

#### DEPARTMENT OF VETERANS AFFAIRS

# OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Inadequate Care by a Clinical Pharmacy Specialist and a Primary Care Provider at the Tennessee Valley Healthcare System in Nashville



The mission of the Office of Inspector General is to serve veterans and the public by conducting effective oversight of the programs and operations of the Department of Veterans Affairs through independent audits, inspections, reviews, and investigations.

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

Report suspected wrongdoing in VA programs and operations to the VA OIG Hotline:

www.va.gov/oig/hotline

1-800-488-8244



# **Executive Summary**

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate an allegation of inadequate care provided by a clinical pharmacy specialist (CPS) at the Tennessee Valley Healthcare System (facility) in Nashville. The OIG received an allegation that a CPS failed to act on a patient's abnormal test results in fall 2018, which led to the patient going undiagnosed and untreated for pancreatic cancer for three months. The OIG opened a healthcare inspection and identified the following additional concerns: the primary care provider's assessment of the patient's unintentional weight loss during an annual physical appointment in summer 2018, facility policies and practices regarding CPSs collaborating with primary care providers when changes occur in patients' conditions, and facility leaders' oversight of patient care provided by CPSs.<sup>2</sup>

The OIG determined that the facility primary care provider failed to acknowledge or assess the patient's unintentional weight loss during an annual physical appointment in summer 2018.<sup>3</sup> The primary care provider documented the patient's weight but did not provide a comparison or analysis of the 48-pound weight loss from the year prior. Unintentional weight loss may be symptomatic of a disease process and must be further evaluated. The primary care provider's plan of care for the patient was an annual follow-up and continued evaluation by the CPS, without mention of the weight loss. The primary care provider's clinical oversight resulted in a missed opportunity to provide the clinical context of significant weight loss to Patient Aligned Care Team (PACT) members caring for the patient.<sup>4</sup> At the time of the OIG review, the primary care provider was no longer employed or contracted by the Veterans Health Administration (VHA); therefore the OIG was not able to get an explanation from the primary care provider about why an assessment of the unintentional weight loss was not done.

The OIG substantiated that the CPS failed to act on a patient's abnormal test results in fall 2018. Upon receiving the patient's abnormal liver function test results, the CPS failed to communicate the results to the patient and document whether a change in the patient's plan of care was needed. The patient's condition declined, and three months later the patient was diagnosed with

<sup>&</sup>lt;sup>1</sup> CPSs are healthcare professionals with expert knowledge and clinical skills in the practice area of comprehensive medication management, which includes initiating, modifying, or discontinuing medication therapy. For purposes of this report, the OIG will discuss only CPSs as defined by VHA Handbook 5005/55, *Staffing*, amended June 7, 2012.

<sup>&</sup>lt;sup>2</sup> VHA Handbook 1101.10 (1), *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014. Primary care providers are "physicians, advanced practice registered nurses, and physician assistants who provide primary care to an assigned panel of patients and in accordance with licensure, privileges, scope of practice or functional statement."

<sup>&</sup>lt;sup>3</sup> Unintentional weight loss is defined as having more than a 5 percent reduction in body weight within 6 to 12 months not due to dieting, exercising, or lifestyle changes.

<sup>&</sup>lt;sup>4</sup> VHA Handbook 1101.10 (1), PACTs are teams of healthcare professionals working together to provide high-quality primary care in partnership with the patient.

pancreatic cancer. Both the CPS and facility leaders reported that the CPS's routine practice was to mail test results to patients; however, neither could verify that this had occurred in this case. Additionally, the primary care provider at this point in time was not aware of the results. The OIG was unable to determine if immediate action by the CPS would have led to the patient receiving a prompt diagnosis and treatment for pancreatic cancer.

After the OIG requested an initial response to these allegations from the facility, prior to opening this inspection, facility leaders reviewed the case and reported counseling the CPS for failure to document both a review of the test results and the choice to continue with the existing plan of care. The OIG did not find evidence that facility leaders counseled the CPS on the failure to communicate the test results to the patient. When interviewed by the OIG, a facility leader did not recognize the requirement to communicate all test results to patients even if a clinician felt that the results were not clinically significant.

The OIG determined that the electronic health record did not reflect a plan for repeat testing based on the abnormalities or notification of the test results to the patient or primary care provider. During an interview with the OIG, the CPS could not recall this case and these labs specifically and stated that the usual practice with results such as these would have been to interpret them as clinically insignificant and continue with the existing plan for follow-up in three months. The OIG does not believe that the lab results were clinically insignificant. Rather, the minimal expected plan of care for this patient should have included repeat liver function testing within four to six weeks, communication of the test results to the patient, and patient education regarding warning symptoms, such as abdominal pain, with directions about when to seek urgent care. This expected plan of care could have been completed by the CPS or accomplished by referral back to the patient's primary care provider.

VHA's current electronic notification system does not ensure that test results are communicated and acted upon by the ordering provider. The OIG issued a healthcare inspection report on June 26, 2019, titled *Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Medical Facility*, that described similar deficiencies with electronic notifications (view alerts) and failure to notify a patient of abnormal test results. The OIG currently has an open recommendation to the Under Secretary for Health to ensure that the planning and implementation of the new electronic medical record includes (a) a fail-safe system that allows communication and tracking of test results to multiple clinical staff members who coordinate patient notification, appropriate follow-up testing, and clinical management, and (b) the ability to monitor actions taken by the responsible provider(s). As the June 2019 recommendation to the

<sup>&</sup>lt;sup>5</sup> VA Office of Inspector General, *Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Medical Facility*, Report No. 19-00022-153, June 26, 2019.

Under Secretary for Health remains open, the OIG does not direct a recommendation to the Under Secretary on the matter in this report.

VHA and the CPS's scope of practice required a consult with a physician "for advanced patient care management beyond the applicant's [CPS's] scope of practice, when changes occur in the patient's condition, and when referrals to higher levels of care are required." Facility policies and practices supported CPSs collaborating with primary care providers when a patient's condition changes. The OIG found no evidence to indicate an overall lack of collaboration between providers and CPSs. The facility utilized scope of practice and care coordination agreements to establish criteria for collaborative practice between CPSs and primary care providers. During interviews, facility staff consistently acknowledged that CPSs were not diagnosticians or licensed independent practitioners and, therefore, had a responsibility to collaborate with the patient's assigned primary care provider when clinically significant changes occurred in a patient's condition.

In the identified patient case, the OIG determined that an opportunity for collaboration was missed. Had the primary care provider documented, assessed, and alerted the other members of the PACT, including the CPS, to the patient's unexplained weight loss in summer 2018, the CPS could have a different context for the clinical significance of the abnormal test results three months later. Although the outcome for this patient may not have changed, it is likely the test results represented liver involvement from progression of pancreatic cancer. Weight loss and elevated blood glucose represented the pancreatic cancer advancing over time. By evaluating the care this patient received, the facility could identify opportunities for improved patient care overall.

The OIG determined that facility leaders provided oversight of patient care delivered by CPSs. The facility complied with VHA and facility policy by requiring that CPSs are credentialed, evaluated, and deemed qualified for a position prior to appointment.<sup>7</sup> The facility's Professional Standards Board performed initial credentialing, ongoing oversight, and monitoring of CPSs' practice through professional practice evaluations.

The OIG made one recommendation to the Veterans Integrated Service Network Director to conduct a comprehensive review of the patient's episode of care and take action as indicated. The OIG made one recommendation to the Facility Director to ensure staff are aware of and follow VHA Directive 1088, *Communicating Test Results to Providers and Patients*.

<sup>&</sup>lt;sup>6</sup> VHA Handbook 1108.11 (1), Clinical Pharmacy Services, amended June 29, 2017.

<sup>&</sup>lt;sup>7</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook expired on October 31, 2017, and has not been updated; Facility Memorandum 626-16-11-25, *Credentialing and Privileging Program*, April 1, 2016.

#### **Comments**

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.

Shal Daish B.

Assistant Inspector General

for Healthcare Inspections

# **Contents**

Executive Summary	i
Abbreviations	vi
Introduction	1
Scope and Methodology	3
Patient Case Summary	4
Inspection Results	6
1. Allegation: Inadequate Care	6
2. Collaboration and Communication Regarding a Change in the Patient's Condition	9
3. Oversight of Patient Care Provided by CPSs	11
Conclusion	12
Recommendations 1–2	14
Appendix A: VISN Director Memorandum	15
Appendix B: Facility Director Memorandum	17
Glossary	19
OIG Contact and Staff Acknowledgments	22
Report Distribution	23

## **Abbreviations**

CPS clinical pharmacy specialist

EHR electronic health record

mg/dL milligrams per deciliter

OIG Office of Inspector General

PACT Patient Aligned Care Team

PPE professional practice evaluation

PSB professional standards board

VHA Veterans Health Administration

VISN Veterans Integrated Service Network

U/L units per liter



## Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate an allegation regarding inadequate care provided by a clinical pharmacy specialist (CPS) at the Tennessee Valley Healthcare System (facility) in Nashville. Specifically, the CPS allegedly failed to act on abnormal test results in fall 2018, which led to a patient going undiagnosed and untreated for pancreatic cancer for three months.

### **Background**

The facility, part of Veterans Integrated Service Network (VISN) 9, is composed of two campuses in Tennessee—the Alvin C. York campus in Murfreesboro, and the Nashville campus—and 12 VA community-based outpatient clinics located in Tennessee and Kentucky. The facility provides primary, secondary, and specialized tertiary care including transplant services. VA classifies the facility as Level 1a, the highest complexity facility classification.<sup>1</sup>

### **Patient Aligned Care Teams**

The facility utilizes Patient Aligned Care Teams (PACTs) to deliver primary care to patients. The Veterans Health Administration (VHA) defines PACTs as teams of healthcare professionals working together to provide high-quality primary care in partnership with the patient.<sup>2</sup> PACTs consist of teamlets that include one full-time primary care provider as well as nursing and administrative support staff. Discipline-specific team members, such as CPSs, social workers, and dieticians, provide care to patients in multiple teamlets. CPSs assist teamlets with comprehensive medication and chronic disease management services for conditions such as diabetes, hypertension, or hyperlipidemia.<sup>3</sup>

## **Primary Care Providers**

Primary care providers are "physicians, advanced practice registered nurses, and physician assistants who provide primary care to an assigned panel of patients and in accordance with licensure, privileges, scope of practice or functional statement." "Primary care is the provision of integrated, accessible health care services," and includes "diagnosis and management of acute

<sup>&</sup>lt;sup>1</sup> The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

<sup>&</sup>lt;sup>2</sup> VHA Handbook 1101.10 (1), Patient Aligned Care Team (PACT) Handbook, February 5, 2014.

<sup>&</sup>lt;sup>3</sup> VHA Handbook 1108.11 (1), Clinical Pharmacy Services, amended June 29, 2017.

<sup>&</sup>lt;sup>4</sup> VHA Handbook 1101.10 (1).

and chronic biopsychosocial conditions, health promotion, disease prevention, overall care management, post deployment care, and patient and caregiver education." VHA leaders expect primary care providers to ensure "the patient's care plan contains medical recommendations for clinically indicated care." Primary care providers also provide leadership to the team including "shared delegation of appropriate care and care processes to appropriate team members." To that end, a primary care provider should recognize significant changes; and in turn, may delegate PACT staff to address patient care concerns. 8

## **Clinical Pharmacy Specialists**

VHA leaders expect CPSs to function at the highest level of clinical practice, serving as midlevel providers to initiate, modify, or discontinue medication therapy. CPSs are healthcare professionals with expert knowledge and clinical skills in the practice area of comprehensive medication management. CPSs possess, at a minimum, a baccalaureate degree in pharmacy and may complete a graduate degree at the doctoral level, postgraduate residency training, or attain certification in a specialty practice area. Within VHA, a CPS may be involved in the care of patients in multiple healthcare settings. When providing certain patient care activities, a scope of practice is required in accordance with VHA Handbook 1108.11. CPSs may provide direct patient care and manage disease states within the parameters of a scope of practice. The CPSs' scope of practice authorizes them to assess patients' responses to medication therapy including ordering, reviewing, and acting on test results in addition to implementing and monitoring pharmacotherapeutic care plans. 11

## **Allegations and Related Concerns**

In February 2019, the OIG received an allegation that a CPS failed to act on a patient's abnormal test results in fall 2018, which led to the patient going undiagnosed and untreated for pancreatic cancer for three months. The OIG Office of Healthcare Inspections reviewed the allegation and determined that a response from facility leaders was warranted. <sup>12</sup> In May 2019, the OIG found the facility's response to be inadequate and requested additional information. In June, facility

<sup>&</sup>lt;sup>5</sup> VHA Handbook 1101.10 (1).

<sup>&</sup>lt;sup>6</sup> VHA Handbook 1101.10 (1).

<sup>&</sup>lt;sup>7</sup> VHA Handbook 1101.10 (1).

<sup>&</sup>lt;sup>8</sup> VHA Handbook 1101.10 (1).

<sup>&</sup>lt;sup>9</sup> VHA Handbook 1108.11 (1); For purposes of this report, the OIG will discuss only clinical pharmacy specialists as defined by VHA Handbook 5005/55, *Staffing*, amended June 7, 2012.

<sup>&</sup>lt;sup>10</sup> VHA Handbook 1108.11 (1).

<sup>&</sup>lt;sup>11</sup> Facility document, Application for Scope of Practice, Clinical Pharmacy Specialist, February 18, 2017.

<sup>&</sup>lt;sup>12</sup> For purposes of this report, the OIG uses the terms facility leaders to include the facility pharmacy chief and associate chief in addition to the facility executive leadership team.

leaders provided a second response, which the OIG determined was also inadequate. The OIG opened a healthcare inspection and identified the following concerns

- Primary care provider's failure to acknowledge or assess the patient's unintentional weight loss during an annual physical appointment in summer 2018,
- Facility policies and practices regarding CPSs collaborating with primary care providers when changes occur in patients' conditions, and
- Facility leaders' oversight of patient care provided by CPSs.

# **Scope and Methodology**

The OIG initiated the inspection in June 2019, and conducted a site visit from July 30, 2019, through August 1, 2019.

Facility staff interviewed included the Chief of Staff, Chief of Pharmacy, Chief of Primary Care, Chief of Informatics, Chief of Community-Based Outpatient Clinics, Patient Safety Manager, Risk Manager, and several CPSs and primary care providers. The OIG team also interviewed the complainant. At the time of the OIG review, the primary care provider was no longer employed or contracted by VHA; therefore, the OIG was not able to get an explanation from the primary care provider about why an assessment of the unintentional weight loss was not done.

The OIG team reviewed documents from October 2017 through August 2019, including the patient's electronic health record (EHR), facility and VHA policies, patient safety documents, CPSs' credentialing and privileging files, quality of care review records, provider evaluation records, and other documents relevant to the inspection. The team focused on the facility's 22 CPSs working under a scope of practice in primary care at the time of the site visit.

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).

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 determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, §7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leadership on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

# **Patient Case Summary**

The patient was in their 60s with a history of diabetes, tobacco use, <u>cataracts</u>, and <u>glaucoma</u>. <sup>13</sup> In early 2018, the patient underwent cataract surgery and was informed by the surgical team of an elevated <u>blood glucose</u>. The patient called the facility and reported to the licensed practical nurse the high glucose reading, and having run out of diabetic medication several days prior to the eye surgery. The licensed practical nurse asked the patient to come into the clinic for an assessment and blood tests.

The following day, the patient obtained blood tests that showed an elevated blood glucose of 335 milligrams per deciliter (mg/dl), and normal <u>liver function tests</u> [<u>aspartate aminotransferase</u> (AST), alanine transaminase (ALT), and <u>bilirubin</u>]. <sup>14</sup> Five days later, a registered nurse provided education to the patient on obtaining blood samples and monitoring daily blood sugars. In early-spring 2018, the patient reported to a registered nurse a blood glucose level ranging from 269 to 329 over the last eight days. <sup>15</sup> Based on the elevated blood glucose, and as ordered by the primary care provider, the registered nurse instructed the patient to increase the diabetic medication. The CPS was consulted to review the medications and assist the patient with diabetic medication management. The CPS entered an order in spring 2018 for a future appointment.

In late spring 2018, the CPS completed an initial evaluation and provided a plan of care for the patient that included medication adjustments, additional blood glucose checks, and a reevaluation in one month. In summer 2018, the patient followed up with the CPS who documented the patient's test results, which had been ordered by the primary care provider for the patient's upcoming annual physical examination. The patient's test results showed an elevated blood glucose of 176 mg/dl, and normal liver function tests. <sup>16</sup> At this visit, the CPS continued the current plan of care, scheduled a three month follow-up, and ordered a hemoglobin A1c and a basic metabolic panel to be completed just before the next CPS visit.

In summer 2018, the primary care provider evaluated the patient for an annual physical examination. At this exam, the patient weighed 169 pounds, representing a decrease of 48 pounds from the patient's last annual physical in summer 2017. The primary care provider reviewed the aforementioned test results with the patient and requested that the patient follow up

<sup>&</sup>lt;sup>13</sup> OIG uses the singular form of they (their) in this instance for privacy purposes.

<sup>&</sup>lt;sup>14</sup> The reference range for AST is 5–34 units per liter and ALT is 0–55 units per liter. The patient's test results in early 2018, were <u>AST 22</u>, <u>ALT 36</u>, total <u>bilirubin 0.5</u> (reference range 0.2–1.3mg/dl).

<sup>&</sup>lt;sup>15</sup> The facility's reference range for blood glucose was 70–99.

<sup>&</sup>lt;sup>16</sup> AST 16 (5–34U/L), ALT, 18 (0–55U/L), total bilirubin 0.3 (0.2–1.3mg/dl).

with the primary care provider in 12 months or sooner, if needed. The primary care provider did not document a comparison of, or an inquiry into, the patient's 48-pound weight loss over the prior 11 months. <sup>17</sup>

In fall 2018, the patient returned for a follow-up appointment with the CPS. The most recent test results available for review by the CPS were the summer 2018 results. <sup>18</sup> The CPS saw the patient, documented the tests completed in summer 2018, and ordered a hemoglobin A1c, <u>lipid panel</u>, and <u>comprehensive metabolic panel</u> including liver function tests to be obtained within the next two weeks. The CPS scheduled a three month follow-up appointment with the patient.

A few days later, the patient's test results showed a blood glucose of 124 mg/dl, and elevated liver function tests (AST and ALT of 65 U/L and 94 U/L) respectively.

In late 2018, during the patient's follow-up appointment with the CPS, the CPS first acknowledged the fall 2018 test results. At this appointment, the patient provided a medical history to the CPS of severe right upper abdomen pain that had lasted for two weeks a few months earlier. The patient indicated, since the fall 2018 follow-up appointment, experiencing intermittent abdominal pain that consistently woke the patient up from sleep. The CPS noted that the patient was jaundiced and requested an immediate evaluation by a primary care provider. A nurse practitioner evaluated the patient, noted the abdominal symptoms on history and jaundice on physical exam, and an increase in the fall 2018 liver function test results. The nurse practitioner advised the patient to have an urgent evaluation at the local community hospital Emergency Department.<sup>19</sup>

The community Emergency Department physician reported back to the facility's nurse practitioner that a <u>computer tomography scan</u> obtained on the patient showed a pancreatic mass, and blood tests showed a total bilirubin of 27 mg/dl (normal = 0.00–0.40 mg/dl). The community Emergency Department evaluation included blood tests that showed elevated liver function tests (AST of 132 and ALT of 152). The patient requested follow-up within the VA facility.

Two days after the patient's follow-up appointment with the CPS, the patient was admitted to the facility for an endoscopic retrograde cholangiopancreatography, endoscopic ultrasound, and a biliary stent placement to be completed at Vanderbilt University. At the University, gastroenterologists completed the two procedures, but biliary stenting was unsuccessful due to the degree of biliary stenosis. The patient returned to the facility after the procedure but then left for home against medical advice.

<sup>&</sup>lt;sup>17</sup> At the time of the OIG review, the primary care provider mentioned in this report was no longer employed or contracted by VHA; the OIG team's attempts to contact the primary care provider were unsuccessful.

<sup>&</sup>lt;sup>18</sup> The patient had not yet completed the previously ordered hemoglobin A1c and a basic metabolic panel.

<sup>&</sup>lt;sup>19</sup> The patient was seen at one of the facility's community-based outpatient clinics located 143 miles from the facility.

The following month, a community oncologist saw the patient and diagnosed pancreatic cancer with lymph node involvement with likelihood of metastatic disease to the liver. The community oncologist documented that the patient was not a good candidate for chemotherapy and recommended an inpatient stay to reattempt biliary stenting. The patient died in early-spring 2019.

# **Inspection Results**

## 1. Allegation: Inadequate Care

During the OIG's review of the allegations regarding the CPS's failure to act on a patient's abnormal test results, the OIG found the patient's recorded weight at the patient's summer 2018 annual physical represented a 48-pound weight loss since the patient's last annual physical in summer 2017. The primary care provider did not acknowledge, analyze, or assess the patient's weight loss.

The OIG also found that upon receiving the patient's abnormal liver function test results in fall 2018, the CPS failed to communicate the results to the patient and document if a change in the patient's plan of care was needed. The OIG reviewed the actions taken by both the primary care provider and the CPS.

# Primary Care Provider's Failure to Acknowledge or Assess Patient's Unintentional Weight Loss

The OIG determined that the primary care provider failed to acknowledge or assess the patient's unintentional weight loss during an annual physical appointment in summer 2018.<sup>20</sup> The primary care provider documented the patient's weight but did not provide a comparison or analysis of the 48-pound weight loss from the year prior.

The role of the primary care provider in evaluating weight loss is to complete a thorough history and physical so that pertinent labs and studies are ordered to effectively and efficiently provide a diagnosis for the patient. Primary care providers should intervene early in a disease process before permanent or irreversible issues develop so that interventions may reverse disease processes with the patient returning to baseline health. The need to fully recognize and evaluate significant changes in a physical exam becomes even more important when patients only present annually for care, as in this case. During an annual exam, all parameters of health should be reviewed in detail, and significant deviations from prior exams should be recognized and a medical plan of care established to address the deviation.

<sup>&</sup>lt;sup>20</sup> Unintentional weight loss is defined as having more than a 5 percent reduction in body weight within 6 to 12 months not due to dieting, exercising, or lifestyle changes.

The EHR from the patient's summer 2018 annual physical examination indicated a clinically significant weight loss despite a denial by the patient of having weight changes. The patient's reduction in weight from summer 2017 to summer 2018, was 22.6 percent; the OIG concluded that the weight loss was more than likely unintentional. Unintentional weight loss may be symptomatic of a disease process and must be further evaluated.

The patient's EHR did not show that clinically significant weight loss was recognized on the annual visit by the primary care provider. The primary care provider's plan of care for the patient was an annual follow-up and continued evaluation by the CPS without mention of weight loss. The primary care provider's clinical oversight resulted in a missed opportunity to provide the clinical context of significant weight loss to PACT members caring for the patient.

#### CPS's Failure to Act on Abnormal Test Results

The OIG substantiated that the CPS failed to act on a patient's abnormal test results in fall 2018. Upon receiving the patient's abnormal liver function test results, the CPS failed to communicate the results to the patient and document if a change in the patient's plan of care was needed. The patient's condition declined, and in late 2018, the patient was diagnosed with pancreatic cancer. The OIG was unable to determine if immediate action by the CPS would have led to the patient receiving a prompt diagnosis and treatment for pancreatic cancer.

VHA requires the communication of outpatient test results by the ordering provider or designee to the patient, "within seven calendar days for results requiring action, and within 14 calendar days for test results not requiring action." VHA and facility policy state the ordering provider is responsible for initiating any clinical action related to abnormal test results including taking appropriate therapeutic actions. <sup>22</sup>

In fall 2018, the CPS received and opened a notification in the EHR containing the patient's newly abnormal liver function test results (<u>ALT</u> and <u>AST</u>). <sup>23</sup> Clinical guidelines state that "elevated ALT or AST above the upper limit of normal in a population without identifiable risk factors is associated with increased liver related mortality." <sup>24</sup> Both the CPS and facility leaders reported that the CPS's routine practice was to mail test results to patients; however, neither the

<sup>&</sup>lt;sup>21</sup> VHA Directive 1088, Communicating Test Results to Providers and Patients, October 5, 2015.

<sup>&</sup>lt;sup>22</sup> VHA Directive 1088; Facility Memorandum 626-17-11-16, *Procedure for Ordering and Reporting Test Results*, December 27, 2017. Abnormal test results fall outside a specified reference range, are not expected, and could be a sign of disease. An abnormal test may require action or an intervention, depending on the clinical status of the patient.

<sup>&</sup>lt;sup>23</sup> The patient's test result for ALT in summer, 2018, was 18 U/L and in fall 2018 increased to 94 U/L. The patient's test result for AST in summer 2018, was 16 U/L and in fall 2018 increased to 65 U/L. Reference ranges for ALT is 0–55 U/L and for AST is 5–34 U/L.

<sup>&</sup>lt;sup>24</sup> The American Journal of Gastroenterology, *ACG Clinical Guideline: Evaluation of Abnormal Liver Chemistries*, vol 112, January 2017.

CPS nor the facility leaders could verify that this had occurred in this case. Additionally, the primary care provider was not aware of the results at this point in time. After the OIG requested an initial response to these allegations from the facility, prior to opening this inspection, facility leaders reviewed the case and expressed having no concerns regarding the care provided by the CPS. However, facility leaders reported counseling the CPS for failure to document a review of the test results and a failure to document the choice to continue with the existing plan of care. The OIG did not find evidence that facility leaders counseled the CPS on the failure to communicate the test results to the patient. When interviewed by the OIG, a facility leader did not recognize the requirement to communicate all test results to patients, even if a clinician felt that the results were not clinically significant.

The OIG determined that the EHR did not reflect a plan for repeat testing based on the abnormalities or notification of the test results to the patient or primary care provider. The minimal expected plan of care for this patient should have included repeat liver function testing within four to six weeks, communication of the test results to the patient, and patient education regarding warning symptoms, such as abdominal pain, with directions about when to seek urgent care. This expected plan of care could have been completed by the CPS or accomplished by referral back to the patient's primary care provider.

#### Additional Concern: Limitations of Notifications in the EHR

The OIG learned through interviews with facility staff that the current EHR used within VHA lacks a process to ensure that test results are communicated and acted upon by the ordering provider.

The responsibility for documentation and action on abnormal test results resides with the ordering provider or an established surrogate. The ordering provider or surrogate receives an electronic notification of test results through the facility's EHR system. Once opened, the electronic notification is considered processed and is automatically removed from the clinician's view. The OIG is concerned that a clinician who is distracted after opening an electronic notification may fail to address the matter before the notification is deleted. Without a second reminder, the clinician may not recall the need to take a specific action for the patient.

Additionally, facility leaders do not have the ability to collectively monitor if action was taken on abnormal test results. VHA's EHR does not link abnormal test results with the actions taken by clinicians in response to the abnormal test results, such as the ordering of additional tests, medications, or follow-up appointments.

The OIG issued a healthcare inspection report on June 26, 2019, titled *Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Medical Facility*, that described similar issues with electronic notifications (view alerts) and a failure to notify a patient of

abnormal test results.<sup>25</sup> The OIG recommended that the Under Secretary for Health ensures that the planning and implementation of the new electronic medical record includes (a) a fail-safe system that allows communication and tracking of test results to multiple clinical staff members who coordinate patient notification, appropriate follow-up testing and clinical management, and (b) the ability to monitor actions taken by the responsible provider(s). As the June 2019 recommendation to the Under Secretary for Health remains open, the OIG does not direct a recommendation to the Under Secretary on the matter in this report.

# 2. Collaboration and Communication Regarding a Change in the Patient's Condition

While the OIG found no evidence to indicate an overall lack of collaboration between facility primary care providers and CPSs, the OIG determined that for the identified patient, an opportunity for collaboration between the primary care provider and CPS was missed.

## **Facility Policies and Practices Regarding CPSs Collaboration**

VHA and the CPS's scope of practice required the CPS to consult a physician "for advanced patient care management beyond the applicant's [CPS's] scope of practice, when changes occur in the patient's condition, and when referrals to higher levels of care are required."<sup>26</sup> The CPS's scope of practice authorized the CPS to order and interpret blood test results.<sup>27</sup> According to VHA and facility policy, CPSs use clinical judgment to determine when changes in a patient's condition fall beyond the CPS's abilities.

The OIG found no evidence to indicate an overall lack of collaboration between providers and CPSs. The OIG determined that facility policies and practices supported CPSs collaborating with primary care providers when patients' conditions changed. The facility utilized scope of practice and care coordination agreements to establish criteria for collaborative practice between CPSs and primary care providers.

The OIG reviewed the scope of practice of the 22 PACT CPSs during the site visit. All 22 scopes of practice were signed and approved by supervising physicians and covered the period of the visit. During interviews, facility staff consistently acknowledged that CPSs were not diagnosticians or licensed independent practitioners, and therefore, had a responsibility to collaborate with a patient's assigned primary care provider when clinically significant changes occurred in a patient's condition. Patients who are seen by a CPS retain an assigned primary care provider, making the physician with whom collaboration is required clear.

<sup>&</sup>lt;sup>25</sup> VA Office of Inspector General, *Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Medical Facility*, Report No. 19-00022-153, June 26, 2019.

<sup>&</sup>lt;sup>26</sup> VHA Handbook 1108.11 (1).

<sup>&</sup>lt;sup>27</sup> VHA Handbook 1108.11 (1).

Interviews with several CPSs and primary care providers revealed that the two professionals used multiple methods of collaboration to communicate changes in a patient's condition. These methods included phone, email, co-signing notes, instant messaging, or in-person. During interviews, CPSs were able to provide anecdotal examples of times they have collaborated with a patient's primary care provider. CPSs reported no difficulties in contacting primary care providers when needed. Primary care providers confirmed that CPSs communicated changes in patient's conditions, and they reported no concerns regarding CPSs' abilities to communicate.

# Missed Opportunity for Collaboration in the Identified Patient's Case

For the identified patient, an opportunity for collaboration between the primary care provider and CPS was missed.

The primary care provider did not provide the members of the PACT with the awareness that weight loss was a significant finding for this patient and that this weight loss might have been used to incorporate or interpret future clinical changes or laboratory abnormalities. As a result of the primary care provider not addressing this patient's significant weight loss at the time of the summer 2018 annual exam, the context for the abnormal liver function test three months later was diminished. However, the patient's yet undiagnosed pancreatic cancer advanced and clinical condition deteriorated in the interim, resulting in obstructive jaundice and unsuccessful biliary stenting.

The CPS failed to notify the primary care provider of the patient's abnormal test results. The CPS could not recall this case and these labs specifically, and stated that the usual practice with results such as these would have been to interpret them as clinically insignificant and continue with the existing plan for follow up in three months. When presented with the specifics of this case, the CPS and facility leaders interpreted these test results as not elevated enough to require action and determined that consultation with the provider was not warranted. However, other CPSs and primary care providers interviewed by the OIG reported they would have interpreted these test results as clinically significant and worthy of communication.

According to the American College of Gastroenterology practice guidelines, ALT levels above 33 U/L in patients should be assessed by a physician. The patient was not taking any medications that would have affected the liver and caused an upward trend of the patient's AST and ALT. This coupled with a history of unexplained weight loss of 48 pounds should have prompted providers to initiate further workup and closer monitoring. Had the primary care provider documented, assessed, and alerted the other members of the PACT, including the CPS, to the patient's unexplained weight loss in summer 2018, the CPS could have had a different context for the clinical significance of the abnormal test results three months later. In addition, a further assessment of the patient's condition could have been initiated by the primary care provider three months prior to the CPS receiving the abnormal test results.

Although the outcome for this patient may not have changed, it is likely the test results represented liver involvement from progression of pancreatic cancer; weight loss, and elevated blood glucose represented the pancreatic cancer advancing over time. By evaluating the care this patient received, the facility could identify opportunities for improved patient care overall.

## 3. Oversight of Patient Care Provided by CPSs

The OIG determined that facility leaders provided oversight of patient care provided by CPSs. The facility utilizes a professional standards board (PSB) and professional practice evaluation (PPE) to initially credential and provide ongoing oversight of CPSs' practice.<sup>28</sup>

## **Professional Standards Board and Credentialing**

The OIG found that the facility complied with VHA and facility policy by requiring that CPSs are credentialed, evaluated, and deemed qualified for a position prior to appointment.<sup>29</sup> Credentialing is a process of screening and evaluating a practitioner's qualifications, including but not limited to licensure, education, training, experience, and health status.<sup>30</sup> VHA requires that CPSs be credentialed but not privileged by VHA facilities as CPSs are not licensed independent practitioners.<sup>31</sup> Instead of privileging, a facility director approves or denies a scope of practice outlining the CPS's delegated clinical duties.<sup>32</sup> A scope of practice, which is required for all CPSs with prescribing authority, is a document in which the CPS requests permissions for patient care duties relevant to a particular practice area (for example, diabetes or hypertension) and setting (inpatient medical facility or outpatient clinic).<sup>33</sup> If the position is aligned within a service, such as Primary Care, both the Chief of Pharmacy and the Chief of Primary Care must approve the CPS's appointment (or employment in a medical staff position) and scope of practice.<sup>34</sup>

<sup>&</sup>lt;sup>28</sup> PPE is a program that evaluates CPSs' quality of care; VHA Handbook 1108.11 (1); Facility Medical Staff Bylaws, September 12, 2017.

<sup>&</sup>lt;sup>29</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook expired October 31, 2017, and has not been updated; Facility Memorandum 626-16-11-25, *Credentialing and Privileging Program*, April 1, 2016.

<sup>&</sup>lt;sup>30</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>31</sup> In VHA, a licensed independent practitioner is a health provider who is permitted by law (in the state of licensure) and by the facility to provide patient care services without supervision or direction, within the limits approved by state licensure regulations, and in accordance with clinical privileges that the facility grants to an individual practitioner; VHA Handbook 1100.19.

<sup>&</sup>lt;sup>32</sup> VHA Handbook 1108.11 (1).

<sup>&</sup>lt;sup>33</sup> VHA Handbook 1108.11 (1); Facility Memorandum 626-19-119-27, *Scope of Practice and Clinical Pharmacy Specialist Professional Practice Evaluation*, July 17, 2019.

<sup>&</sup>lt;sup>34</sup> VHA Handbook 1108.11 (1); VHA Handbook 1100.19.

The OIG found that credentialing and applications for a scope of practice were reviewed and approved by the facility's PSB. The facility's policy was that the PSB was chaired by the Chief of Staff and included the Chief of Pharmacy, other designated service chiefs, and representatives from credentialing and privileging, and human resources.<sup>35</sup> The facility's PSB reviews the required credentialing elements noted above, along with the CPS's references and any history of disciplinary action, and makes recommendations for approval or denial of the CPS's credentials to the facility's Medical Executive Board.<sup>36</sup> To further ensure adequate training, before working independently, newly appointed CPSs are mentored by peers in the CPS's chosen clinical specialty for a minimum of one month. Facility leaders require that contracted CPSs undergo the same vetting process as CPSs who are VA employees.

#### **Professional Practice Evaluation**

The OIG found that the facility complied with VHA and facility policy by requiring that a CPS with a scope of practice participate in a PPE program that regularly reviews the CPS's clinical care.<sup>37</sup> There are two types of PPEs: focused professional practice evaluation that assesses newly appointed practitioners, and ongoing professional practice evaluation that biannually evaluates continued quality of care.<sup>38</sup> In addition, VHA requires CPSs to complete clinical care reviews of peers to evaluate the quality of care provided.<sup>39</sup> Facility policy requires that five patient chart reviews be completed quarterly for each CPS.<sup>40</sup> The OIG reviewed the 22 CPSs' applications for scope of practice, PPE, and clinical care review documents and found no deficiency.<sup>41</sup>

## **Conclusion**

The OIG determined that the facility primary care provider failed to acknowledge or assess the patient's unintentional weight loss during an annual physical appointment in summer 2018. The primary care provider documented the patient's weight but did not provide a comparison or analysis of the 48-pound weight loss from a year prior.

<sup>&</sup>lt;sup>35</sup> Facility Medical Staff Bylaws, September 12, 2017.

<sup>&</sup>lt;sup>36</sup> The facility's Medical Executive Board, chaired by the Chief of Staff, worked on behalf of the medical staff to oversee governance, leadership and performance improvement activities; Facility Medical Staff Bylaws, September 12, 2017

<sup>&</sup>lt;sup>37</sup> VHA requires PPE to cover six broad categories: patient care, medical/clinical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and facility-based practice; VHA Handbook 1108.11 (1); Facility Memorandum 626-19-119-27.

<sup>&</sup>lt;sup>38</sup> VHA Handbook 1108.11 (1).

<sup>&</sup>lt;sup>39</sup> VHA Handbook 1108.11 (1).

<sup>&</sup>lt;sup>40</sup> Facility Memorandum 626-19-119-27.

<sup>&</sup>lt;sup>41</sup> The OIG team reviewed focused professional practice evaluation documents for seven CPSs who had focused professional practice evaluation performed during the time of the review.

The OIG substantiated that the CPS failed to act on a patient's abnormal test results in fall 2018. However, the OIG was unable to determine if immediate action by the CPS would have led to the patient receiving a prompt diagnosis and treatment for pancreatic cancer. The OIG determined that the CPS failed to communicate abnormal test results to the patient, as required by VHA and facility policy. The OIG found that the CPS also did not document a change in the patient's plan of care. After the OIG requested an initial response to these allegations from the facility, prior to opening this inspection, facility leaders reviewed the case and reported counseling the CPS for failure to document a review of the test results and failure to document the choice to continue with the existing plan of care. The OIG did not find evidence that facility leaders counseled the CPS on the failure to communicate the test results to the patient. When interviewed by the OIG, a facility leader did not recognize the requirement to communicate all test results to patients, even if a clinician felt that the results were not clinically significant.

The current EHR used within VHA lacks a process to ensure that test results are communicated and acted upon by ordering providers. The OIG currently has an open recommendation to the Under Secretary for Health to ensure that the planning and implementation of the new electronic medical record includes (a) a fail-safe system that allows communication and tracking of test results to multiple clinical staff members who coordinate patient notification, appropriate follow-up testing and clinical management, and (b) the ability to monitor actions taken by the responsible provider(s). Therefore, the OIG does not direct a recommendation to the Under Secretary on the matter in this report.

The OIG determined that facility policies and practices supported CPSs collaborating with primary care providers when a patient's condition changed. The facility utilized scope of practice and care coordination agreements to establish criteria for collaborative practice between CPSs and primary care providers. During interviews, facility staff consistently acknowledged that CPSs were not diagnosticians or licensed independent practitioners, and therefore, had a responsibility to collaborate with the patient's assigned primary care provider when clinically significant changes occurred in a patient's condition.

Although the OIG found no evidence to indicate an overall lack of collaboration between providers and CPSs, in this case, the OIG determined that an opportunity for collaboration was missed. The primary care provider did not provide the PACT with the awareness that weight loss was a significant finding for this patient and that this weight loss might have been used to incorporate or interpret future clinical changes or laboratory abnormalities. The CPS failed to notify the primary care provider of the patient's abnormal test results. The CPS could not recall this case and these labs specifically, and stated that the usual practice with results such as these would have been to interpret them as clinically insignificant and continue with the existing plan for follow up in three months. Had the primary care provider documented, assessed, and alerted the other members of the PACT, including the CPS, to the patient's unexplained weight loss in summer 2018, the CPS could have had a different context for the clinical significance of the

abnormal test results three months later. Although the outcome for this patient may not have changed, it is likely the test results represented liver involvement from progression of pancreatic cancer; weight loss, and elevated blood glucose represented the pancreatic cancer advancing over time. By evaluating the care this patient received, the facility could identify opportunities for improved patient care overall.

The OIG found that facility leaders provided oversight of patient care delivered by CPSs. The facility's PSB performed initial credentialing, ongoing oversight, and monitoring of CPS practice through PPE.

## Recommendations 1-2

- 1. The Veterans Integrated Service Network Director conducts a comprehensive review of the patient's care including collaboration among Patient Aligned Care Team members and takes action as indicated.
- 2. The Tennessee Valley Healthcare System Director ensures facility staff are aware of and follow Veterans Health Administration Directive 1088, *Communicating Test Results to Providers and Patients*, specifically the requirement for the ordering clinician to communicate all test results to patients.

# **Appendix A: VISN Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

Date: May 12, 2020

From: Director, VA MidSouth Healthcare Network (10N9)

Subj: Healthcare Inspection—Inadequate Care by a Clinical Pharmacy Specialist and a Primary Care

Provider at the Tennessee Valley Healthcare System in Nashville

To: Director, Office of Healthcare Inspections (54HL06)

Director, GAO/OIG Accountability Liaison (VHA 10EG GOAL Action)

- 1. I have reviewed the draft report "Inadequate Care by a Clinical Pharmacy Specialist and a Primary Care Provider" from the Office of the Inspector General (OIG) and I concur with the recommendations from this focused review of July 30, 2019.
- 2. I would like to take this opportunity to thank the OIG Team for this consultative visit and the opportunity to respond to these findings.

(Original signed by:)

Cynthia Breyfogle, FACHE

## **VISN Director Response**

#### **Recommendation 1**

The Veterans Integrated Service Network Director conducts a comprehensive review of the patient's care including collaboration among Patient Aligned Care Team members and takes action as indicated.

Concur.

Target date for completion: September 30, 2020

#### **Director Comments**

A comprehensive review was completed of the Veteran's health record, including interviews with the facility Chief of Staff, Associate Chief of Staff for Ambulatory Care, and Associate Service Chief of Pharmacy, Clinical & Educational Programs, review of the referenced OIG report, and the facility's previous response to the OIG. The findings of the comprehensive clinical review included assessment of the three allegations referencing: (1) Inadequate Care, (2) Collaboration and Communication Regarding a Change in the Patient's Condition, and (3) Oversight of Patient Care Provided by CPSs. In summary, the VISN 9 Comprehensive Clinical Review did not find that the overall Standard of Care was breached. However, opportunities were identified to strengthen communication and collaboration practices, resulting in the following actions:

After a review of the facility's initial response to the OIG, dated April 26, 2019, the VISN found that there was documentation that a verbal discussion had occurred with the CPS on April 3, 2019. The Associate Service Chief of Pharmacy, Clinical & Educational Programs, had a discussion with the CPS concerning appropriate documentation and communication of abnormal laboratory values to patients. As this was a verbal discussion, no written documentation would be expected.

VISN discussed this with Facility Chief of Staff, who concurred that clinical staff should take timely action on abnormal lab tests and document their plan of care. Chief of Staff communicated with all clinical disciplines regarding VHA Directive 1088, Communicating Test Results to Providers and Patients, reinforcing expectations to review and act upon laboratory results, including appropriate communication and documentation in a timely manner in coordination with scheduled appointments. This was completed on April 8, 2020. The facility will monitor compliance through review of 30 random cases per month until threshold of 90% or greater is sustained for 3 consecutive months. Compliance will be reported and monitored at VISN QSV Committee.

# **Appendix B: Facility Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

Date: April 24, 2020

From: Director, Tennessee Valley Healthcare System (626/00)

Subj: Healthcare Inspection—Inadequate Care by a Clinical Pharmacy Specialist and a Primary Care

Provider at the Tennessee Valley Healthcare System in Nashville

To: Director, VA MidSouth Healthcare Network (10N9)

- I have reviewed the draft report entitled "Inadequate Care by a Clinical Pharmacy Specialist and a Primary Care Provider" from the Office of Inspector General (OIG) and I concur with recommendations 1 and 2 from the focused review of July 30, 2019. The Tennessee Valley Healthcare System and VISN 9 have developed actions to address the two recommendations which are attached.
- 2. I would like to thank the OIG Survey Team for the consultative visit. The recommendations will strengthen our processes to deliver consistent quality care to our Veterans.

Please feel free to contact me if you have additional questions.

(Original signed by:)

Jennifer L. Vedral-Baron, MN, ARNP, NP-C, FAANP, FACHE Health System Director

# **Facility Director Response**

#### **Recommendation 2**

The Tennessee Valley Healthcare System Director ensures facility staff are aware of and follow Veterans Health Administration Directive 1088, *Communicating Test Results to Providers and Patients*, specifically the requirement for the ordering clinician to communicate all test results to patients.

Concur.

Target date for completion: August 1, 2020

#### **Director Comments**

The Tennessee Valley Healthcare System will ensure all ordering clinicians received a copy of VHA Directive 1088 and received additional guidance for awareness and compliance. Under the direction of the Chief of Staff, the Deputy Chief Quality, Safety & Value Service will ensure compliance with the reporting of all abnormal AST and ALT Liver Function Tests to Veterans within seven calendar days from the date the report becomes available or ensure Veteran has a follow-up appointment within 30 days of the report becoming available which addresses the abnormal labs. Compliance will be monitored and assessed via random manual data pulls of at least 30 cases per month until 90 percent or greater compliance is sustained for three consecutive months. This monthly random audit includes 10 records specifically focused on Clinical Pharmacy Specialist communication compliance with the Primary Care Provider regarding abnormal AST and ALT lab results.

# **Glossary**

**alanine transaminase.** An enzyme in the blood used along with other clinical tests to diagnose and monitor liver disease. <sup>1</sup>

**aspartate aminotransferase.** An enzyme in the blood used along with other clinical tests to diagnose and monitor liver disease.<sup>2</sup>

**basic metabolic panel.** Eight lab tests that gives the provider information about metabolism, kidney health, blood glucose level and electrolyte and acid/base balance.<sup>3</sup>

**biliary stenosis or stricture.** Also known as bile duct stricture, occurs when the bile duct gets smaller or narrower. The bile duct is the tube that takes bile from the liver to the small bowel. Patients with mild biliary strictures may not show any symptoms, but the stricture causes abnormalities in the blood and a rise in some of the liver enzymes. <sup>4</sup>

biliary stent. A metal or plastic tube used to open a narrowing of the bile duct. <sup>5</sup>

bilirubin. A yellow to orange bile pigment that normally circulates in the plasm.<sup>6</sup>

**blood glucose.** Blood sugar.<sup>7</sup>

cataract. A clouding of the lens of the eye.8

**comprehensive metabolic panel.** A blood test checking blood glucose, electrolytes, calcium, cholesterol, kidney and liver function.<sup>9</sup>

<sup>&</sup>lt;sup>1</sup> Medline Plus, Medical Encyclopedia, *Alanine transaminase blood test*. <a href="https://medlineplus.gov/ency/article/003473.htm">https://medlineplus.gov/ency/article/003473.htm</a>. (The website was accessed on August 12, 2019.)

<sup>&</sup>lt;sup>2</sup> Medline Plus, Medical Encyclopedia, *Aspartate aminotransferase blood test*. https://medlineplus.gov/ency/article/003472.htm. (The website was accessed on August 12, 2019.)

<sup>&</sup>lt;sup>3</sup> Lab Tests Online, *Basic Metabolic Panel*. <a href="https://labtestsonline.org/tests/basic-metabolic-panel-bmp">https://labtestsonline.org/tests/basic-metabolic-panel-bmp</a>. (The website was accessed September 26, 2019)

<sup>&</sup>lt;sup>4</sup> Cleveland Clinic, *Biliary stricture*. <a href="https://my.clevelandclinic.org/health/diseases/15796-biliary-stricture">https://my.clevelandclinic.org/health/diseases/15796-biliary-stricture</a>. (The website was accessed October 17, 2019.)

<sup>&</sup>lt;sup>5</sup> Cleveland Clinic, *Biliary stricture: Management and Treatment*. <a href="https://my.clevelandclinic.org/health/diseases/15796-biliary-stricture/management-and-treatment">https://my.clevelandclinic.org/health/diseases/15796-biliary-stricture/management-and-treatment</a>. (The website was accessed October 17, 2019)

<sup>&</sup>lt;sup>6</sup> Cleveland Clinic, *Bilirubin*. <a href="https://my.clevelandclinic.org/health/diagnostics/17845-bilirubin">https://my.clevelandclinic.org/health/diagnostics/17845-bilirubin</a>. (The website was accessed on February 6, 2020.)

<sup>&</sup>lt;sup>7</sup> Mayo Clinic, *Blood sugar testing: Why, when and how*, <a href="https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/blood-sugar/art-20046628">https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/blood-sugar/art-20046628</a>. (The website was accessed September 23, 2019.)

<sup>&</sup>lt;sup>8</sup> Mayo Clinic, *Cataracts*. <a href="https://www.mayoclinic.org/diseases-conditions/cataracts/symptoms-causes/syc-20353790">https://www.mayoclinic.org/diseases-conditions/cataracts/symptoms-causes/syc-20353790</a>. (The website was accessed September 23, 2019.)

<sup>&</sup>lt;sup>9</sup> Medline Plus, Medical Encyclopedia, *Comprehensive Metabolic Panel*. <a href="https://medlineplus.gov/metaboliCPSanel.html">https://medlineplus.gov/metaboliCPSanel.html</a>. (The website was accessed on July 2, 2019.)

**computed tomography scan**. An imaging study that uses X-rays and computers to produce images of a cross-section of the body.  $^{10}$ 

**diabetes.** A disorder of the body, also known as diabetes mellitus, caused by a combination of hereditary and environmental factors usually resulting from inadequate secretion or use of insulin in the body.<sup>11</sup>

**endoscopic ultrasound.** A minimally invasive procedure using sound waves to assess digestive and lung diseases. <sup>12</sup>

**endoscopic retrograde cholangiopancreatography.** A procedure used to diagnose narrowing of ducts in the gallbladder and pancreas.<sup>13</sup>

**glaucoma.** A disease process that damages the eye's optic nerve and can result in vision loss and blindness. <sup>14</sup>

**hemoglobin A1C.** A common blood test used to diagnose and treat diabetes and reflects the average blood sugar level for past two to three months.<sup>15</sup>

hyperlipidemia. the presence of too much lipids or fat in the blood. 16

**hypertension.** High blood pressure. 17

**jaundice.** A yellowing of the skin created by a disease process. <sup>18</sup>

lipid panel. A blood test measuring four types of fats in the blood, including cholesterol. 19

<sup>&</sup>lt;sup>10</sup> Cleveland Clinic, *Computed tomography*. <a href="https://my.clevelandclinic.org/health/diagnostics/4808-computed-tomography-ct-scan">https://my.clevelandclinic.org/health/diagnostics/4808-computed-tomography-ct-scan</a>. (The website was accessed on November 12, 2019.)

<sup>&</sup>lt;sup>11</sup>Merriam-Webster, *Definition of diabetes*. <a href="https://www.merriam-webster.com/dictionary/diabetes%20mellitus">https://www.merriam-webster.com/dictionary/diabetes%20mellitus</a>. (The website was accessed on October 15, 2019.)

<sup>&</sup>lt;sup>12</sup> Mayo Clinic, *Endoscopic ultrasound*. <a href="https://www.mayoclinic.org/tests-procedures/endoscopic-ultrasound/about/pac-20385171">https://www.mayoclinic.org/tests-procedures/endoscopic-ultrasound/about/pac-20385171</a>. (The website was accessed on October 7, 2019.)

<sup>&</sup>lt;sup>13</sup> John Hopkins Medicine, *Gastroenterology and Hepatology*.

<a href="https://www.hopkinsmedicine.org/gastroenterology\_hepatology/clinical\_services/advanced\_endoscopy/endoscopic\_retrograde\_cholangiopancreatography.html">https://www.hopkinsmedicine.org/gastroenterology\_hepatology/clinical\_services/advanced\_endoscopy/endoscopic\_retrograde\_cholangiopancreatography.html</a>. (The website was accessed on October 7, 2019)

<sup>&</sup>lt;sup>14</sup> National Institute of Health, National Eye Institute, *Glaucoma*. <a href="https://nei.nih.gov/health/glaucoma/glaucoma\_facts">https://nei.nih.gov/health/glaucoma/glaucoma\_facts</a>. (The website was accessed September 23, 2019.)

<sup>&</sup>lt;sup>15</sup> Mayo Clinic, *A1C test*. <a href="https://www.mayoclinic.org/tests-procedures/a1c-test/about/pac-20384643">https://www.mayoclinic.org/tests-procedures/a1c-test/about/pac-20384643</a>. (The website was accessed September 23, 2019.)

<sup>&</sup>lt;sup>16</sup> Merriam-Webster, *Definition of hyperlipidemia*. <a href="https://www.merriam-webster.com/dictionary/hyperlipidemia">https://www.merriam-webster.com/dictionary/hyperlipidemia</a>. (The website was accessed on October 15, 2019.)

<sup>&</sup>lt;sup>17</sup> Merriam-Webster, *Definition of hypertension*. <a href="https://www.merriam-webster.com/dictionary/hypertension">https://www.merriam-webster.com/dictionary/hypertension</a>. (The website was accessed on October 15, 2019.)

<sup>&</sup>lt;sup>18</sup> Merriam-Webster, *Definition of jaundice*. <a href="https://www.merriam-webster.com/dictionary/jaundiced">https://www.merriam-webster.com/dictionary/jaundiced</a>. (The site was accessed on September 23, 2019.)

<sup>&</sup>lt;sup>19</sup> Mayo Clinic, *Speaking of health: dyslipidemia*. <a href="https://mayoclinichealthsystem.org/hometown-health/speaking-of-health/love-your-lipids">https://mayoclinichealthsystem.org/hometown-health/speaking-of-health/love-your-lipids</a>. (The website was accessed on November 26, 2019.)

**liver function tests.** Blood tests used to measure how well the liver is performing and to diagnose and monitor liver disease. <sup>20</sup>

<sup>&</sup>lt;sup>20</sup> Mayo Clinic, *Liver function tests*. <a href="https://www.mayoclinic.org/tests-procedures/liver-function-tests/about/pac-20394595">https://www.mayoclinic.org/tests-procedures/liver-function-tests/about/pac-20394595</a>. (The site was accessed September 23, 2019.)

# **OIG Contact and Staff Acknowledgments**

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Judy Montano, Director Amanda Barry, MSW Linda Bay, DNP, RN Karen Berthiaume, RPh, BS Craig Byer, MS RRA Lin Clegg, PH. D Jonathan Duckart, MPS Joseph Etherage, PsyD, ABPP Dawn Rubin, JD Thomas Wong, DO
Other Contributors	Sheyla Desir, MSN, RN Sarah Mainzer, BSN, JD Chastity Osborn, DNP, RN Natalie Sadow, MBA

## **Report Distribution**

#### **VA** Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA MidSouth Healthcare Network (VISN 9)
Director, Tennessee Valley Healthcare System, Murfreesboro, TN (626)

#### **Non-VA Distribution**

House Committee on Veterans' Affairs

House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies

House Committee on Oversight and Reform

Senate Committee on Veterans' Affairs

Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies

Senate Committee on Homeland Security and Governmental Affairs

National Veterans Service Organizations

Government Accountability Office

Office of Management and Budget

U.S. Senate: Lamar Alexander, Marsha Blackburn, Mitch McConnell, Paul Rand

U.S. House of Representatives:

Tennessee: Scott DesJarlais, Jim Cooper, John Rose, Mark Green, David Kustoff Kentucky: James Comer, Brett S. Guthrie, Hal Rogers

OIG reports are available at www.va.gov/oig.