



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Alleged Inappropriate
Anesthesia Practices at the
James E. Van Zandt
VA Medical Center
Altoona, Pennsylvania



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complainant's allegations regarding an anesthesiologist who provided outpatient sedation services at the James E. Van Zandt VA Medical Center (Facility) in Altoona, Pennsylvania. Specifically, the complainant alleged

- The anesthesiologist did not follow Veterans Health Administration (VHA) and Facility policies for controlled medication waste;
- The anesthesiologist did not individualize patient medication dosing and used more anesthetic/sedation medication than the recommended guidelines for outpatient procedures; and
- Facility leaders did not hold the anesthesiologist accountable with comprehensive oversight processes.

The OIG did not substantiate that the anesthesiologist failed to follow VHA and Facility policies for controlled medication waste. The anesthesiologist documented administering the entire amount of each controlled medication removed from the Facility's automated medication dispensing machine. Because the entire amount was used, the anesthesiologist did not need to document wasted medication.

The OIG did not substantiate that the anesthesiologist failed to individualize patient medication dosing. OIG staff reviewed 20 patients identified by the Facility as receiving care from the anesthesiologist. The anesthesiologist varied medication dosing for 18 of the 20 identified patients.

The OIG substantiated that the anesthesiologist used more anesthetic/sedation medication for outpatient procedures than Food and Drug Administration approved manufacturer's instructions recommended for 17 of the 20 identified patients. However, OIG staff were unable to establish why the anesthesiologist used medications in this manner as the anesthesiologist was discharged midway through the OIG review process.

The OIG substantiated that Facility leaders did not provide oversight of the anesthesiologist according to VHA and Facility privileging and ongoing monitoring policies. Facility leaders determined providers' privileges and confirmed the quality of care delivered by providers through Ongoing Professional Practice Evaluations. However, when Facility leaders renewed the anesthesiologist's privileges in spring 2017, the privileges were not facility-specific. Additionally, the anesthesiologist's Ongoing Professional Practice Evaluation did not include monitoring of drug usage, which is a relevant, provider-specific data element. The reason for the lack of documented oversight was unclear.

Although the Facility did not identify issues to report to the National Practitioner Data Bank or State Licensing Board when the anesthesiologist was discharged from employment, the OIG determined that the Facility should reevaluate if the provider should be reported for the practice of administering medications that were inconsistent with Food and Drug Administration approved manufacturer's instructions that may have placed patients at increased sedation risk.¹

During this inspection, OIG staff identified other issues related to the anesthesiologist's patient care. The anesthesiologist did not follow Facility policy for pre-procedure documentation for 14 of the 20 identified patients. Furthermore, the anesthesiologist did not follow Facility policy to transfer all patients requiring general anesthesia to a designated VA or non-VA Facility.

In reviewing the Facility's documented patient complaints in the Patient Advocate Tracking System, OIG staff did not find complaints regarding the anesthesiologist. However, the Facility's Patient Advocate did not document and track complaints on the Patient Advocate Tracking System as required by VHA. Instead, the Patient Advocate tracked all Facility patient complaints on a desktop spreadsheet. In addition, from November 2015 through July 2016, 761 of the 822 documented patient complaints did not have an issue description, and 173 of the 822 complaints did not have documentation of either an action to resolve the complaint or if the complaint was resolved.

The OIG made four recommendations related to anesthesia needs and services, provider oversight, National Practitioner Data Bank and State Licensing Board reporting, and Patient Advocate Tracking Systems database requirements.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan. (See Appendixes B and C, pages 21–24 for the Directors' comments.) Based on information received from the Facility to show compliance with new policies and data regarding the Facility's anesthesia practice and complaint tracking process, the OIG considers recommendations 1 and 4 closed. The OIG will follow up on the planned actions for recommendations 2 and 3 until they are completed.



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¹ The Facility's identified reasons for discharge of the anesthesiologist were not related to the anesthesiologist's inconsistent medication administration practice.

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Abbreviations

ASA PS	American Society of Anesthesiologist Physical Status
EHR	electronic health record
FDA	Food and Drug Administration
fentanyl	fentanyl citrate
FY	fiscal year
GI	gastrointestinal
mcg	micrograms
mg	milligrams
NPDB	National Practitioner Data Bank
OIG	Office of Inspector General
OPPE	Ongoing Professional Practice Evaluation
PATS	Patient Advocate Tracking System
provider	licensed independent practitioner
SLB	State Licensing Board
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complainant's allegations regarding an anesthesiologist who provided outpatient sedation services at the James E. Van Zandt VA Medical Center (Facility), Altoona, Pennsylvania.

Background

The Facility is a 51-bed, Level 3² medical center that provides a range of inpatient and outpatient services. The Facility is part of Veterans Integrated Service Network (VISN) 4 and serves a veteran population of approximately 26,000 throughout 14 counties in Pennsylvania. The Facility has five community based outpatient clinics located in DuBois, Indiana County, Johnstown, Mapleton Depot, and State College, Pennsylvania.

Facility Outpatient Procedures

As a Level 3 medical center, the Facility administers care to low-volume, low-risk patients. The Facility is not approved to perform surgeries requiring general anesthesia;³ but, is approved to provide diagnostic and outpatient surgical gastrointestinal (GI) procedures, including upper endoscopies⁴ and colonoscopies.⁵ However, the Facility stopped providing outpatient surgical GI procedures in July 2016 due to the lack of an anesthesiologist or other providers⁶ qualified to administer sedation. Since July 2016, the Facility refers patients either to the VA Pittsburgh Healthcare System or to Non-VA Care⁷ for GI and other procedures that require general anesthesia and sedation.

² Veterans Health Administration (VHA) facilities are classified into three levels with Level 1 representing the most complex facilities, Level 2 moderately complex facilities, and Level 3 the least complex facilities. Level 3 facilities provided few or no complex clinical programs to low volume, low risk patients, and have small or no research and teaching programs.

³ Standard Operating Procedure 11M-13, *Guidelines for Sites for Surgical Procedures and Anesthesia Types*, December 2014.

⁴ An upper endoscopy (also called an esophagogastroduodenoscopy) is a procedure in which a doctor uses an endoscope, a small camera on a tube, to see the lining of the upper GI tract.

⁵ A colonoscopy is a procedure where a doctor uses an endoscope to look inside the rectum and colon. During a colonoscopy, the provider may remove polyps or collect tissue samples and send them to the laboratory for testing.

⁶ VHA Directive 1073, *Moderate Sedation by Non-Anesthesia Providers*, December 30, 2014.

⁷ Non-VA Care is care provided to eligible veterans outside of the VA when VA facilities are not feasibly available, such as when a patient lives too far from a VA facility, a specialist is not available at the patient's VA, or it takes too long for a patient to be seen at a VA facility.

Procedural Anesthesia and Sedation

Anesthesia is a complete or partial loss of sensation (usually pain), with or without the loss of consciousness, because of disease, injury, or the administration of an anesthetic agent.⁸ Anesthesia consists of several components, including sedation (calming nervous excitement),⁹ unconsciousness, analgesia (lack of pain), and amnesia (lack of memory). Specific medications target each one of these anesthesia components, have different effects, and result in different levels of anesthesia.¹⁰

For the purposes of this report, the OIG describes three levels of anesthesia: moderate sedation/anesthesia, deep sedation/anesthesia, and general anesthesia. The provider's decision about which level of anesthesia to provide for each patient's anesthesia plan requires sound medical judgment based on a review of patient factors (such as medical history) and preferences, procedure requirements, and potential risks and benefits.^{11,12}

Moderate Sedation/Anesthesia

Moderate sedation/anesthesia is a medication-induced depression of consciousness used to minimize pain and anxiety while patients undergo diagnostic or surgical procedures.¹³ The level of consciousness allows the provider to arouse patients with verbal commands and/or light touch; thus, patients are able to cooperate during the procedure to requests by the provider.¹⁴ VA facilities routinely use moderate sedation/anesthesia for patients during GI procedures, which

⁸ Venes, Donald, M.D., M.S.J., ed. *Taber's Cyclopedic Dictionary*. <https://www.tabers.com/tabersonline/view/Tabers-Dictionary/764983/all/anesthesia>. (The website was accessed on September 11, 2017.)

⁹ Venes, Donald, M.D., M.S.J., ed. *Taber's Cyclopedic Dictionary*. <https://www.tabers.com/tabersonline/view/Tabers-Dictionary/749557/all/sedation?q=sedation%20anesthesia&ti=0>. (The website was accessed on September 11, 2017.)

¹⁰ National Institute of General Medical Sciences. *Anesthesia Fact Sheet*. https://www.nigms.nih.gov/education/Pages/factsheet_Anesthesia.aspx. (The website was accessed on August 3, 2017.)

¹¹ American Society of Anesthesiologists. *Statement on Anesthesia Care for Endoscopic Procedures*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/statement-on-anesthesia-care-for-endoscopic-procedures.pdf>. (The website was accessed on June 29, 2017.)

¹² VA National Center for Patient Safety. *Moderate Sedation Toolkit for Non-Anesthesiologists*. <https://www.patientsafety.va.gov/docs/modSedationtoolkit/CurriculumGuideMST.pdf>. (The website was accessed on July 18, 2017.)

¹³ American Society of Anesthesiologists. *Distinguishing Monitored Anesthesia Care (MAC) from Moderate Sedation/Analgesia (Conscious Sedation)*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/distinguishing-monitored-anesthesia-care-from-moderate-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.); VHA Directive 1073.

¹⁴ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

include upper endoscopies and colonoscopies.¹⁵ Staff who are qualified to administer moderate sedation/anesthesia include physicians, trained registered nurses, certified registered nurse anesthetists, and anesthesiologists.¹⁶ With moderate sedation, patients are able to breathe normally on their own without medical intervention, such as an endotracheal tube,¹⁷ to maintain the patient's airway (intubation).¹⁸

Deep Sedation/Anesthesia

Deep sedation is a medication-induced depression of consciousness in which patients are not easily aroused but will respond to repeated or painful stimulation.^{19,20} When deep sedation occurs, a patient generally maintains cardiac function and the ability to breathe independently; however, the patient risks experiencing a cardiac event or the inability to independently maintain an airway (breathe).²¹ The provider must be able to rescue²² patients in the event of cardiac or

¹⁵ VA National Center for Patient Safety. *Moderate Sedation Toolkit for Non-Anesthesiologists*. <https://www.patientsafety.va.gov/docs/modSedationtoolkit/CurriculumGuideMST.pdf>. (The website was accessed on July 18, 2017.)

¹⁶ VHA Directive 1073.

¹⁷ An endotracheal tube is placed into the windpipe (trachea) through the mouth or nose to assist with breathing or attached to a mechanical device that will breathe for the patient.

¹⁸ When a patient is intubated, a tube is placed into the windpipe through the mouth and the patient is hooked up to a breathing machine.

¹⁹ Painful stimulation includes a sternal rub in which the provider creates a turning pressure on the patient's sternum (breastbone) or pinching the patient's finger or toe to get the patient to respond.

²⁰ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

<http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

²¹ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

<http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

²² Rescue means to save a person from a hazardous situation that is life-threatening or to restore an organ to its normal function after an illness or a treatment that has damaged it. Venes, Donald, M.D., M.S.J., ed. *Taber's Cyclopedia Dictionary* 20th ed. Philadelphia, PA: F.A. Davis Company; 2005.

respiratory arrest or failure due to these inherent deep sedation/anesthesia risks.^{23,24} Anesthesiologists and nurse anesthetists have the training to rescue a patient in deep sedation.²⁵

General Anesthesia

General anesthesia is a medication-induced complete loss of consciousness in which patients are unable to be aroused, even with repeated painful stimulation.²⁶ General anesthesia is commonly used for surgery in the operating room and may be the preferred choice for patients with particular co-morbidities and mental or psychological impediments to cooperation. General anesthesia is also used for patients who have a history of failed moderate sedation.²⁷ However, general anesthesia medications include paralytics, which require intubation due to the inability of patients to breathe on their own.²⁸ Because of the increased risk of respiratory failure, patients are also at a higher risk for life-threatening events such as cardiac failure.²⁹ Providers, such as

²³ American Society of Anesthesiologists. *Distinguishing Monitored Anesthesia Care (MAC) from Moderate Sedation/Analgesia (Conscious Sedation)*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/distinguishing-monitored-anesthesia-care-from-moderate-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

²³ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

<http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

²³ VHA Directive 1073.

²⁴ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

<http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

²⁵ VHA Directive 1073.

²⁶ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

<http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

²⁷ American Society of Anesthesiologists. *Statement on Anesthesia Care for Endoscopic Procedures*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/statement-on-anesthesia-care-for-endoscopic-procedures.pdf>. (The website was accessed on June 29, 2017.)

²⁸ Paralytics are medications used to paralyze a patient, causing the muscles in the body to stop working, including the muscles that help fill the lungs with oxygen.

²⁹ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

[http://asahq.org/~media/Sites/increased the risk ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf](http://asahq.org/~media/Sites/increased%20the%20risk%20ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf). (The website was accessed on June, 29, 2017.)

anesthesiologists and nurse anesthetists, can administer general anesthesia and rescue a patient if needed.³⁰

Outpatient Procedure Sedation/Anesthesia Medications

Controlled Medications

Controlled medications, such as opioids,³¹ are subject to strict federal requirements due to their inherent safety risks and potential for abuse.³² VHA requires automated electronic dispensing records document the type and amount of controlled medications used for individual patients.³³ To ensure that staff account for all controlled medications within the Facility, VHA requires providers to document and sign for the amount administered to the patient and the amount not used or wasted.³⁴ A second authorized health professional must witness and sign for any medication waste disposal. Fentanyl citrate (fentanyl) and midazolam are controlled medications.^{35,36}

Fentanyl

Fentanyl is a synthetic opioid used for pain control in sedation and anesthesia. Fentanyl may cause serious, life-threatening side effects, including difficulty breathing or a decrease in heart rate. Individualized dosing; based on factors including age, weight, and the type of procedure; is necessary due to the potential for serious adverse events.³⁷

³⁰ VHA Directive 1073.

³¹ Opioids are a class of drugs used to reduce pain. The use can lead to addiction. Overdose can lead to respiratory depression and death. Some of these drugs are illegal, such as heroin.
<https://www.cdc.gov/drugoverdose/opioids/index.html>. (The website was accessed on September 8, 2017.)

³² U.S. Food and Drug Administration. *Controlled Substances Act*.
<https://www.deadiversion.usdoj.gov/21cfr/21usc/>. (The website was accessed on July 27, 2017.)

³³ VHA Directive 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010. This VHA handbook was scheduled for recertification on or before the last working day of September 2010 but has not yet been updated.

³⁴ VHA Directive 1108.01.

³⁵ Food and Drug Administration. *Fentanyl Injection*.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/016619s034lbl.pdf. (The website was accessed on July 20, 2017.)

³⁶ Food and Drug Administration. *Midazolam Pharmacy Package*.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208878Orig1s000lbl.pdf. (The website was accessed on July 20, 2017.)

³⁷ Food and Drug Administration. *Fentanyl Injection*.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/016619s034lbl.pdf. (The website was accessed on July 20, 2017.)

Midazolam

Midazolam is a non-opioid, injectable sedation medication, typically given in combination with fentanyl for patients undergoing an outpatient GI procedure.³⁸ As with fentanyl, midazolam may cause serious, life-threatening side effects, which include difficulty breathing and respiratory or cardiac arrest. Midazolam requires individualized dosing, particularly when used in combination with other medications such as fentanyl; because the patient's response varies based on factors such as age, weight, and physical status.³⁹ Fentanyl administered in combination with midazolam may cause profound sedation, low blood pressure, respiratory or cardiac arrest, or death.⁴⁰

Non-controlled Medications

Providers may also use non-controlled medications (medications that are not subject to strict federal requirements), such as propofol,⁴¹ in combination with controlled medications for sedation during outpatient diagnostic and surgical procedures.^{42,43} VHA does not require documentation of non-controlled medication waste.^{44,45}

Propofol

Propofol is an injectable medication that provides patient sedation during GI procedures. This medication may cause low blood pressure, airway obstruction, and cessation of breathing, resulting in cardiac or respiratory arrest or death.⁴⁶ These rapid, profound changes may require

³⁸ Triantafillidis, et al. Sedation in Gastrointestinal Endoscopy: Current Issues. *World Journal of Gastroenterology*. January 28, 2013.

³⁹ Food and Drug Administration. *Midazolam Pharmacy Package*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208878Orig1s000lbl.pdf, (The website was accessed on July 20, 2017.)

⁴⁰ Food and Drug Administration. *Fentanyl Injection*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/016619s034lbl.pdf, (The website was accessed on July 20, 2017.)

⁴¹ Although propofol currently is not considered a controlled medication, the Drug Enforcement Agency is considering adding propofol to the list of controlled medications because of its sedating/hypnotic properties.

⁴² American Society for Gastrointestinal Endoscopy. *Propofol Use during Gastrointestinal Endoscopy*. November 2000.

⁴³ Triantafillidis, et al. Sedation in Gastrointestinal Endoscopy: Current Issues. *World Journal of Gastroenterology*. January 28, 2013.

⁴⁴ Federal Register Part II Department of Justice Drug Enforcement Administration 21 CFR Part 1308. *Proposed Rules: Schedules of Controlled Substances: Placement of Propofol into Schedule IV*. October 27, 2010.

⁴⁵ VHA Directive 1108.01.

⁴⁶ American Society of Anesthesiologists. *Statement on Safe Use of Propofol*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/statement-on-safe-use-of-propofol.pdf>, (The website was accessed on July 20, 2017.)

rescuing of patients who enter an unintended state of general anesthesia.⁴⁷ However, propofol may also allow patients to recover from sedation within a shorter timeframe than other sedatives.⁴⁸ VHA restricts the use of propofol for sedation during GI procedures to anesthesiologists, nurse anesthetists, and trained licensed independent practitioners (providers).⁴⁹

Comprehensive Provider Oversight

To ensure that qualified, competent healthcare providers provide patient care, VHA requires VA facilities to have procedures/policies that define the prerequisites to hire a provider as well as oversee the provider's ongoing patient care.⁵⁰

VHA defines clinical privileging as the process of approving the patient procedures and services a provider can perform. Peer references, professional experience, health status, education, training, and licensure determine a provider's clinical competence and clinical privileges. In general, written clinical privileges must be provider-, service-, and facility-specific, and reviewed every year to ascertain whether a facility continues to provide a service or has the resources to provide those services. Facility medical leaders determine if the provider meets the specific criteria for privileging, and once established, the facility considers the provider to be privileged for that particular medical procedure. A provider must be privileged using the identified provider-, service-, and facility-specific privileges when he/she begins work with the facility. Providers are re-privileged every two years.⁵¹

VHA requires a process, called the Ongoing Professional Practice Evaluation (OPPE), to monitor the ongoing performance of the provider as well as assist in determining if the provider will be re-privileged. This oversight process involves the service chief's evaluation of the provider's professional performance and includes data specific to the provider's practice, such as surgical case review, electronic health record (EHR) review, infection control review, and drug usage evaluation. Data must be provider-specific, reliable, easily retrievable, timely, justifiable, and comparable. The OPPE includes data from direct observation and EHR reviews and confirms the quality of care delivered by privileged providers, allowing the facility to identify professional practice trends affecting patient safety and quality of care. The service chief is responsible for

⁴⁷ American Society of Anesthesiologists. *Statement on Safe Use of Propofol*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/statement-on-safe-use-of-propofol.pdf>. (The website was accessed on July 20, 2017.)

⁴⁸ American Society for Gastrointestinal Endoscopy. *Propofol Use during Gastrointestinal Endoscopy*. November 2000.

⁴⁹ VHA Directive 1073.

⁵⁰ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This VHA handbook was scheduled for recertification on or before the last working day of September 2010 but has not yet been updated.

⁵¹ VHA Handbook 1100.19.

establishing whether a provider does or does not meet established criteria.⁵² Facility policy requires leadership review this data on a regular basis, minimally every six months.⁵³

VHA also requires facilities to file a report with the National Practitioner Data Bank (NPDB) and/or State Licensing Board (SLB) when a provider has issues of professional competence/conduct.⁵⁴ VHA provider issues to consider when reporting to the NPDB or SLB or renewing a provider's clinical privileges include malpractice payments, actions against the provider's clinical privileges⁵⁵ that have exceeded 30 days, negative actions or findings by peer review organizations or private accreditation entities, and adverse actions taken on the provider's licensure and/or professional society membership.⁵⁶ VHA has broad authority to report to the SLB those professionals (including providers, nurses, dentists, and optometrists) whose behavior or clinical practice substantially fails to meet accepted standards of practice (such as not following recommended manufacturer instructions for medication dosing) that raise concerns for patients' safety.⁵⁷

Allegations

The OIG received a complaint regarding allegations about a Facility anesthesiologist's medication practices:

- The anesthesiologist⁵⁸ did not follow VHA and Facility policies for controlled medication waste.
- The anesthesiologist did not individualize patient medication dosing and used more anesthetic/sedation medication than the recommended guidelines for outpatient procedures.
- Facility leaders did not hold the anesthesiologist accountable with comprehensive oversight processes.

⁵² VHA Handbook 1100.19.

⁵³ Medical Center Memorandum 11-26, *Medical Staff Credentialing and Privileging*. November 2016.

⁵⁴ VHA Handbook 1100.17, *National Practitioner Data Bank Reports*, December 28, 2009; VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005 (amended February 5, 2018).

⁵⁵ VHA Handbook 1100.17.

⁵⁶ VHA Handbook 1100.19; National Practitioner Data Bank, U.S. Department of Health and Human Services, Chapter E, <https://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp?page=APreface.jsp>. (The website was accessed on February 27, 2018).

⁵⁷ VHA Handbook 1100.18.

⁵⁸ VHA officials confirmed that the anesthesiologist in question no longer works at the Facility.

Scope and Methodology

The OIG initiated the review in May 2017 and conducted a site visit June 13–14, 2017. During the site visit, OIG staff toured the Same Day Procedure Room and Post-Anesthesia Care Unit.

OIG staff interviewed the complainant, the anesthesiologist,⁵⁹ clinical care providers, quality management staff, Facility and VISN 4 leaders, and other Facility staff knowledgeable about Anesthesia Service operations. As of August 2017, the anesthesiologist no longer worked for the Facility.

OIG staff reviewed VHA and Facility policies and procedures, patient safety documents, medication usage and waste reports, credentialing and privileging files, American Society of Anesthesiologists' guidelines, Food and Drug Administration (FDA) approved manufacturer's medication instructions, and relevant medical journal articles.

Prior to the OIG inspection, VISN 4 leaders requested that the Facility select 20 of the anesthesiologist's patients for a non-protected review by an external⁶⁰ anesthesiologist. The Facility sent the 20 patient EHRs to the Chief of Anesthesiology at the Corporal Michael J. Crescenz VA Medical Center in Philadelphia, Pennsylvania, who conducted the review of the anesthesiology care. The EHR review between spring 2015 and spring 2016 included a wide range of diagnostic procedures for patients at varying weights. OIG staff also used these patients to complete a comprehensive EHR review, which included an assessment of patient adverse events⁶¹ with poor outcomes⁶² related to anesthetic/sedation medications. OIG staff verified both the external anesthesiologist's review of the identified patients and the Facility's summary of the external anesthesiologist's review.

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

⁵⁹ OIG staff were unable to establish why the anesthesiologist used more anesthetic/sedation medication for outpatient procedures than Food and Drug Administration approved manufacturer's instructions recommended for 17 of the 20 identified patients because the anesthesiologist was discharged from the Facility midway through the review process.

⁶⁰ An external provider is a provider who works at a different medical center.

⁶¹ In this report, the OIG considered adverse events as related to anesthetic/sedation medications. Patient's adverse events include allergic reaction, hypotension, hypertension, bradycardia, arrhythmia, aspiration, respiratory depression/arrest, and cardiac arrest.

⁶² Poor outcomes from anesthesia may range from numbness of a site that has received an injection to memory loss, confusion, and high fever and muscle contractions that may even cause death. Many patients who have a significant adverse reaction must remain hospitalized until they recover.

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to substantiate or not substantiate an allegation when the available evidence is insufficient to determine whether or not an alleged event or action took place.

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

Inspection Results

Issue 1: Documentation of Controlled Medication Waste

The OIG did not substantiate that the anesthesiologist failed to follow VHA and Facility policies for documenting controlled medication waste.

VHA and Facility policies require providers to document the usage of all controlled medications including the amount administered and the amount wasted.⁶³

To monitor the amount of medication removed for administration, the Facility used an Omnicell,⁶⁴ which was an automated medication-dispensing machine that electronically recorded the amount and type of medication a staff member, such as the anesthesiologist, removed from the Omnicell unit.⁶⁵ The staff member, who removed the medication, recorded in the unit log the amount of medication not used or wasted. The wasting procedure required a second health professional to witness and document, with a signature, if the medication was wasted.⁶⁶

To determine if the anesthesiologist accounted for the controlled medications used during his procedures, OIG staff reviewed the EHRs and controlled medications records from the Omnicell for each of the 20 identified patients, and noted the amount of fentanyl and midazolam the anesthesiologist documented as administered to each patient. OIG staff compared the amounts of the medications removed from the Omnicell to the amounts documented as administered to each patient.

The OIG found that the anesthesiologist consistently documented administering the entire amount of each controlled medication removed from the Omnicell for each patient. Because the anesthesiologist documented that he used the entire amount of each controlled medication, it was not necessary for him to document medication waste.

Issue 2: Patient Medication Dosing

Individualized Medication Dosing

The OIG did not substantiate that the anesthesiologist failed to individualize patient medication dosing.

VHA requires that the anesthesia provider of record, such as an anesthesiologist, determine the appropriate prescriptions (written orders) for pre-operative medications as necessary to conduct

⁶³ VHA Directive 1108.01; Medical Center Memorandum 10P-16, *Ordering, Dispensing, Delivery, and Disposition of Controlled Substances*, October 2015.

⁶⁴ Omnicell is the name of the Facility's automated medication dispensing machine.

⁶⁵ VHA Directive 1108.01.

⁶⁶ VHA Directive 1108.01.

anesthesia during a procedure.⁶⁷ The anesthesiologist must formulate and discuss the anesthesia plan and prescribed anesthetic/sedation medications with the patient. The plan should be based on several individual patient factors including a review of the patient's medical, anesthesia, and medication history; physical examination including respiratory and cardiac issues; and diagnostic data (such as laboratory tests).⁶⁸ From this medical information, the anesthesiologist orders and administers anesthetic/sedation medication according to a plan specifically tailored for the patient.

OIG staff reviewed the 20 patients' EHRs to determine the amount of fentanyl, midazolam, and propofol the anesthesiologist documented as ordered and administered during outpatient GI procedures to each of the patients. In addition, OIG staff reviewed the anesthesiologist's documentation of patients' ages, weights, and respiratory status.

Overall, the OIG found that 18 of the 20 patients received a different combination of medication doses. Two patients, who received the same dosage, had similar weights and respiratory assessments.

Amounts of Medication Used

The OIG substantiated that the anesthesiologist used larger doses of anesthetic/sedation medication than recommended by the FDA approved manufacturer's instructions.

To ensure the safe administration and distribution of medications to patients, an agreement between the FDA and VA made the FDA responsible for providing quality assurance for all drugs VHA procures, stores, and distributes. This quality assurance includes standards for nation-wide manufacturing, processing, packing, and distribution of all drugs as well as the biologic safety of each drug.⁶⁹ Since 1938, all new drugs for sale or distribution in the United States must be approved for safety and effectiveness by the FDA.^{70,71} This approval includes a review of the drug manufacturer's data from testing the drug, and proposed labeling with

⁶⁷ VHA Handbook 1123, *Anesthesia Service*, March 7, 2007.

⁶⁸ VHA Handbook 1907.01.

⁶⁹ U.S. Food & Drug Administration, Domestic MOUs.

<https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm>. (The website was accessed on October 20, 2017.)

⁷⁰ U.S. Food & Drug Administration, Milestones in U.S. Food and Drug History,

<https://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/EvolvingPowers/ucm2007256.htm>. (The website was accessed on October 20, 2017.)

⁷¹ The Federal Food, Drug, and Cosmetic (FDC) Act of 1938, 21 U.S.C. § 301, 355. (1938).

manufacturer recommended instructions or prescribing information. The review process ensures that these drugs are safe and effective for their intended purpose.^{72,73}

Using the FDA approved manufacturer's instructions, OIG staff calculated the recommended medication doses for each of the 20 patients and compared the calculations to the amount of fentanyl, midazolam, and propofol administered by the anesthesiologist. These recommended medication guidelines and algorithms were established to assist providers' decision-making; however, guidelines are not meant to replace a provider's clinical judgement.^{74,75,76,77}

For at least one of the medications given for sedation/anesthesia during a procedure, the anesthesiologist administered more than the recommended dose to 17 of the 20 patients:

- Fentanyl: the OIG found that the anesthesiologist administered a dose within the FDA recommended medication guidelines for all 20 patients that received fentanyl. However, the fentanyl dose administered to each of these patients was equal to the FDA maximum recommended initiation dose of 100 micrograms (mcg) for sedation/anesthesia.⁷⁸

⁷² Requirements on content and labeling for human prescription drug and biological products, 21 CFR §§ 201.56 and 201.57.

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm>. (The website was accessed on October 20, 2017.)

⁷³ FDA *Approved Drugs: Questions and Answers*. <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm054420.htm>. (The website was accessed on September 8, 2017.)

⁷⁴ American Society of Anesthesiologists. *Statement on Anesthesia Care for Endoscopic Procedures*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/statement-on-anesthesia-care-for-endoscopic-procedures.pdf>. (The website was accessed on June 29, 2017.)

⁷⁵ Food and Drug Administration. *Fentanyl Injection*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/016619s034lbl.pdf. (The website was accessed on July 20, 2017.)

⁷⁶ Food and Drug Administration. *Midazolam Pharmacy Package*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208878Orig1s000lbl.pdf. (The website was accessed on July 20, 2017.)

⁷⁷ Food and Drug Administration. *Diprivan Injectable Emulsion*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/019627s046lbl.pdf. (The website was accessed on July 20, 2017.)

⁷⁸ Food and Drug Administration. *Fentanyl Injection*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/016619s034lbl.pdf. (The website was accessed on July 20, 2017.)

- Midazolam: the OIG found that 5 of the 20 patients received midazolam above the FDA maximum suggested initiation dose of 5 milligrams (mg) for adults and 3.5 mg for patients who were at or above the age of 60.⁷⁹
- Propofol: the OIG found that 13 of the 19⁸⁰ patients received an initial propofol bolus⁸¹ dose above the FDA maximum recommended guidelines based on the patient's weight. When patients receive additional boluses during a procedure (known as maintenance), the FDA recommends each bolus dose should be between 10–20 mg.⁸² Thirteen of 15 maintenance patients received at least one bolus dose above the FDA maximum recommended guidelines. In addition, bolus doses of propofol are not recommended for anesthesia maintenance in patients who are over 55 years old.^{83,84} Twelve of the 15 patients, who received a maintenance bolus dose of propofol, were over 55 years old.

Although the OIG found issues with dosing above the recommended guidance, OIG staff did not find that the reviewed patients suffered adverse outcomes^{85,86} related to the administered doses.

An external anesthesiologist (from another VA Facility) reviewed the anesthesia given to the 20 patients and found issues in 17 cases. When the Facility's Acting Procedure Clinic and Specialty Clinic Chief evaluated the external review data for the 20 patients, he commented that, given the results of the external review, "there is an opportunity for quality improvement."

⁷⁹ Food and Drug Administration. *Midazolam Pharmacy Package*.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208878Orig1s000lbl.pdf. (The website was accessed on July 20, 2017.)

⁸⁰ One of the 20 patients did not receive any propofol.

⁸¹ A bolus is a concentrated amount of medication given rapidly intravenously. Venes, Donald, M.D., M.S.J., ed. *Taber's Cyclopedic Dictionary* 20th ed. Philadelphia, PA: F.A. Davis Company; 2005.

⁸² Food and Drug Administration. *Diprivan Injectable Emulsion*.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/019627s046lbl.pdf. (The website was accessed on July 20, 2017.)

⁸³ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*. (The website was accessed on June 29, 2017.)

⁸⁴ Food and Drug Administration. *Diprivan Injectable Emulsion*.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/019627s046lbl.pdf. (The website was accessed on July 20, 2017.)

⁸⁵ An adverse patient outcome results from adverse events from anesthetic/sedation medications. Adverse events include allergic reaction, hypotension, hypertension, bradycardia, arrhythmia, aspiration, respiratory depression/arrest, and cardiac arrest.

⁸⁶ An adverse patient outcome from anesthesia may range from numbness of a site that has received an injection to memory loss, confusion, and high fever and muscle contractions that may cause death. Many patients with a significant adverse reaction must remain hospitalized until they recover.

Issue 3: Comprehensive Provider Oversight

The OIG substantiated that Facility leaders did not provide oversight of the anesthesiologist according to VHA and Facility credentialing and privileging and ongoing supervision policies.

As required by VHA and Facility policy, the provider's privileges must be provider-, service-, and facility-specific.⁸⁷ According to Facility policy, the service chief is responsible for delineating the criteria used to determine provider privileges. The service chief also acts as the providers' supervisor and confirms the providers' quality of care through OPPEs.⁸⁸

The anesthesiologist's privileges, renewed in spring 2017, included management of patients under general anesthesia during surgical and certain other medical procedures and supervision of critically ill patients in special care units. The Facility is a Level 3 medical center and does not care for critically ill patients.⁸⁹ Therefore, Facility leaders should not have granted those privileges to the anesthesiologist. Facility leaders have revised the anesthesiologist's privileging forms.

Facility leaders monitored the anesthesiologist through OPPEs in accordance with VHA and Facility guidelines. However, according to the anesthesiologist's OPPE, the data reviewed did not include drug usage. The specific medical care provided by the anesthesiologist was to administer controlled drugs and other sedating agents that may cause unconsciousness that could put patients at serious health risk.⁹⁰ The OPPE lacked this type of data review and did not meet the intent of VHA policy to monitor data that was provider-specific as well as reliable, timely, easily retrievable (Omniceil), justifiable, and easily comparable. The reason for this lack of supervisory documentation was unclear; however, a review of this data may have identified a pattern of the anesthesiologist prescribing anesthesia medications inconsistent with FDA approved manufacturer's instructions increasing the patients' risks of respiratory and cardiac arrest and/or failure. The identification, by Facility leaders, of an increased and unnecessary risk to patient safety and/or any resulting suspension or reduction of clinical privileges due to the anesthesiologist's prescribing conduct should have generated a report to the NPDB and/or the SLB.

On December, 19, 2017, Facility leaders informed OIG staff that the anesthesiologist's conduct, at the time he left Facility employment, did not meet the specific criteria or definitions for Facility leaders to send a report to the NPDB or SLB. Although the anesthesiologist was

⁸⁷ VHA Handbook 1100.19.

⁸⁸ Medical Center Memorandum 11-26, *Medical Staff Credentialing and Privileging*, November 2016.

⁸⁹ VHA facilities are classified into three levels with Level 1 representing the most complex facilities, Level 2 the moderately complex facilities, and Level 3 the least complex facilities.

⁹⁰ An anesthesiologist administers anesthesia which is an induction using medications or other agents to produce a loss of sensation with or without the loss of consciousness. <https://www.merriam-webster.com/dictionary/anesthesia>. (The website was accessed on August 31, 2017.)

discharged in summer 2017 from employment for non-patient care issues, the OIG determined that the Facility had not identified the anesthesiologist's practice of administering medications inconsistent with FDA approved manufacturer's instructions when making the decision to not report.

Issue 4: Other Issues

During the course of the OIG review, OIG staff identified issues with Facility pre-procedure patient classifications, general anesthesia misuse, and the Patient Advocate's complaint documentation.

American Society of Anesthesiologists Physical Status Classification System

The OIG determined that the anesthesiologist did not correctly use the required American Society of Anesthesiologist Physical Status (ASA PS) Classification System ranges.

VHA and Facility policies require completion of a pre-procedure evaluation prior to an outpatient procedure, including a medical history and physical and the assignment of an ASA PS Classification.⁹¹ The Classification System ranges from ASA PS I to ASA PS VI based on the health status of the patient. ASA PS I is a normal, healthy patient, and ASA PS VI is a brain-dead patient.⁹²

The anesthesiologist scored the patients using scores of "1-2" and "2+" in 14 of the 20 patients' pre-procedure documentation. Although "1" and "2" corresponded to the defined I and II scores in the ASA PS Classification System, scores such as "1-2" and "2+" used by the anesthesiologist were undefined criterion scores.

General Anesthesia

The OIG determined that the anesthesiologist gave a patient general anesthesia at the Facility instead of transferring the patient to a designated medical center.

Facility policy states that all patients who require general anesthesia must have their procedures transferred to VA Pittsburg Healthcare System or Non-VA Care;⁹³ however, one patient in the OIG review received general anesthesia during an outpatient procedure at the Facility. Because

⁹¹ VHA Directive 1073; VHA Handbook 1907.01; VHA Handbook 1123; Standard Operating Procedure 11M-31, *Pre-Anesthesia Responsibilities*, January 2015.

⁹² American Society of Anesthesiologists. *ASA Physical Status Classification System*. <http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/asa-physical-status-classification-system.pdf>. (The website was accessed on June 29, 2017.)

⁹³ Standard Operating Procedure 11M-13, *Guidelines for Sites for Surgical Procedures and Anesthesia Types*, December 2014.

general anesthesia medications cause a complete loss of consciousness⁹⁴ and a patient may experience respiratory and cardiac failure,⁹⁵ medical equipment and experienced staff must be available in a unit (often called postanesthesia care unit or intensive care unit) that specifically treats patients for these life threatening conditions.⁹⁶ The Facility is a Level 3 Facility and does not have a surgical unit, intensive care unit, or postanesthesia unit to care for patients after receiving general anesthesia.

According to Facility policy, the patient should have been transferred to a designated medical center that was equipped to safely handle general anesthesia patients.⁹⁷ The anesthesiologist chose to administer general anesthesia at the Facility.

Patient Advocacy Program

The OIG determined that the Facility Patient Advocate did not document patient complaints in the web-based Patient Advocate Tracking System (PATS), document issue descriptions and actions, and track complaint resolutions.

VHA requires that VA facilities have a Patient Advocacy Program to ensure that patient complaints are resolved in a proactive and timely manner.^{98,99} VHA also requires full utilization of PATS to track patient complaints. Entering all complaints in PATS provides Facility and national leaders with a comprehensive understanding of patient issues and concerns. The Facility Quality Manager uses PATS data to focus quality improvement efforts.¹⁰⁰

When reviewing patient complaints, OIG staff did not find complaints regarding the anesthesiologist. However, the OIG determined that the Patient Advocate documented patient

⁹⁴ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

<http://asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf>. (The website was accessed on June 29, 2017.)

⁹⁵ American Society of Anesthesiologists. *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*.

[http://asahq.org/~media/Sites/increased the risk ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf](http://asahq.org/~media/Sites/increased%20the%20risk%20ASAHQ/Files/Public/Resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf). (The website was accessed on June, 29, 2017.)

⁹⁶ Standards for Postanesthesia Care, American Society of Anesthesiologists, October 15, 2014.

⁹⁷ Standard Operating Procedure 11M-13.

⁹⁸ Timely is defined “as soon as possible, but no longer than seven days after the complaint is made.” If the complaint requires more than seven days, the patient complaint data must be updated continuously until there is a resolution.

⁹⁹ VHA Handbook 1003.4, *VHA Patient Advocacy Program*, September 2, 2005. This VHA handbook was rescinded and replaced by VHA Directive 1003.04, *VHA Patient Advocacy*, February 7, 2018. The 2005 handbook covers the events reviewed in this report.

¹⁰⁰ VHA Handbook 1003.4.

complaints on a desktop spreadsheet and did not utilize PATS. In addition, 761 of 822 patient complaints documented from November 2015 through July 2016 did not have an issue description, and 173 of 822 complaints did not note the action taken or resolution of the complaint.

Conclusion

The OIG did not substantiate that the anesthesiologist failed to follow VHA and Facility policies for controlled medication waste. Because the anesthesiologist documented that the entire amount of medication was used, he did not need to document wasted medication.

The OIG did not substantiate that the anesthesiologist failed to individualize patient medication dosing.

The OIG substantiated that the anesthesiologist used more anesthetic/sedation medication for outpatient procedures than FDA approved manufacturer's instructions recommended. The OIG findings indicated that the anesthesiologist's conduct, in using larger than FDA approved manufacturer's instructed medication doses, may have increased patients' risk of respiratory and cardiac failure from the amount of anesthetic medications given during the procedure.

The OIG substantiated that Facility leadership did not provide oversight of the anesthesiologist according to VHA and Facility credentialing and privileging and ongoing monitoring policies. Although the Facility did not identify issues to report to the NPDB or SLB when the provider left VA employment, the OIG determined that the Facility should reevaluate if the provider should be reported for the practice of administering medications inconsistent with FDA approved manufacturer's instructions.

During the OIG review, OIG staff identified three other issues, two of which pertained to the anesthesiologist's conduct while providing patient care. The anesthesiologist did not follow Facility policy for patients' pre-procedure documentation; the anesthesiologist gave general anesthesia to a patient although Facility policy required that patients needing general anesthesia should be transferred to designated facilities; and the Patient Advocate did not use PATS as required.

Recommendations 1–4

1. The James E. Van Zandt VA Medical Center Director ensures that the James E. Van Zandt VA Medical Center's anesthesia needs and services are evaluated and align with Veterans Health Administration and James E. Van Zandt VA Medical Center policies.
2. The James E. Van Zandt VA Medical Center Director ensures that service chief provider oversight includes facility-specific privileges and provider-specific Ongoing Professional Practice Evaluations.
3. The James E. Van Zandt VA Medical Center Director ensures that James E. Van Zandt VA Medical Center leaders consult with the Office of Chief Counsel to determine if the anesthesiologist should be reported to the National Practitioner Data Bank and the State Licensing Board for administering medications inconsistent with the Food and Drug Administration approved manufacturer's instructions.

4. The James E. Van Zandt VA Medical Center Director ensures that the Patient Advocate enters all patient complaints into the Patient Advocate Tracking Systems database; documents issue descriptions and actions taken; and tracks all complaints to resolution.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: May 18, 2018

From: Director, VA Healthcare-VISN 4, (10N4)

Subj: Healthcare Inspection— Alleged Inappropriate Anesthesia Practices at the James E. Van Zandt VA Medical Center, Altoona, Pennsylvania

To: Director, Bedford Office of Healthcare Inspections (54BN)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed and concur with *the findings and recommendations* in the OIG report, *Healthcare Inspection—Alleged Inappropriate Anesthesia Practices at the James E. Van Zandt VA Medical Center, Altoona, Pennsylvania.*

(Original signed by:)

Michael D. Adelman, M.D., Director
VA Healthcare-VISN 4

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: June 7, 2018.

From: Director, James E. Van Zandt VA Medical Center (503/00)

Subj: Healthcare Inspection—Alleged Inappropriate Anesthesia Practices at the James E. Van Zandt VA Medical Center, Altoona, Pennsylvania

To: Director, VA Healthcare-VISN 4 (10N4)

1. Thank you for the opportunity to review the draft OIG report on the review of the James E. Van Zandt VA Medical Center. I concur with the recommendations.
2. Our response to the report recommendations is attached. If additional information is needed, please contact the Chief, Quality Management at (814) 943-8164, extension 7321.

(Original signed by:)

Sigrid Andrew, MS, Director

James E. Van Zandt VA Medical Center

Comments to OIG's Report

Recommendation 1

The James E. Van Zandt VA Medical Center Director ensures that the James E. Van Zandt VA Medical Center's anesthesia needs and services are evaluated and align with Veterans Health Administration and James E. Van Zandt VA Medical Center policies.

Concur.

Target date for completion: Completed June 1, 2018

Director Comments

The Chief of Staff with Quality Management staff conducted a comprehensive review of facility's anesthesia needs and services. The anesthesia types of local and monitored anesthesia care (MAC) are the levels of anesthesia provided at the James E. Van Zandt Medical Center which is in alignment with Veteran Health Administration policies. This information has been communicated to facility staff. Facility memoranda are being revised to reflect this action.

OIG Comments

Based on information received from the Facility, the OIG considers this recommendation closed.

Recommendation 2

The James E. Van Zandt VA Medical Center Director ensures that service chief provider oversight includes facility-specific privileges and provider-specific Ongoing Professional Practice Evaluations.

Concur.

Target date for completion: August 30, 2018

Director Comments

The Chief of Staff will evaluate privileges and Ongoing Professional Practice Evaluations to determine compliance with facility-specific privileges and provider-specific Ongoing Professional Practice Evaluations. When opportunities for improvement are identified, service chiefs will update privileges and Ongoing Professional Practice Evaluations. All changes will be reviewed for approval at the Medical Executive Council.

Recommendation 3

The James E. Van Zandt VA Medical Center Director ensures that James E. Van Zandt VA Medical Center leaders consult with the Office of Chief Counsel to determine if the

anesthesiologist should be reported to the National Practitioner Data Bank and the State Licensing Board for administering medications inconsistent with the Food and Drug Administration approved manufacturer's instructions.

Concur.

Target date for completion: June 22, 2018

Director Comments

The James E. Van Zandt VA Medical Center Director is consulting with the Office of Chief Counsel to determine if the anesthesiologist should be reported to the National Practitioner Data Bank and the State Licensing Board for administering medications inconsistent with the Food and Drug Administration approved manufacturer's instructions.

Recommendation 4

The James E. Van Zandt VA Medical Center Director ensures that the Patient Advocate enters all patient complaints into the Patient Advocate Tracking Systems database; documents issue descriptions and actions taken; and tracks all complaints to resolution.

Concur.

Target date for completion: Completed June 1, 2018

Director Comments

The Chief of Stakeholder Relations addressed the concern with the Patient Advocate and Patient Experience Specialist. The team has been using PATS, on a regular basis, since October 2017. Within the last two months; we have changed the data entry points as it relates to the facilities area of responsibility, developed clearer guidelines on language and descriptions, developed a one week expectation for closing reports and are in the process of developing training for all staff so communication can be done almost exclusively in PATS.

We have also outlined work hours to decrease the open consults and emphasized that all Veteran feedback should be entered to allow for a better understanding of patient experience. Finally we gave our first briefing on PATS data May 14, 2018 to all senior leaders within the facility and plan to continue the brief on a monthly basis.

OIG Comments

Based on information received from the Facility, the OIG considers this recommendation closed.

OIG Contact and Staff Acknowledgments

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