
**Department of Veterans Affairs**
**Office of Inspector General**

**Office of Healthcare Inspections**

**Report No. 17-01542-273**

# Healthcare Inspection

# Sterile Compounding Environment and Practices
# Overton Brooks VA Medical Center
# Shreveport, Louisiana

**June 15, 2017**

**Washington, DC 20420**

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# Table of Contents

# Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a confidential referral involving the sterile compounding environment and practices at the Overton Brooks VA Medical Center (facility), Shreveport, LA. The purpose of this review was to determine whether deficient conditions in the compounding pharmacy placed patients at risk.

We confirmed that the facility did not comply with key elements of United States Pharmacopeia (USP) <797> (which outlines safe sterile compounding requirements and practices) as initially identified in October 2016 by the Louisiana Board of Pharmacy. The Board's findings included a lack of proper cleaning of the compounding rooms and incomplete air and surface testing and certification in compounding areas. During our January 2017 site visit, we found continuing noncompliance with USP <797> requirements including cleaning, environmental monitoring, employee competencies, and quality assurance activities. Non-compliance with USP <797> requirements could result in contamination of compounded sterile products and patient infections.

Cleaning logs from September 2016 through January 27, 2017, reflected 4 days where there was no evidence of appropriate cleaning and mopping of floors. We also found that hand soap and a hazardous spill kit were not available in the sterile compounding areas where hazardous medications are prepared.

Pharmacy staff with actual or possible compounding responsibilities did not complete all training and competency elements annually as required. Only 18 percent of applicable employees had all the training and competency documentation required as of January 27, 2017. Employees who lack the necessary training and competency could inadvertently prepare compounded sterile products in an unsafe manner, thereby placing patients at risk.

A qualified contractor completed environmental testing and certification of entry and compounding areas on January 14, 2016. However, facility staff did not ensure complete air and surface testing and certification every 6 months thereafter. Appropriate air and surface testing was completed on February 1, 2017.

Pharmacy managers did not report the Louisiana Board of Pharmacy's inspection findings to either facility or Veterans Integrated Service Network (VISN) leaders, to the facility's Pharmacy and Therapeutics or Infection Control Committees, or to the facility's Patient Safety Manager. Because the Board provided its report only to Pharmacy managers, it was incumbent upon the Chief of Pharmacy Service to communicate this information to those with a need to know. Facility leaders learned of the Louisiana Board of Licensing reports after OIG's unannounced January 2017 site visit. The Chief of Pharmacy Service retired on March 31, 2017.

In February 2017, Food and Drug Administration (FDA) investigators conducted an extensive and detailed review of the facility's compliance with FDA guidance on

compounded sterile preparations (CSPs). Details of that review can be found on FDA's website.

Facility and VISN leaders implemented interim measures to assure patient safety that included sending all chemotherapy CSP orders to the Alexandria, LA, VA Medical Center for compounding; outsourcing all routine compounding to a local pharmacy; and limiting CSP activities to immediate use (≤1 hour beyond use date) for emergent/overnight needs. Facility and VISN officials are currently working through an extensive action plan to correct the identified USP <797> deficiencies before re-opening the onsite pharmacy compounding areas.

We did not find evidence that patients developed infections from administration of CSPs. We reviewed the electronic health records of hospitalized patients who were administered CSPs and who were diagnosed with selected types of infections subsequent to the CSP administration in FYs 2016–2017 through January 6, 2017. None of the patients developed infections after intravenous infusions or injections of compounded medications.

We made two recommendations to the VISN Director focusing on the implementation of corrective actions and processes to fully comply with USP <797> requirements, and communication of external review results to facility leaders.

## Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes B and C, pages 13–17 for the Directors' comments.) We will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

# Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a confidential referral involving the sterile compounding environment and practices at the Overton Brooks VA Medical Center (facility), Shreveport, LA. The purpose of this review was to determine whether deficient conditions in the compounding pharmacy placed patients at risk.

# Background

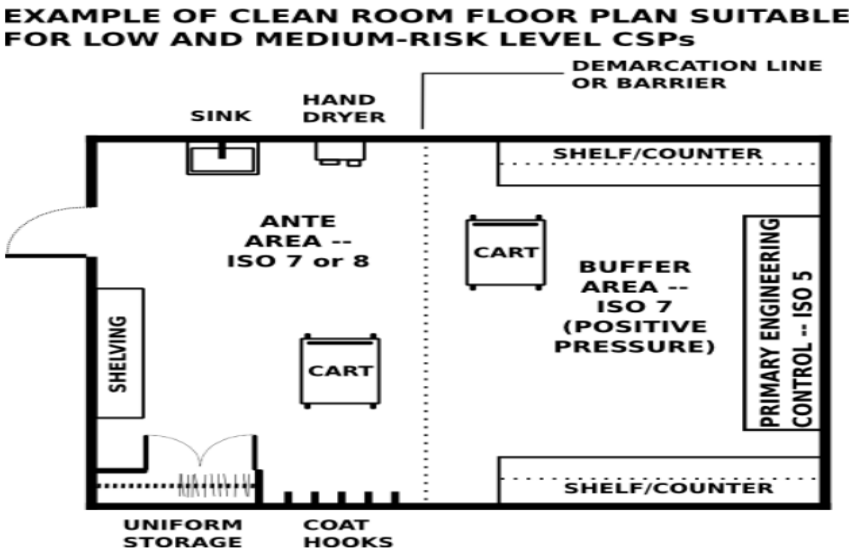
The facility is a 103-bed facility that provides a broad range of inpatient and outpatient healthcare services and is part of Veterans Integrated Service Network (VISN) 16.

Compounded Sterile Preparations (CSPs). CSPs are admixtures (solutions of sterile substances) that need to be assembled under aseptic conditions to prevent contamination. Examples of CSPs include intravenous (IV) fluids, chemotherapy, and antibiotics, and epidural injections to relieve back pain. To promote patient and employee safety, Veterans Health Administration (VHA) pharmacies must comply with requirements for CSPs as outlined in United States Pharmacopeia (USP) chapter <797>.[1] Employees preparing CSPs must use proper aseptic techniques to prevent contamination of admixtures. Aseptic technique includes a clean environment, employee training, and continuous testing of prepared products.

Additionally, the physical design and environmental testing of compounding areas are key components in ensuring patient and employee safety. Schematic A, below, shows a traditional sterile compounding suite, followed by a glossary[2,3] of useful terms.

[1] ASHP Guidelines on Compounding Sterile Preparations, http://www.ajhp.org/content/71/2/145, Accessed April 1, 2017.
[2] Ibid.
[3] The Joint Commission, *Glossary for the Medication Compounding Certification*, 2016

**Figure. Schematic A – A Traditional Sterile Compounding Suite Design**




*Source: Compounding – Rx-wiki*

The **Ante area** is where employee hand hygiene, donning personal protective equipment (for example: booties, gown, and gloves), and CSP labeling are performed. Environmental monitoring (air and surface testing) must be completed and documented every 6 months, or more often, if conditions change. Regular cleaning and mopping is required.

A **beyond use date** (BUD) is the date assigned to a CSP to ensure it maintains sterility and stability until administration to the patient. Because microbial growth increases over time, shorter BUDs may be applied when aseptic technique or environmental sterility cannot be assured.

The **Buffer area** (clean area/room or IV room) is where the primary engineering control, Laminar Air Flow Hood (LAFH), or Biological Safety Cabinet (BSC) is physically located. Environmental monitoring must be completed and documented every 6 months, or more often, if conditions change. Regular cleaning and mopping is required.

A **BSC** (or chemo [chemotherapy] hood) is an enclosed, ventilated workspace with a high-efficiency particulate air (HEPA) filter for product protection and inward vertical air flow for employee protection when preparing hazardous medications. Hood certifications must be completed and documented every 6 months, at a minimum, by an appropriately qualified individual.

**Environmental monitoring** involves air and surface testing in the hoods and in the ante and buffer rooms. Air testing includes sampling for viable and non-viable airborne

particles[4] that could compromise environmental sterility if microorganisms exceed specified thresholds. Per the American Society of Health-System Pharmacists (ASHP), surface testing includes swabbing of work and other surfaces to assess for contamination and provides facilities with "a snapshot of the effectiveness of their disinfection procedures."[5] Environmental monitoring must be completed and documented by a qualified contractor initially, every 6 months, and when hoods or rooms are renovated.

Environmental monitoring also includes surveillance of air pressure and temperature. Per ASHP, "Any controlled temperature area used for CSPs or for storage of sterile products or CSPs must be monitored at least once daily and results documented in a log."[6] Further, "Since positive and/or negative pressure rooms are required for sterile compounding, the appropriate differential pressure on air displacement velocities must be maintained. Results of pressure differential and/or velocity of air displacement must be reviewed and documented each shift (at least daily) or by a continuous device with alarms."[7]

The **International Organization of Standards** (ISO) is a classification of particulate matter in room air. A lower ISO number reflects a lower number of airborne particles, and thus, a higher sterility level.

An **LAFH** is a ventilated cabinet for compounding non-hazardous sterile products (such as antibiotics) with HEPA-filtered airflow moving at the same speed and in the same direction (horizontal) with no or minimal cross-over of air streams. LAFHs must be tested and certified every 6 months, at a minimum, by an appropriately qualified individual.

As of late January 2017, the facility's onsite pharmacy prepared approximately 75–100 patient-specific CSPs in designated pharmacy areas daily.

Prior Reports

A search did not identify relevant facility-specific reports involving sterile compounding or other pharmacy operations. See Appendix A for other relevant OIG reports published in the past 3 years.

[4] Viable particles are living organisms, such as bacteria or fungal spores. Nonviable particles are particles that do not contain a living organism, such as particles shed from paper or dust.
[5] American Society of Health-System Pharmacists. ASHP Guidelines on Compounding Sterile Preparations, Am J Health-Syst Pharm. 2014; 71:145–66.
[6] Ibid.
[7] Ibid.

Concerns

On January 18, 2017, the VA OIG received information that the facility relinquished its Louisiana Pharmacy Permit[8] (license) to avoid possible administrative action due to non-compliance with USP <797>. The Louisiana Board of Pharmacy's (Board's) compliance officer conducted an onsite inspection on October 21, 2016 and found a variety of USP <797> deficiencies. The Board's compliance officer placed the permit on a restricted basis, limited to CSP of low-risk items to be used within 12 hours (≤12-hour BUD) until the cleaning and certification deficiencies were corrected.

The Board's compliance officer conducted a follow-up site visit on January 17, 2017 and found that while some conditions had improved since October, "serious <797> deficiencies" remained, reporting the most notable to be:

- A lack of proper cleaning of the compounding rooms (no consistent monthly cleaning and no consistent mopping of floors)
- Incomplete certification (room certifications were overdue, very limited surface sampling, and no viable air sampling)

Further, Pharmacy leaders had not complied with the Board's recommendation to limit CSP of low-risk items to ≤12-hour BUD.

Our review focused on the deficiencies identified by the Board as "notable," as well as pharmacy staff competencies, quality assurance (QA) and oversight activities, and clinical review to determine patient harm. Food and Drug Administration (FDA) investigators conducted an extensive and detailed review of the facility's compliance with FDA guidance on CSPs. FDA's report can be accessed at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM550760.

# Scope and Methodology

We initiated our review on January 24, 2017 and completed our work in March 2017. We conducted an unannounced site visit January 26–27 and accompanied FDA investigators on an unannounced site visit February 6–8. We interviewed the individual who reported the pharmacy compounding concerns prior to our visit. We also interviewed the facility's Infection Control Coordinator, Pharmacy Service Chief, pharmacy supervisor and staff, and senior facility and VISN leaders.

We reviewed the Board's inspection reports; relevant FDA, USP, and VHA guidance regarding CSPs; facility policies and procedures, cleaning and other environmental logs, sterile compounding room and hood testing and certification data; pharmacy training

[8] Although the state generally has no jurisdiction in federal health care facilities, the facility has maintained this permit for many years as it is a requirement for the facility to have pharmacy students and trainees.

and competency records; fiscal year (FY) 2016 quality data related to infection control and prevention; and Infection Control Committee (ICC) and Pharmacy and Therapeutics (P&T) Committee meeting minutes for FYs 2015–2017 through January 31, 2017. We also inspected the general pharmacy and the ante area, two buffer rooms (chemo and IV), chemo storage room, and housekeeping room in the sterile compounding suite.

We reviewed individual patient electronic health records (EHRs) to determine whether patients developed infections after IV infusion or injection of CSPs, which could be an indication of contaminated products. We specifically reviewed diagnoses made in FY 2016–2017 through February 2017 of selected blood stream infections, infections of the bones of the spinal column (vertebral osteomyelitis), infections of joints resulting from organisms in the blood stream (septic arthritis), abscesses near the spinal cord (epidural abscesses), and eye (intraocular) infections[9] after infusions or injections of CSPs.

VHA Handbook 1108.07, *Pharmacy General Requirements*, April 17, 2008, cited in this report expired April 30, 2013 and has not been updated. We considered this policy to be in effect, as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),[10] the VA Under Secretary for Health (USH) mandated the "…continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."[11] The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "…the timely rescission or recertification of policy documents over which their program offices have primary responsibility."[12]

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

[9] There were no intraocular infections noted during the review period.
[10] VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 10, 2017.
[11] VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.
[12] Ibid.

# Inspection Results

### Issue 1: Non-compliance with Select Aspects of USP <797> Standards for CSPs

During our January 2017 site visit, we found that the facility was not in compliance with select aspects of USP <797> requirements for cleaning, environmental monitoring, employee competencies, and QA activities. Specifically, the facility did not consistently meet:

a) Cleaning requirements in sterile compounding areas.

Per facility policy, floors must be mopped "7 days per week including holidays" in "all areas where compounding of preparations occur[s]."[13] We reviewed cleaning logs for September 2016 through January 27, 2017. While 3 monthly logs reflected 100-percent compliance, the October and December 2016 logs were missing 2 days each.

During our inspection of the area, we also found that hand soap and a hazardous spill kit were not available in the sterile compounding areas where hazardous medications are prepared.

b) Environmental monitoring requirements in buffer and ante areas.

A qualified contractor completed air and surface testing and certification on January 14, 2016; however, the facility did not ensure that testing and certification due in July 2016 was completed. Further, only partial viable air and surface testing was completed in October 2016, making these required certifications substantially overdue. The pharmacy supervisor provided us with e-mails and other documentation showing that some efforts had been made to secure environmental testing; however, those efforts were unsuccessful.[14] Complete viable air and surface testing was conducted on February 1, 2017.

Although not specifically defined in USP <797>,[15] many VHA pharmacies also conduct periodic in-house surface testing between semi-annual certifications. However, we found that the facility's policy requires microbiological air and surface sampling only initially, annually, and when an LAFH is moved or room renovated. We were not provided with documentation that in-house air or surface sampling had been periodically conducted in accordance with specimen monitoring guidelines. As such, facility leaders

[13] Overton Brooks VA Medical Center, Pharmacy Internal Policy, No. 14, September 9, 2014.
[14] Based on staff members' descriptions, it appears that the relevant Services did not prioritize the need for testing and certification in the same way.
[15] USP <797> states that surface sampling shall be performed in all ISO classified areas **on a periodic basis**. ASHP states that surface sampling should be conducted "Periodically, as defined by compounding and infection control personnel…"

could not be assured that the approximately 27,000–36,500[16] CSPs compounded after that date were completed in an aseptic environment.

Further, facility policy states, "Individual CSP room temperatures, humidity, and [air] pressures [differentials] will be continuously monitored by Engineering Service."[17] We reviewed hard copy logs kept by Pharmacy staff for September 2016-January 2017. We found:

**Table. Percent Compliance with Monthly Documentation September 2016–January 2017**

| | Air Pressure Differential | Temperature and Humidity |
|---|---|---|
| September | 100 | 0 |
| October | 94 | 0 |
| November | 100 | 93 |
| December | 94 | 94 |
| January | 100 | 100 |

*Source: OIG summarization of facility pharmacy's logs*

Per FDA guidance, "It is vital for rooms of higher air cleanliness to have a substantial positive pressure differential relative to adjacent rooms of lower air cleanliness."[18] Further, temperature and humidity monitoring are important as employee compliance with garbing requirements is "highly dependent" on employee comfort.[19] Facility leaders were unable to provide us with documentation of actions taken when temperature, humidity, or air pressure differentials fell outside of specifications.

c) Requirements to verify the competence of employees who prepare CSPs.

Competencies did not reflect that all pharmacy staff with actual or possible compounding responsibilities completed all training and competency elements annually as required. Per facility policy, specific competency requirements are described as:[20]

- The ability to prepare CSPs using sterile technique. The employee's ability to accomplish this task is measured through a simulation, in which employees prepare a "dummy" CSP, known as a media sample. These samples are kept at room temperature and observed for cloudiness, which is indicative of bacterial growth.

[16] This calculation is based on 75-100 CSPs compounded daily x 365 days.
[17] Overton Brooks VA Medical Center, Pharmacy Internal Policy, No. 14, September 9, 2014.
[18] *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice*, U.S. Department of Health and Human Services Food and Drug Administration, September 2004
[19] Eric Kostango, MBS, RPh, FASHP. http://forums.pharmacyonesource.com/t5/Pharmacy-Practice/Temperature-Humidity-Standards-in-Compounding-Facilities/td-p/9361 Retrieved March 22, 2017.
[20] Overton Brooks VA Medical Center, Pharmacy Internal Policy, No. 14, September 9, 2014.

Evaluation of work practices and sterile technique follows any signs of bacterial growth.

- Hand hygiene. The facility uses fingertip sampling to assess the employee's ability to maintain the appropriate degree of hand hygiene. Fingertip sampling involves placement of the employee's gloved fingertips on agar plates to assess for microbial contamination. Bacterial growth exceeding specified levels will prompt a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures.
- Direct observation of employee practices in preparing CSPs. This involves a "hands-on" test, as observed and scored by a pharmacy supervisor or designee, of an employee's hygiene, cleaning, garbing, gloving, preparation, and handling of materials. A score of 90 percent is required.
- A written exam after review of a video and selected literature on sterile compounding. A score of 80 percent is required.

We reviewed relevant documents for the 12-month period preceding our site visit of 17 pharmacy employees with actual or possible compounding responsibilities. Only 3 of the 17 employees (18 percent) had all the training and competency documentation required as of January 27, 2017. The pharmacy supervisor and Chief had the responsibility to ensure training and competency documentation completion. While pharmacy staff did complete some training and competency testing, several training documents were missing as of February 1.

d) Appropriate QA monitoring and reporting.

Per ASHP, "The purpose of a QA program is to provide a mechanism for monitoring, evaluating, correcting, and improving activities and processes. A QA program should review and analyze objective data and use these data to develop action plans. Facilities should actively work to correct problems detected and improve activities and processes as needed."[21] Per the facility's patient safety policy,[22] reportable hazardous or unsafe conditions include circumstances (other than a patient's own disease process or condition) that increase the probability of an adverse event.

Despite the critical nature of the Board's findings, Pharmacy managers did not report the October or January inspection reports showing deficiencies to either facility or VISN leaders, the ICC or P&T Committee, or the facility's Patient Safety Manager. Facility leaders did not learn of the Board's findings until after our unannounced January 2017 site visit.

We also reviewed the facility's ICC and P&T Committee meeting minutes for FYs 2016–2017 through February 2017. We did not identify regular reporting or

[21] American Society of Health-System Pharmacists. ASHP Guidelines on Compounding Sterile Preparations, Am J Health-Syst Pharm. 2014; 71:145–66.
[22] Overton Brooks VA Medical Center Memorandum 00-05, *Patient Safety Program*, January 21, 2015.

standing agenda discussion regarding USP <797> compliance, issues of environmental sampling, or sterility testing.

Because the Board provided its report to just Pharmacy leaders, it was incumbent upon the Chief of Pharmacy Service to communicate this information to those with a need to know. It was unclear why the Chief of Pharmacy Service did not share the information. He retired on March 31, 2017.

Interim Safety Measure Timeline:

On January 27, facility leaders limited the facility's CSP activities to the ≤12 hour BUD in accordance with the Board's recommendation until contractor air and surface testing could be completed (scheduled for February 1) and certified.[23] The facility added evening staff to accomplish this.

On February 6–8, OIG accompanied FDA investigators on a portion of their unannounced visit. The FDA observed several conditions of immediate concern:

- A pharmacy technician did not follow sterile protocol when donning PPE, sanitizing materials and hands, or preparing CSPs,
- A HEPA filter had not been changed on one hood since 2012, and
- Rust and/or debris were present on benches and equipment in sterile areas.

These additional observations prompted facility and VISN leaders to take the following actions:

- Starting February 6, the Alexandria, LA, VA Medical Center prepared all chemotherapy CSPs for the facility.
- As of February 8, the facility outsourced all routine compounding to a local contract pharmacy.

To limit disruptions in patient care, the facility continued to prepare emergent/overnight CSPs on an immediate use[24] (≤1 hour BUD) basis.

Facility and VISN officials are currently working through an extensive action plan to correct the identified USP <797> deficiencies. Actions include developing a 5-year contract for required testing and certification, implementing improved in-house monitoring systems of equipment and the environment, assigning specific housekeeping personnel to pharmacy compounding areas to improve cleanliness, and ensuring

[23] Air and surface sampling results were received late February 6. All surface testing passed; one air sample (ante-room) failed. FDA expressed concerns, however, about the number and location of surface samples taken.

[24] The immediate-use category should be reserved for emergent use or situations in which adhering to low-risk compounding procedures would add additional risk due to delays in patient care.

applicable staff are appropriately trained and competent to perform CSP-related or cleaning functions.

**Issue 2: Patient Safety**

We did not find evidence that patients developed infections from administration of CSPs. We reviewed the EHRs of all 37 hospitalized patients diagnosed with selected types of infections subsequent to CSP administration, or who underwent specific procedures in FYs 2016–2017 through January 6, 2017, which involved the use of a CSP. The types of infections included:

- 15 blood stream infections
- 6 cases of vertebral osteomyelitis
- 4 cases of septic arthritis
- 1 epidural abscess
- 11 other noninfectious diagnoses (cardiac issues, failure to thrive, lymphoma, complications of dialysis, arthrocentesis/aspiration and/or injection of joint or bursa; without ultrasound guidance, fluoroguide for spine injection)

None of the patients developed infections after IV infusions or injections of compounded medications. Many of the patients reviewed had positive blood, fluid, or tissue cultures prior to admission or transfer to the facility.

We also reviewed the facility's ICC and P&T Committee meeting minutes for FYs 2016–2017 through February 2017. These minutes did not reflect infection trends attributed to an infectious cause or contaminated CSPs.

# Conclusions

We confirmed that the facility did not comply with key elements of USP <797> as initially identified by the Louisiana Board of Pharmacy in October 2016, including a lack of proper cleaning of the compounding rooms and incomplete air and surface testing and certification in compounding areas. During our January 2017 site visit, we found continuing noncompliance with USP <797> requirements including cleaning, environmental monitoring, employee competencies, and QA activities.

Cleaning logs for September 2016 through January 27, 2017, reflected 4 days where there was no evidence of appropriate cleaning and mopping of floors. We also found that hand soap and a hazardous spill kit were not available in the sterile compounding areas where hazardous medications are prepared.

Pharmacy staff with actual or possible compounding responsibilities did not complete all training and competency elements annually as required. Only 18 percent of applicable employees had all the training and competency documentation required as of January 27, 2017.

Environmental testing and certification of buffer and ante areas was completed by a qualified contractor on January 14, 2016. However, the facility did not ensure complete air and surface testing and certification every 6 months thereafter. Appropriate testing was completed on February 1, 2017.

Pharmacy managers did not report the Louisiana Board of Pharmacy's inspection findings to either facility or VISN leaders, to the ICC or P&T Committees, or to the facility's Patient Safety Manager. Because the Board provided its report only to Pharmacy managers, it was incumbent upon the Chief of Pharmacy Service to communicate this information to those with a need to know. Facility leaders did not learn of the Board's findings until after our unannounced January 2017 site visit. The Chief of Pharmacy retired on March 31, 2017.

Facility and VISN leaders have implemented interim measures to assure patient safety, including sending all chemotherapy CSPs orders to the Alexandria, LA, VA Medical Center for compounding; outsourcing all routine compounding to a local pharmacy; and limiting CSP activities to emergent/overnight (≤1 hour BUD). Facility and VISN officials are currently working through an extensive action plan to correct the identified USP <797> deficiencies before re-opening the onsite pharmacy compounding areas.

We did not find evidence that patients developed infections from administration of CSPs. We reviewed the EHRs hospitalized patients who were administered CSPs and who were diagnosed with selected types of infections subsequent to the CSP administration in FYs 2016–2017 through January 6, 2017. None of the patients developed infections after IV infusions or injections of compounded medications.

We made two recommendations.

# Recommendations

**Recommendation 1.** We recommended that the Veterans Integrated Service Network Director ensure that facility leaders implement corrective actions and processes to fully comply with United States Pharmacopeia <797> requirements, test the effectiveness of these actions and processes before resuming full compounded sterile preparations operations, and monitor compliance of key elements through a facility or Veterans Integrated Service Network-level committee.

**Recommendation 2.** We recommended that the Veterans Integrated Service Network Director issue guidance to facility staff requiring that results of external reviews be provided to facility leaders as soon as those results are available.

**Appendix A**

# Prior OIG Reports
# February 1, 2014 through May 10, 2017

## *Facility Reports*

### Healthcare Inspection – Patient Care Deficiencies and Mental Health Therapy Availability, Overton Brooks VA Medical Center, Shreveport, Louisiana

*1/7/2016 | 14-05075-447 | Summary | Report*

### Combined Assessment Program Review of the Overton Brooks VA Medical Center, Shreveport, Louisiana

*3/31/2014 | 14-00308-105 | Summary | Report*

### Community Based Outpatient Clinic and Primary Care Clinic Reviews at Overton Brooks VA Medical Center, Shreveport, Louisiana

*3/14/2014 | 14-00228-94 | Summary | Report*

## *Topic Related Reports*

### Combined Assessment Program Summary Report – Evaluation of Compounded Sterile Product Practices in Veterans Health Administration Facilities

*5/10/2017 | 16-03807-223 | Summary | Report*

**Appendix B**

# VISN Director Comments

## Department of Veterans Affairs

## Memorandum

**Date:** May 8, 2017

**From:** Director, South Central VA Health Care Network (10N16)

**Subj:** Healthcare Inspection— Sterile Compounding Environment and Practices, Overton Brooks VA Medical Center, Shreveport, Louisiana

**To:** Director, Rapid Response (54RR)
Director, Management Review Service (VHA 10E1D MRS Action)

1. The South Central VA Health Care Network (VISN 16) has reviewed and concurs with the response submitted by the Overton Brooks VA Medical Center, Shreveport, LA, regarding the Sterile Compounding Environment and Practices Draft Report.

Skye McDougall, PhD
Director, South Central VA Health Care Network (10N16)

**Appendix C**

# Facility Director Comments

**Department of Veterans Affairs**

# Memorandum

**Date:** May 3, 2017

**From:** Interim Medical Center Director, Overton Brooks VA Medical Center (667/00)

**Subj:** Healthcare Inspection— Sterile Compounding Environment and Practices, Overton Brooks VA Medical Center, Shreveport, Louisiana

**To:** Network Director, South Central VA Health Care Network (10N16)

1. This is Overton Brooks VA Medical Center's response to Recommendations 1 and 2.

2. If you have questions regarding this response, please contact Mr. Scott Fischer, Interim Chief, Pharmacy Service at (318) 990-4998.

Richard L. Crockett, MBA
Interim Medical Center Director

# Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

**OIG Recommendations**

**Recommendation 1.** We recommended that the Veterans Integrated Service Network Director ensure that facility leaders implement corrective actions and processes to fully comply with United States Pharmacopeia <797> requirements, test the effectiveness of these actions and processes before resuming full compounded sterile preparations operations, and monitor compliance of key elements through a facility or Veterans Integrated Service Network-level committee.

Concur

Target date for completion: The Second week of May 2017 the facility will begin compounding sterile preparations.

- Facility response: On March 1, 2017, Overton Brooks Veterans Medical Center (OBVAMC) established an USP 797/800 Interdisciplinary Subcommittee with the Veterans Integrate Service Network (VISN) Pharmacy Lead as well as the National Pharmacy Benefit Manager (PBM) to address the deficiencies and the remodeling of the Intravenous (IV) sterile area. The USP 797-800 Interdisciplinary Subcommittee discussed the process of resuming hazardous and non-hazardous compounded sterile products at OBVAMC. Discussion included room requirements for the utilization of a Compounding Aseptic Containment Isolator (CACI) for hazardous and Compounding Aseptic Isolator (CAI) for non-hazardous materials in an appropriate environment. A specific timeline action plan for IV room reactivation had been developed.

- On March 13, 2017, the USP 797-800 Interdisciplinary Subcommittee provided their initial report to the Pharmacy and Therapeutics (P&T) Committee.

- On March 22, 2017, two memorandums with Standing Operating Procedures (SOPs) were signed by the Interim Medical Center Director. Both memorandums were published and distributed to all Pharmacy and Environmental Management Service (EMS) employees. Competencies were also completed for both Pharmacy and EMS with regard to Personal Protective Equipment (PPE) and their roles and responsibilities prior to entry the sterile compounding area(s).

- On March 27, 2017, the USP 797-800 Subcommittee provided a status update to the Medical Executive Board (MEB) through the P&T committee.

- On March 28, 2017, CAI & CACI units arrived at OBVAMC.

- March 30, 2017: CAI & CACI Vendor on station for CAI set-up and pharmacy staff CAI & CACI training

- March 31, 2017: Environmental Testing Vendor on station for CAI environmental testing

- On March 31, 2017, USP 797-800 Subcommittee provided a status update to OBVAMC Executive Leadership.

- On April 4, 2017: Initial weekly and quarterly audit performed by OBVAMC Quality, Safety & Value Service.

- On April 5, 2017: Vendor selected for OBVAMC pharmacy staff aseptic technique training & testing with proposed date April 17, 2017

- On April 17, 2017: Vendor on station for environmental testing of CACI with results expected April 28, 2017. The environmental testing was not completed due to an unexpected quality control issue with the CACI. It was determined that the CACI door frame was bent, causing the failure of the smoke study. The CACI vendor shipped another door frame to OBVAMC on April 25, 2017.

- On April 17, 2017 week: Vendor on site for aseptic technique training, didactic training, didactic training test with certification, gloved finger-tipped testing and media fill testing with results expected in 2 weeks from each test.

- On April 25, 2017: Vendor replaced bent door frame and performed environmental testing on CACI as well as CAI to keep on the same schedule. Results pending with expected date in 2 weeks.

- Estimated date for utilizing the CAI and CACI enabling reinstatement of IV Sterile Compounding meeting the USP 797 and USP 800 guidelines on station is the second week of May 2017.

- The project award date is estimated to be completed by the middle of September 2017 and this will be the final corrective measure of the newly-constructed IV Sterile Compounding Area meeting the USP 797 and USP 800 guidelines.

- All updates will be reported through the P&T committee on monthly basis and updates will be reported through the MEB on a monthly basis.

**Recommendation 2.** We recommended that the Veterans Integrated Service Network Director issue guidance to facility staff requiring that results of external reviews be provided to facility leaders as soon as those results are available.

Concur

Target date for completion: May 15, 2017

Facility response: A Standard Operating Procedure on how to notify Senior Leadership as well the Quality, Safety & Value department about external visitors has been developed and added to a current memorandum. The memorandum addendums will be routed for approval and signature to the Interim Medical Center Director on May 5, 2017. On May 3, 2017, a checklist on how to prepare for an external visit was also provided to all Service Chiefs via email and placed on our internal SharePoint for quick access.

**Appendix D**

# OIG Contact and Staff Acknowledgments

| | |
|---|---|
| **Contact** | For more information about this report, please contact the OIG at (202) 461-4720. |
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**Appendix E**

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