple checks; they're reporting stuff up [to leaders]. . . How long can we sustain that?

VA acknowledges the importance of monitoring employee burnout as evidenced by its inclusion within VA's annual All Employee Survey (AES).<sup>86</sup> The OIG evaluated AES responses related to burnout symptoms from facility pharmacy staff and all facility staff prior to and following the new EHR's implementation in 2022. AES scores in 2021 reflected that 54 percent of pharmacists surveyed experienced at least one symptom of burnout compared to 75 percent in 2022. In 2021, 44 percent of facility staff surveyed reported at least one symptom of burnout compared to 51

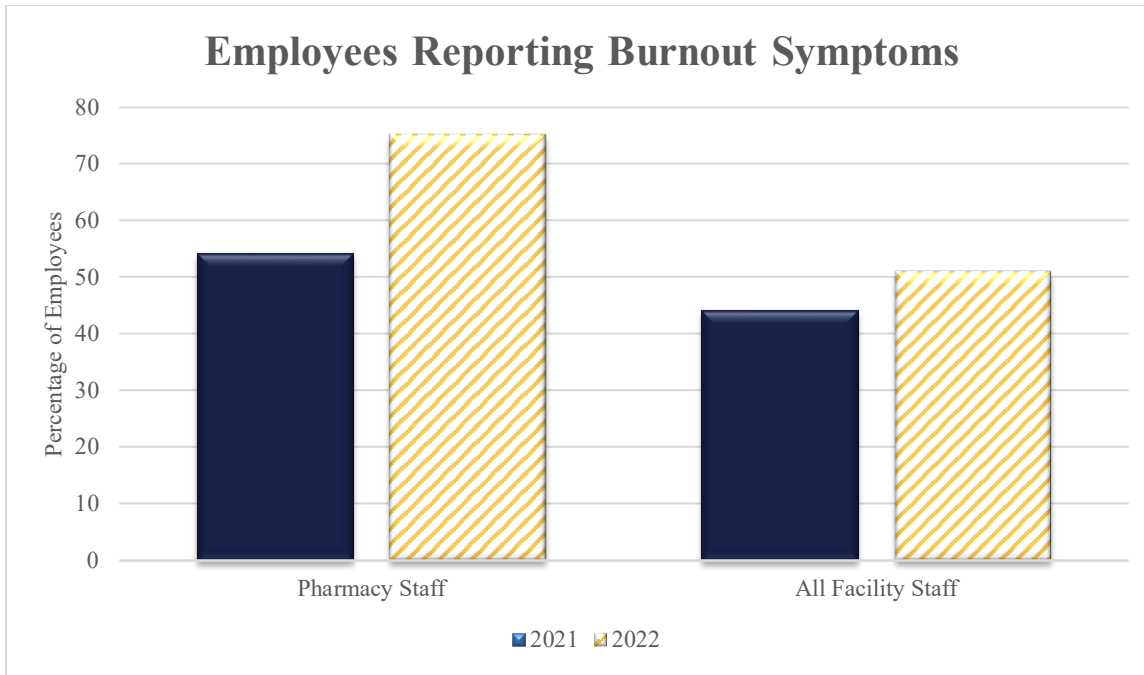
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<sup>84</sup> Christina Maslach and Michael P. Leiter, "Understanding the burnout experience: recent research and its implication for psychiatry," Employee morale is a sense of purpose and confidence employees have for the future; *Merriam-Webster.com Dictionary*, "morale," accessed August 1, 2023, <https://www.merriam-webster.com/dictionary/morale>; Suzanne Beyea, "Employee morale and patient safety," *Patient Safety First* 80 no. 6 (December 2004), <https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/S0001-2092%2806%2960692-3?sid=nlm%3Apubmed>; Louise Hall et al., "Healthcare Staff Wellbeing, Burnout, and Patient Safety: A Systemic Review."

<sup>85</sup> "Forum Summer 2019: Access and the MISSION Act, VA National Center for Organizational Development," accessed August 17, 2023, <https://www.hsr.d.research.va.gov/publications/forum/summer19/>.

<sup>86</sup> The AES seeks to provide a "big picture of the employee experience." VHA Directive 1003, *VHA Veteran Patient Experience*, dated April 14, 2020. AES categories include burnout, job satisfaction, employee engagement, best places to work, exhaustion, and turnover.

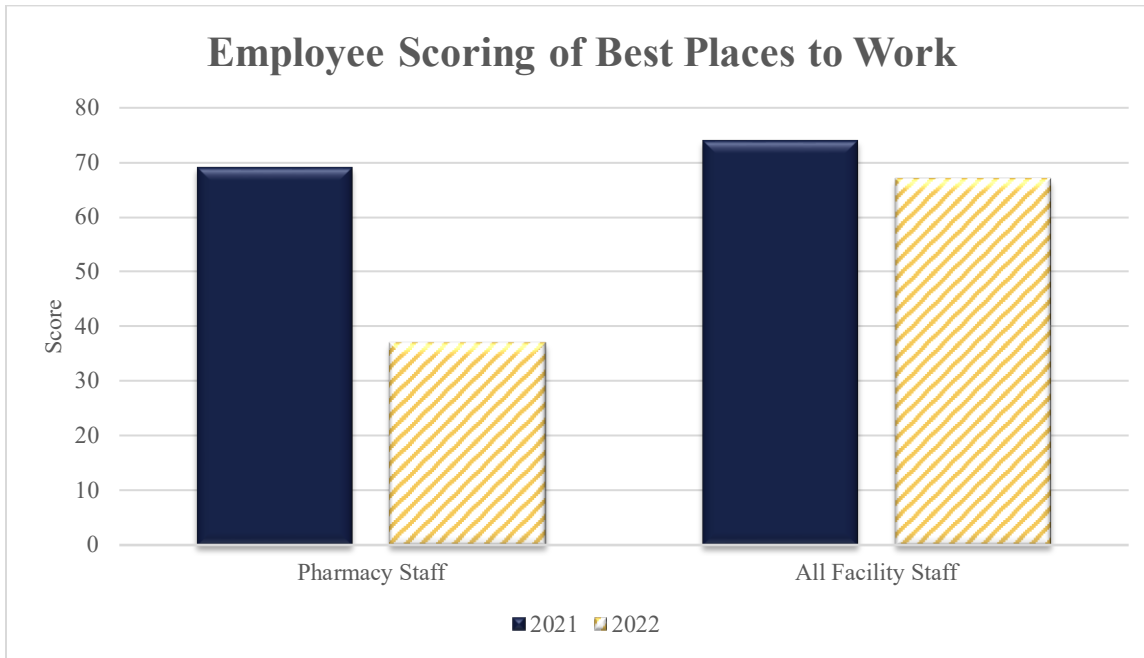
percent in 2022. The best places to work score for pharmacy staff decreased by 32 points, while the score for all facility staff decreased by seven points (see figures 6 and 7).<sup>87</sup>



**Figure 6.** 2021 and 2022 facility staff and Pharmacy Service AES burnout percentage data before and after new EHR implementation.

Source: VHA 2021 and 2022 AES Snapshot Reports.

<sup>87</sup> The OIG compared 2021 and 2022 facility AES results. A facility leader informed the OIG that VA launched the 2022 AES on June 6, 2022, 37 days after the new EHR’s implementation at the facility. Burnout is measured as a percentage score ranging from 0–100; lower percentages are more favorable. “Best Places to Work” is a summary measure of the group’s satisfaction with the job, organization, and likelihood to recommend VA as a good place to work. The score ranges from 0–100 points; higher scores are more favorable. “2022 VA All Employee Survey (AES), Questions by Organizational Health Framework,” VA, accessed July 26, 2023, [https://dvagov.sharepoint.com/:w:/r/sites/AESHelpDesk/\\_layouts/15/Doc.aspx?sourcedoc=%7BF6550A11-35BB-42E5-8C0A-CED3A6D18C95%7D&file=2022%20AES%20Instrument-%20Questions%20by%20Theme.docx&action=default&mobileredirect=true](https://dvagov.sharepoint.com/:w:/r/sites/AESHelpDesk/_layouts/15/Doc.aspx?sourcedoc=%7BF6550A11-35BB-42E5-8C0A-CED3A6D18C95%7D&file=2022%20AES%20Instrument-%20Questions%20by%20Theme.docx&action=default&mobileredirect=true). (This site is not publicly accessible.)



**Figure 7.** 2021 and 2022 facility staff and Pharmacy Service AES best places to work data. The figure is a visual representation of best places to work scores for facility and Pharmacy Service staff before and after new EHR implementation.

Source: VHA 2021 and 2022 AES Snapshot Reports.

Facility pharmacy employees, including the chief of pharmacy, told the OIG that challenges with the new EHR negatively impacted pharmacy staff morale. The OIG surveyed frontline pharmacy staff to explore their experience after implementation of the new EHR and found 77 percent reported decreased morale.<sup>88</sup> A pharmacy employee expressed to the OIG that “a lot of this decrease has to do with patient safety concerns. No one ever wants to make a mistake and harm a patient.” The OIG survey also showed that pharmacy staff experienced psychological conflict when using an EHR system that was perceived as risky. This cultivated a climate in which staff were at risk for moral injury.<sup>89</sup>

VHA pharmacy and patient safety leaders told the OIG of a need for increased staff vigilance to avoid patient harm as the new EHR is fundamentally unsafe. Facility leaders described experiences synonymous with moral injury related to the new EHR.

<sup>88</sup> The OIG team surveyed a total of 47 frontline pharmacy staff. Of the 47 frontline pharmacy staff, 36 reported a decrease in morale, two staff reported an increase in morale, four staff reported no change in morale, and five staff did not provide a response to the survey.

<sup>89</sup> Victoria Williamson, et al., “Moral injury: the effect on mental health and implications for treatment,” *The Lancet Psychiatry*, Volume 8, Issue 6 (June 2021): 453–455, [https://doi.org/10.1016/S2215-0366\(21\)00113-9](https://doi.org/10.1016/S2215-0366(21)00113-9). Moral injury is “the strong cognitive and emotional response that can occur following events that violate a person’s moral or ethical code”; Marc S. Williams, “Misdiagnosis: Burnout, moral injury, and implications for the electronic health record,” *Journal of the American Medical Informatics Association*, 28, no. 5 (2021): 1047–1050, <https://doi.org/10.1093/jamia/ocaa244>.

- “One of the biggest concerns for our staff is this fear of . . . accidentally causing patient harm . . . That stress that’s associated with our staff working in a potentially unsafe environment like this is very taxing and you know they try to do their due diligence.”
- “What I expect from an EHR is that it makes things more efficient and safer, that it really protects against human error. What I see here is that humans are protecting against EHR error.”
- “Well, it actually keeps me up at night, but the whole EHR keeps me up at night. Do I think there's been an adverse outcome and that we just don't know about it yet? Probably yeah . . . All of [the executive leadership team] have trouble sleeping because we worry about everything.”

The OIG concluded that pharmacy staff were subjected to high levels of stress from challenges with the new EHR and awareness of the risk for patient harm. This stress contributed to burnout, job dissatisfaction, decreased morale, and experiences synonymous with moral injury. The OIG is concerned that if new EHR usability issues persist, staff may succumb to the effects of burnout and inadvertently expose patients to harm.

## Conclusion

Following the first deployment of the new EHR, VHA became aware of pharmacy-related high-risk patient safety and usability issues. However, EHR deployment continued and contributed to patient safety issues at the facility and ongoing usability challenges resulting in inaccurate medication information.

The new EHR also contributed to pharmacy-related patient safety issues nationally. An error in software coding resulted in the transmission of incorrect medication information from new EHR sites to legacy EHR sites when prescriptions were filled through the CMOP. Although a software patch to correct the error occurred within a week of discovery, the patch did not resolve incorrect prescription data sent prior to the patch.

Further data transmission issues related to non-CMOP medication and allergy information also resulted in patient safety issues. As of September 2023, the data transmission issues have affected approximately 250,000 new EHR site patients who received care at a legacy EHR site. Affected patients have not been notified of their risk of harm and the OIG remains concerned for their safety.

VHA leaders sent a series of notifications about the new EHR transmission issues and outlined recommended actions to mitigate the risk of harm for patients previously cared for at a new EHR site. The notifications included instructions for legacy site leaders to have providers perform multistep manual safety checks to replace automated software safety checks when prescribing new medications for patients previously cared for at a new EHR site. VHA leaders did not

identify outcome measures in these communications. The OIG is concerned that a mitigation that is complex, time consuming, and relies on provider vigilance is not sustainable and may lead to burnout and medication-related patient safety events.

Further, implementation of the new EHR challenged pharmacy staff to provide safe medication management and avoid patient harm. This resulted in (1) a prescription backlog at the facility, which required a permanent 62 percent increase in clinical pharmacists; (2) the creation of numerous workarounds and educational materials to complete pharmacy work processes; and (3) pharmacy staff burnout, job dissatisfaction, decreased morale, and experiences synonymous with moral injury. The OIG is concerned that the new EHR is lessening pharmacy staff efficiency, requiring workarounds and educational materials that are overwhelming for pharmacy staff, and that staff may succumb to burnout, which could adversely affect patient care.

## Recommendations 1–9

1. The Deputy Secretary ensures mitigation of the high-risk pharmacy-related patient safety issues identified during the May 2021 National Center for Patient Safety visit.
2. The Under Secretary for Health evaluates whether the new electronic health record reflects accurate patient medication information per Veterans Health Administration requirements and takes action as indicated.
3. The Deputy Secretary ensures the resolution of pharmacy-related usability issues identified in this report.
4. The Deputy Secretary ensures correction of inaccurate medication data transmitted to the Health Data Repository.
5. The Under Secretary for Health determines the need for and implements a comprehensive strategy to review patients affected by inaccurate medication data transmitted to the Health Data Repository to evaluate whether harm occurred, the need for patients to undergo testing or treatment, and the appropriateness of institutional disclosures.
6. The Under Secretary for Health ensures patients affected by inaccurate medication data transmitted to the Health Data Repository are notified of the risk of harm per Veterans Health Administration requirements.
7. The Under Secretary for Health ensures legacy site providers are aware of mitigations needed for patients previously treated at a new electronic health record site and monitors compliance.
8. The Under Secretary for Health ensures that pharmacist staffing levels are assessed and addressed prior to the implementation of the new electronic health record at additional VA sites.
9. The Under Secretary for Health evaluates the underlying technical and functional issues resulting in workarounds and educational materials needed to perform pharmacy-related operations within the new electronic health record and takes action as indicated.

## Appendix A: Usability Issues in the New EHR

Through a review of patient safety reports captured in the JPSR system, interviews, document reviews, and electronic communication, the OIG learned about usability issues within the new EHR that contributed to inaccurate medication information.

**Table A.1. Examples of Usability Issues in the New EHR's Pharmacy Domain**

Usability Issue	Description
<b>Examples of Usability Issues that Can Contribute to Inaccurate Medication Orders</b>	
Order Entry	There are multiple options for providers to enter free text directions for medication orders.
Bidirectional Communication	Prescription changes made in the pharmacy dispensing software are not reflected in the new EHR.
Legacy EHR Data Migration	Medication administration instructions did not migrate from the legacy system to the new EHR.
Providers Can Order Unavailable Medications	Providers can unknowingly order medications that are not readily available at their local VA pharmacy.
Pharmacist Prescription Transcription	Pharmacists must manually re-type prescription orders if a patient needs a partial supply of medication.
Automatic Discontinuation of Orders	The new EHR can automatically discontinue medication orders without notifying the provider.
<b>Examples of Usability Issues that Can Contribute to Inaccurate Medication Reconciliation</b>	
Active Medication Lists	Updates to a patient's active medication list may not be reflected at the patient's next appointment.
After-Visit Summary	Providers are unable to reliably print and subsequently provide an after-visit summary to patients.
<b>Examples of Usability Issues that Can Contribute to Inaccurate Medication Dispensing</b>	
Pharmacist Medication Selection	A pharmacist must manually review and select a medication in the pharmacy dispensing software that best matches the ordered medication from the new EHR.
Wrong Dispensing Pharmacy Selected	The pharmacy selected to dispense the medication defaults to the last selected pharmacy instead of the local VA pharmacy.

*Source: OIG analysis of facility pharmacy-related patient safety issues.*



## Appendix B: Patient Case Summary

Below is an example of a patient whose care was influenced by inaccurate medication data.

*In spring 2023, a facility patient with posttraumatic stress disorder and traumatic brain injury with resulting adrenocortical hypofunction was admitted to a legacy EHR site Residential Rehabilitation Treatment Program.<sup>90</sup>*

*Four days prior to admission, a legacy EHR site pharmacist used the legacy EHR remote data feature to perform a reconciliation of medications prescribed through the new EHR with the patient and available “computer data” to “develop an accurate and up to date medication regimen.” The patient’s spouse, who is the patient’s caregiver and assists with medications and tasks related to memory, was not part of this process.*

*The data available to the legacy EHR site pharmacist from the facility’s new EHR did not include the patient’s most recent prednisone prescription from approximately one month prior to the planned admission.*

*On the day of admission to the Residential Rehabilitation Treatment Program, a nurse practitioner performed another medication reconciliation with the patient, who responded to some questions regarding the purpose of the medications with “I don’t know.” While entering the medications to be given during the Residential Rehabilitation Treatment Program admission into the legacy EHR, one medication triggered an inaccurate alert of a significant drug-drug interaction with another medication. The nurse practitioner chose to “override” the warning message by entering the justification that it was “renewal of current therapy.” As the most recent prednisone prescription was not visible in the legacy medical record without using JLV, prednisone appeared to have been completed by the patient at least three months prior to admission and was therefore not prescribed in the admission medication orders.*

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<sup>90</sup> Traumatic Brain Injury may cause the pituitary gland, a part of the brain, to stop functioning properly. When the pituitary gland stops functioning properly, the adrenal glands are not stimulated to produce adequate cortisol. This is called secondary adrenocortical hypofunction or secondary adrenal insufficiency. Insufficient cortisol may cause extreme fatigue, low blood pressure, fainting, low blood sugar, irritability, or depression and can lead to life-threatening conditions. Patients may be prescribed daily prednisone, a cortisol replacement, at a dose that replaces the amount that is missing; American Psychological Association, “*posttraumatic stress disorder (PTSD)*,” accessed August 29, 2023, [APA Dictionary of Psychology](#); PTSD is “a disorder that may result when an individual lives through or witnesses an event in which he or she believes that there is a threat to life or physical integrity and safety and experiences fear, terror, or helplessness.”; Mayo Clinic, “*Traumatic brain injury*,” accessed September 6, 2023, <https://www.mayoclinic.org/diseases-conditions/traumatic-brain-injury/symptoms-causes/syc-20378557>. A traumatic brain injury “usually results from a violent blow or jolt to the head or body . . . these injuries can result in long-term complications or death”; VHA Directive 1162.02, *Mental Health Residential Rehabilitation Treatment Program*, July 15, 2019. “Mental Health Residential Rehabilitation Treatment Program (MH RRTP) is the umbrella term for the array of programs and services that comprise mental health residential care.” One of the programs includes a residential PTSD program.

*On the fifth day of admission, the patient exhibited unusual behavior described as variably withdrawn and then angry. The patient was not communicating in a “normal way” with nursing staff and approached the nurse stating, “I need more prednisone. When I feel like this, I need to increase my dose.” When the nurse replied that prednisone was not on the patient’s medication list, the patient noted, “I have a secondary adrenal insufficiency and I need to take prednisone for the rest of my life.”*

*The patient became increasingly anxious about medication and reported feeling faint. While lying in bed, the patient began attempting to find the active prednisone order via personal cell phone. A nurse described the patient’s behavior as having,*

*a hard time focusing and could not read the prednisone order and was getting frustrated. [The patient] handed me this [sic] phone. Orders read: Take prednisone 5 mg PO [orally], 2 tabs in the am and 1 tab in the PM. Veteran agreeable for 911 to be called “please tell them no lights and sirens.”*

*The patient received prednisone at a local emergency room, was given prescriptions and instructions for daily prednisone, and returned to the Residential Rehabilitation Treatment Program later that evening.*

## Appendix C: Office of the Deputy Secretary Memorandum

### Department of Veterans Affairs Memorandum

Date: March 1, 2024

From: Deputy Secretary (001)

Subj: Healthcare Inspection—Electronic Health Record Modernization Caused Pharmacy-Related Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus ((VIEWS 11413855))

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the Department of Veterans Affairs (VA) Office of Inspector General (OIG) draft report “Electronic Health Record Modernization Caused Pharmacy-Related Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus.” The report contains nine recommendations for VA, and I concur with all nine recommendations.

2. VA’s pharmacy programs have long achieved success through a culture of safety and continuous process improvement. I want to acknowledge and thank our pharmacy community for using the same approach to identify the improvements that are needed within the Federal Electronic Health Record (EHR) and also thank OIG for their recognition of the time that facility staff have dedicated to this mission and the effort to ensure safe care for patients.

3. Over a year ago, the Electronic Health Record Modernization (EHRM) Pharmacy Council and Oracle Health Government Services, Inc. (Oracle Health) identified an initial set of critical items to be sequentially addressed through regular code upgrades. Since then, VA has made incremental but steady progress. Significant improvements have been realized in system performance and in the clinician ordering experience. Several enhancements have also been delivered to improve pharmacy fulfillment processes, but this is an area where further work remains to enable increased efficiency for pharmacy staff. As of today, all but one of the initially identified priority enhancements have been delivered. The final feature, which will automate the synchronization of prescription information between the Oracle Health provider and pharmacy applications, has been installed and is undergoing testing now.

4. VA recognizes that the work is not yet done. Ultimately, the desired end state of VA’s pharmacy enhancement efforts is reduced time and steps required by pharmacists during verification and dispensing workflows, and reduced time and steps required by providers during prescription ordering and renewal. More work is being done beyond the block updates to address longer-term considerations, including inpatient controlled substance ordering; provider provenance for renewal of controlled substance prescriptions; digital signature; and support resources needed for perpetual inventory implementation.

5. VA providers, pharmacists and Veterans deserve a system that performs as promised and continues to keep pace with their unique demands. My expectation is that this system will continue to be a shared priority for VA and Oracle Health, and that Oracle Health will remain committed to prioritizing and accelerating the work on pharmacy matters.

*(Original signed by:)*

Tanya J. Bradsher

## Office of the Deputy Secretary Response

### Recommendation 1

The Deputy Secretary ensures mitigation of the high-risk pharmacy-related patient safety issues identified during the May 2021 National Center for Patient Safety visit.

Concur

Nonconcur

Target date for completion: March 2024

### Deputy Secretary Comments

The Department of Veterans Affairs (VA) Electronic Health Record Modernization Integration Office (EHRM-IO), the Veterans Health Administration (VHA) and Oracle Health (OH) coordinated to identify software changes that would address pharmacy-related issues raised during the National Center for Patient Safety visit in May 2021. Development of these software changes was prioritized and targeted for release in the biannual code block releases, which are designed to provide multiple enhancements and software updates at one time to minimize the impact and disruption to end users. All live electronic health record modernization (EHRM) sites and affiliates (e.g., associated remote sites) receive the block release. The Block 8 release in February 2023 and Block 9 release in August 2023 addressed all but two of the issues identified in Table 2 of the report. The Block 10 release, which was implemented over February 9-10, 2024, included software changes approved by the EHRM Pharmacy Council that are expected to address the last two issues: the consistency of prescription and order status and refills in the new electronic health record (EHR). VA will monitor the efficacy of Block 10 release and provide an update to the VA Office of the Inspector General (OIG) when more data is available.

### Recommendation 3

The Deputy Secretary ensures the resolution of pharmacy-related usability issues identified in this report.

Concur

Nonconcur

Target date for completion: February 2025

### Deputy Secretary Comments

VA acknowledges the importance of the pharmacy-related usability limitations in the new EHR system. VA is committed to continually optimizing the system as it is being implemented at new sites.

VA has a well-established process for resolving issues identified by the users, which at a high level includes intake, assessment, prioritization, solution development, testing, implementation, and monitoring. This process has already been leveraged to perform a significant amount of work on the pharmacy-related usability issues identified in Appendix A of the report. For example: the February 2023 Block 8 release addressed the ordering of unavailable medications and the automatic discontinuation of orders; the August 2023 Block 9 release addressed legacy data migration; and the February 2024 Block 10 release is expected to address bidirectional communication and after-visit summary issues. However, some of the remaining issues require longer term efforts, many of which are already in process. VA will continue work to ensure that all of these issues are appropriately addressed in a timely manner.

## Recommendation 4

The Deputy Secretary ensures correction of inaccurate medication data transmitted to the Health Data Repository.

Concur

Nonconcur

Target date for completion: February 2025

### Deputy Secretary Comments

The issue in the interface that caused transmission of incorrect medication VA Unique Identifiers (VUIDs) to the Health Data Repository (HDR) was fixed on April 7, 2023. Data transmitted prior to that fix (between October 24, 2020, and April 7, 2023) is currently stored within HDR with the incorrect VUIDs. Data transmitted and stored after April 7, 2023, has the correct medication VUIDs.

VHA Directive 1108.07 General Pharmacy specifies that, “Non-controlled prescriptions are valid for one year from the date of issue, unless otherwise specified. Controlled substance CIII-V prescriptions are valid for six months from the date of issue, unless otherwise specified. CII prescriptions greater than 14 days from the date of issue should be verified for continued need prior to dispensing.” (Section 13.a.6) Therefore, any prescription stored in HDR that is older than one year has expired and can be addressed through attrition. To ensure that these expired prescriptions are not received by downstream software, including safety checks, they will be marked inactive in HDR as they expire. The initial inactivation of EHRM records in HDR, which inactivated records older than 485 days, was run on November 15, 2023. The inactivation script will be run on a recurring basis through August 5, 2024, when the last record stored with this issue will be inactivated (April 7, 2023 + 485 days). This will address any further issues with inaccurate medication VUID data.

During troubleshooting and testing for the corrupt medication VUID incident, additional data was identified that is not defined in the Interface Control Document (ICD). Missing data includes events beyond dispenses, such as status changes at expiration or discontinuation. A New Service Request (NSR; NSR20230921 "EHRMI Additional Med Info for Health Data Repository") was submitted on September 28, 2023, to address the missing data in the interface between Millennium and HDR. This NSR is in the EHRM-IO backlog and is undergoing review. The redesign of the ICD and the associated interface to address the requirements in this NSR, in addition to the attrition of incorrect medication VUIDs as prescriptions expire in the one-year period between April 7, 2023, and April 7, 2024, will address the consequences listed in this report. VA estimates that it will be able to implement the updated interface as a part of the Block 12 release in February 2025.

## Appendix D: Office of the Under Secretary for Health Memorandum

### Department of Veterans Affairs Memorandum

Date: February 12, 2024

From: Under Secretary for Health (10)

Subj: Office of Inspector General (OIG) Draft Report, Electronic Health Record Modernization Caused Pharmacy-Related Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus (VIEWS 11275211)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on OIG's draft report on the electronic health record modernization (EHRM) and pharmacy-related patient safety issues at the VA Ohio Healthcare System in Columbus. The Veterans Health Administration (VHA) concurs with all the recommendations and provides action plans for the recommendations made to the Under Secretary for Health (2 and 5-9). Responses to recommendations 1, 3 and 4 are provided by the Deputy Secretary.

2. VHA Pharmacy Benefits Management (PBM), the EHRM Pharmacy Council and the Columbus Pharmacy Service appreciate OIG's recognition of the significant work and commitment of pharmacy employees to rapidly adapt to the new electronic health record (EHR) and accomplish the challenges of modernizing the system as VHA strives to become a high reliability organization. OIG mentioned hearing repeatedly of the long hours and considerable workload of facility staff dedicated to VA's mission and recognized their efforts to ensure safe care for patients. We are proud of our employees and their commitment to Veterans.

3. VHA agrees with OIG regarding the importance of evaluating underlying technical and functional impacts that require workarounds and educational materials to perform pharmacy-related functions within the new EHR. VHA will continue development of rapid and reliable processes for quickly identifying and resolving issues within the new EHR. Collectively, VA and VHA embrace OIG's recommendations as renewed opportunities to improve the system's usability, expand its capabilities and align the new EHR with VHA's workflows and best practices.

4. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at [VHA10BGOALACTION@va.gov](mailto:VHA10BGOALACTION@va.gov).

*(Original signed by:)*

Shereef Elnahal M.D., MBA



## Office of the Under Secretary for Health Response

### Recommendation 2

The Under Secretary for Health evaluates whether the new electronic health record reflects accurate patient medication information per Veterans Health Administration requirements and takes action as indicated.

Concur

Nonconcur

Target date for completion: December 2024

### Under Secretary for Health Comments

The Pharmacy Benefits Management (PBM) Medication Information Management/Medication Reconciliation Office will review the patient medication information data available in the OH system and cross reference the data elements outlined as required per VHA Directive 1164 Essential Medication Information and VHA Directive 1345 Medication Reconciliation. For any gaps that are noted, the PBM Medication Information Management/Medication Reconciliation Office will send a report through the EHRM Pharmacy Council for review and potential action/collaboration with EHRM-IO for resolution.

### Recommendation 5

The Under Secretary for Health determines the need for and implements a comprehensive strategy to review patients affected by inaccurate medication data transmitted to the Health Data Repository to evaluate whether harm occurred, the need for patients to undergo testing or treatment, and the appropriateness of institutional disclosures.

Concur

Nonconcur

Target date for completion: May 2024

### Under Secretary for Health Comments

The Clinical Episode Review Team (CERT), along with subject matter experts from program offices such as PBM Services, the National Center for Patient Safety (NCPS) and the National Center for Ethics in Health Care, reviewed the feasibility and effectiveness of a lookback with the available data and will continue to explore options in this area. Should harm or close calls be identified, VHA will follow the processes of VHA Directives 1050.01 VHA Quality and Patient Safety Programs and VHA Directive 1004.08 Disclosure of Adverse Events to Patients.

## Recommendation 6

The Under Secretary for Health ensures patients affected by inaccurate medication data transmitted to the Health Data Repository are notified of the risk of harm per Veterans Health Administration requirements.

Concur

Nonconcur

Target date for completion: May 2024

### Under Secretary for Health Comments

One of the most important aspects of patient safety is ensuring patients and their providers communicate clearly and regularly about medications. VHA wants ensure Veterans know how to partner with their provider to help prevent an unanticipated harm related to medications. Medication reconciliation, where the patient and provider talk over patients' medications and allergies, is an essential element of every patient care encounter. VHA will leverage this opportunity to remind patients about the importance of medication reconciliation and encourage them to come prepared to talk over their medications with their provider. VHA will collaborate with CERT to develop and execute a communications plan to engage Veterans on the issues, risks, and actions that need to be taken to mitigate the risks. The goal of the communication plan will be to encourage patients who have been seen at a EHRM facility to bring their medications with them to all in-person and virtual appointments at VistA or EHRM facilities to facilitate medication reconciliation and to have them alert their provider if they visit more than one VA facility. As mailed letters are not always opened by patients, this plan will explore different modalities (text, email, call center responses, etc.) to ensure robust coverage.

## Recommendation 7

The Under Secretary for Health ensures legacy site providers are aware of mitigations needed for patients previously treated at a new electronic health record site and monitors compliance.

Concur

Nonconcur

Target date for completion: June 2023

### Under Secretary for Health Comments

The critical period for vigilance by providers at legacy sites is through August 2024, when the remaining prescriptions that were affected by the medication VUID misidentification will be renewed and corrected or lapsed (discontinued or expired). NCPS issued communication to all VHA facilities about this issue in April 2023 and June 2023. The June 2023 NCPS Patient Safety

Notice included a voluntary clinical reminder order check tool to ensure providers are aware that patients were previously seen at an EHRM site so that they can complete manual order checks. Compliance monitoring included monitoring facility receipt of the Patient Safety Notice. All sites acknowledged receipt of the Patient Safety Notice.

### **OIG Comments**

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

### **Recommendation 8**

The Under Secretary for Health ensures that pharmacist staffing levels are assessed and addressed prior to the implementation of the new electronic health record at additional VA sites.

Concur

Nonconcur

Target date for completion: February 2025

### **Under Secretary for Health Comments**

The EHRM Pharmacy Council currently collaborates with and will continue to collaborate with facilities and their associated Veteran Integrated Service Networks regarding upcoming implementations in order to: (1) review the hiring of appropriate pharmacist staffing levels by evaluating the prescription processing data (prescriptions per hour) from Medical Centers that have implemented the new EHR to help extrapolate and assess the baseline pharmacist staffing levels; (2) ensure results of the staffing analysis and a short-term plan for remote, supplemental pharmacist, and onsite support is incorporated into the Readiness Checklists/guidance documents; and (3) ensure remote and onsite staff are available during EHRM implementation to maintain expected levels of pharmacy workload measured by prescription wait times and pending queues consistent with VHA Directive 1108.07 Pharmacy General Requirements.

### **Recommendation 9**

The Under Secretary for Health evaluates the underlying technical and functional issues resulting in workarounds and educational materials needed to perform pharmacy-related operations within the new electronic health record and takes action as indicated.

Concur

Nonconcur

Target date for completion: February 2025

## **Under Secretary for Health Comments**

VA agrees that the presence of workarounds could serve as one indicator of complex problems. The EHRM Pharmacy Council and the EHRM-IO Program Management Office (PMO) will evaluate the prioritized and ranked list of NSRs, and EHRM-IO PMO will collaborate with the appropriate Contracting Officer to obtain an estimated cost and implementation date for each NSR associated with a workaround to known pharmacy-related functions.

## Appendix E: VISN Director Memorandum

### Department of Veterans Affairs Memorandum

Date: February 9, 2024

From: Director, The VA Healthcare System Serving Ohio, Indiana, and Michigan (10N10)

Subj: Healthcare Inspection—Electronic Health Record Modernization Caused Pharmacy-Related  
Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus

To: Office of the Under Secretary for Health (10)  
Director, Office of Healthcare Inspections (54HL06)  
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to review and comment on OIG's draft report for the Healthcare Inspection—Electronic Health Record Modernization Caused Pharmacy-Related Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus.
2. Leaders and subject matter experts from VISN 10 and VA Central Ohio Healthcare System provided input and concur with the responses provided by Offices of the Deputy Secretary and Under Secretary for Health.
3. If you have additional questions or need further information, please contact the VISN Quality Management Officer.

*(Original signed by:)*

Laura E. Ruzick, FACHE  
Network Director

## Appendix F: Facility Director Memorandum

### Department of Veterans Affairs Memorandum

Date: February 9, 2024

From: Director, VA Central Ohio Healthcare System (757/00)

Subj: Healthcare Inspection—Electronic Health Record Modernization Caused Pharmacy-Related  
Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus

To: Director, VA Healthcare System Serving Ohio, Indiana, and Michigan (10N10)

1. Thank you for the opportunity to review and comment on OIG's draft report for the Healthcare Inspection—Electronic Health Record Modernization Caused Pharmacy-Related Patient Safety Issues Nationally and at the VA Central Ohio Healthcare System in Columbus.
2. Leaders and subject matter experts from VA Central Ohio Healthcare System and VISN 10 provided input and concur with the responses provided by Offices of the Deputy Secretary and Under Secretary for Health.
3. If you have questions or need additional information, please contact the Chief, Quality, Safety & Innovation Service.

*(Original signed by:)*

Marc Cooperman, MD  
Medical Center Director

## OIG Contact and Staff Acknowledgments

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