US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Ineffective Oversight of Community Care Providers' Special-Authorization Drug Prescribing Increased Pharmacy Workload and Veteran Wait Times

Audit | **23-01583-183** | **August 15, 2024**

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Executive Summary

Veterans can receive health care from community providers that VA pays for when certain criteria are met, such as long appointment wait times or the unavailability of specialty care at their local VA facilities. Prescriptions written by these healthcare providers for veterans must be filled by a VA pharmacy.[1] Since 2020, the number of veterans receiving some or all their care in the community has increased, so VA pharmacies are processing more community care prescriptions. Specifically, from fiscal year (FY) 2020 through FY 2023, the number of community care prescriptions VA pharmacies processed rose from about 2.7 million to about 4.4 million, an increase of about 64 percent. The total cost of those prescriptions increased by about 131 percent during the same period, from about $368.7 million to about $850.8 million.[2]

The VA MISSION Act of 2018 consolidated several community care programs into a single Veterans Community Care Program, which VA launched in June 2019.[3] Under this program, the Veterans Health Administration (VHA) may purchase healthcare services in the community for veterans through Community Care Network (CCN) contracts, which it has done by contracting with two third-party administrators (TPAs). These two TPAs manage five regional networks under five contracts with VHA.[4] The TPAs in turn contract individually with community providers that become part of the TPAs' regional networks (referred to in this report as provider contracts). TPAs are expected to enforce CCN contract terms that apply to community provider performance and compliance with VHA standards.

VHA operates a VA National Formulary (the formulary) that lists drugs that must be available for prescription at all VA medical facilities. The formulary management process is intended to provide pharmaceuticals and supplies of quality and value to all eligible veterans. Community providers must first consider items on the formulary when writing prescriptions before requesting nonformulary items, just as VA healthcare providers do.

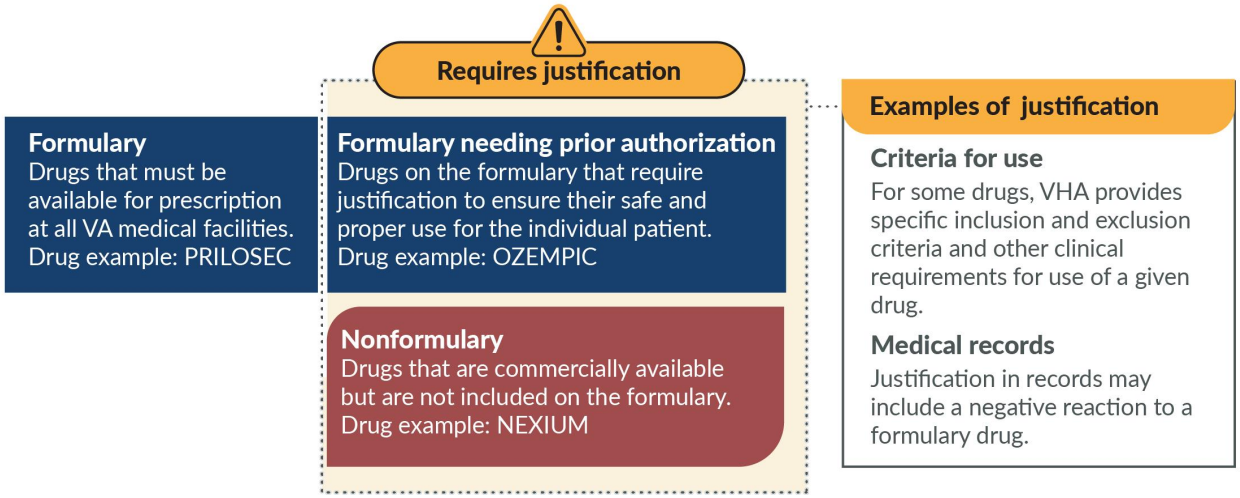
[1] Certain drugs are designated on an Urgent/Emergent Formulary listing. These items may be filled at outside pharmacies under specific provisions for community care. The scope of this audit only included routine drugs and not urgent/emergent drugs.

[2] The number and cost of community care prescriptions are rounded numbers. The rounded calculations are based on 2,696,790 and 4,426,774 prescriptions in FYs 2020 and 2023, respectively, so the percent increase totals 64.14 percent. Furthermore, the costs of the prescriptions in FYs 2020 and 2023 are $368,700,084 and $850,751,054, respectively, with the increase totaling 130.74 percent. For readability, rounded numbers are used in the body of the report.

[3] John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, Pub. L. No. 115-182, 132 Stat. 1393 (2018).

[4] Third-party administrators are contracted entities that provide administrative and operational support for VHA community care programs. Each of the five CCN contracts began with a base period of one year (starting in 2018) with seven renewable one-year options. In total these contracts and their option periods are valued up to about $86.1 billion.

In certain situations, veterans may require drugs that are either not listed on the formulary or are listed but require justification before being dispensed to veterans—these are called nonformulary or prior-authorization drugs, respectively, but in this report are collectively referred to as special-authorization drugs. The CCN contracts require that community providers submit medical documentation with the prescription to the VA pharmacy to justify requests for these drugs. VA pharmacies receive prescriptions from community providers electronically, by fax, or by hand from the veteran. Summary figure 1 shows the different drug designations and whether justification is required before a VA pharmacy can fill the prescription.



Summary figure 1. *Formulary drugs compared to special-authorization drugs that require justification.*

Source: VA Office of Inspector General analysis of VHA Directive 1108.08, Formulary Management Process*, July 29, 2022.*

VA's Pharmacy Benefits Management Services (PBM) oversees and monitors formulary drugs and makes certain that these drugs are available at VA pharmacies. The Office of Integrated Veteran Care (IVC) is responsible for overseeing access to care in the community and the TPAs. In turn, TPAs are contractually obligated to instruct and mandate that their community providers comply with VA's formulary and related justification processes when prescribing special-authorization drugs. According to VA guidance, VA pharmacy chiefs are responsible for ensuring that pharmacies process special-authorization drug requests within 96 hours (four days) of receiving the prescription.[5]

[5] VHA Directive 1108.08, *VHA Formulary Management Process*, July 29, 2022, sec. 5.k.2. The directive requires that nonformulary drugs be processed within 96 hours, and that time frame is suggested for prior-authorization drugs as well. For the purposes of this audit, the OIG applied the 96 hours as a standard for both types of special-authorization requests, and PBM agreed this approach was reasonable.

The VA Office of Inspector General (OIG) conducted this audit to determine if VHA's oversight of the TPAs ensured that community providers prescribed special-authorization drugs in accordance with VA standards.[6]

To achieve this objective, the audit focused on verifying whether justifications were provided for special-authorization drug requests and whether processing was completed within VHA's timelines. However, throughout the course of the audit, the OIG identified a large number of prescriptions (formulary and special-authorization drugs) from community providers that VA pharmacists canceled, rejected, or removed. Though these prescriptions were not the main focus of this audit, the OIG conducted limited testing to determine why VA pharmacists did not process them. The results of this secondary analysis are documented in the last section of the report.

What the Audit Found

The OIG determined that VHA, and specifically IVC, did not provide adequate oversight of the TPAs to ensure that community providers prescribed special-authorization drugs in accordance with VHA guidance. The OIG estimates that VA pharmacists did not receive medical justification for about 96,500 of 97,200 prescriptions (about 99 percent) for special-authorization drug requests when community providers submitted the initial prescription to the VA pharmacy, creating additional work for VA pharmacists to request and obtain the justification. Though VA pharmacy chiefs took steps to develop and implement local processes to request medical justifications and monitor these requests, some VA pharmacies experienced prescription backlogs because of the increased number of community care prescriptions. Community care prescriptions were difficult to manage and strained pharmacy staff resources. As a result, an estimated 39,100 of the 97,200 special-authorization community care prescriptions (about 40 percent) exceeded VHA's expected approval time of four days, and when this happened, veterans waited an average of about 11 days for their prescriptions to be approved.[7] In addition, the OIG questioned a total of about $200.2 million in costs for prescriptions that VHA dispensed to veterans that lack evidence of justification to support the approval of the special-authorization drug. This amount is based on the OIG's estimate that prescriptions valued at about $45.3 million—or about $3.8 million per month—were dispensed to veterans from May 2022 through April 2023 without proper justification.[8] The remaining $154.9 million is the OIG's estimate of what VHA will pay to issue special-authorization prescriptions to veterans without

[6] See appendix A for the report's scope and methodology.

[7] Appendix B explains the team's statistical sampling approach.

[8] For readability, rounded numbers are used in the body of the report. The number the audit team used was $45,335,626 (the OIG's estimated value of prescriptions that lacked justification) divided by 12 (number of months), which equals $3,777,974 (value of prescriptions lacking justification per month). See appendix C for more information on the questioned costs.

justification from May 2023 through September 2026 (the same time period that covers the contract options for all five regional CCN contracts with both TPAs). This projection assumes no changes are made to the terms of the current CCN contracts to improve community providers' compliance with VHA requirements when these drugs are prescribed.

VHA will continue to be at risk for filling community care prescriptions without proper justification until it takes steps to evaluate the terms of its current CCN contracts and develops a plan to be implemented with the next generation of contracts to improve the capabilities of the electronic prescription system for community providers. At the time of the audit, VHA was in the process of reevaluating the CCN contracts but did not yet have an award date for the next generation of the contracts.

The excessive wait times for special-authorization prescriptions occurred in part because the electronic prescription system that community providers use could not alert community providers that a drug was not listed on the VA formulary and does not allow users to attach medical justification with the prescription. Instead, community providers had to access to a PBM-developed public website to identify a drug's formulary status and separately fax the medical justification to the VA pharmacy. In addition, the TPAs did not make sure community providers completed training on VA's formulary. As reported by the TPAs, less than 2 percent of community providers completed TPA-developed training on the formulary and the required procedures for prescribing these drugs, which includes providing a medical justification with the prescription for a VA pharmacist to review before dispensing the drug to a veteran.

Ultimately, veterans who received prescriptions from community providers for special-authorization drugs waited longer than they should to receive prescriptions—and longer than VHA has tracked because the data PBM captures on prescription processing times are inaccurate. Though the audit team determined that VA pharmacies were not able to process an estimated 40 percent of these prescriptions within the 96-hour standard, PBM's dashboard showed that only about 5 percent of veterans' community care prescriptions for the same review period were not processed within 96 hours. The dashboard inaccuracies were due in part to many VA pharmacists entering the date they received the medical justification from the community provider rather than the date they received the prescription. Further, the dashboard does not track processing times for prior-authorization drugs—it only tracks nonformulary drugs, further skewing the dashboard's data.

VHA needs to improve oversight across multiple offices—including IVC, PBM, and medical facility pharmacies and community care offices—to hold the TPAs accountable when community providers do not follow CCN contract procedures when prescribing special-authorization drugs. IVC should enhance its monitoring of community providers' prescribing practices, and PBM also should make certain that VA pharmacists consistently document these prescriptions in veterans' medical records. All of these special-authorization drug requests should also be captured in PBM's tracking dashboard to improve the accuracy and

completeness of data on approval processing times. Doing so will help VHA consider information needed to reevaluate the terms for the next generation of CCN contracts.

Finally, the OIG also determined that VA pharmacists canceled, rejected, and removed about 1.3 million prescriptions from February 1, 2022, through April 30, 2023. The majority, an estimated 705,000 prescriptions, lacked a community care referral authorizing the veteran to receive services from the prescribing community provider, rendering those prescriptions invalid. VA pharmacists reported spending hours validating these prescriptions that ultimately could not be filled, contributing to prescription backlogs and staffing workload. Other reasons these prescriptions went unprocessed were duplicate prescriptions, community providers switched to formulary alternatives, or the prescription lacked medical justification. PBM could use data related to these unprocessed prescriptions to better inform decisions related to community provider education and outreach, staffing, and other efforts to minimize processing delays and unproductive work.

What the OIG Recommended

The OIG made seven recommendations to the under secretary for health: (1) require IVC and PBM to consider system capabilities that could improve community providers' compliance with prescribing these drugs; (2) task IVC to train community providers and implement a process to improve tracking of provider compliance with prescribing special-authorization drugs; (3) direct PBM to improve information collected in the PBM dashboard and provide IVC personnel access to the data; (4) direct PBM to require VA pharmacy personnel to document community care special-authorization drug requests in the veteran's medical record when the prescription is received and clarify the processing time for special-authorization drugs; (5) direct PBM to emphasize that pharmacists are responsible for reporting a community provider to the medical facility's community care office when the provider does not comply with VA documentation requirements for special-authorization drug requests; (6) direct community care offices to submit the appropriate reporting form to the TPAs when community providers are not compliant; and (7) direct PBM to develop standardized requirements for how VA pharmacists code prescriptions that are canceled, rejected, or removed.

VA Management Comments and OIG Response

The under secretary for health concurred or concurred in principle with the OIG's seven recommendations and requested that recommendation 4 be closed. PBM's actions to address recommendation 4—clarifying and updating its business rules requiring facility pharmacy staff to document community care special-authorization drug requests in the veteran's medical record when the pharmacy receives the prescription and to process prescriptions within 96 hours—are found to be sufficient by the OIG, which now considers this recommendation closed. VHA's proposed corrective measures for the remaining recommendations are responsive to their intent. The OIG will monitor implementation of the remaining recommendations and will close them

when VHA provides sufficient evidence of progress addressing the issues identified. The full text of the under secretary's comments is in appendix D.

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Assistant Inspector General
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Contents

Abbreviations

CCN	Community Care Network
FY	fiscal year
IVC	Office of Integrated Veteran Care
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management Services
TPA	third-party administrator
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Glossary

Community Care Network (CCN): "The VA Community Care Network (CCN) is VA's direct link with community providers to ensure Veterans receive timely, high-quality care. CCN uses industry-standard approaches and guidelines to administer services, pay for services promptly, and manage the network to its full potential."[9]

Community Care Network contract (CCN contract): A contract signed between the Veterans Health Administration and third-party administrators that manage VA's community care networks.[10]

community provider: A healthcare provider who contracts with a third-party administrator to provide treatment or services in a local non-VA setting to veterans through the Community Care Network.[11]

criteria for use: A standard for the use of a drug developed by Pharmacy Benefits Management Services that describes the patient populations most likely to benefit from use of a specified drug with inclusion and exclusion criteria for patient use based on available clinical evidence related to safety and efficacy. Criteria for use can be employed to justify prescribing both formulary and nonformulary drugs as required.[12]

formulary: A list of drugs, called the VA National Formulary, that must be available for prescription at all VA medical facilities, some of which may require justification before being dispensed to a patient.[13]

justification: A documented reason for the appropriateness of the drug being prescribed, which is submitted before the drug is dispensed to patients.[14]

nonformulary drug: A drug that is not listed on the formulary and therefore requires justification before being dispensed to a patient.[15]

prior-authorization drug: A formulary drug that requires justification before being dispensed to a patient.[16]

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[9] "Community Care Network—Information for Providers" (web page), VA, accessed March 5, 2024, https://www.va.gov/COMMUNITYCARE/providers/Community-Care-Network.asp.

[10] IB-10-1125-Community Care Network (CCN) Fact Sheet, January 21, 2022.

[11] IB-10-1188-Community Care Network Fact Sheet, June 8, 2023. (Note, however, that care providers may also contract directly with medical centers.)

[12] VHA Directive 1108.08, sec. 3.b.

[13] VHA Directive 1108.08, sec. 3.p.

[14] VA OIG analysis of United Healthcare Optum, *VA CCN Provider Manual*, April 2023, and TriWest Healthcare Alliance, *CCN Provider Handbook*, October 2023.

[15] VHA Directive 1108.08, sec. 3.h.

[16] VHA Directive 1108.08, sec 3.i.

provider contract: The contract signed between a community healthcare provider and a third-party administrator of VA's care delivered in a local setting.[17]

special-authorization drugs: The term used in this report to collectively refer to nonformulary or prior-authorization drugs, both of which require justification before being dispensed to a patient.[18]

third-party administrators (TPAs): Companies that contract with VA to manage the five regional networks of community providers; two TPAs have CCN contracts with VA at the time of this audit.[19]

[17] VA OIG analysis of United Healthcare Optum, *VA CCN Provider Manual*, and TriWest Healthcare Alliance, *CCN Provider Handbook*.

[18] OIG-derived term.

[19] IB-10-1125-Community Care Network (CCN) Fact Sheet, January 21, 2022.

Introduction

The Veterans Health Administration (VHA) operates a VA National Formulary (the formulary) that lists prescription drugs and drug-related supplies that must be available at all VA medical facilities. The formulary management process is meant to provide quality pharmaceuticals and supplies to all eligible veterans.

VA pays for veterans to receive health care from community-based providers when certain conditions are met, such as long appointment wait times or unavailability of specialty care at the veterans' local VA facilities. The VA MISSION Act of 2018 consolidated several community care programs into the Veterans Community Care Program in June 2019.[20] Under this program, VHA may purchase care for veterans through Community Care Network (CCN) contracts with third-party administrators (TPAs).[21] The CCN groups VA medical facilities into five regions managed by two TPAs.[22] In turn, the TPAs establish contracts with their community providers who render services to veterans within the established regions. This report refers to the contracts

- between VHA and the TPAs as "CCN contracts," and
- between TPAs and individual community providers as "provider contracts."

TPAs are expected to enforce CCN contract terms that apply to each community provider.

Typically, when a community provider writes a prescription for a veteran, it must be filled by a VA medical facility pharmacy.[23] The formulary is the only product list authorized for TPA-approved community providers to use when prescribing drugs to veterans. Community providers—like VA care providers—must justify prescriptions for drugs that are not on the formulary before VA pharmacies can dispense them. In addition, some drugs are included on the formulary but still must be authorized prior to being dispensed. They are referred to collectively in this report as "special-authorization drugs" and are described more fully in the following section on Drug Classifications.

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[20] John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, Pub. L. No. 115-182, 132 Stat. 1393 (2018).

[21] According to an internal VA website, in addition to CCN contracts, VA facilities may also enter into local veteran care agreements with community providers, which are intended to be used in limited situations when contracted services through the CCN are either not provided or not sufficient to ensure veterans can get the care they need. These contracts are outside the scope of this audit. "Veterans Care Agreements" (web page), accessed September 9, 2023, https://www.va.gov/communitycare/providers/veterans_care_agreements.asp.

[22] TPAs are contracted entities that provide administrative and operational support for VHA community care programs. Each of the five CCN contracts with the two TPAs began with a base period of one year (starting in 2018) with seven renewable one-year options. In total these contracts and their option periods are valued up to about $86.1 billion.

[23] Certain drugs are designated on an Urgent/Emergent Formulary listing. These items may be filled at non-VA pharmacies under specific provisions for community care. The scope of this audit only included routine or maintenance drugs that are required to be filled at a VA pharmacy.

As context, more veterans receive some or all of their care in the community since at least 2019, increasing the number of community care prescriptions VA pharmacies process. From fiscal year (FY) 2020 through FY 2023, medical facilities experienced an increase of about 64 percent in the number of overall community prescriptions (formulary and special-authorization drugs) they processed. In addition, the total cost of those prescriptions increased by about 131 percent during the same period, with an average increase of about $160.7 million over the three fiscal years.[24] Figure 1 shows the growth in the number and cost of community care prescriptions VA pharmacies processed from FY 2020 through FY 2023.[25]

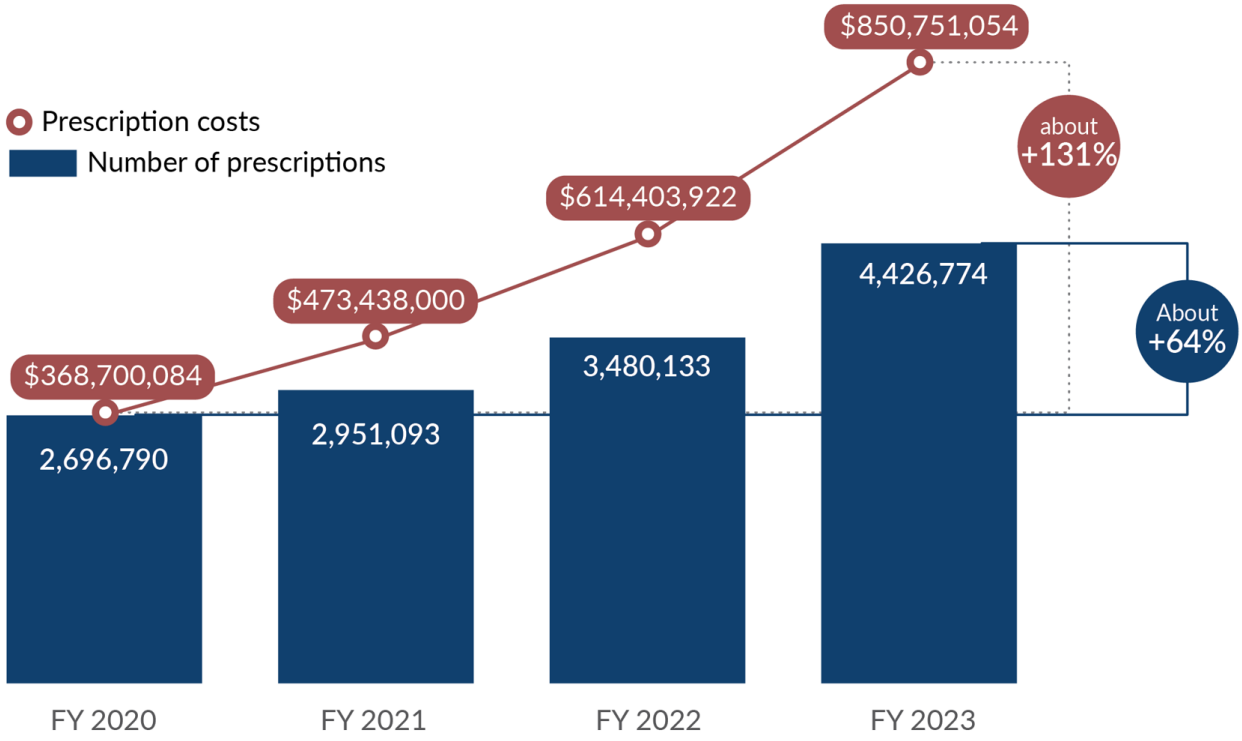

Figure 1. *Increase in community care prescriptions and costs by fiscal year.*

Source: Pharmacy Benefits Management Services Dashboard, Community Care Prescription Fills Summary Report.

The total cost of community care prescriptions that were not on VHA's formulary increased by about 180 percent during the same period, with an average increase of about $63.5 million. The

[24] The number and cost of community care prescriptions in the text reflect rounded numbers. The rounded calculations are based on 2,696,790 and 4,426,774 prescriptions in FYs 2020 and 2023, respectively. The increase then totals 64.15 percent. Furthermore, the costs of the prescriptions in FYs 2020 and 2023 are $368,700,084 and $850,751,054, respectively, with the increase totaling 130.7 percent. For readability, rounded numbers are used in the body of the report.

[25] The audit team did not examine the relationship between the increase in the cost of drugs and the increase in the number of community care prescriptions.

OIG was not able to report on the value of prior-authorization drug prescriptions because VHA does not track that information separately.

The VA Office of Inspector General (OIG) conducted this audit to determine if VHA's oversight of the TPAs ensured that community providers prescribed nonformulary and prior-authorization drugs (referred to in this report as special-authorization drug requests) in accordance with VHA standards.

Drug Classifications

Veterans may require drugs that are either not listed on the formulary or are listed but require justification before being dispensed to veterans. The National Formulary Committee designates a drug as a prior-authorization drug.[26] Drugs that require justification can either be on or off the formulary. Figure 2 shows the different formulary drug designations and whether justification is required before a VA pharmacy can fill the prescription.

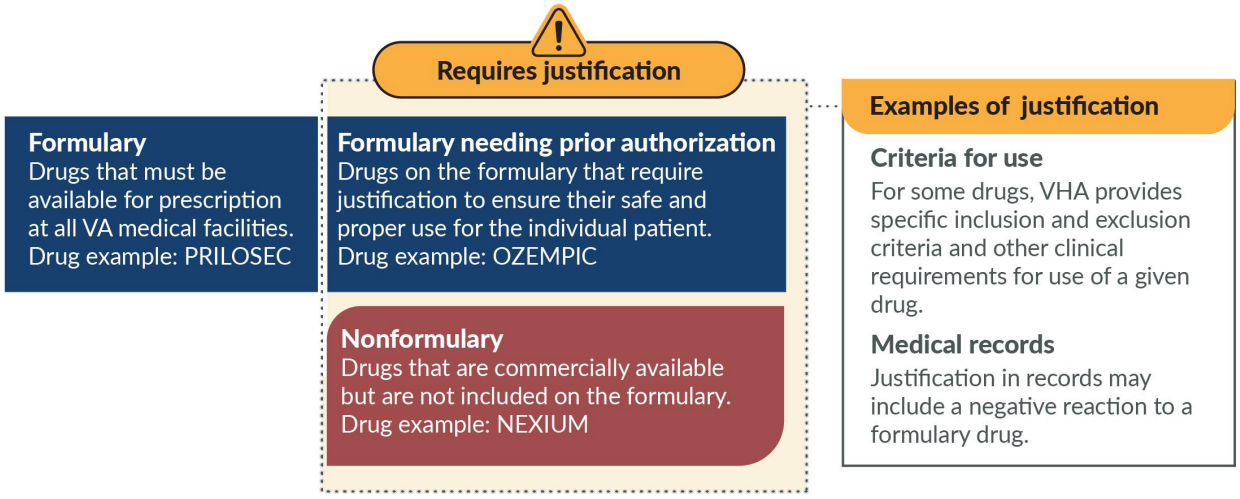

Figure 2. *Formulary drugs compared to special-authorization drugs that require justification.*

Source: VA OIG analysis of VHA Directive 1108.08, Formulary Management Process, *July 29, 2022.*

The two classes of special-authorization drugs within the scope of this audit are grouped together in this report because they have similarities in the way they are processed:

1. **Prior-authorization drugs:** PBM designates a subset of formulary agents as prior-authorization drugs based on a review for appropriateness of use before they are dispensed in order to support veterans' safe and proper use of drugs received within VA.[27]

[26] VHA Directive 1108.08, *VHA Formulary Management Process*, secs. 3.f.(1), 3.p, 3.h, and 3.i, July 29, 2022.

[27] VHA Directive 1108.08, sec 6.n.

2. **Nonformulary drugs:** VA medical facilities establish processes and procedures to ensure approval decisions are justified and timely.[28] Formulary alternatives should be considered when clinically appropriate.

To assist with assessing the appropriateness of particular drugs, the National Formulary Committee developed criteria for use for certain drugs that identify the patient populations most likely to benefit from the drug and detail the inclusion and exclusion criteria based on available clinical evidence related to the drug's safety and efficacy. As figure 2 indicates, criteria for use may exist for both formulary and nonformulary drugs and are the preferred means of justification for drugs that require it. These documents are available to the public on the Pharmacy Benefits Management Services (PBM) website.

Community providers can prescribe drugs that are not on the formulary or that require prior authorization if they follow VHA procedures to justify the use of these drugs. Most importantly, community providers must submit medical documentation that justifies a need for a special-authorization drug, or criteria for use when required, with these types of prescriptions to the VA pharmacy for review. In addition, an explanation of need from medical specialists may suffice for justification for some prior-authorization drug requests.

Inbound Electronic Prescriptions and VHA's Data Systems

In 2017, to improve the ability of VA pharmacies to deliver drugs to veterans as quickly and efficiently as possible, PBM, the Offices of Patient Care Services and Information and Technology, and IVC implemented a system to receive inbound electronic prescriptions from an external medical provider (such as a community provider or staff at a Department of Defense treatment facility).[29] This process is known as electronic prescribing, which enables VA pharmacies to receive and process electronic community care prescriptions.[30] Figure 3 illustrates the electronic prescribing process as it should occur between community providers and VA pharmacies.

[28] VHA Directive 1108.08, sec. 6.m.

[29] The electronic prescription system contract is owned by the Office of Integrated Veteran Care and the Offices of Patient Care Services and Information and Technology.

[30] VA Office of Information and Technology, *Pharmacy Reengineering Inbound ePrescribing 3.1 User Guide,* June 2020.

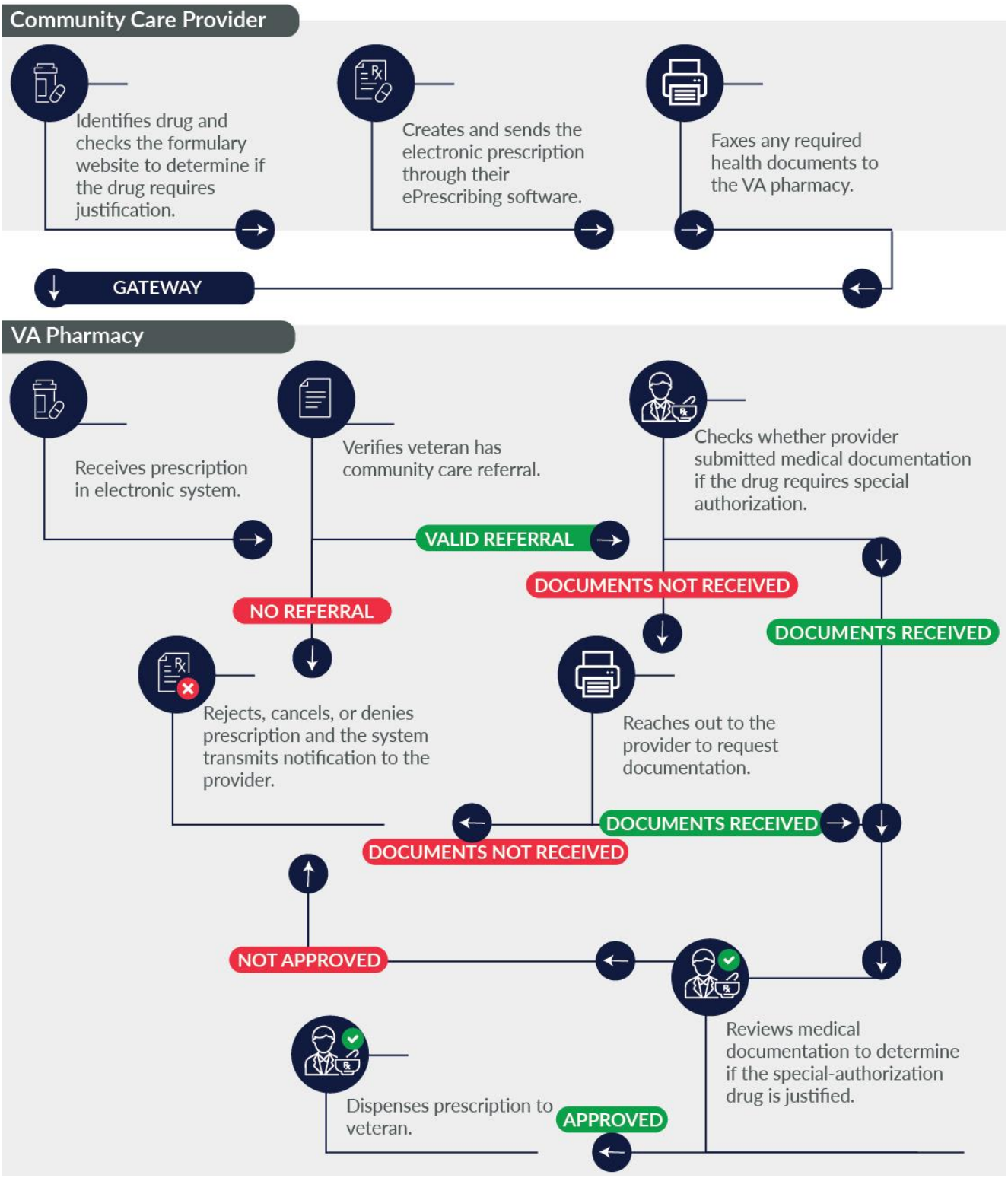

Figure 3. *Community care prescription processing.*

Source: VA Office of Information and Technology, Pharmacy Reengineering Inbound ePrescribing 3.1 User Guide*, June 2020; VA OIG analysis of VA pharmacy processes.*

Community providers send electronic prescriptions to a commercially available, web-based software application, which serves as an interface or gateway to all participating electronic prescribing providers nationwide and allows users to manage VA pharmacy information and search for an electronic prescription.[31] Community providers can search and select a drug to electronically prescribe for a veteran within the prescribing software. The software then conducts auto-checks (patient, provider, and drug) and transmits the electronic prescription to VA's outpatient pharmacy. Once there, a medical facility pharmacist conducts additional validations to include receipt of medical documentation, if required, and drug name and dosage checks. Once validated, the pharmacist can accept the electronic prescription and transmit it to the Pending Outpatient Orders file for additional accuracy checks to verify patient, drug name, and dosage before dispensing.

Applicable Guidance

VHA Directive 1108.08 defines the formulary management process and guidance for prescribing nonformulary drugs and prior-authorization formulary drugs, which this report collectively calls special-authorization drugs. According to this directive, special-authorization drugs are only approved when decisions are justified, formulary alternatives do not exist, or the veteran has one or more of the following documented circumstances:

- Contraindication to the formulary drug
- Adverse reaction to the formulary drug
- Failed response to the formulary drug
- Previous success with a nonformulary drug and concern that a change to a formulary drug would introduce serious risk

The directive also establishes time frames for processing special-authorization drugs requests:

- **Nonformulary** drug requests "are reviewed and the requestor notified of the decision within 96 hours of receipt of the submission.... If the necessary information is not received in a timely manner, the reviewer will work with the VA provider to complete the request within 96 hours."[32]

[31] Providers can also submit prescriptions using fax, or the veteran can hand-deliver the prescription to the VA pharmacy. It should also be noted that the team did not include medical centers that use Cerner in the audit scope because the external prescription process is different.

[32] VHA Directive 1108.08, sec. 6.m.1.c.

- **Prior-authorization** drugs requests "are reviewed and the requestor notified of the decision as soon as possible, ideally within 96 hours of the receipt of the submission."[33]

Because the directive requires nonformulary drugs to be processed in 96 hours and is a target time frame for prior-authorization drugs as well, the audit team applied the 96 hours as a standard for both types of requests and obtained PBM's agreement that doing so was reasonable.

VHA Directive 1108.07 states that medical facilities must have adequate staff in place to ensure compliance with the formulary prescribing guidance and CCN contract requirements.[34] The directive also states that community providers who are unwilling to comply with VA's formulary management process should be reported to the facility or Veterans Integrated Service Network (VISN) community care office.[35]

Contract Requirements

Both TPAs signed CCN contracts with VHA that include the requirements for TPAs overseeing community providers' compliance with prescribing standards. TPAs approve community providers to be part of a network once a provider has signed a contract with the TPA overseeing that region. This process requires TPAs to confirm that community providers and facilities meet the requirements of nationally recognized accrediting organizations and all applicable federal and state regulatory mandates for services, facilities, and providers.

According to the CCN contracts, when community providers prescribe drugs, the prescriptions must be processed by a VA pharmacy. VA pharmacies can only fill prescriptions that are associated with authorized care—meaning a veteran is referred to the community by VHA for care.

In addition, the TPA must always

- instruct its community providers that prescriptions are required to be prescribed in accordance with the formulary,
- instruct its community providers to use the VA Formulary Advisor website developed by PBM to search for formulary alternatives to nonformulary drugs in the same VA drug class, and

[33] VHA Directive 1108.08, sec. 6.n.5.c.

[34] VHA Directive 1108.07, *General Pharmacy Service Requirements*, sec. 7.b.7, November 28, 2022. This directive was amended on October 4, 2023; however, changes to the directive did not apply to the audit team's period of review (May 2022 through April 2023).

[35] VHA Directive 1108.07, app. C, sec. 1. VHA divides the United States into 18 regional networks, known as VISNs, which manage day-to-day functions of medical centers and provide administrative and clinical oversight. See www.va.gov/HEALTH/visns.asp.

- ensure that community providers submit all special-authorization drug prescriptions with proper medical documentation to the VA pharmacy.

Community providers also sign individual contracts with their TPA during their credentialing process. These provider contracts contain standardized language that states the providers agree to treat veterans according to the terms and conditions of the contract and the applicable provider handbook supplied by the TPAs. These handbooks state that community providers must submit medical documentation for special-authorization drug requests with the prescription to a VA pharmacy. Providers can submit prescriptions using electronic prescribing or fax, or the veteran can hand-deliver the prescription to the VA pharmacy; however, documentation must be submitted by standard or electronic fax. The VA pharmacy will determine if a request is approved and dispense the drug as appropriate or may deny the request if it doesn't meet the formulary requirements or if medical documentation is not received from the community provider.

Roles and Responsibilities

Three lines of authority, each headed by a different assistant under secretary for health, work within VHA on the special-authorization drug process. Each line of authority has its own organizational structure and different responsibilities.

An assistant under secretary for health oversees the Office of Patient Care Services. PBM reports to Patient Care Services. VHA Directive 1108.08 states that PBM provides oversight and monitoring of formulary drugs and drug-related supplies to make sure these items are available at VA medical facilities.[36]

An assistant under secretary for health oversees the Office of Operations. VISNs and medical facilities are under its authority. According to VHA Directive 1108.08, VA medical facility directors manage pharmacy operations and monitor implementation of, and compliance with, the formulary management process.[37] The directive also states that VA medical facility pharmacy chiefs should review and approve or otherwise decide (for example, discontinue or reject) routine special-authorization drug requests within a standard time frame.[38] According to VHA Directive 1108.07, concerns about community providers who are unwilling to conform to VA's formulary process should be reported to the VISN or facility community care staff, who can then submit these reports directly to the TPA or to the Office of Integrated Veteran Care (IVC) for action.[39]

[36] VHA Directive 1108.08, sec. 5.e.

[37] VHA Directive 1108.08, sec. 5.j.3.

[38] VHA Directive 1108.08, sec. 5.k.2.

[39] VHA Directive 1108.07, app. C, sec. 1; Community Care Network Pharmacy, "VA PBM Frequently Asked Questions (FAQ)," November 6, 2020. The FAQ notes the direct-to-TPA option versus the IVC option. Each TPA has a different reporting form, as discussed later in the report.

An assistant under secretary for health oversees IVC, which oversees access to care, including community care. IVC is responsible for oversight of the TPAs, who in turn are contractually required to make sure their community providers comply with the formulary requirements.

Figure 4 breaks down the three lines of authority related to processing special-authorization drugs.

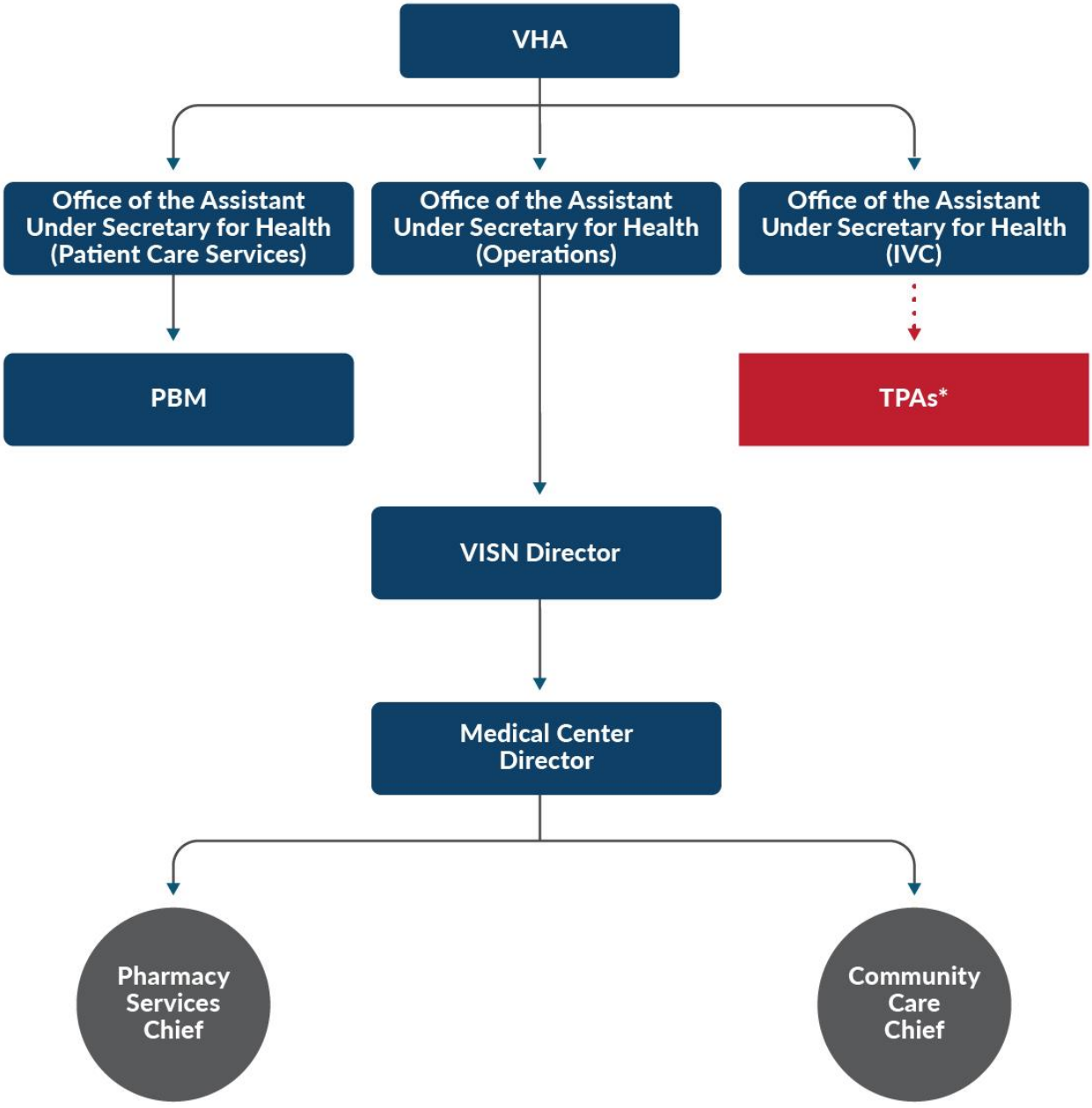

Figure 4. *VHA organizational structure concerning special-authorization drug prescribing.*

Source: VA OIG analysis of VHA organizational charts and VHA Directive 1108.08.

** TPAs are set off in red to reflect that they are private companies. TPAs are bound by the terms and conditions of their CCN contracts.*

Results and Recommendations

Finding: IVC Did Not Ensure TPAs Enforced Requirements for Community Providers' Prescribing of Special-Authorization Drugs, Increasing Workloads for VA Pharmacies and Veteran Wait Times

The OIG determined that IVC's oversight of the TPAs did not ensure that community providers prescribed special-authorization drugs in accordance with VA guidance. Specifically, VA pharmacists rarely received justifications for special-authorization drugs when community providers submitted the initial prescription, in part because the electronic prescription system lacked the functionality to include required documentation. Also, the TPAs trained less than 2 percent of community providers on VA's national formulary procedures. As a result, community care prescription processing often exceeded VHA's standard of four days, and veterans waited an average of about 11 days for their prescriptions to be processed. The risks to veterans from extended wait times depend on the veteran's health conditions and the use of the prescribed drug.[40]

VA pharmacists reported experiencing ongoing staffing challenges and had community care prescription backlogs because the increased number of those prescriptions required additional processing time. The extent of these issues went undetected because PBM did not have reliable data on prescription processing times due to how VA pharmacists documented prescription receipt dates. This meant receipt dates were not always recorded when prescriptions were first received.

The deficiencies the audit team identified persisted in part because of ineffective oversight at multiple levels of VA—from IVC to local facility pharmacies and community care offices. As a result, VA did not hold the TPAs accountable for making certain that community providers followed procedures when prescribing special-authorization drugs. Furthermore, although the two TPAs developed and made training available to community providers, neither required providers to complete it. As a result of the identified weaknesses detailed in the following sections, the OIG questioned about $200.2 million in prescription costs that lacked justification from community providers.[41]

Unless VA strengthens its controls and CCN contract oversight, it cannot adequately monitor TPA compliance with current and future contract requirements related to overseeing community providers' prescribing practices that increase veterans' risk of harm.

[40] VA OIG, *Care Concerns and Failure to Coordinate Community Care for a Patient at the VA Southern Nevada Healthcare System in Las Vegas*, Report No. 22-02113-75, February 15, 2024.

[41] See appendix C for more details on questioned costs.

The following determinations support the OIG's finding:

- Community providers rarely submitted justifications for special-authorization drug requests with the initial prescription largely because of electronic system deficiencies and untrained providers, leading to about $200.2 million in questioned costs.
- VA pharmacies experienced community care prescription backlogs, due in part to staffing and other challenges.
- PBM data on processing times for special-authorization drug requests were unreliable and masked wait times because of inconsistent tracking of the date of receipt.
- Veteran wait times for completed community care prescription processing averaged 11 days from VA pharmacies' receiving the prescription, largely attributable to missing community care documentation.
- IVC and VA pharmacies provided inadequate oversight for VHA to hold the TPAs accountable for noncompliance with CCN contract requirements.
- VA pharmacists canceled, rejected, or removed many community care prescriptions that were invalid, duplicated, or incomplete.

What the OIG Did

The audit team identified special-authorization drug requests from community providers processed at VA medical facilities from May 2022 through April 2023. This population included about 97,200 prescriptions that community providers submitted to VA pharmacies that VA pharmacists then processed. The team analyzed a statistical sample (stratified random sample) of 117 prescriptions to assess the timeliness of prescription processing and whether the required justifications from community providers were included.

Two electronic surveys were conducted, one in July and one in August 2023. The first was directed to 138 VA medical facility pharmacy chiefs to determine the frequency of necessary follow-up with community providers related to unsupported special-authorization drug requests and how this process affected the timeliness of filling prescriptions. The second survey was sent to 137 VA medical facility community care chiefs to determine the extent to which local

community care staff interacted with pharmacy staff to address providers who are not responsive to VA pharmacy requests for justification of special-authorization drugs.[42]

The team also interviewed officials from PBM, IVC, the TPAs, and medical facilities who are responsible for overseeing or processing these prescriptions; visited nine VA medical facilities to observe their processes and procedures for receiving and reviewing prescriptions from community providers for special-authorization drugs; analyzed PBM guidance and web-based dashboards for tracking community care prescriptions; and discussed the results of the sample review with PBM officials to make them aware of identified issues.

The OIG analyzed a second statistical sample from a population of about 1.3 million prescriptions submitted by community providers from February 1, 2022, through April 30, 2023, that VA pharmacists canceled, rejected, or removed. These prescriptions included formulary, nonformulary, and prior-authorization drugs. Prescriptions for formulary drugs were included in this analysis because they could not be readily removed from the population. However, the OIG believes that this analysis is important because it informs VHA of the factors that influence why prescriptions written by community providers are not filled and the resulting risks to veterans. The team analyzed a statistical sample (stratified random sample) of 51 prescriptions to determine why VA pharmacists did not process them. The results of this analysis are discussed in the section "VA Pharmacists Canceled, Rejected, or Removed Community Care Prescriptions That Were Invalid, Duplicated, or Incomplete."

Community Providers Rarely Submitted Justifications for Special-Authorization Drug Requests with the Initial Prescription

From the statistical sample review of 117 special-authorization drug requests from community providers to VA medical facilities for processing from May 2022 through April 2023, the OIG estimated that VA pharmacists did not receive medical justification with the initial prescription for more than 99 percent (96,500 of 97,200 prescriptions) of those requests.

The audit team analyzed the justification source for all 117 requests in the sample and estimated that of the 97,200 prescriptions, about 22 percent (or 21,500) were ultimately justified by the community provider.[43] Another 38 percent (37,100) were justified by VA pharmacists researching patients' medical records. The remaining 40 percent (38,600) were processed

[42] The team received a 100 percent response rate for both surveys. However, respondents were not required to answer all questions. Consequently, the numerator and denominator used to calculate the percentage of responses to each question may differ and are detailed in the report. Some pharmacy chiefs and facility community care chiefs oversee multiple medical centers; as a result, the number of survey takers is not a one-to-one ratio of pharmacy chiefs to facility community care chiefs.

[43] Of the 117 requests in the sample, one prescription that was justified by the community provider came in with the medical justification with the initial prescription and is included in this 22 percent.

without justification. Table 1 details the estimates from the team's analysis of the justifications for the 117 sampled prescriptions.

Table 1. Special-Authorization Community Care Prescription Justification

Evidence of justification before processing	Justification source	Number of prescriptions processed
Yes	Community provider	21,500 (22%)
Yes	VA pharmacist	37,100 (38%)
No	None identified by provider or pharmacist	38,600 (40%)
		Total: 97,200 (100%)

Source: VA OIG estimates of special-authorization community care prescriptions based on sample results.

Note: The number of prescriptions is estimated based on the sample and rounded.

VA pharmacists can approve special-authorization drugs if certain criteria are met. These include when

- the veteran has a documented adverse reaction to a formulary drug,
- the veteran has a documented inadequate therapeutic response to a formulary drug, or
- no formulary alternative exists.

TPA provider guidance states that community providers must submit medical documentation with the prescription to the VA pharmacy when prescribing these drugs.[44] For some special-authorization drugs, PBM also developed criteria for use, based on available clinical evidence related to a drug's safety and efficacy, that describe the patient populations that would most likely benefit from a particular drug. According to the deputy chief consultant for formulary management, when criteria for use exists for a special-authorization drug, it is the preferred justification.

Of the 97,200 community care prescriptions, about 46,800 required criteria for use. However, the audit team estimated about 77 percent of these prescriptions (about 35,900) did not have this documentation. When community providers do not respond to requests for medical justification, VA pharmacists have to use their professional judgment whether to approve the request without the required justification or deny it, which can also result in frustrating delays for veterans.

[44] United Healthcare Optum, *VA CCN Provider Manual*, April 2023; TriWest Healthcare Alliance, *CCN Provider Handbook*, October 2023.

Ninety-four percent of the 138 pharmacy chiefs surveyed reported that obtaining justification for special-authorization drugs is a major challenge. On the audit team's survey, one chief said, "Many of the community care providers we receive prior authorization drug requests from lack knowledge and understanding of the VHA National Formulary."

Issuing prescriptions without obtaining justification for special-authorization drugs also occurred because community providers did not have an effective standardized and automated mechanism for seamlessly prescribing these drugs for VA pharmacy processing, and TPAs did not ensure community providers completed relevant training. These weaknesses, discussed in the sections that follow, led to questioned costs of about $200.2 million related to the prescriptions VA pharmacists processed without any justification.

Ineffective Electronic Prescription System

A PBM official reported that the system VA pharmacies use to accept electronic prescriptions from community providers does not have the same capabilities as the in-house system VA providers use to electronically prescribe drugs. They further explained to the audit team that, when community providers prescribe a drug for a veteran, they cannot use their system to automatically determine if the drug requires additional justification or to attach required documentation to the prescription. Community providers must refer to a PBM website to determine formulary designations and then submit justifications for special-authorization drugs separately through a standard or electronic fax. In contrast, the PBM official confirmed that when VA providers prescribe a drug for a veteran using the VA electronic systems, they are alerted if a justification is needed and can submit one in real time with the request.

In addition, VA pharmacists confirmed they can communicate with in-house providers electronically if they have questions about a prescription, but not with community providers. Instead, VA pharmacists stated they rely heavily on telephone calls with community providers to resolve any questions. VA pharmacists also reported to the team that it is difficult to get in touch with community providers. They typically must leave messages, and providers do not always call back.

Although the community providers' system lacks the functionality for automatic checks, PBM does offer a public website for VA and non-VA users, such as community providers, to search for formulary information. The website is meant to allow users to enter a drug name in a search field to identify VA formulary drugs and special-authorization drugs. A PBM official reported being aware that the current electronic prescription software lacks the capability to allow community providers to transmit electronic prescriptions with medical documentation simultaneously. The official also stated that another electronic prescription software, called SureScripts, is available that could address some of these challenges. With SureScripts, PBM could upload the VA formulary to allow community providers to identify formulary drugs without having to check a secondary website. The audit team did not evaluate the capabilities

reported about this replacement software because VA pharmacies were not using it at the time of the audit.

Despite system challenges, VA's CCN contracts with the TPAs to provide administrative and operational support require that the TPAs make sure that community providers' prescribing practices conform with VA guidance.

Recommendation 1 is for IVC and PBM to improve community provider compliance with prescribing special-authorization drugs, including considering system capabilities to support simultaneous transmittals of justifications with prescriptions and enhance communications between VA pharmacists and community providers.

Failure of TPAs to Ensure Provider Training and Compliance

The CCN contracts with TPAs state that "the Contractor [TPA] must always instruct and mandate its CCN providers [community providers] that prescriptions must always be prescribed in accordance with VA's national formulary, which includes provisions for requesting non-formulary drugs." The contracts also state, "The Contractor must develop and conduct an Annual Training Program Curriculum that must include training for CCN [community] providers." This mandated training includes segments related to using VA's formulary. This must include web-based and virtual trainings as well as written training materials. Furthermore, the TPAs' credentialing process requires community providers to sign provider contracts with the TPAs. These contracts state, "Provider [the community entity, such as a medical center or practice] and its affiliated Individual [community] Providers agree to be bound by, and comply with, the Provider Handbook applicable to each Program under which Provider and its affiliated Individual Providers provide Covered Services to a Beneficiary."

The audit team confirmed through interviews and a review of materials that the TPAs developed training that included information for community providers on the formulary and required processes for prescribing special-authorization drugs. In addition, TPAs also made available the handbooks and manuals that mandated community providers submit medical justifications with prescriptions to the VA pharmacy, as well as instructions for accessing the formulary website.

However, the TPAs reported to the audit team that only 2 percent of community providers, or about 24,200 of the more than 1.2 million providers in the TPAs' networks, have completed training modules since 2020. The TPAs reported to the team that they relied on the provider credentialing process and the individual provider contracts to make community providers aware of their contractual obligations to use the formulary. However, the team reviewed some provider contracts and did not find the details on the process in the contracts. If TPAs rely only on credentialing and provider contracts to convey the formulary requirements, neither VHA nor the TPAs have assurance that individual providers are aware of the procedures for prescribing special-authorization drugs that are described in the training and manuals.

The TPAs also reported that VA personnel can request additional education for individual providers based on perceived needs (for example, when a provider habitually does not comply with CCN contract requirements). These requests can come from IVC, PBM, and VA medical facilities through the TPA call center. At the time of the audit, TPAs had not received any requests from VA personnel to educate community providers on requirements for prescribing special-authorization drugs. In addition, TPAs also reported that they do not communicate provider training completion rates to VA, and to their knowledge, VA personnel never requested them.

Recommendation 2 tasks IVC to train community providers on the VA's formulary and implement a process to improve tracking of training completion and community providers' compliance with VA guidance on submitting prescriptions for special-authorization drugs.

Questioned Costs

The OIG questioned about $200.2 million in costs related to the lack of justifications for special-authorization drug requests from community providers. Special-authorization prescriptions dispensed to veterans without proper justification were valued at about $45.3 million—or about $3.8 million per month—from May 2022 through April 2023. The remaining $154.9 million is the OIG's estimate of what VA will pay to issue special-authorization prescriptions to veterans without justification from May 2023 through September 2026 (the same period that covers the contract options for all five regional CCN contracts with both TPAs). VHA continues to be at risk for filling community care prescriptions without proper justification until corrective action is taken, which could involve evaluating the terms of its current and future CCN contracts with TPAs. VHA periodically reevaluates the terms of the CCN contracts, and at the time of the audit, the next generation of contracts—which VHA was still developing—did not have an anticipated award date. As a result, the audit team calculated questioned costs by multiplying its per month estimate (about $3.8 million) by 53 months, covering May 2022 through September 2026, which includes the option years that cover the same time for all five current CCN contracts with the TPAs. This projection assumes no changes are made to the terms of the current CCN contracts to improve community providers' compliance with VA requirements when these drugs are prescribed. See appendix C for more details on questioned costs.

VA Pharmacies Experienced Community Care Prescription Backlogs

Although VA pharmacies took steps to develop and implement local processes to monitor special-authorization drug requests (with varying levels of success) and request medical justification when needed, they faced significant prescription backlogs from community providers. As stated earlier, the number of community care prescriptions has increased by more than about 131 percent just from FY 2020 through FY 2023, contributing to pharmacy workloads. The nine VA pharmacies the team visited all had a backlog of community care prescriptions—with an average of about 111 prescriptions pending five days or longer—around

the time of the visits. Each facility reported that its pharmacy chief took actions to increase pharmacy staffing or augment staffing with other available resources.

Local Processes to Request Justification

Veterans are at greater risk for delays in receiving prescriptions when VA pharmacists must constantly follow up with community providers. To help ensure requests are not lost and to minimize wait times, medical facilities the team visited implemented local processes such as standard operating procedures or filing systems to track unsupported prescription requests while they waited for a response from the community provider.

At all nine VA pharmacies, the team observed pharmacists implementing tracking for community care prescriptions awaiting decisions. These processes varied greatly in organization and complexity. They included

- centralized processing of special-authorization drugs, such as a pilot program in VISN 21 in which five medical centers routed special-authorization drug requests to a VISN team for approval or denial;
- local computer lists maintained in the electronic prescription system's holding queues, Microsoft Teams channel groups, and shared folders; and
- paper filing systems.

In addition, to help reduce the need for VA pharmacists to follow up with community providers, some VA pharmacies conducted outreach to educate providers who regularly prescribe special-authorization drugs. For example, one facility developed a promotional bulletin that included information on the formulary and how to search it to determine a drug's designation. Another pharmacy took proactive steps to alert gastrointestinal community providers of the preferred formulary options for colonoscopy preparation drugs and listed the drugs that required prior authorization.

VHA Staffing Challenges

Seventy-five of 138 pharmacy chiefs (54 percent) reported on the OIG survey that pharmacists processed community care prescriptions on a rotating basis or as a secondary duty. According to VHA guidance, facilities must have adequate staff in place to manage processes related to prescribing formulary and nonformulary drugs; however, VHA lacks a pharmacy staffing model that accounts for the increase in processing prescriptions from community providers.[45] Multiple pharmacy chiefs attributed the inability to meet the 96-hour processing standard to staffing issues. Pharmacy chiefs' comments on the OIG's survey included the following:

[45] The requirement for adequate staffing is in VHA Directive 1108.07, sec. 7.b.7.

- "Labor intensive process for pharmacy so there is a need for significant staff growth and more community outreach and education."
- "We are supposed to enter prior authorization drug request consults in the medical record but currently we do not as that takes an incredibly long time to enter and process via that pathway and the pharmacist involved with this is barely keeping up with the workload. We have added a technician to help and plan to add another pharmacist to assist."
- "Increased volume of community care prescriptions can impact workload and staffing needs as more time is required to address them. There are varying levels of understanding by IVC staff regarding community care prescriptions and there's some knowledge deficit that makes it difficult for them to support Pharmacy when issues arise."

Some medical facilities increased staffing or leveraged other resources to help their pharmacists manage the community care prescription workload. For example, the Kansas City VA Medical Center in Missouri established a special support agreement with PBM's Virtual Pharmacy Services at a cost not to exceed $471,000 per year so that facility pharmacists did not have to perform the administrative checks related to prescription processing—including patient profile review for allergies, potential adverse reactions, drug interactions, and appropriate dosage for age and condition. Furthermore, in FY 2023, the OIG analyzed medical facility staffing shortages and reported that pharmacists and pharmacy technicians ranked in the top 25 occupation groups with severe shortages.[46] The team is not making a recommendation regarding staffing because another OIG report in 2021 included a recommendation, which remains unimplemented, to develop staffing models; in response, VHA set a target date of September 2025 to conduct a gap analysis of all developed and missing staffing models, including pharmacy.[47] VHA continues to work toward defining the roles, responsibilities, and timelines for developing the missing medical center staffing models.

The OIG also received hotline complaints reporting staffing challenges and their effects on VA pharmacists' ability to process community care prescriptions within the 96-hour standard. The following example reflects the type of hotline complaint the OIG received during the audit.

[46] VA OIG, *OIG Determination of Veterans Health Administration's Severe Occupational Staffing Shortages Fiscal Year 2023*, Report No. 23-00659-186, August 22, 2023.

[47] VA OIG, *Review of Veterans Health Administration Staffing Models*, Report No. 20-01508-214, August 19, 2021. The OIG recommended that the under secretary for health "coordinate with VA to evaluate the status of, and provide a timeline for, the development, validation, and implementation of Veterans Health Administration staffing models for all occupations."

Example 1

Two complainants at the VA medical facility in Leeds, Massachusetts, alleged the facility had insufficient pharmacy personnel to process community care prescriptions, causing a backlog of community care prescriptions and negatively affecting the quality of care for veterans.

PBM Data on Special-Authorization Drug Request Processing Times Were Unreliable and Masked Wait Times

PBM developed a dashboard that tracks approval processing times for nonformulary drugs. However, this dashboard does not track approval processing times for prior-authorization drug requests, which are subject to the same processing as nonformulary requests. This discrepancy results in incomplete data. Furthermore, VA pharmacists inconsistently documented prescription receipt dates in the medical system—most documented the date they received supporting documentation from the community provider instead of the date they initially received the prescription, which creates inaccurate data on processing times in PBM's dashboard and masks the actual time veterans' wait for these prescriptions to be processed.

Data on Processing Times Were Incomplete and Inaccurate

Although PBM's dashboard tracks approval processing times for nonformulary requests, the audit team estimated, based on its sample analysis, that VA pharmacists did not create a drug consult for about 7,500 of 40,200 prescriptions for nonformulary drug requests (19 percent). As a result, the dashboard understated the actual number of nonformulary requests VA pharmacies received.[48]

Not tracking approval processing times for prior-authorization drug requests also contributes to incomplete data on the dashboard. The audit team found that VA pharmacies experienced challenges when processing community care prescriptions for drugs that require prior authorization, yet incomplete data make it difficult to detect that these requests were affected in the same ways as nonformulary drugs.

Based on the sample review, most VA pharmacists documented prescription receipt dates in the veteran's medical record as the date they received supporting documentation from the community provider, instead of the date they initially received the prescription. This created inaccurate processing times in PBM's dashboard because the more common practice does not

[48] A drug consult is "an administrative process to adjudicate medication requests for all non-formulary medications and other VHA medical facility locally determined medication requests to aid workflow." VA pharmacists use drug consults to process nonformulary drug requests, and PBM uses consult information to calculate processing times of these requests. Pharmacy Benefits Management Services, *Business Rules for Completing Drug Consults in CPRS*, January 2024.

capture the time the pharmacist waits for supporting documentation to approve the request. While the dashboard tracks timeliness of nonformulary requests based on VA consult data (the recorded consult start and end dates), it does not include the time VA pharmacists spent requesting justification documents from community providers.

The audit team's sample analysis shows that VA pharmacies were not able to process an estimated 40 percent of veterans' community care prescriptions for special-authorization drugs within 96 hours of receiving the prescription, per the standard, whereas PBM's dashboard showed a much smaller number for the same review period: only about 5 percent of nonformulary prescriptions went unprocessed within the 96-hour standard.

According to its guidance, PBM established the dashboard to accomplish several key goals:

- Standardize the drug consult adjudication process across facilities to ensure that veterans receive timely (less than 96 hours) approval of nonformulary prescription requests entered through the nonformulary process.
- Provide a tool and process to identify issues related to data entry, including incorrectly entered codes for community care prescriptions.
- Provide a tool for facilities to review nonformulary requests pending for more than 48 hours, adding an additional opportunity to review and process all requests within the 96-hour standard.
- Provide accurate and complete data on nonformulary drug requests, approval rates, and compliance with the drug approval process, and inform the continued development of formulary policy.[49]

The audit team also identified through site interviews and the sample analysis that VA pharmacists were not consistently documenting prescription receipt dates for special-authorization drug requests in the veterans' medical records until after they received all necessary justifications from the community providers.

Example 2

A pharmacist at the VA medical facility in South Carolina received a prescription on February 1, 2023, for a drug used to treat moderate to severe skin disease. The pharmacist did not receive justification for this nonformulary prescription until February 15, 2023, after attempting to contact the community provider twice. The VA pharmacist entered and approved the prescription request into the veteran's medical record on February 17, 2023. In PBM's data, this prescription reflects a processing time of one day since it is based on the February 17, 2023, date.

[49] Pharmacy Benefits Management Services, *Business Rules for Completing Drug Consults in CPRS*.

Calculating the total processing time using the date the VA pharmacy received the prescription, the audit team determined that it took 16 days.

As a result, PBM and IVC were unaware of the magnitude of the challenges VA pharmacists experienced in processing community care special-authorization requests and missed opportunities to hold the TPAs accountable for ensuring community providers prescribing these drugs complied with VHA requirements including submitting justifications or authorizations with the initial drug request.

Recommendation 3 tasks PBM with updating the dashboard to more accurately capture special-authorization drug request processing times and providing IVC access to this information for contract management purposes.

Veteran Wait Times for Completed Community Care Prescription Processing Averaged 11 Days

From the sample review, the OIG estimates that 39,100 of the 97,200 special-authorization drug requests (about 40 percent) took longer to process than the VA standard of 96 hours (four days). On average, veterans waited 11 days for their prescriptions when VA pharmacies experienced delays in receiving documentation from community providers. Figure 5 illustrates the distribution of the prescriptions that VA pharmacies could not process within the 96-hour standard. It shows that nearly half of the prescriptions were processed between five and seven days, largely due to delays caused by trying to get the necessary justifications that should have been attached to the initial drug request by the community provider.

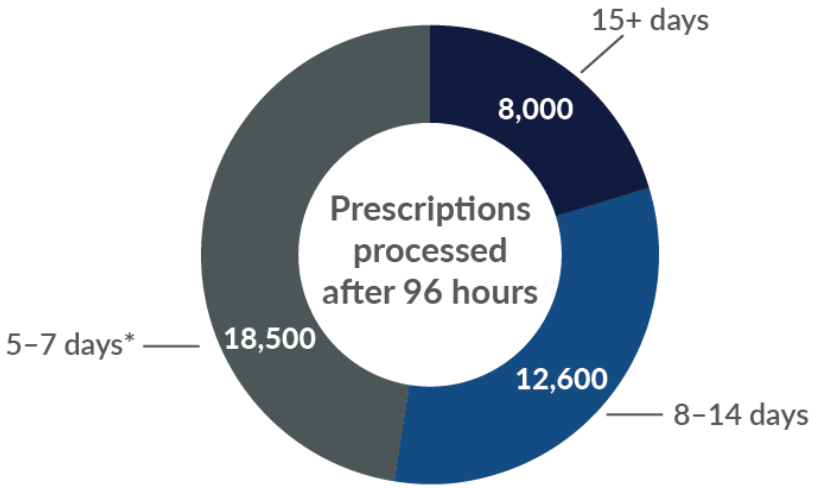

Figure 5. *Distribution of prescriptions that exceeded the 96-hour processing standard.*

Source: VA OIG analysis of sampled prescriptions and statistician estimates.

** Any approval on the fourth day was considered as having met the processing standard. See appendix A for processing time calculations.*

The following examples detail instances when veterans experienced excessive wait times to receive prescriptions for special-authorization drugs.

Example 3

A veteran at the VA medical center in Phoenix, Arizona, waited seven days to receive approval for a drug used to manage Parkinson disease symptoms. After receiving the initial prescription, the VA pharmacist had to contact the community provider to obtain the medical justification to fill the prescription—a process that took five days after the date the prescription was written.

Example 4

A veteran at the VA medical center in Sheridan, Wyoming, waited 13 days to receive approval for a drug used to delay progression of symptoms of amyotrophic lateral sclerosis (ALS). The pharmacist contacted the community provider two times before the provider responded with the medical justification to fill the prescription.

Example 5

A veteran at a VA medical center in Loma Linda, California, waited 31 days to receive approval for a drug used to treat adults with certain types of multiple myeloma (blood cancer). The pharmacist contacted the community provider three times before obtaining the medical justification to fill the prescription.

The audit team further estimated from its statistical sample that for roughly 58,100 of 97,200 prescriptions (about 60 percent) processed within 96 hours, approximately 45,100 were recorded as filled and 13,000 were not filled for the veteran.[50] Further, an estimated 15,400 of the 45,100 filled prescriptions (34 percent) still lacked proper justifications despite their approval. The 13,000 prescriptions were not filled for reasons including VA's inability to obtain required justification from the community provider, or the community provider changed to a formulary alternative after coordinating with a VA pharmacist. Ultimately, veterans who received special-authorization prescriptions from community providers during the audit review period waited an average of 11 days from the time the prescription was received for processing to be completed, instead of within the four-day standard. The incomplete and inconsistent information in the data dashboard used by oversight personnel masked these wait times and the challenges VA pharmacists experienced.

Recommendation 4 directs PBM to require that VA pharmacy personnel document community care prescriptions for special-authorization drugs in the veteran's medical record when the

[50] The population of 97,200 included prescriptions that VA pharmacists canceled, rejected, or removed due to lack of medical documentation from the community provider.

pharmacy receives the prescription and clarify that the 96-hour processing time is a requirement for these types of drug requests.

IVC and VA Pharmacies Provided Inadequate Oversight for VHA to Hold TPAs Accountable for Noncompliance with CCN Contract Requirements

Issues the audit team identified (such as special-authorization drug requests without required justification or documentation, community care prescription backlogs, increased workloads for pharmacy personnel with limited staffing resources, and excessive veteran wait times to receive prescriptions) persisted in part because of ineffective oversight across multiple levels of VHA—from IVC to VA pharmacies and local-level community care offices.

TPAs Lack Data and CCN Contracts Omit Surveillance Metrics on Routine Prescriptions

IVC's oversight of the TPAs does not ensure that community providers prescribe special-authorization drugs in accordance with VHA guidance. Specifically, IVC lacks a reliable mechanism to evaluate community providers' processes for prescribing these drugs or to hold the TPAs accountable for ensuring VA pharmacists received all the necessary information to process these prescriptions within 96 hours of the initial request.[51]

Each CCN contract has a Quality Assurance Surveillance Plan to evaluate the contractor's performance on specific objectives.[52] However, the audit team identified that these plans for both TPAs only include metrics to track performance related to urgent and emergent prescription requests, which veterans fill at local participating network pharmacies, whereas routine prescriptions must be filled at a VA pharmacy. As a TPA representative explained, TPA staff do not have access to data related to routine prescriptions because VA is the owner of all associated information. A representative from the other TPA agreed, stating that it did not develop performance objectives, metrics, and review procedures pertaining to management of routine prescriptions for its community providers because it did not have access to the necessary data.

In addition, a senior PBM official was unaware of any formal process to establish oversight of community providers' prescribing practices. According to this official, PBM monitors the rate at which special-authorization drugs are prescribed—in-house compared to community care—and

[51] Government Accountability Office, *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014. For more on internal controls, see appendix A.

[52] The Quality Assurance Surveillance Plan is the same for each of the CCN contracts and identifies performance objectives, metrics, and requirements for measuring performance. The performance scores are calculated by region and are based on four healthcare service areas: primary care, general care, complementary and integrative care, and dental care.

the cost difference between special-authorization and formulary drugs. The PBM official also reported that IVC does not verify TPA statements that community providers understand and comply with VA's formulary and related processes.

While a process does exist for VA pharmacists or community care office staff to report issues with prescription processing, IVC has not communicated to them the importance of using the process to draw attention to the challenges VA pharmacists experience.

Recommendation 5 directs PBM to routinely remind pharmacists that they are responsible for reporting community providers who are not including justifications with special-authorization drug requests to the local community care office. This will help IVC hold TPAs accountable for ensuring VA pharmacists have the necessary information to process community care prescriptions within 96 hours.

Coordination Was Lacking to Address Providers Who Are Unresponsive to Requests for Justifications and Other Required Documentation

The community care office at each facility serves as the liaison between VHA and community providers.[53] According to VHA guidance, VA pharmacists should report community providers who are not complying with the formulary processes to the facility or VISN community care office.[54] Ninety-nine of the 138 pharmacy chiefs surveyed (72 percent) reported that their facility community care office does not have a role in assisting with the processing of special-authorization drug requests from community care. This may be due in part, however, to the limited reporting by pharmacists to their community care office regarding noncompliant community providers because of the pharmacy staffing challenges, backlog, and workload increases detailed earlier in this report.

When pharmacists do not report the problem to their facility or VISN community care office, IVC cannot use its available options to hold the TPA accountable. Depending on the TPA, VA employees, including pharmacists or community care office staff, can submit a Potential Quality Issue Referral report or a Health Care Quality Concern report directly to the TPA for review; alternatively, they can submit these reports to IVC for action.[55] VA also has an internal process to report potential safety concerns using the Joint Patient Safety Reporting tool. A pharmacy

[53] Community Care Network Pharmacy, "VA PBM Frequently Asked Questions" states, "If a CCN Provider does not respond to legitimate VA Pharmacy inquiries regarding prescriptions they have ordered, they should be reported to the local OCC office [facility community care office] for referral to the TPA."

[54] VHA Directive 1108.07, app. C.

[55] United Healthcare Optum, VA Community Care Network Potential Quality Issue (PQI) Referral Form, https://vacommunitycare.com/9983cdfc-f1b5-48f8-8af5-95c13fe54d51 (Optum report form); TriWest Healthcare Alliance, Health Care Quality Concern Form, https://www.triwest.com/globalassets/vapc3-veteran-files/forms/health-care-quality-concern-form.pdf.

representative stated that VISN 21 facilities use this tool for any potential safety concerns, including delayed prescriptions, since safety risks are possible if veterans do not get medications on time.[56] They also have a community care representative on their processing team who would be aware of these issues and could submit the appropriate reporting form to the TPA.

There were indicators that coordinating with community care offices can be valuable. For example, during the audit team's visit to the W.G. (Bill) Hefner VA Medical Center in Salisbury, North Carolina, the pharmacy chief asked to attend the team's interview with the facility community care chief to establish a working relationship between the two offices. During that meeting, the chiefs agreed to coordinate to resolve situations when community providers do not respond promptly to requests for justification of special-authorization drug prescriptions.

When facility community care officials are unaware of problems with timely justifications, they cannot take action to notify the TPAs, who are responsible for ensuring community providers prescribe drugs and submit proper documentation in accordance with VHA requirements.

Recommendation 6 directs facility community care offices to work with pharmacy personnel to submit Potential Quality Issue Referral reports or Health Care Quality Concern reports to TPAs when community providers are not compliant with VA's documentation requirements for special-authorization drugs.

VA Pharmacists Canceled, Rejected, or Removed Many Community Care Prescriptions That Were Invalid, Duplicated, or Incomplete

In the course of the audit, the team identified a large number of prescriptions (formulary and special-authorization drugs) from community providers that VA pharmacists canceled, rejected, or removed. Accordingly, the team conducted limited testing using a second sample to determine why VA pharmacists did not process the drugs. This sample identified about 1.3 million prescriptions for formulary, nonformulary, and prior-authorization drugs that community providers submitted but VA pharmacists canceled, rejected, or removed from February 1, 2022, through April 30, 2023. The team analyzed a statistical sample of 51 prescriptions to determine why a VA pharmacist did not process them.[57]

The audit team estimated that VA pharmacists canceled, rejected, or removed approximately 705,000 prescriptions during the sample time frame because the veteran lacked a referral to receive services from the community provider, making the prescription invalid. VA pharmacists reported spending hours trying to validate prescriptions that ultimately could not be filled because they lacked community provider authorizations. Other reasons these prescriptions went

[56] VA OIG, *Care Concerns and Failure to Coordinate Community Care for a Patient at the VA Southern Nevada Healthcare System in Las Vegas.*

[57] See appendix B for additional information on statistical sample design.

unprocessed were the identification of duplicate prescriptions, the prescription by community providers was changed to alternative drugs, or the lack of medical justification.

According to the VHA directive on formulary management, if the community provider does not provide justification for special-authorization drugs, the VA pharmacist will discontinue the request. The community provider may submit a new request once the necessary information is available.[58] However, from interviews with VA pharmacists, the team determined that most pharmacists still tried to fill prescriptions, even past the 96-hour standard, and only canceled prescriptions as a last resort.

The audit team observed that VA pharmacists did not consistently include reasons for canceling, rejecting, or removing prescriptions, nor were they required to do so, even though the electronic prescription system has this capability. Further, the guidance does not say who should notify veterans when these actions are taken on their prescriptions; rather the guidance only requires VA to notify the requestor—in other words, the community provider—of the decision.[59] PBM could use data on these unfilled prescriptions to better inform decisions related to community provider education and outreach, staffing, and other efforts to minimize processing delays and unproductive workloads. Considering the estimated magnitude of community provider prescriptions that VA pharmacists did not approve, recommendation 7 directs PBM to develop standardized electronic system requirements for how VA pharmacists code community care prescription requests that are canceled, rejected, or removed to help determine if further corrective action is required.

Conclusion

Based on the OIG's analysis of statistical samples during the audit review period, veterans who received prescriptions from community providers for nonformulary and prior-authorization drugs waited an average of about 11 days from the providers' initial request to the VA pharmacy to the completion of processing—exceeding VHA's 96-hour standard. Oversight officials were not aware of these wait times due to unreliable data in the PBM dashboard, in part because pharmacy personnel used inconsistent start times (some using the date of the prescription's receipt and others designating the date documentation was received).

In interviews, some VA pharmacists said they considered the lack of responsiveness from community providers to their requests for missing justifications for the prescribed drugs to constitute a patient safety event because of the risk of adverse impacts on veterans' health or treatment. VA pharmacies took their own steps to develop and implement local processes. These steps included making repeated requests for missing documentation, researching VA medical records, and then reviewing and tracking special-authorization prescriptions through completion.

[58] VHA Directive 1108.08, secs. 6.m.1.c and 6.n.5.c.

[59] VHA Directive 1108.08, secs. 6.m.1.c and 6.n.5.c.

Doing so added to VA pharmacy workloads and prescription backlogs, given large increases in the number of community care prescriptions in recent years and already strained pharmacy staffing resources.

Community providers were also hampered by an electronic prescription system that did not alert them when they prescribed a drug not listed on the VA formulary (requiring those providers to look it up on a separate website). The system also lacked the functionality for community providers to simultaneously send the required justification for nonformulary drugs with the prescription to the VA pharmacy. Prior authorizations and justifications had to be sent separately by fax.

Monitoring of the community providers' prescribing practices was insufficient for IVC to be fully aware of the extent of the identified problems and system deficiencies that impeded provider compliance. Insufficient oversight also prevented IVC from holding the TPAs accountable to contractual obligations or requesting additional training for community providers. TPAs also lacked access to data or requests from VHA on the extent of the problem that might have triggered corrective action.

The weaknesses the OIG has highlighted in this report and related recommendations are meant to help PBM and IVC better determine the requirements for the next generation of CCN contracts that position TPAs to provide more effective monitoring. Those requirements should address community provider compliance with VHA standards for special-authorization prescribing to help ensure that veterans' wait times for prescriptions is reduced and to alleviate unnecessary strain on pharmacy staffs' workloads. The OIG questioned about $200.2 million in costs that lacked evidence to support approval of the prescribed special-authorization drug.[60]

Recommendations 1–7

The OIG made the following recommendations to the under secretary for health:

1. Require the Office of Integrated Veteran Care and Pharmacy Benefits Management Services to improve community provider compliance when prescribing special-authorization drugs and being responsive to VA pharmacy inquiries. This should include consideration of electronic system capabilities to attach medical justifications, allow community providers to have real-time access to VA's formulary when prescribing drugs, and enable two-way communication between community providers and VA pharmacists electronically.
2. Task the Office of Integrated Veteran Care to train community providers on the VA formulary and implement a process to improve tracking of training completion and

[60] See appendix C for additional information on the calculation of monetary impact.

community providers' compliance with VA guidance on submitting prescriptions for special-authorization drugs.

3. Direct Pharmacy Benefits Management Services to update its dashboard to more accurately capture special-authorization drug request processing times and provide the Office of Integrated Veteran Care access to this information for contract management purposes.
4. Instruct Pharmacy Benefits Management Services to require that VA pharmacy personnel document community care prescriptions for special-authorization drugs in the veteran's medical record (in consults when applicable or medical notes) when the pharmacy receives the prescription and make clear that the 96-hour processing time is a requirement for these types of drug requests.
5. Require Pharmacy Benefits Management Services to routinely remind pharmacists that they are responsible for reporting a community provider to the medical facility's community care office when the provider does not comply with VA documentation requirements for special-authorization drug requests.
6. Charge facility community care offices to work with pharmacy personnel to report when they receive information from VA pharmacists that community providers did not comply with VA's documentation requirements for special-authorization drugs. Reporting mechanisms can include submitting Potential Quality Issue Referral reports or Health Care Quality Concern reports to third-party administrators.
7. Direct Pharmacy Benefits Management Services to standardize requirements for how VA pharmacists code drug requests from community providers in the electronic system that were canceled, rejected, or removed to help VHA determine if corrective actions need to be taken on processes, contract terms, or guidance.

VA Management Comments

The under secretary for health concurred with recommendations 4, 5, and 7; concurred in principle with recommendations 1, 2, 3, and 6; and provided an action plan for each. Appendix D includes the full text of the under secretary's comments.

To address recommendation 1, IVC and PBM will develop a plan to improve community provider accountability, compliance, and responsiveness when prescribing special-authorization drugs.

While IVC concurs with the intent of recommendation 2, VHA's response stated that "contractual requirements will take precedence." IVC will review the contract terms related to the TPAs' requirement to train community providers on prescribing special-authorization drugs. In addition, IVC intends to review the process for tracking training completion and identify ways

to improve providers' compliance with VA guidance regarding special-authorization drug prescriptions.

In response to recommendation 3, VHA noted that it is taking steps to enhance the dashboard, a process that does not depend on the next generation of CCN contracts. PBM's new "prototype business intelligence report"—a tool being developed to identify and track drugs that require additional approval—is scheduled for completion in September 2024. The report will be accessible by IVC to assess special-authorization drug request processing times and identify opportunities to improve.

VHA requested closure of recommendation 4, as PBM updated the business rules on its SharePoint site in February 2024, requiring pharmacy staff to document special-authorization drugs in the veteran's medical record when the pharmacy receives the prescription and requires a processing expectation time of 96 hours or less. PBM also presented on these requirements during a chief of pharmacy teleconference on November 1, 2023.

PBM is working to implement further updates to its business rules in response to recommendation 5, regarding pharmacists' reporting responsibilities with respect to noncompliant community providers. This information will be announced during the national pharmacy chiefs' teleconference at the end of July 2024 and, at least quarterly thereafter, will be a standing agenda reminder on these calls.

For recommendation 6, VHA will review current guidance and processes for opportunities to improve coordination between facility community care offices and pharmacy personnel and will determine the best way to report community providers that do not comply with guidance on prescribing special-authorization drugs.

To address recommendation 7, PBM agreed to standardize how VA medical facilities code electronic prescriptions that were canceled, rejected, or removed and planned to send out guidance by September 2024. Following this guidance, PBM will work with the VHA Operations Office and IVC regarding any necessary corrective actions.

OIG Response

PBM's actions to address recommendation 4—clarifying and updating its business rules requiring facility pharmacy staff to document community care special-authorization drug requests in the veteran's medical record when the pharmacy receives the prescription and to process prescriptions within 96 hours—are found to be sufficient by the OIG, which now considers this recommendation closed. VHA's proposed corrective measures for the remaining recommendations are responsive to their intent. The OIG will monitor implementation of the remaining recommendations and will close them when VHA provides sufficient evidence of progress addressing the issues identified.

Appendix A: Scope and Methodology

Scope

The audit team conducted its work from April 2023 through May 2024. The team analyzed a sample from a total of about 97,200 community care prescriptions requiring special authorization that were submitted to VA from May 2022 through April 2023. The team also statistically sampled canceled, rejected, and removed community care prescriptions from February 1, 2022, through April 30, 2023. This second population consisted of 1,329,260 electronic prescription requests.

Methodology

The audit team identified and reviewed the five Community Care Network contracts with the two third-party administrators (TPAs), applicable laws and regulations, VA policies and procedures, and processes related to providers that prescribe special-authorization drugs.

The team also statistically sampled and reviewed 117 community care prescriptions for special-authorization drugs during the review period. The first sample review included

- assessing prescription processing times by examining veterans' electronic health records to identify the prescription date and comparing it to the date the VA pharmacist completed the review,[61]
- calculating the time it took VA pharmacists to receive additional support from community providers,
- identifying the number of prescriptions that included all required documentation on first submission, and
- determining the number of prescriptions that community providers submitted that followed VA guidance.

A second statistical sample review of 51 prescriptions included identifying the reason for rejections, removals, and cancellations.

To provide context and identify causes related to these sample review findings, the team conducted in-person site visits to nine medical facilities to further assess causes for delayed

[61] For example, if the VA pharmacy received a prescription by 9 a.m. Monday and processed it on Friday at 2 p.m., four days have passed (Monday to Tuesday being one day and so forth), but 101 hours have elapsed, which exceeds the 96-hour standard. Technically, this prescription would be noncompliant with VA's standard, but the audit team deemed all prescriptions processed on the fourth day as meeting the 96-hour standard. This was necessary because the audit team could not always determine the exact hour VA received the prescription on day one, so a conservative methodology was used for tracking elapsed time.

processing of special-authorization drugs. While on-site, the team observed how VA pharmacists processed, managed, and tracked community care prescriptions. The nine sites visited were the (1) Northampton VA Medical Center in Leeds, Massachusetts; (2) Northern California Healthcare System in Sacramento; (3) Puget Sound Healthcare System in Seattle, Washington; (4) Sioux Falls VA Medical Center in Sioux Falls, South Dakota; (5) Gulf Coast Healthcare System in Biloxi, Mississippi; (6) North Texas Healthcare System in Dallas; (7) Augusta Healthcare System in Augusta, Georgia; (8) W.G. (Bill) Hefner Salisbury VA Medical Center in Salisbury, North Carolina; and (9) Kansas City VA Medical Center in Kansas City, Missouri.

Finally, the team interviewed officials from Pharmacy Benefits Management Services (PBM) and the Office of Integrated Veteran Care to determine specific oversight and monitoring responsibilities related to tracking special-authorization drugs. The team interviewed TPA personnel to determine the type of training TPAs provided to community providers on the proper procedures for prescribing special-authorization drugs. The team also assessed the content accuracy of the TPA training against Veterans Health Administration Directive 1108.08.

The audit team conducted two electronic surveys. The first surveyed 138 medical facility pharmacy chiefs to determine the frequency of necessary follow-up with community providers related to unsupported special-authorization drug requests and how this process affected VA staffing and the timeliness of filling prescriptions. The second surveyed 137 facility community care chiefs to determine the extent to which local community care staff interact with pharmacy staff to ensure prompt responsiveness to pharmacists' requests for justifications when prescribing special-authorization drugs. The team received a 100 percent response rate for each survey. The team reviewed and analyzed the responses and followed up for clarification or additional information as needed. Some pharmacy chiefs and facility community care chiefs oversee multiple medical centers, so the number of respondents is not precisely the same for the two surveys.

Internal Controls

The team assessed controls relevant to the audit's objective. This included an assessment of the internal control components: control environment, risk assessment, control activities, information and communication, and monitoring components.[62] In addition, the team reviewed the principles of internal controls as associated with the objective.[63] The team identified internal control weaknesses during this audit and proposed recommendations to address the following control deficiencies.

[62] Government Accountability Office, *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014.

[63] Since the audit was limited to the internal control components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

- Component: Control Environment
    - Principle 2: Exercise oversight responsibility.
    - Principle 5: Enforce accountability.
- Component: Risk Assessment
    - Principle 7: Identify, analyze, and respond to risk.
- Component: Information and Communication
    - Principle 14: Communicate internally.
- Component: Monitoring
    - Principle 16: Perform monitoring activities.
    - Principle 17: Evaluate issues and remediate deficiencies.

Fraud Assessment

The audit team assessed the risk that fraud and noncompliance with provisions of laws, regulations, contracts, and grant agreements, significant within the context of the audit objective, could occur during this audit. The team exercised due diligence in staying alert to any fraud indicators during the course and scope of the audit. The Office of Inspector General (OIG) did not identify any instances of fraud or potential fraud during this audit.

Data Reliability

The audit team obtained community care prescription data from the Corporate Data Warehouse to assess prescription processing timeliness; evidence of justification; reasons for canceled, rejected, and removed prescriptions; and the questioned costs of prescriptions that lacked justification. To test the accuracy, reliability, and completeness of the prescription data that were used to support findings, conclusions, and recommendations related to the audit objectives, the team performed multiple steps such as requesting supporting documentation from the VA pharmacist who processed the prescription request, interviewing pharmacy personnel, and reviewing veteran's medical records in the electronic health system. These steps did not disclose any inaccuracies with the prescription data obtained from the Corporate Data Warehouse and the team determined that all data used were sufficiently reliable for the intended purposes.

Government Standards

The OIG conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that the OIG plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions

based on audit objectives. The OIG believes the evidence obtained provides a reasonable basis for the findings and conclusions based on the audit objectives.

Appendix B: Statistical Sampling Methodology

Approach

To accomplish the objective, the audit team reviewed a statistical sample of special-authorization drugs submitted by community providers from May 2022 through April 2023. The team used statistical sampling to quantify the number of prescriptions that lacked medical justification and exceeded the VA processing time standard. The audit team also reviewed a second sample to determine why VA pharmacists canceled, rejected, or removed some formulary and special-authorization community care prescription requests.

Population

The first of the two samples was drawn from an audit population of 71,534 special-authorization drug requests identified from prior-authorization drug request consults found in the Corporate Data Warehouse created from May 2022 through April 2023 and another 121,606 electronic prescriptions from the electronic prescription system orders with a date from May 2022 through April 2023.[64] After removing duplicate requests, the audit team identified 140,649 unique requests from these two data sources (consults and electronic prescriptions; see table B.1).[65] These unique requests composed the review population for this audit. Given the scope of the audit, the "target population" was further refined. The target population for this audit consists of only original requests (no prescription refills or prior orders of the same prescription for the same veteran). Based on the review of a probability sample (see sampling design section) from this sampling frame, the OIG estimated this target population to consist of 97,200 requests.

The second sample was drawn from a review population of 1,329,260 electronic prescription requests from the electronic prescription system that had a status of canceled, rejected, or removed and a message date from February 1, 2022, through April 30, 2023.[66]

[64] Consults and electronic prescription orders were identified as nonformulary using the Corporate Data Warehouse "National Formulary Flag" associated with each local drug identifier. Consults and electronic prescription orders were identified as prior-authorization drugs by matching the National Drug Code to a cross-reference provided by VA. All consults had a corresponding health factor. Consults were identified as community care by health factor or by the provider identifier for those consults associated with an outpatient order.

[65] A unique request was identified as a unique patient, drug, and station combination. Some requests were associated with both a consult and an electronic prescription order.

[66] A holding queue for electronic prescriptions produces messages that help VA sites track and monitor external requests for drugs. There could be multiple transmitted messages for the same patient and drug combination during the time frame.

Table B.1. Estimated In-Scope Special-Authorization Requests

Request	Estimate	90 percent confidence interval			Sample size	Rounded estimate
		Margin of error	Lower limit	Upper limit		
In scope (percent)	97,217 (69%)	8,232 (6%)	88,985 (63%)	105,449 (75%)	117	97,200
Out of scope (percent)	43,432 (31%)	8,232 (6%)	35,200 (25%)	51,664 (37%)	52	43,400
Total	**140,649**	—	—	—	**169**	**140,600**

Source: VA OIG analysis of in-scope special-authorization drug requests.

Sampling Design

As stated previously, the audit team conducted two sample reviews to address the audit objective. For the first sample, the audit team statistically selected (using a stratified random sample) special-authorization community care prescriptions submitted to VA pharmacies, assessed the timeliness of processing the prescriptions, and reviewed approvals to determine if justification for the prescription existed in the veteran's medical record. The sample review included quantifying the difference between PBM's universe of nonformulary community care prescriptions and the OIG's identified universe to determine the potential impact of PBM's universe being overstated or understated.

This sample consisted of the following six strata identified from completed special-authorization drug requests identified using consult data and electronic processing data:

- Stratum 1: Request identified in a consult, but not in an electronic order; no issued prescription identified
- Stratum 2: Request identified in a consult, but not in an electronic order; issued prescription identified
- Stratum 3: Request identified in a consult and in an electronic order; no issued prescription identified
- Stratum 4: Request identified in a consult and in an electronic order; issued prescription identified
- Stratum 5: Request identified in an electronic order, but not in a consult; no prescription identified
- Stratum 6: Request identified in an electronic order, but not in a consult; issued prescription identified

The number of orders in each stratum, along with each stratum's sample size, are displayed in table B.2.

Table B.2. Strata Table for Special-Authorization Drugs

Strata	Sampling frame totals	Number of sampled drugs
1	26,522	19
2	21,720	16
3	1,363	5
4	20,204	25
5	11,364	9
6	59,476	43

Source: VA OIG statistician's stratified population. Data were obtained from the Corporate Data Warehouse.

For the second sample, the audit team statistically selected (using a stratified random sample) electronic prescriptions that were canceled, rejected, or removed to determine why the VA pharmacist did not process the prescription. This universe represents the number of prescriptions that required additional documentation from the community provider that was never received, lacked a community care referral (invalidating the prescription), or changed to a formulary alternative.

This sample review included assessing whether the reasons could be determined for rejected, removed, or canceled prescriptions.

The sample for objective 2 consisted of the following three strata:

- Stratum 1: Canceled prescription requests
- Stratum 2: Rejected prescription requests
- Stratum 3: Removed prescription requests

The number of requests in each stratum, along with each stratum's sample size, is displayed in table B.3.

Table B.3. Strata Table for Canceled, Rejected, and Removed Prescriptions

Stratum	Sampling frame total	Number of sampled electronic prescription requests
1. Canceled	466,822	18
2. Rejected	601,676	23

Stratum	Sampling frame total	Number of sampled electronic prescription requests
3. Removed	260,762	10
Total	**1,329,260**	**51**

Source: VA OIG statistician's stratified population. Data were obtained from the Corporate Data Warehouse.

Based on the team's sampling assumptions, the OIG statistician determined that a sample size of 51 is adequate for statistically demonstrating a possible problem, even though the population size was about 1.3 million prescriptions. The population size is not relevant for determining the adequacy of the sample size (for example, the adequacy with respect to a population size of 1.3 million prescriptions would be no different from that of a population size of 10,000 or 100 million prescriptions when statistical sampling is conducted correctly). As shown in table B.5 under "Projections," the sample size of 51 was sufficient to show a problem with a 90 percent confidence level.

Weights

Samples were weighted to represent the population from which they were drawn, and the weights were used in the estimate calculations. For example, the team calculated the error rate estimates by first summing the sampling weights for all sample records that contained the given error, then dividing that value by the sum of the weights for all sample records.

Projections and Margins of Error

The projection is an estimate of the population value based on the sample. The associated margin of error and confidence interval show the precision of the estimate. If the OIG repeated this audit with multiple sets of samples, the confidence intervals would differ for each sample but would include the true population value approximately 90 percent of the time.

The OIG statistician employed statistical analysis software to calculate estimates, margins of error, and confidence intervals that account for the complexity of the sample design.

The sample size was determined after reviewing the expected precision of the projections based on the sample size, potential error rate, and logistical concerns of the sample review. While precision improves with larger samples, the rate of improvement decreases significantly as more records are added to the sample review.

With the exception of monetary projections, the projections in this report were obtained using standard methods that rely on an approximately normal sampling distribution. This method is inadequate for the monetary projections due to the substantial skew in the amounts observed in the sample. Given this condition, a bootstrapping method, involving 100,000 bootstrap iterations,

was used to produce one-sided lower bounds for the monetary estimates.[67] These lower bounds provide coverage that is greater than or equal to the required 90 percent coverage, based on a 90 percent confidence level. That is, if this audit were repeated numerous times, the 90 percent bootstrapped lower bound would be less than or equal to the true monetary value in at least 90 percent of repeated samples.

Figure B.1 shows the effect of progressively larger sample sizes on the margin of error.

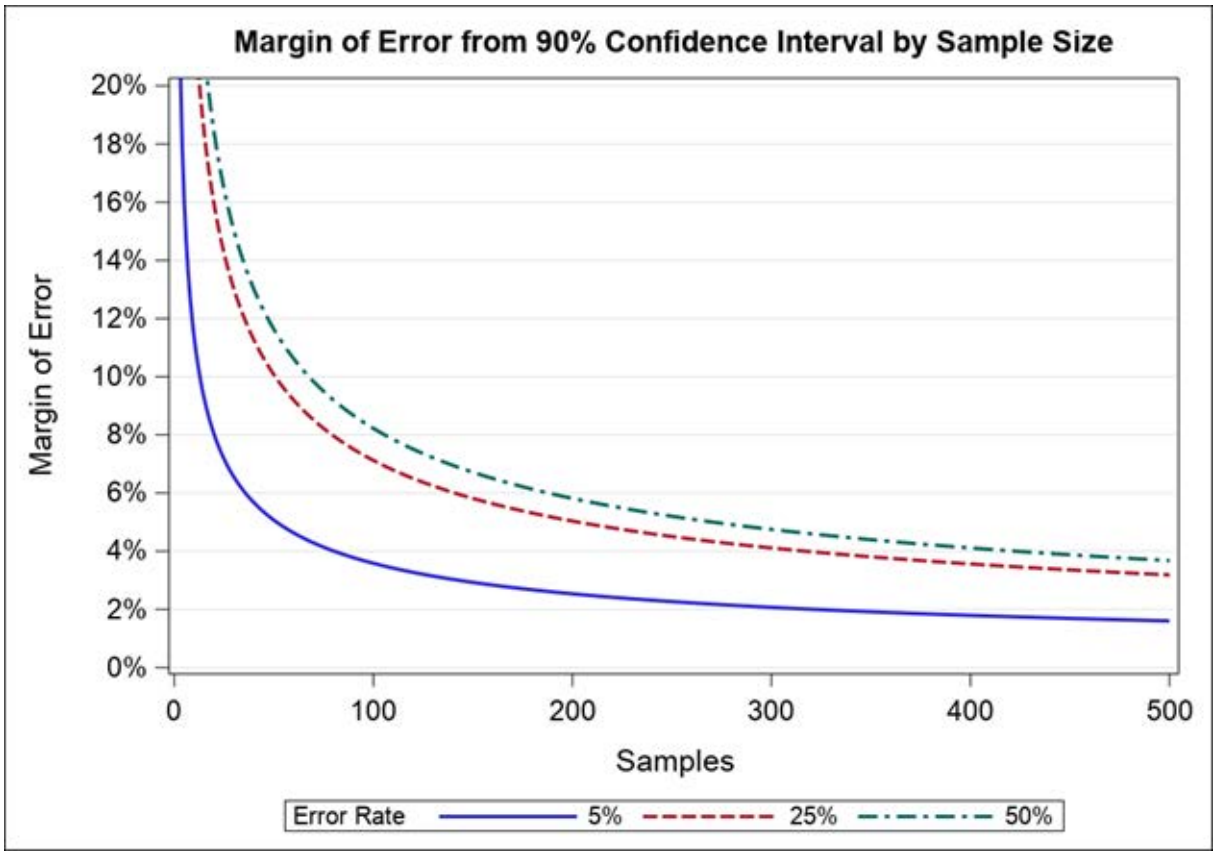

Figure B.1. *Effect of sample size on margin of error.*
Source: VA OIG statistician's analysis.

Projections

The audit team projected the sample results across the universe of identified special-authorization drug requests from community providers. Specifically, the team used the sample results to estimate the following:

[67] Bootstrapping is a method by which sample data are estimated not just by width, but also by shape of the sampling distribution. This can be helpful when there is an expectation that the sampling distribution is not normal, such as when sampling from heavily skewed populations.

- Average number of days to process special-authorization drug prescriptions after 96 hours (table B.4, estimate 1). This projection represents sampled items that took longer than 96 hours to process and the average number of days it took to process the prescription after the 96 hours.

- Number and percentage of prescriptions that lacked medical documentation when community providers submitted the initial prescription to the VA pharmacy (table B.4, estimate 2). This projection represents the sample items that lacked justification at the time of submission and required follow-up from the VA pharmacist to the community provider.

- Number and percentage of prescriptions that had a medical justification, provided by the community provider, for the special-authorization drug (table B.4, estimate 3). This projection represents sampled items that had a medical justification that came from the community provider.
- Number and percentage of prescriptions that had a medical justification, provided by the VA pharmacist, for the special-authorization drug (table B.4, estimate 4). This projection represents sampled items that had a medical justification that came from the VA pharmacist.
- Number and percentage of prescriptions that lacked supporting documentation to justify use of a special-authorization drug (table B.4, estimate 5). This projection represents sampled items that did not have required criteria for use or other medical documentation to support the use of the drug requested.
- Number and percentage of prescriptions that required criteria for use to justify use of a special-authorization drug (table B.4, estimate 6). This projection represents sampled items that had required criteria for use.
- Number and percentage of prescriptions that lacked required criteria for use to justify the special-authorization drug (table B.4, estimate 7). This projection represents sampled items that had criteria for use, but the sampled item lacked evidence that criteria for use existed.

- Number and percentage of prescriptions that lacked a consult (table B.4, estimate 8). This projection represents sampled items that lacked a consult. The team used this data to compare timeliness of prescription processing to PBM's dashboard.
- Number and percentage of prescriptions that took greater than four days (96 hours) to process (table B.4, estimate 9). This projection represents sampled items that had a prescription received date and prescription approval date that was greater than four days.

- Number and percentage of prescriptions that took between five and seven days to process (table B.4, estimate 10). This projection represents sampled items that had a prescription received date and prescription approval date that was between five and seven days.

- Number and percentage of prescriptions that took between eight and 14 days to process (table B.4, estimate 11). This projection represents sampled items that had a prescription received date and prescription approval date that was between eight and 14 days.

- Number and percentage of prescriptions that took at least 15 days to process (table B.4, estimate 12). This projection represents sampled items that had a prescription received date and prescription approval date that was 15 days or greater.

- Number and percentage of prescriptions that took less than or equal to four days (96 hours) to process (table B.4, estimate 13). This projection represents sampled items that had a prescription received date and prescription approval date that was less than or equal to four days.
- Number and percentage of prescriptions that were processed within four days (96 hours) and issued (table B.4, estimate 14). This projection represents sampled items that pharmacists processed within four days and showed evidence that the prescription was issued.

- Number and percentage of prescriptions that were processed within four days (96 hours) and but not issued (table B.4, estimate 15). This projection represents sampled items that pharmacists processed within four days but did not show evidence that the prescription was filled.

- Number and percentage of prescriptions that were processed within four days (96 hours) and issued without justification for the special-authorization drug (table B.4, estimate 16). This projection represents sampled items that pharmacists processed within four days, showed evidence that the prescription was issued, and lacked justification for the special-authorization drug.

Table B.4. Statistical Projections Summary for Special-Authorization Drugs

Estimate name	Estimate number	90 percent confidence interval			Sample count	Sample size	Rounded estimate
		Margin of error	Lower limit	Upper limit			
1. Average number of days to process after 96 hours	11	2	9	13	46	117	11
2. No justification at time of submission	96,468 (99.2%)	8,630 (1.9%)	87,489 (96.1%)	104,749 (100.0%)	116	117	96,500 (99%)
3.Justification from community provider	21,463 (22.1%)	6,004 (6.2%)	15,459 (15.9%)	27,467 (28.3%)	26	117	21,500 (22%)
4. Justification from VA pharmacist	37,129 (38.2%)	7,344 (7.6%)	29,785 (30.6%)	44,472 (45.7%)	46	117	37,100 (38%)
5. No justification: included	38,625 (39.7%)	7,086 (7.3%)	31,539 (32.4%)	45,711 (47.0%)	45	117	38,600 (40%)
6. Drugs that had criteria for use	46,842 (48.2%)	7,648 (7.9%)	39,193 (40.3%)	54,490 (56.1%)	56	117	46,800 (48%)
7. Criteria for use not completed	35,901 (76.6%)	7,119 (9.5%)	28,782 (67.2%)	43,021 (86.1%)	44	56	35,900 (77%)
8. Nonformulary without a consult	7,539 (18.7%)	3,750 (8.3%)	3,789 (10.4%)	11,290 (27.0%)	9	46	7,500 (19%)
9. Overall drugs greater than 96 hours	39,134 (40.3%)	7,439 (7.7%)	31,695 (32.6%)	46,573 (47.9%)	46	117	39,100 (40%)
10. Timeliness of prescription processing, 5–7 days	18,490 (19.0%)	6,029 (6.2%)	12,461 (12.8%)	24,519 (25.2%)	22	117	18,500 (19%)
11. Timeliness of prescription processing, 8–14 days	12,646 (13.0%)	5,182 (5.3%)	7,464 (7.7%)	17,828 (18.3%)	15	117	12,600 (13%)
12. Timeliness of prescription processing, 15 days or more	7,998 (8.2%)	4,403 (4.5%)	3,595 (3.7%)	12,401 (12.8%)	9	117	8,000 (8%)

Estimate name	Estimate number	90 percent confidence interval			Sample count	Sample size	Rounded estimate
		Margin of error	Lower limit	Upper limit			
13. Overall drugs within 96 hours	58,083 (59.7%)	7,439 (7.7%)	50,644 (52.1%)	65,522 (67.4%)	71	117	58,100 (60)
14. Prescriptions processed and issued within 96 hours	45,101 (77.6%)	6,651 (7.2%)	38,450 (70.4%)	51,752 (84.8%)	56	71	45,100 (78%)
15. Prescriptions processed within 96 hours and issued without justification	15,352 (34.0%)	4,897 (10.4%)	10,455 (23.7%)	20,249 (44.4%)	19	56	15,400 (34%)
16. Prescriptions processed within 96 hours but not issued	12,982 (22.4%)	4,707 (7.2%)	8,275 (15.2%)	17,689 (29.6%)	15	71	13,000 (22%)

Source: VA OIG statistician's projections based on in-scope requests.

The audit team also projected sample results across the universe of identified canceled, rejected, and removed prescriptions. The team used the sample results to project the number and percentage of prescriptions that were canceled, rejected, or removed because the veteran lacked a community care referral to the provider that wrote the prescription. This projection is based on the team's second sample and represents prescriptions that VA pharmacists did not process (table B.5).

Table B.5. Statistical Projections Summary for Canceled, Rejected, or Removed Prescriptions

Estimate name	Estimate number	90 percent confidence interval			Sample size	Total sample count	Rounded estimate
		Margin of error	Lower limit	Upper limit			
Did not have a community care referral (percent)	704,604 (53.0%)	148,990 (11.2%)	555,613 (41.8%)	853,594 (64.2%)	51	27	705,000 (53%)

Source: VA OIG statistician's projections, based on in-scope requests.

The team also questioned costs based on a complete review of special-authorization drugs submitted by community providers in the sample. Each of those drug requests was analyzed to determine whether the community provider or VA pharmacist included required justification. The team then calculated the cost of each sampled drug without this documentation to estimate the cost of all drugs in the audit population without documentation (table B.6).

The drug costs are based on the unit price for each drug, multiplied by the number of units originally dispensed to the veteran. The team also included the cost of all subsequent fills in the total drug cost (table B.6, estimate 1). The required statistical analysis accounted for the stratified sampling plan associated with the sampled drugs.

In addition, the sampled amounts included numerous low dollar values and a few high dollar values. Because of these variances in the cost data, the high dollar values are influential and can cause the statistical estimates to be imprecise. Given this limitation, OIG statisticians recommended that the team report conservative estimates of the monetary amounts. Conservative estimates are the 90 percent confidence, one-sided lower bounds associated with the point estimates (best-guess estimates) of the cost sums.

Table B.6. Statistical Projections Summary for Special-Authorization Drugs: One-Sided Lower Limit of Monetary Estimates

Estimate name	Estimate number	90 percent confidence interval: one-sided lower limit		Sample count	Sample size	Rounded estimate for one-sided lower limit
		Margin of error	Lower limit			
Sum of drug costs that lacked justification	$129,531,404	$84,195,778	$45,335,626	30	169	$45,300,000

Source: VA OIG statistician's projections, based on in-scope requests.

Using the lower-limit estimate for the sum of total extended costs, the OIG questioned about $45.3 million in prescription costs. This number is based on the audit team's analysis of special-authorization drug requests that identified about 15,400 prescriptions that lacked required justification and were approved and filled from May 2022 through April 2023.The OIG further estimated that prescriptions without justifications could result in $200.2 million in questioned costs if VA does not take corrective actions while the current CCN contracts are still in effect. Specifically, the additional questioned costs represent the option years that cover the same time for all five CCN contracts with the TPAs. See appendix C for more details on the questioned costs.

Appendix C: Monetary Benefits in Accordance with Inspector General Act Amendments

Recommendation	Explanation of Benefits	Better Use of Funds	Questioned Costs[68]
1–7	The OIG questioned about $45.3 million in prescription costs based on the team's analysis of special-authorization drug requests, which revealed an estimated 15,400 prescriptions were approved and dispensed to veterans without justification during a 12-month period from May 2022 through April 2023. This equates to about $3.8 million each month for prescriptions without justification. The audit team calculated questioned costs by multiplying the per month estimate by 53 months, from May 2022 through September 2026, which includes the option years for all five regional CCN contracts with both TPAs.*	$0	$200,232,348
	Total	**$0**	**$200,232,348**

** The OIG believes that VA will continue to be at risk for filling and dispensing community care prescriptions without proper justification until it takes steps to evaluate the terms of its current CCN contracts and develops a plan to be implemented with the next generation of CCN contracts to improve the capabilities of the electronic prescription system for community providers. At the time of the audit, the next generation of contracts did not have an expected award date.*

[68] The OIG questions costs when VA action or inaction (such as spending or failure to fully compensate eligible beneficiaries) is determined by the OIG to violate a provision of law, regulation, contract, grant, cooperative agreement, or other agreement; when costs are not supported by adequate documentation; or when they are expended for purposes that are unnecessary or unreasonable under governing authorities. Within questioned costs, the OIG must, as required by section 405 of the IG Act, report unsupported costs. Unsupported costs are those determined by the OIG to lack adequate documentation at the time of the audit. Of the about $200,232,348 in questioned costs, all were unsupported costs.

Appendix D: VA Management Comments, Under Secretary for Health

Department of Veterans Affairs Memorandum

Date: June 11, 2024

From: Under Secretary for Health (10)

Subj: Office of Inspector General (OIG) Draft Report, Ineffective Oversight of Community Care Providers' Special-Authorization Drug Prescribing Increased Pharmacy Workload and Veteran Wait Times (VIEWS 11829825)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review and comment on the OIG draft report on oversight of Community Care providers' special-authorization drug prescribing. The Veterans Health Administration (VHA) concurs in principle with recommendations 1, 2, 3, and 6. In addition, VHA concurs with recommendations 4, 5, and 7. VHA provides action plans in the attachment.

2. VHA appreciates the work performed by the OIG. The continued partnership with the OIG is critical to the effective delivery and oversight of community care services.

The OIG removed point of contact information prior to publication.

(Original signed by)

Shereef Elnahal, M.D., MBA

Attachment

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

Ineffective Oversight of Community Care Providers' Special-Authorization Drug Prescribing Increased Pharmacy Workload and Veteran Wait Times

2023-01583-AE-0061

Recommendation 1. Require the Office of Integrated Veteran Care and Pharmacy Benefits Management Services to improve community provider compliance when prescribing special-authorization drugs and being responsive to VA pharmacy inquiries. This should include consideration of electronic system capabilities to attach medical justifications, allow community providers to have real-time access to VA's formulary when prescribing drugs, and enable two-way communication between community providers and VA pharmacists electronically.

VHA Comments: Concur in Principle

VHA recognizes the importance of ensuring the Third-Party Administrators (TPA) enforce contract requirements for community providers' prescribing of special-authorization drugs. Integrated Veteran Care (IVC) and Prescription Benefit Management (PBM) will explore developing a plan to improve community provider accountability and compliance when prescribing special-authorization drugs and improve responsiveness to VA pharmacy inquiries.

Status: In Progress Target Completion Date: May 2025

Recommendation 2. Task the Office of Integrated Veteran Care to train community providers on the VA formulary and implement a process to improve tracking of training completion and community providers' compliance with VA guidance on submitting prescriptions for special-authorization drugs.

VHA Comments: Concur in Principle

VHA recognizes the importance of ensuring the Third-Party Administrators (TPA) enforce contract requirements for community provider training. While IVC concurs with the spirit of the recommendations, contractual requirements will take precedence. IVC will examine the Community Care Network Contract terms that require third-party administrators to train community providers on the VA formulary. IVC will review the process for tracking and training completion and explore developing a plan to improve providers compliance with VA Guidance on submitting prescriptions for special authorization drugs.

Status: In Progress Target Completion Date: May 2025

Recommendation 3. Direct Pharmacy Benefits Management Services to update its dashboard to more accurately capture special-authorization drug request processing times and provide the Office of Integrated Veteran Care access to this information for contract management purposes.

VHA Comments: Concur in Principle

VHA concurs in principle because activities to enhance the dashboard are under development and not dependent on the next generation of Community Care Network contracts. Pharmacy Benefits Management Services (PBM) is developing a tool to identify and track medications that require additional review and processing. PBM anticipates the prototype business intelligence report will be ready by late September 2024. Once the business intelligence report is validated, access will be provided to IVC. Based on the review of PBM reports, IVC will review current guidance and processes to identify

opportunities for improvement and determine the most appropriate mechanism for capturing special-authorization drug request processing times.

Status: In progress Target Completion Date: November 2024

Recommendation 4. Instruct Pharmacy Benefits Management Services to require that VA pharmacy personnel document community care prescriptions for special-authorization drugs in the veteran's medical record (in consults when applicable or medical notes) when the pharmacy receives the prescription and make clear that the 96-hour processing time is a requirement for these types of drug requests.

VHA Comments: Concur

PBM presented information on the November 1, 2023, Chief of Pharmacy teleconference and posted revised business rules for the adjudication of non-formulary and prior authorization requests on the PBM SharePoint site in February 2024. The actions taken and the evidence provided (see attachments) demonstrate that PBM has issued requirements for pharmacy staff to document community care prescriptions in the Veteran's medical record and that 96 hours or less is the timeliness expectation. Closure of this recommendation is requested.

Status: Complete Target Completion Date: February 2024

Recommendation 5. Require Pharmacy Benefits Management Services to routinely remind pharmacists that they are responsible for reporting a community provider to the medical facility's community care office when the provider does not comply with VA documentation requirements for special-authorization drug requests.

VHA Comments: Concur

PBM will edit the National Drug Consult Business Rules and present the information on a national pharmacy chief's call by July 31, 2024. After the initial presentation, PBM will add a standing agenda reminder for the Chiefs call at least quarterly.

Status: In progress Target Completion Date: August 2024

Recommendation 6. Charge facility community care offices to work with pharmacy personnel to report when they receive information from VA pharmacists that community providers did not comply with VA's documentation requirements for special-authorization drugs. Reporting mechanisms can include submitting Potential Quality Issue Referral reports or Health Care Quality Concern reports to third-party administrators.

VHA Comments: Concur in Principle

VHA agrees coordination between facility community care offices and pharmacy personnel concerning community providers who are not complying with formulary processes can be improved. Current guidance and processes will be reviewed to identify opportunities for improvement and determine the most appropriate mechanism for the reporting of non-compliance of community care providers.

Status: In Progress Target Completion Date: May 2025

Recommendation 7. Direct Pharmacy Benefits Management Services to standardize requirements for how VA pharmacists code drug requests from community providers in the electronic system that were

canceled, rejected, or removed to help VHA determine if corrective actions need to be taken on processes, contract terms, or guidance.

VHA Comments: Concur

PBM will develop standardized recommendations for the VA medical facilities related to coding/comments in the inbound e-prescribing software system and estimates guidance will be finalized and disseminated to the VA medical facilities no later than September 2024. Once this guidance is issued, PBM will coordinate with the VHA Operations Office and IVC to determine if any corrective actions are required.

Status: In progress Target Completion Date: September 2024

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

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