



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare  
Inspection Summary Report:  
Evaluation of Medication  
Management in Veterans  
Health Administration  
Facilities, Fiscal Year 2021



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**Figure 1.** *Veterans Affairs Building, Washington, DC.*

Source: <https://www.gsa.gov/real-estate/gsa-properties/visiting-public-buildings/veterans-administration-building> (accessed June 24, 2021).

## Abbreviations

CHIP	Comprehensive Healthcare Inspection Program
FDA	Food and Drug Administration
HCS	Health care system or healthcare system
OIG	Office of Inspector General
VAMC	VA medical center
VHA	Veterans Health Administration



## Report Overview

The Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of randomly selected Veterans Health Administration (VHA) facilities. Comprehensive healthcare inspections are one element of the OIG's overall efforts to ensure that the nation's veterans receive high-quality and timely VA healthcare services. The OIG inspects each facility approximately every three years and selects and evaluates specific areas of focus each year. The purpose of this report's evaluation was to determine whether VHA facility senior managers complied with selected medication management requirements related to remdesivir use.

The OIG initiated unannounced inspections and performed this evaluation at 34 VHA medical facilities from November 30, 2020, through August 23, 2021.<sup>1</sup> Each inspection involved interviews with key staff and reviews of clinical and administrative processes. The results in this report are a snapshot of VHA performance at the time of the fiscal year 2021 OIG inspections and may help VHA leaders identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.<sup>2</sup>

## Inspection Results

The OIG found that VHA met many elements of expected performance, including the availability of staff to receive remdesivir shipments. However, the OIG found deficiencies with patient/caregiver education and timely reporting of adverse events to the Food and Drug Administration.

## Conclusion

The OIG conducted detailed medication management evaluations at 34 VHA facilities and found opportunities for staff to improve patient education and timely reporting of adverse events to the Food and Drug Administration for treatments provided under Emergency Use Authorization. The OIG subsequently issued one recommendation for improvement to the Under Secretary for Health in conjunction with Veterans Integrated Service Network directors and facility senior leaders. VHA leaders should use the results in this report to improve operations and clinical care

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<sup>1</sup> Remdesivir was not administered to patients at the Edith Nourse Rogers Memorial Veterans' Hospital (Bedford, Massachusetts), Louis A. Johnson VA Medical Center (VAMC) (Clarksburg, West Virginia), Manchester VAMC (New Hampshire), Samuel S. Stratton VAMC (Albany, New York), Sheridan VAMC (Wyoming), VA Central Western Massachusetts Healthcare System (HCS) (Leeds), VA Finger Lakes HCS (Bath, New York), VA Hudson Valley HCS (Montrose, New York), VA Maine HCS (Augusta), VA Western Colorado HCS (Grand Junction), and White River Junction VAMC (Vermont).

<sup>2</sup> Fiscal year 2021 began October 1, 2020, and ended September 30, 2021.

at the facility level. The recommendation addresses a systems issue that may eventually interfere with the delivery of quality health care.

## **VA Comments**

The Under Secretary for Health concurred with the comprehensive healthcare inspection findings and recommendation and provided an acceptable improvement plan (see appendix C, page 10, and the response within the body of the report for the full text of the executive's comments). The OIG will follow up on the planned action for the open recommendation until it is completed.



JOHN D. DAIGH, JR., M.D.  
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## Contents

Abbreviations .....	ii
Report Overview .....	iii
Inspection Results .....	iii
Purpose and Scope .....	1
Methodology .....	4
Results and Recommendations .....	5
Recommendation 1 .....	6
Appendix A: Comprehensive Healthcare Inspection Program Recommendations .....	7
Appendix B: Parent Facilities Inspected .....	8
Appendix C: Office of the Under Secretary for Health Comments .....	10
OIG Contact and Staff Acknowledgments .....	11
Report Distribution .....	12



## Purpose and Scope

The Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of randomly selected Veterans Health Administration (VHA) facilities. Comprehensive healthcare inspections are one element of the OIG's overall efforts to ensure that the nation's veterans receive high-quality and timely VA healthcare services. The OIG inspects each facility approximately every three years.

While the OIG selects and evaluates specific areas of focus on a rotating basis each year, the evaluation of VHA facilities' medication management programs is an ongoing review topic because the Caregivers and Veterans Omnibus Health Services Act of 2010 designates oversight of patient care quality and safety to leaders at the national, network, and facility levels.<sup>1</sup> These leaders are directly accountable for program integration and communication within their level of responsibility.

The purpose of this report's evaluation was to determine whether VHA facility senior managers complied with selected requirements and guidelines related to remdesivir use. The results in this report are a snapshot of VHA performance at the time of the fiscal year 2021 OIG reviews.<sup>2</sup>

On May 1, 2020, the Food and Drug Administration (FDA) authorized the emergency use of remdesivir. At that time, remdesivir was an unapproved, investigational antiviral medication for the treatment of adults and children hospitalized with severe COVID-19.<sup>3</sup> The FDA provided information on specific laboratory tests to be ordered prior to and during the administration of remdesivir. Additionally, the FDA required providers to report potentially related adverse events.<sup>4</sup>

VA issued a memorandum on May 8, 2020, outlining the use of remdesivir under the FDA's Emergency Use Authorization criteria.<sup>5</sup> Due to the limited supply and specific storage requirements of remdesivir, VA needed someone to be available 24 hours a day, 7 days a week

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<sup>1</sup> Caregivers and Veterans Omnibus Health Services Act of 2010, Pub. L. No. 111-163, § 505 (2010).

<sup>2</sup> Fiscal year 2021 began October 1, 2020, and ended September 30, 2021.

<sup>3</sup> Gilead Sciences, Inc., *Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir*, May 1, 2020.

<sup>4</sup> Gilead Sciences, Inc., *Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir*.

<sup>5</sup> Assistant Under Secretary for Health for Operations Memo, *Remdesivir Distribution for Department of Veterans Affairs (VA) Patients*, May 8, 2020.

to accept overnight, cold-chain shipments of the drug and report any unused medication to the Emergency Pharmacy Services group.<sup>6</sup>

On August 28, 2020, the FDA amended the Emergency Use Authorization criteria for remdesivir to include “suspected or laboratory-confirmed COVID-19 in all hospitalized adult[s].”<sup>7</sup> The FDA subsequently approved remdesivir on October 22, 2020, for use in adult patients requiring hospitalization for the treatment of COVID-19.<sup>8</sup>

To determine whether VHA facilities complied with requirements related to the administration of remdesivir, the OIG interviewed key employees and managers and reviewed electronic health records of 825 patients who were administered remdesivir under Emergency Use Authorization from May 8 through October 21, 2020. The OIG assessed the following performance indicators:

- Staff availability to receive medication shipments
- Medication orders used proper name
- Staff determined patients met criteria for receiving medication prior to administration
- Required testing completed prior to medication administration
  - Potential pregnancy
  - Kidney assessment (estimated glomerular filtration rate)<sup>9</sup>
  - Liver assessment (alanine transferase or serum glutamic pyruvic transaminase)<sup>10</sup>
- Patient/caregiver education provided
- Staff reported any adverse events to the FDA

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<sup>6</sup> Assistant Under Secretary for Health for Operations Memo, *Remdesivir Distribution for Department of Veterans Affairs (VA) Patients*. “The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the patient.” Centers for Disease Control and Prevention, *Vaccine Storage and Handling Toolkit*, September 29, 2021.

<sup>7</sup> Food and Drug Administration, “FDA News Release: COVID-19 Update: FDA Broadens Emergency Use Authorization for Veklury (remdesivir) to Include All Hospitalized Patients for Treatment of COVID-19,” August 28, 2020.

<sup>8</sup> Food and Drug Administration, “FDA News Release: FDA Approves First Treatment for COVID-19,” October 22, 2020.

<sup>9</sup> “Your kidneys filter your blood by removing waste and extra water to make urine. The glomerular filtration rate (GFR) shows how well the kidneys are filtering...Getting an accurate GFR level is challenging...It is for this reason that healthcare professionals use a formula to estimate GFR (eGFR).” “Estimated Glomerular Filtration Rate (eGFR),” National Kidney Foundation, accessed May 4, 2022, <https://www.kidney.org/atoz/content/gfr>.

<sup>10</sup> Alanine transferase, also referred to as serum glutamate pyruvate transaminase, is “an enzyme found in the liver and other tissues.” A high level may be indicative of liver damage. “Alanine transferase,” National Cancer Institute, accessed May 4, 2022, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/alanine-transferase>.

The OIG initiated unannounced inspections and performed this evaluation at 34 VHA medical facilities from November 30, 2020, through August 23, 2021.<sup>11</sup> Each inspection involved interviews with key staff and reviews of clinical and administrative processes. The results in this report may help VHA leaders identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

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<sup>11</sup> Remdesivir was not administered to patients at the Edith Nourse Rogers Memorial Veterans' Hospital (Bedford, Massachusetts), Louis A. Johnson VA Medical Center (VAMC) (Clarksburg, West Virginia), Manchester VAMC (New Hampshire), Samuel S. Stratton VAMC (Albany, New York), Sheridan VAMC (Wyoming), VA Central Western Massachusetts Healthcare System (HCS) (Leeds), VA Finger Lakes HCS (Bath, New York), VA Hudson Valley HCS (Montrose, New York), VA Maine HCS (Augusta), VA Western Colorado HCS (Grand Junction), and White River Junction VAMC (Vermont).

## Methodology

The OIG evaluated compliance with selected medication management requirements through comprehensive healthcare inspections and randomly selected six Veterans Integrated Service Networks (VISNs) for review during fiscal year 2021. All facilities assigned to these VISNs were then inspected virtually. The 34 VHA medical facilities with staff who administered remdesivir represented a mix of size, affiliation, geographic location, and VISN.

The OIG published individual CHIP reports for each facility. For this report, the OIG analyzed data from the individual facility reviews to identify system-wide trends and generally used 90 percent as the expected level of compliance for the areas discussed.

This report's recommendation for improvement targets a problem that can influence the quality of patient care significantly enough to warrant OIG follow-up until VHA leaders complete corrective actions. The comments and action plan submitted by the Under Secretary for Health in response to the report recommendation appear within the report. The OIG accepted the action plan that the Under Secretary for Health developed based on the reason for noncompliance.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.<sup>12</sup> The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

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<sup>12</sup> Pub. L. No. 95-452, 92 Stat 1101, as amended (codified at 5 U.S.C. App. 3).

## Results and Recommendations

The OIG found that VHA met many elements of expected performance, including the availability of staff to receive remdesivir shipments. However, across the facilities inspected in fiscal year 2021, the OIG found deficiencies with patient or caregiver education and timely reporting of adverse events to the FDA.

Under the Emergency Use Authorization, VA Pharmacy Benefits Management Services required healthcare providers to provide the *Fact Sheet for Patients and Parents/Caregivers*; inform patients and/or caregivers that remdesivir was not an FDA-approved medication; provide the option to refuse the medication; and advise patients and/or caregivers of known risks, benefits, and alternatives to remdesivir prior to administration.<sup>13</sup> Of the 825 patients who received remdesivir, the OIG determined that healthcare providers did not

- provide 62 percent of patients or caregivers with the *Fact Sheet for Patients and Parents/Caregivers*,
- inform 41 percent of patients or caregivers that remdesivir was not an FDA-approved medication,
- notify 32 percent of patients or caregivers of their option to refuse the medication,
- inform 37 percent of patients or caregivers of the risks and benefits of remdesivir, or
- advise 59 percent of patients or caregivers of the alternatives to receiving remdesivir prior to administration.

This could have resulted in patients or caregivers lacking the information needed to make a fully informed decision to receive the medication. Interviewed leaders reported believing that providers educated patients or caregivers but did not document it.

Additionally, under the Emergency Use Authorization, the FDA required that the “prescribing health care provider and/or the provider’s designee are/is responsible for mandatory reporting of all medication errors and adverse events” potentially related to and occurring during remdesivir treatment within seven calendar days of event onset.<sup>14</sup> The OIG found that staff did not report 10 of the 42 (24 percent) adverse events to the FDA. Further, 6 of the 32 (19 percent) reported adverse events were not done so within seven days. Timely reporting of adverse events to the FDA supports transparency and evaluation of medication safety. Reasons for noncompliance included awaiting guidance from VA Pharmacy Benefits Management on the process for adverse event reporting.

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<sup>13</sup> VA Pharmacy Benefits Management Services, *Remdesivir Emergency Use Authorization (EUA) Requirements*, May 2020.

<sup>14</sup> Gilead Sciences, Inc., *Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir*.

Given the FDA’s approval of remdesivir for use in adult patients hospitalized with COVID-19, the OIG made no recommendations related to the Emergency Use Authorization requirements.<sup>15</sup> However, given the significant deficiencies noted during this review, the OIG is issuing a recommendation because VHA facility staff continue to administer other medications under emergency use authorizations, and patient safety should be a priority.

## Recommendation 1

1. The Under Secretary for Health, in conjunction with Veterans Integrated Service Network directors and facility senior leaders, ensures healthcare providers inform patients and/or caregivers when a medication is not FDA-approved; provide the option to refuse the medication; and advise them of the known risks, benefits, and alternatives prior to administration.

VHA concurred.

Target date for completion: November 2022

Under Secretary for Health response: Veterans Health Administration (VHA), Office of Oversight, Risk and Ethics, National Center for Ethics in Health Care, in collaboration with the Office of the Assistant Under Secretary for Health for Operations, will issue a Memorandum reminding the Department of Veterans Affairs, Veterans Integrated Service Network Directors, medical facility Directors and senior leaders to ensure practitioners comply with the following:

- a) Informed consent must be obtained prior to initiating a treatment or procedure as outlined in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, and
- b) For treatments and procedures authorized for use under U.S. Food and Drug Administration’s Emergency Use Authorization (EUA), informed consent must be obtained as outlined in the EUA in addition to VHA Handbook 1004.01.

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<sup>15</sup> Food and Drug Administration, “FDA News Release: FDA Approves First Treatment for COVID-19,” October 22, 2020.

## Appendix A: Comprehensive Healthcare Inspection Program Recommendations

The table below outlines one OIG recommendation aimed at reducing a vulnerability that may lead to patient safety issues or adverse events. The recommendation is attributable to the Under Secretary for Health, in conjunction with VISN directors and facility senior leaders. The intent is for these leaders to use the recommendation to guide improvements in clinical care. The recommendation addresses a systems issue that, if left unattended, may potentially interfere with the delivery of quality health care.

**Table A.1. Summary Table of Recommendations**

Healthcare Processes	Review Elements	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Remdesivir Use in VHA	<ul style="list-style-type: none"> <li>• Staff availability for medication shipment receipt</li> <li>• Medication order naming</li> <li>• Satisfaction of inclusion criteria prior to medication administration</li> <li>• Required testing prior to medication administration</li> <li>• Patient/caregiver education</li> <li>• Adverse event reporting to the FDA</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare providers inform patients and/or caregivers when a medication is not FDA-approved; provide the option to refuse the medication; and advise them of the known risks, benefits, and alternatives prior to administration.</li> </ul>	<ul style="list-style-type: none"> <li>• None</li> </ul>

## Appendix B: Parent Facilities Inspected

**Table B.1. Parent Facilities Inspected  
 (October 1, 2020, through September 30, 2021)**

<b>Names</b>	<b>City</b>
Bay Pines VA Healthcare System	Bay Pines, FL
Beckley VA Medical Center	Beckley, WV
Charles George VA Medical Center	Asheville, NC
Cheyenne VA Medical Center	Cheyenne, WY
Durham VA Health Care System	Durham, NC
Eastern Oklahoma VA Health Care System	Muskogee, OK
Fayetteville VA Coastal Health Care System	Fayetteville, NC
Hampton VA Medical Center	Hampton, VA
Herschel "Woody" Williams VA Medical Center	Huntington, WV
Hunter Holmes McGuire VA Medical Center	Richmond, VA
James A. Haley Veterans' Hospital	Tampa, FL
James J. Peters VA Medical Center	Bronx, NY
Martinsburg VA Medical Center	Martinsburg, WV
Miami VA Healthcare System	Miami, FL
Montana VA Health Care System	Fort Harrison, MT
North Florida/South Georgia Veterans Health System	Gainesville, FL
Northport VA Medical Center	Northport, NY
Oklahoma City VA Health Care System	Oklahoma City, OK
Orlando VA Healthcare System	Orlando, FL
Providence VA Medical Center	Providence, RI
Salem VA Medical Center	Salem, VA
Syracuse VA Medical Center	Syracuse, NY
VA Boston Healthcare System	Jamaica Plain, MA
VA Caribbean Healthcare System	San Juan, PR
VA Connecticut Healthcare System	West Haven, CT
VA Eastern Colorado Health Care System	Aurora, CO
VA Maryland Health Care System	Baltimore, MD
VA New Jersey Health Care System	East Orange, NJ
VA New York Harbor Healthcare System	New York, NY

<b>Names</b>	<b>City</b>
VA Salt Lake City Health Care System	Salt Lake City, UT
VA Western New York Healthcare System	Buffalo, NY
W.G. (Bill) Hefner VA Medical Center	Salisbury, NC
Washington DC VA Medical Center	Washington, DC
West Palm Beach VA Medical Center	West Palm Beach, FL

*Source: VA OIG.*

## Appendix C: Office of the Under Secretary for Health Comments

### Department of Veterans Affairs Memorandum

Date: August 18, 2022

From: Under Secretary for Health (10)

Subj: OIG Draft Report, Comprehensive Healthcare Inspection Summary Report:  
Evaluation of Medication Management in Veterans Health Administration  
Facilities, Fiscal Year 2021 2022-00814-HI-1231 (VIEWS # 8028645)

To: Office of Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report Comprehensive Healthcare Inspection Summary Report: Evaluation of Medication Management in Veterans Health Administration Facilities, Fiscal Year 2021 2022-00814-HI-1231. The Veterans Health Administration (VHA) concurs with the recommendation and provides an action plan.
2. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at [VHA10BGOALACTION@va.gov](mailto:VHA10BGOALACTION@va.gov).

*(Original signed by:)*

Shereef Elnahal, M.D., MBA

## OIG Contact and Staff Acknowledgments

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