



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

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Concerns Related to the  
Management of a Patient's  
Medication at Three VA Medical  
Centers and Inaccurate Response  
to a Congressional Inquiry at the  
VA Illiana Health Care System

Orlando, Florida  
Indianapolis, Indiana  
Danville, Illinois



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](http://www.va.gov/oig/hotline)**

**1-800-488-8244**



## Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complaint regarding a patient's (patient) medication management and related congressional correspondence at the VA Illiana Health Care System (system), Danville, Illinois.

Specifically, the complainant alleged

- The patient was prescribed 300 milligrams (mg) of amitriptyline, and Veterans Health Administration (VHA) providers failed to explain that this dosing was higher than the drug labeling maximum for outpatients and the risks of the high dosage;<sup>1</sup>
- The patient experienced toxic effects from amitriptyline including tachycardia and short-term memory loss;<sup>2</sup> and
- The January 3, 2017, System Director's response to an inquiry from Senator Joe Donnelly included inaccurate information.

The OIG team reviewed the patient's electronic health record for the period of care from 2012 through mid-2018 at the Lake Baldwin community based outpatient clinic (CBOC) under the Orlando VA Medical Center; the Richard L. Roudebush VA Medical Center; the West Lafayette CBOC;<sup>3</sup> and the system. The OIG substantiated that VA providers did not explain that the amitriptyline dosing was higher than the drug labeling for outpatients or the risks of the high dosage to the patient. Specifically, the OIG team found that in 2012, the Orlando VA Medical Center provider who ordered an electrocardiogram did not inform the patient about an abnormality noted on the electrocardiogram, did not follow up with additional evaluation to assess, and did not discuss the potential that the high dose of amitriptyline contributed to the abnormality.<sup>4</sup> Although VHA providers generally documented risk and benefit discussions for medications as required, none documented specific discussions about risk and benefits related to the high dose of amitriptyline (300 mg).

---

<sup>1</sup> Amitriptyline is a tricyclic antidepressant (TCA) medication used for the treatment of major depression.

<sup>2</sup> Tachycardia is a condition of relatively rapid heart action. Merriam-Webster, <https://www.merriam-webster.com/dictionary/tachycardia>. (The website was accessed on May 17, 2018.)

<sup>3</sup> In August 2017, the system's West Lafayette CBOC, located in Lafayette, Indiana, realigned under the Richard L. Roudebush VA Medical Center, Indianapolis, Indiana.

<sup>4</sup> An electrocardiogram is a test that measures a heart's electrical activity. The measured time intervals indicate how long the electrical wave takes to pass through the heart and indicates normal or irregular activity. American Heart Association, "Electrocardiogram (ECG or EKG)," [http://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsDiagnosisofHeartAttack/Electrocardiogram-ECG-or-EKG\\_UCM\\_309050\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsDiagnosisofHeartAttack/Electrocardiogram-ECG-or-EKG_UCM_309050_Article.jsp). Updated September 11, 2015. (The website was accessed on June 5, 2018.)

The OIG was unable to substantiate or not substantiate that the patient experienced tachycardia as a result of taking amitriptyline because of other potential causes such as the patient's history of heart disease, other medical conditions, and smoking. However, as noted above, the OIG team found that the ordering provider did not inform the patient of a 2012 abnormal electrocardiogram or follow up with further cardiac evaluation. Although the patient reported a history of cardiac disease, risk factors, and cardiac symptoms throughout the years of VHA care, providers did not refer the patient for a medical evaluation of cardiac functioning. Additionally, except for once in mid-2016 at the patient's request, providers did not order blood tests to determine levels of amitriptyline or its metabolites including a time when the patient's levels could have been increased as a result of having stopped smoking cigarettes.<sup>5</sup> The OIG team also found that the provider who ordered a mid-2016 blood test did not notify the patient that the results indicated a subtherapeutic level of amitriptyline. Further, the OIG team found that in 2017, there was no follow-up to the patient's expressed cardiac concerns due to a failed collaboration between the system's treating psychiatrist and primary care provider.

The OIG was unable to substantiate or not substantiate that the patient experienced short-term memory loss as a result of taking amitriptyline because of other potential existing causes for memory problems such as depression and anxiety disorders, diazepam usage, and a history of head injury. The OIG team found that at various points over the years from 2012 through mid-2018, VHA providers took action regarding the patient's reported memory concerns.

The OIG substantiated that the January 3, 2017, System Director's response to Senator Donnelly's September 29, 2016, letter was not timely and included inaccurate information. In the response, the System Director incorrectly stated that providers reduced the patient's amitriptyline dosage by more than 50 percent during the patient's 2015 inpatient psychiatry unit admission. Additionally, the patient informed the OIG team that while the congressional response asserted that the patient was satisfied with the mental health care that was provided, the patient never expressed satisfaction as claimed. The OIG also found that the administrative employee assigned to prepare the response had limited experience in responding to congressional inquiries and may not have consulted with the treating psychiatrist in preparation of the response. Additionally, system administrative staff did not retain background documentation, as required by system policy. Further, the System Director's response exceeded the VHA mandated 30-day time frame for responding to congressional mail.

The OIG made eight recommendations related to evaluations of the patient's cardiac care, Orlando VA Medical Center providers' compliance with patient notification and follow-up of

---

<sup>5</sup> For the class of drugs that includes amitriptyline, tobacco use can diminish the therapeutic impact of the medication; therefore, a patient should be monitored for dose adjustment upon smoking cessation. Prescribers' Digital Reference, "Amitriptyline Hydrochloride - Drug Summary." <http://www.pdr.net/drug-summary/Amitriptyline-Hydrochloride-amitriptyline-hydrochloride-1001.5733>, 2018. (The website was accessed on February 8, 2018.)

electrocardiograms, Richard L. Roudebush VA Medical Center providers' compliance with patient notification and follow-up of medication blood level tests, the strengthening of system processes for (a) effective clinical consultation between mental health and collaborating primary care providers and (b) congressional inquiry responses, and an evaluation of system staff actions and approval processes in preparation of the letter to Senator Donnelly.

## Comments

The Veterans Integrated Service Network and System Directors concurred with Recommendations 1, 2, 4 and 6–8, concurred in principle with Recommendations 3 and 5, and provided acceptable action plans. (See Appendixes B–G, pages 32–46 for the comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed. The Executive in Charge also submitted comments. (See Appendix A, page 29, and OIG response below.)

## OIG Response to Executive in Charge Comments

There are times when the OIG and the Executive in Charge must agree to disagree. This report addresses an allegation that a patient was not informed of the cardiac risk of high doses of a medication. A second allegation was that senior VA leaders, in their response to a member of Congress, inaccurately stated that the patient was satisfied with VA medical care. The OIG notes that in the same communication, VA leaders were not accurate in their presentation of the patient's medical management. To address these allegations, the OIG reviewed in detail the medical care the patient received at VA medical centers. The draft report with appropriate detail was provided to VA leaders to permit their analysis and comment. It is reasonable for both VA to assert that cardiac care was appropriate and for the patient to assert that he/she was not informed about the potential cardiac impact of the medical treatment. It is more difficult to understand how communication with a member of Congress could be wrong on the facts of the case and misrepresent the views of the veteran. The OIG recognizes and fully complies with law to ensure that the data presented is appropriate for the intended audience.



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

## Contents

Executive Summary .....	i
Abbreviations .....	v
Introduction .....	1
Scope and Methodology .....	8
Patient Case Summary .....	9
Inspection Results .....	18
Issue 1: Medication Risks and Benefits .....	18
Issue 2: Medication Toxicity Effects.....	19
Issue 3: System Director Response to Congressional Inquiry .....	24
Conclusion .....	27
Recommendations 1–8.....	28
Appendix A: Executive in Charge Comments.....	29
Appendix B: VISN 8 Director Comments .....	32
Appendix C: Orlando VA Medical Center Director Comments.....	33
Appendix D: VISN 10 Director Comments.....	38
Appendix E: Richard L. Roudebush VA Medical Center Director Comments .....	39
Appendix F: VISN 12 Director Comments .....	42
Appendix G: VA Illiana Health Care System Director Comments .....	43
OIG Contact and Staff Acknowledgments .....	47
Report Distribution .....	48

## Abbreviations

CBOC	community based outpatient clinic
CNS	clinical nurse specialist
DoD	Department of Defense
ECG	electrocardiogram
ED	Emergency Department
EHR	electronic health record
mg	milligram
MoCA	Montreal Cognitive Assessment
NP	nurse practitioner
OIG	Office of Inspector General
PA	physician assistant
PCP	primary care provider
SNRI	serotonin and norepinephrine reuptake inhibitor
SSRI	selective serotonin reuptake inhibitor
TCA	tricyclic antidepressant
VISN	Veterans Integrated Service Network
VHA	Veterans Health Administration



## Introduction

### Purpose

The VA Office of Inspector General (OIG) conducted an inspection to evaluate allegations regarding a patient's (patient) medication management and related congressional correspondence at the VA Illiana Health Care System (system), Danville, Illinois.

### Background<sup>6</sup>

The system, part of Veterans Integrated Service Network (VISN) 12, has 300 beds that include 42 inpatient, 35 domiciliary, and 217 community living center beds. The system includes four community based outpatient clinics (CBOC) located in Decatur, Mattoon, Peoria, and Springfield, Illinois, and served over 33,500 veterans in fiscal year 2017.

### VISN Realignment

In fiscal year 2016, Veterans Health Administration (VHA) initiated the realignment of the VISNs within five districts to fit within the state boundaries of these districts. A system leader confirmed that the system's West Lafayette CBOC, located in Lafayette, Indiana, realigned under the Richard L. Roudebush VA Medical Center (Indianapolis VAMC), Indiana, in August 2017.

### Tachycardia

Electrical signals sent across heart tissue control a person's heart rate. Tachycardia, a common heart rhythm disorder, occurs when something disrupts the normal electrical signals that control the rate of the heart's pumping action.<sup>7</sup> This abnormality produces rapid electrical signals that cause a heart to beat faster than normal while at rest.<sup>8</sup> In tachycardia, the heart beats faster than

---

<sup>6</sup> The OIG team reviewed the Patient's care at the Orlando VA Medical Center, currently part of VISN 8, and the Richard L. Roudebush VA Medical Center, currently part of VISN 10, in addition to the system. Within the context of this report, the Patient received the longest period of psychiatric care at the system and therefore, the OIG team included background information solely on the system.

<sup>7</sup> Mayo Clinic, "Tachycardia." <https://www.mayoclinic.org/diseases-conditions/tachycardia/symptoms-causes/syc-20355127>, March 8, 2018. (The website was accessed on June 6, 2018.)

<sup>8</sup> Tachycardia occurs when an adult heart rate is more than 100 beats per minute. [http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Tachycardia-Fast-Heart-Rate\\_UCM\\_302018\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Tachycardia-Fast-Heart-Rate_UCM_302018_Article.jsp), September 2016. (The website was accessed on June 26, 2018.)

normal in the heart's upper (atria) or lower (ventricles) chambers or both while at rest.<sup>9</sup> Many factors can cause tachycardia including damage to heart tissue from heart disease, smoking, and medication side effects. Signs and symptoms of tachycardia include rapid pulse rate, lightheadedness, and heart palpitations. In some cases, tachycardia may not cause symptoms and is discovered through an electrocardiogram (ECG).<sup>10</sup> Providers also evaluate tachycardia using several other tests including portable ECG monitoring devices or cardiac imaging.<sup>11</sup> If untreated, tachycardia at uncontrolled high rates can lead to heart failure or stroke.<sup>12</sup>

## Memory Loss

Problems with memory can have multiple causes. Some of the reversible memory loss causes include a tumor or brain infection, emotional disorders such as anxiety or depression, and medications, such as diazepam.<sup>13</sup> Normal age-related memory loss does not interfere with daily independent living.<sup>14</sup> The International Classification of Diseases, tenth revision, defines organic brain syndrome as “either a long term deterioration of intellectual function and memory (dementia) or a short term disturbance of orientation, judgement, or consciousness (delirium).”<sup>15</sup> To diagnose cognitive impairment, providers may order blood tests and brain-imaging tests, and

---

<sup>9</sup> A normal heart includes four chambers: Upper chambers are the right and the left atria; and lower chambers are the right and left ventricles. Mayo Clinic (website), “Tachycardia.” <https://www.mayoclinic.org/diseases-conditions/tachycardia/symptoms-causes/syc-20355127>, March 8, 2018. (The website was accessed on June 6, 2018.)

<sup>10</sup> An ECG is a test that measures a heart's electrical activity. The measured time intervals indicate how long the electrical wave takes to pass through the heart and indicates normal or irregular activity. American Heart Associations “Electrocardiogram (ECG or EKG).” [http://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsDiagnosisofHeartAttack/Electrocardiogram-ECG-or-EKG\\_UCM\\_309050\\_Article.jsp#.WzI8LP0UID8](http://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsDiagnosisofHeartAttack/Electrocardiogram-ECG-or-EKG_UCM_309050_Article.jsp#.WzI8LP0UID8), September 11, 2015. (The website was accessed on June 5, 2018.)

<sup>11</sup> Mayo Clinic, “Tachycardia, Diagnosis and Treatment.” <https://www.mayoclinic.org/diseases-conditions/tachycardia/diagnosis-treatment/drc-20355133>, March 8, 2018. (The website was accessed on June 6, 2018.)

<sup>12</sup> Mayo Clinic, “Tachycardia, Symptoms and Causes.” <https://www.mayoclinic.org/diseases-conditions/tachycardia/symptoms-causes/syc-20355127>, March 8, 2018. (The website was accessed on June 6, 2018.)

<sup>13</sup> Diazepam is a benzodiazepine medication used to relieve anxiety symptoms. Mayo Clinic. <https://www.mayoclinic.org/drugs-supplements/diazepam-oral-route/description/drg-20072333>, March 1, 2017. (The website was accessed on May 21, 2018.)

<sup>14</sup> Mayo Clinic, “Memory loss: When to seek help.” <https://www.mayoclinic.org/diseases-conditions/alzheimers-disease/in-depth/memory-loss/art-20046326>, June 27, 2017. (The website was accessed on June 25, 2018.)

<sup>15</sup> The International Classification of Diseases “is a diagnostic coding system implemented by the World Health Organization.” The tenth revision became effective in the United States on October 1, 2015. [http://doc.mayoclinichealthsolutions.com/mmsidocuments/MMS\\_ICD\\_FAQ\\_FINAL.pdf](http://doc.mayoclinichealthsolutions.com/mmsidocuments/MMS_ICD_FAQ_FINAL.pdf), September 2015. (The website was accessed on June 25, 2018.); ICD10Data.com, <https://www.icd10data.com/ICD10CM/Codes/F01-F99/F01-F09/F09-/F09>, 2018. (The website was accessed on June 25, 2018.)

conduct question-and-answer tests, such as the Montreal Cognitive Assessment (MoCA).<sup>16</sup> Additionally, providers may refer to a specialist in diagnosing cognitive disorders, such as a geriatrician, neurologist, psychiatrist, or psychologist.<sup>17</sup>

## Amitriptyline

Current medical literature advises prescribing the lowest effective dose of amitriptyline, a tricyclic antidepressant (TCA) medication used for the treatment of major depression.<sup>18</sup> TCAs increase central nervous system levels of serotonin and norepinephrine, two neurotransmitters.<sup>19</sup> For outpatient adults, amitriptyline is initially prescribed at dosing levels of 75 milligrams (mg), in divided doses, or 50 to 100 mg once daily at bedtime. Once therapeutic benefit is achieved, the usual maintenance dosage is 50 to 100 mg per day. Hospitalized patients may require 100 mg as an initial dose and a maximum dose of 300 mg per day.<sup>20</sup> In some cases, to achieve therapeutic benefit, an outpatient may require a dosage higher than recommended in the drug labeling (referred to as off-label use).

---

<sup>16</sup> Memory loss: When to seek help, Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/alzheimers-disease/in-depth/memory-loss/art-20046326>, June 27, 2017. (The website was accessed on June 25, 2018.); the MoCA is a standardized test of cognitive impairment for ages 55-85 that health professionals use to determine severity of cognitive impairment and Alzheimer's Disease (dementia), MoCA Montreal - Cognitive Assessment. <https://www.mocatest.org/faq/>, 2018. (The website was accessed on May 30, 2018.); Dementia.org, "Diagnosing Dementia: The Montreal Cognitive Assessment (MoCA)." <https://www.dementia.org/diagnosing-dementia-the-montreal-cognitive-assessment>, July 2, 2015. (The website was accessed on June 25, 2018.)

<sup>17</sup> "Memory loss: When to seek help," Mayo Clinic.

<sup>18</sup> Prescribers' Digital Reference, "Amitriptyline Hydrochloride - Drug Summary." <http://www.pdr.net/drug-summary/Amitriptyline-Hydrochloride-amitriptyline-hydrochloride-1001.5733>, 2018. (The website was accessed on February 8, 2018.); PubMed Health, "Amitriptyline (By mouth)." <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0008944/>, June 1, 2018. (The website was accessed on February 20, 2018.); Mayo Clinic, "Amitriptyline (Oral Route)." <https://www.mayoclinic.org/drugs-supplements/amitriptyline-oral-route/description/DRG-20072061>, March 1, 2017. (The website was accessed on February 20, 2018.); depression (major depressive disorder or clinical depression) is a common but serious mood disorder. ...To be diagnosed with depression, the symptoms must be present for at least two weeks... Several persistent symptoms in addition to low mood are required for a diagnosis of major depression." National Institute of Mental Health, "Depression." <https://www.nimh.nih.gov/health/topics/depression/index.shtml>. (This website was accessed on June 26, 2018.)

<sup>19</sup> Mayo Clinic, "Tricyclic antidepressants and tetracyclic antidepressants." <https://www.mayoclinic.org/diseases-conditions/depression/in-depth/antidepressants/art-20046983>, June 28, 2016. (The website was accessed on May 21, 2018.)

<sup>20</sup> Prescribers' Digital Reference, "Amitriptyline Hydrochloride - Drug Summary."

Amitriptyline may cause side effects such as blurred vision, memory impairment, and a drop in blood pressure when moving from sitting to standing.<sup>21</sup> TCAs including amitriptyline can also cause tachycardia and prolonged cardiac conduction time including non-specific intra-ventricular conduction delay.<sup>22</sup> The use of TCAs is contraindicated for patients with cardiac disease such as a history of myocardial infarction and tachycardia. Providers should closely monitor patients with any cardiac disease, using ECGs and clinical exams.<sup>23</sup> Specifically, an ECG prolonged duration of the electrical wave through the right and left bottom heart ventricles (QRS wave) can be a sign of cardiac injury due to TCA toxicity.<sup>24</sup> Further, current medical literature recommends obtaining ECGs approximately every hour for patients with signs of TCA toxicity until the patient is asymptomatic for several hours.<sup>25</sup> Additionally, tobacco smoking can diminish the therapeutic impact of TCAs; therefore, a patient should be monitored for dose adjustment upon smoking cessation.<sup>26</sup> To discontinue amitriptyline following prolonged treatment, patients should be gradually tapered off the medication. A patient's abrupt discontinuation can cause nausea, vomiting, diarrhea, or flu-like symptoms.<sup>27</sup>

## Off-Label Medication Use

Once the Food and Drug Administration approves a drug for use, providers may prescribe the drug for an unapproved use if it is medically appropriate. The unapproved use of an approved drug is called off-label use. Providers may prescribe off-label use to treat a medical condition that the drug was not specifically approved to treat including ordering the drug in a different

---

<sup>21</sup> A side effect is "a secondary and usually adverse effect" of a drug. Merriam-Webster Dictionary. <https://www.merriam-webster.com/dictionary/side%20effect>, June 20, 2018. (The website was accessed on May 22, 2018.); Prescribers' Digital Reference, "Amitriptyline Hydrochloride - Drug Summary."

<sup>22</sup> G W Kerr, A C McGuffie, S Wilkie, "Tricyclic antidepressant overdose: a review," Emergency Medicine Journal, 2001, 18: 235-241. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1725608/pdf/v018p00236.pdf>. (The website was accessed on June 12, 2018.)

<sup>23</sup> Prescribers' Digital Reference, "Amitriptyline Hydrochloride - Drug Summary."

<sup>24</sup> The QRS is the wave that represents the right and left bottom chambers or ventricles. American Heart Association, "Electrocardiogram (ECG or EKG)." [http://www.heart.org/HEARTORG/Conditions/HeartAttack/DiagnosingaHeartAttack/Electrocardiogram-ECG-or-EKG\\_UCM\\_309050\\_Article.jsp#.WxZ2zP0UIQA](http://www.heart.org/HEARTORG/Conditions/HeartAttack/DiagnosingaHeartAttack/Electrocardiogram-ECG-or-EKG_UCM_309050_Article.jsp#.WxZ2zP0UIQA), July 2015. (The website was accessed on June 5, 2018.); Richard A Harrigan MD and William J Brady MD, "ECG abnormalities in tricyclic antidepressant ingestion" The American Journal of Emergency Medicine, Volume 17, Issue 4, July 1999, pages 387-393. <https://www.sciencedirect.com/science/article/pii/S0735675799900943?via%3Dihub>. (The website was accessed on June 12, 2018.)

<sup>25</sup> VA Pharmacy Benefits Management, UpToDate, Steven D Salhanick, MD, "Tricyclic antidepressant poisoning." Website updated March 1, 2018. This information is from a website that is not accessible to the public. (The website was accessed on April 19, 2018.)

<sup>26</sup> Prescribers' Digital Reference, "Amitriptyline Hydrochloride - Drug Summary."

<sup>27</sup> Prescribers' Digital Reference, "Amitriptyline Hydrochloride - Drug Summary."

form (such as an oral solution rather than an approved capsule) or a dose outside the approved dose ranges.<sup>28</sup>

## Treatment Risk and Benefits

The Joint Commission requires that facilities provide patients with education about the actions and potential side effects of prescribed medication.<sup>29</sup> VA and Department of Defense (DoD) clinical guidelines recommend that patients receive individualized information regarding their treatment options for depression including the risks and benefits of those options.<sup>30</sup>

VHA requires that providers document clinical information that is accurate and clinically-relevant, and includes identification of appropriate risk factors.<sup>31</sup> VHA defines risks as “possible undesirable outcomes of a treatment or procedure, including known side effects, complications, serious social or psychological harms, or other adverse outcomes.”<sup>32</sup>

Additionally, providers must document the patient’s informed consent and discussion, and patients must provide prior voluntary consent related to any treatment or procedure.<sup>33</sup> A component of VHA’s informed consent process includes describing the expected benefits and known risks associated with the recommended treatment.<sup>34</sup>

VHA allows oral informed consent for treatments that are “low risk and within broadly-accepted standards of medical practice,” such as the administration of most drugs. Providers must document the consent and discussion in the patient’s electronic health record (EHR), but VHA does not require a specific format.<sup>35</sup> Providers are not required to obtain repeat informed consent where the treatment plan is part of multiple or recurrent treatments, and there are no significant changes; nor if there is no “change in the patient's condition or diagnosis that would reasonably be expected to alter the original informed consent.”<sup>36</sup>

---

<sup>28</sup> U.S. Food and Drug Administration, “Understanding Unapproved Use of Approved Drugs “Off Label.” <https://www.fda.gov/ForPatients/Other/OffLabel/default.htm>, February 5, 2018. (The website was accessed May 31, 2018.)

<sup>29</sup> The Joint Commission E-edition, Behavioral Health Program, Chapter: Medication Management, Effective Date: January 13, 2018. This information is from a website that is not accessible to the public. (The website was accessed June 5, 2018.)

<sup>30</sup> VA/DoD Clinical Practice Guidelines for Management of Major Depressive Disorder. <https://www.healthquality.va.gov/guidelines/MH/mdd/>, page 29. (The website was accessed on January 29, 2018.)

<sup>31</sup> VHA Handbook 1907.01, Health Information Management and Health Records, March 19, 2015.

<sup>32</sup> VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, revised September 20, 2017.

<sup>33</sup> VHA Handbook 1907.01; VHA Handbook 1004.01.

<sup>34</sup> VHA Handbook 1004.01.

<sup>35</sup> VHA Handbook 1004.01.

<sup>36</sup> VHA Handbook 1004.01.

Regarding off-label prescribing, VHA does not specifically require providers to discuss off-label use of medication with patients but advises that

Evidence of benefit (and importantly, risk) should be explicitly reviewed in the context of standard therapies for the population or condition and recommendations for (or against) use should be based on the quality of evidence as well as the net benefit (potential benefits minus potential harms).<sup>37</sup>

The system's medication management policy required pharmacy staff to provide patients with all information required for the proper use of the drug and offer education, counseling, and written drug information as appropriate to patients.<sup>38</sup>

### Communication of Test Results

VHA requires that the diagnostic provider communicate test results to the ordering provider, or designee, within a time frame that allows for prompt attention and appropriate action to be taken. From March 2009 until October 2015, VHA policy required that the ordering provider communicated all test results to the patient within 14 days and initiated appropriate clinical action and followed up on the results.<sup>39</sup> Further, the ordering provider or designee was required to document in the EHR that the patient received and understood the communication.<sup>40</sup>

### Congressional Inquiries

VHA policy informs VHA leaders of the required steps in congressional correspondences, including timelines. For general congressional mail not involving mismanagement, malpractice, or prohibited personnel actions, VHA respondents have 30 days from receipt of the mail to respond. VHA leaders must provide responses that are "timely, factually correct, and consistent with VHA and Departmental policy."<sup>41</sup>

---

<sup>37</sup> VA Center for Medication Safety, Pharmacy Benefits Management Services, "Pharmaceutical Use Outside of Approved Indications, Guidance on "Off-label" Prescribing." This information is from an internal VA website and not accessible to the public. (The website was accessed on May 31, 2018.)

<sup>38</sup> VA Illiana Health Care System, Medical Center Memorandum Number 119-15, *Medication Management*, April 2015; this Memorandum was rescinded and replaced by Medical Center Memorandum Number 119-15, *Medication Management*, September 2017. The 2017 policy has the same or similar language as the 2015 policy about information that must be provided to the patient.

<sup>39</sup> VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This directive was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015 that requires the ordering provider inform the patient of results requiring action within seven calendar days and of normal tests results within 14 days.

<sup>40</sup> VHA Directive 2009-019. Directive 1088 does not include this documentation requirement.

<sup>41</sup> VHA Directive 2012-017, *Veterans Health Administration Correspondence Management*, June 25, 2012, expired June 30, 2017, and has not been updated.

The system standard operating procedure for congressional responses details processes and staff responsibilities. Upon receipt of a congressional inquiry, the System Director's staff notifies the appropriate service chief to prepare a draft response within 10 days. The service chief then assigns the task of preparing a response to the Service Preparer.<sup>42</sup> A system staff member and the Chief, Quality Management told the OIG that the Service Preparer should consult with the service chief and any treating clinicians, and prepare and submit the response along with background information to the Director's Secretary. The service chief and system Chief of Staff review and approve the response prior to the System Director's review and signature. After the System Director approves the letter, administrative staff forward the response to the appropriate congressional office and retain a copy of the response and background documentation.<sup>43</sup> The system used a shared electronic site to track the timelines, responsible staff, and the approval status.

System staff must not scan documents related to the congressional response into the patient's EHR, but the files are subject to VHA record retention rules. The system must retain background documentation used to draft the response in paper files for seven years and in electronic files indefinitely.

## Allegations

On November 15, 2017, the OIG received an electronically submitted complaint. Specifically, the complainant alleged

- The patient was prescribed 300 milligrams (mg) of amitriptyline, and Veterans Health Administration (VHA) providers failed to explain that this dosing was higher than the drug labeling maximum for outpatients and the risks of the high dosage;
- The patient experienced toxic effects from amitriptyline including tachycardia and short-term memory loss; and
- The January 3, 2017, System Director's response to an inquiry from Senator Joe Donnelly included inaccurate information.

On January 15, 2018, the Office of Healthcare Inspections Hotline Working Group received the referral and opened an inspection on January 19, 2018.

---

<sup>42</sup> The system Quality Management Chief told the OIG that the service chief and the administrative officer are generally the points of contact, but any employee designated by the service chief can draft the response.

<sup>43</sup> VA Illiana Health Care System, *Standard Operating Procedure (Sop) #1, Congressional Response Process*, November 2013 (reviewed November 2016).

## Scope and Methodology

The OIG initiated the inspection on February 14, 2018. The OIG team reviewed the patient's EHR for the period of care from 2012 through mid-2018. The OIG team reviewed the patient's care at the Lake Baldwin CBOC under the Orlando VA Medical Center (Orlando VAMC), Florida; the Indianapolis VAMC and West Lafayette CBOC, Indiana; and the system. The OIG team also reviewed private non-VA medical records that the patient provided. The OIG team reviewed relevant system policies, VHA directives and handbooks, VA/DoD Guidelines, The Joint Commission Behavioral Health standards, and medical literature.

The OIG team interviewed the patient and the following system leaders and staff: the former System Director; former Acting Chief of Staff; Chiefs of: Quality Management, Mental Health; CBOCs and Primary Care; a Mental Health physician assistant (PA); a nurse practitioner (NP); a registered nurse; and the CBOCs Administrative Officer. The OIG team also interviewed two treating psychiatrists (Psychiatrists 2 and 3).<sup>44</sup>

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 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.

---

<sup>44</sup> Psychiatrist 2 was affiliated with the system and Psychiatrist 3 was initially with the system but then realigned under Indianapolis VAMC in August 2017.

## Patient Case Summary

### The Patient's Care at the Orlando VAMC

In late 2012, the patient established care at the Orlando VAMC and met with a primary care provider (PCP) at the Lake Baldwin CBOC.<sup>45</sup> The PCP documented the patient's reported multiple medical problems and risk factors including hypertension, "[history] of sinus tachycardia—controlled on Metoprolol,"<sup>46</sup> coronary artery disease with a history of myocardial infarction, type 2 diabetes, chronic obstructive pulmonary disease, tobacco use (smoking), and chronic pain. The patient reported that private non-VA providers<sup>47</sup> prescribed medications for these conditions that included aspirin, metoprolol, and tramadol. The patient also reported taking amitriptyline 300 mg per day and diazepam 40 mg per day as prescribed by previous non-VA providers. Per the patient's report, the amitriptyline had been prescribed for 20 years and the diazepam for 10 years. The PCP ordered an ECG, documented that the patient was notified of test results in person, and signed the note at 11:08 am. The ECG results did not indicate an abnormal conduction time at the time the PCP notified the patient in person of test results.<sup>48</sup> That information was not known until a cardiologist reviewed the ECG and identified a non-specific intra-ventricular conduction delay at 8:46 pm. As such, there was no evidence that the patient was notified of the cardiologist's interpretation of a non-specific intra-ventricular conduction delay.<sup>49</sup> The PCP requested a same-day mental health evaluation.

That day, a psychology resident documented the patient's reported diagnostic history that included depression and other mental health conditions.<sup>50</sup> The patient reported numerous psychiatric interventional treatments in the past. During the evaluation, the patient reported symptoms of depression and other mental health disorders. The patient's scores on rating scales

---

<sup>45</sup> The Lake Baldwin CBOC is aligned under the Orlando VA Medical Center.

<sup>46</sup> Metoprolol is a drug used to treat cardiac conditions including angina (chest pain) and hypertension. Prescribers' Digital Reference, "Metoprolol Titrated, Drug Summary." <http://www.pdr.net/drug-summary/Metoprolol-Tartrate-metoprolol-tartrate-3114.5976>, 2018. (The website was accessed on June 23, 2018.)

<sup>47</sup> In this report, the OIG team used the term "private non-VA provider(s)" to refer to providers accessed by the Patient independently and not through VA programs.

<sup>48</sup> Urine and blood tests were obtained from the Patient in late 2012. Test results were documented in the PCP's note approximately six weeks later.

<sup>49</sup> A non-specific intra-ventricular conduction delay is defined by ECG results of a widened QRS without the features of right or left bundle branch blocks. Romain Eschalier MD, Ph.D. et al., "Nonspecific intraventricular conduction delay: Definitions, prognosis, and implications for cardiac resynchronization therapy," *Heart Rhythm*, 12, Issue 5 (May 1, 2015): 1071-1079. <https://www.sciencedirect.com/science/article/pii/S1547527115000739>. (The website was accessed on May 19, 2018.)

<sup>50</sup> A psychology resident is a trainee who obtained a doctoral degree and is fulfilling supervised experience requirements for licensure and other continuing education objectives in a psychologist residency program. <https://www.psychology-education.com/psychologist-residency/>. (The website was accessed on July 9, 2018.)

for two mental health disorders indicated a severe level of symptoms. The psychology resident documented that the patient “does not believe [the] current medication regimen is optimal” and that the patient “has participated in [talk] therapy, but has not found it to be helpful.” The psychology resident diagnosed the patient with depression and facilitated same-day linkage with a psychiatrist for medication evaluation.

Later that day, a psychiatrist (Psychiatrist 1) prescribed an atypical antipsychotic medication as adjunctive treatment to amitriptyline. A week later, the patient reported that symptoms had improved. The patient agreed to discontinue diazepam. Four days after stopping diazepam, the patient developed severe withdrawal symptoms. Psychiatrist 1 acknowledged the nursing assessment, noted a decrease in withdrawal symptoms, and offered the patient inpatient detoxification. The patient declined Psychiatrist 1's offer for inpatient detoxification and requested to remain on diazepam.

In early 2013, the patient began treatment with a mental health nurse practitioner (NP 1) who continued the amitriptyline and diazepam and increased the atypical antipsychotic medication, with a stated goal to titrate off diazepam and amitriptyline “as tolerated.” The patient stated that the non-VA family PCP prescribed medications for the past six years. The patient reported attempting “to wean [him/her]self off of Amitriptyline slowly in the past and...felt physically ill.”<sup>51</sup> The patient provided pharmacy records listing “prescriptions from the past 2 to 3 years.”<sup>52</sup> NP 1 added hyperlipidemia to the list of the patient's medical conditions.<sup>53</sup> NP 1 noted the “non-specific intra-ventricular conduction delay” from the ECG performed approximately four weeks earlier. Over the next two weeks, the patient met with a social worker for two psychotherapy sessions with future appointments to be scheduled as needed.

At the next visit a month later, NP 1 noted that the patient denied side effects and consented to decrease amitriptyline by a quarter of a tablet (37.5 mg) at bedtime and continue if tolerated. NP 1 did not document the rationale for the dose decrease. NP 1 planned to consider adding an additional antidepressant next visit.

Approximately one month later, the patient reported to NP 1 about not decreasing the amitriptyline dose due to depression symptoms. The patient again denied side effects from the psychiatric medications. NP 1 continued amitriptyline and diazepam, increased the dose of the previously ordered atypical antipsychotic medication and added lithium. NP 1 ordered laboratory tests for two weeks later to check kidney and liver functioning, and lithium levels. Within a

---

<sup>51</sup> The OIG uses gender neutral terminology to protect patients' privacy.

<sup>52</sup> The records included nine mental health medications other than the amitriptyline and diazepam.

<sup>53</sup> Hyperlipidemia is commonly referred to as high cholesterol. American Heart Association, “Prevention and Treatment of High Cholesterol (Hyperlipidemia).” <https://www.heart.org/en/health-topics/cholesterol/prevention-and-treatment-of-high-cholesterol-hyperlipidemia>. (The website was accessed on July 26, 2018.)

week, NP 1 documented the laboratory test result notification letter to the patient indicating satisfactory results and no need for concern.

After four weeks, the patient reported persisting depression symptoms and memory problems. NP 1 increased the lithium dosage and continued other medications as prescribed. To evaluate the patient's memory problems, NP 1 ordered a computerized tomography scan of the patient's head; results were normal.<sup>54</sup> Six weeks later, the patient reported mood improvement but ongoing problems with concentration. NP 1 again increased lithium due to a sub-therapeutic blood level, and other medications were continued as before. Approximately six weeks later, the patient reported stopping the lithium as it was not helpful. NP 1 added an antidepressant (Antidepressant 1) and continued amitriptyline, diazepam, and the previously order atypical antipsychotic medication. The patient was to return in three months.

The patient telephoned the Lake Baldwin CBOC about three months later and reported having moved to another state to live with a relative due to homelessness. The patient requested medications be mailed there. Per the EHR documentation of the phone call: "Pt [patient] also wanted this writer to thank [NP 1] and [the social worker] for their services." The EHR note further indicated that the patient reported that the staff were instrumental in helping with the management of mental health issues, and that the patient was very grateful for their assistance and services.

## **The Patient's Care at the Indianapolis VAMC**

In fall 2013, the patient called the Veterans Crisis Line and reported being out of medications. The crisis line social worker arranged for the patient to be seen at the Indianapolis VAMC Emergency Department (ED), and the patient presented to the ED as planned. The ED physician refilled the medication prescriptions and advised the patient to go for a walk-in mental health evaluation.

At the patient's initial primary care appointment in 2014,<sup>55</sup> the patient reported suffering from depression for decades with a history of many psychiatric interventional treatments and multiple psychiatric medications. The patient also reported having reduced medications except for diazepam.

The PCP referred the patient to mental health triage where a clinical nurse specialist (CNS 1) assessed the patient that same day. The patient was not reporting hallucinations. CNS 1 refilled the amitriptyline 300 mg per day and diazepam 40 mg per day. CNS 1 referred the patient to the

---

<sup>54</sup> A computerized tomography scan is a series of X-ray images to provide more detailed information about internal injuries and to diagnose disease or injury. Mayo Clinic, "CT scan." <https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675>, 2018. (This website was accessed on June 4, 2018).

<sup>55</sup> The patient missed a scheduled 2013 primary care appointment.

West Lafayette CBOC due to the travel distance, and a CBOC primary appointment was scheduled.<sup>56</sup>

The patient presented to the scheduled West Lafayette CBOC primary care appointment approximately six weeks later. The PCP acknowledged the patient's prior care at the Orlando VAMC and the Indianapolis VAMC although the PCP did not document reviewing the 2012 ECG. The PCP documented the patient's medical conditions consistent with prior VHA notes. The PCP referred the patient to mental health for an intake, but system West Lafayette CBOC staff canceled the consult because the patient subsequently decided to remain at the Indianapolis VAMC.

A different mental health CNS (CNS 2) evaluated the patient for psychiatric medication management five weeks later. The patient reported benefit from amitriptyline and diazepam and requested continuation of these two medications. The patient reported "dry mouth" but declined CNS 2's offer to try a different medication. CNS 2 agreed to continue the medications if the patient submitted a urine drug screen, and that "any use of medications not prescribed, illicit substance or absence of + [positive] result for benzodiazepine prescribed could result in taper and discontinuation of diazepam." The EHR did not include evidence that the patient completed the urine drug screen.

In summer 2014, the patient returned to CNS 2 and agreed to comply with prescribing requirements in order to continue to receive diazepam. The patient reported taking lower doses of amitriptyline and diazepam, and CNS 2 noted "[w]ill increase amitriptyline to 300 mg at hs [bedtime], as patient reported lower dose is not effective for depression. Will also increase diazepam back to 10 mg qid prn [four times a day as needed] for anxiety."

At the next appointment, the patient reported having "a drug test done [while seeking a job] that came back positive, 'for angel dust,'" and attributed the test result to amitriptyline. The patient told CNS 2 about wanting to discontinue all medications. CNS 2 noted that the patient "...would not agree to taper schedule and refused off[er] for continued follow-up appointments for medication management."

## **The Patient's Care at the System**

Two days later, the patient presented to the West Lafayette CBOC for the scheduled intake appointment with a social worker. The patient scored in the moderately severe depression level on a standard clinical rating, and the social worker made a referral for medication management. Nine days later, the patient told a psychiatrist (Psychiatrist 2) about being on antidepressants for about 22 years. Psychiatrist 2 further documented that the patient had been "started on TCAs"

---

<sup>56</sup> The West Lafayette CBOC was aligned under the system at this time.

[tricyclic antidepressants - presumably amitriptyline], was switched to selective serotonin reuptake inhibitors (SSRIs) at some point but did not do well on the SSRIs, and was back on amitriptyline.<sup>57</sup> Psychiatrist 2 recommended the patient continue amitriptyline at 300 mg per day and reduce diazepam to 30 mg per day with a plan to decrease diazepam by an additional 2.5 mg every two weeks. The system appointed the patient to return in two months.

The patient did not present for the scheduled psychiatry appointment two months later. A month after the missed appointment, the patient presented to the clinic and told a nurse practitioner (NP 2) about having anxiety attacks on the lower diazepam dose. NP 2 prescribed the amitriptyline and diazepam at the previous doses of 300 and 30 mg per day, respectively, and added a serotonin and norepinephrine reuptake inhibitor (SNRI) medication with a plan for the patient to return in two months.<sup>58</sup>

Three months later, the patient contacted the system pharmacy and requested an increased dose of diazepam. In response, the West Lafayette CBOC nurse sent the patient a letter with a scheduled appointment with Psychiatrist 2. Three weeks later, the patient presented to the West Lafayette CBOC and requested an increase of diazepam. Psychiatrist 2 denied the request and prescribed 25-30 mg per day as needed. Psychiatrist 2 also continued amitriptyline at 300 mg per day; discontinued the previously ordered SNRI as it was not tolerable; and initiated a trial of another antidepressant (Antidepressant 2).<sup>59</sup> A return visit was planned for two months. Before the next visit took place, the patient phoned the Veterans Crisis Line requesting assistance getting the amitriptyline prescription filled.<sup>60</sup> The patient reported being “off of it for the past 5 days because the refill has not arrived in the mail.” The patient further reported being unable to sleep and having mood swings, was suffering, and in crisis. A system social worker telephoned the patient for follow-up and documented that the patient reported that the medication subsequently arrived.

The patient canceled the next appointment with Psychiatrist 2. Approximately five months after the last visit, the patient met with a physician assistant (PA). The patient reported discontinuing the Antidepressant 2 due to lack of effect and requested to restart the previously ordered atypical antipsychotic. The PA consulted with Psychiatrist 2. Psychiatrist 2 did not approve any medication changes or additions. The PA did not prescribe the atypical antipsychotic and continued the amitriptyline and diazepam dosages as prescribed. Approximately five weeks later,

---

<sup>57</sup> SSRIs are another class of antidepressants. Mayo Clinic, “Selective serotonin reuptake inhibitors.” <https://www.mayoclinic.org/diseases-conditions/depression/in-depth/ssris/art-20044825>, May 17, 2018. (The website was accessed on May 29, 2018.)

<sup>58</sup> An SNRI is used to treat depression and anxiety.

<sup>59</sup> Antidepressant 2 was a tetracyclic antidepressant and similar to a TCA.

<sup>60</sup> VA Office of Mental Health Services, *Suicide Prevention, Veterans Crisis Line*. [https://www.mentalhealth.va.gov/suicide\\_prevention/index.asp](https://www.mentalhealth.va.gov/suicide_prevention/index.asp), 2017. (This website was accessed on May 23, 2018.)

the patient returned to the PA and denied any medication side effects. The PA continued amitriptyline and diazepam with no changes.

The next month, the patient phoned the clinic and talked with a nurse about taking amitriptyline 300 mg for a long time and feeling like it was no longer effective. The patient further described trying to quit the medication on his/her own in the past but would become "violently" ill. The patient wanted to talk with a provider about getting off the medication. The following day, the patient met with the PA and complained of ongoing depression and anxiety symptoms, as well as increasing memory problems. The PA noted the patient talked about trying to stop the medication, becoming very ill and having "to return to it immediately." The patient requested inpatient admission to manage withdrawal from amitriptyline and diazepam. Psychiatrist 2 agreed to arrange an admission, and the PA notified the patient.

As scheduled, the patient was admitted to the system inpatient psychiatry unit the following week. The patient wanted to discontinue all medications except blood pressure medication. The patient complained of increasing memory problems and talked about going back to driving a truck professionally but being unable to do so while on medications other than the ones taken for blood pressure. The patient did not know that the admission would be to a secured psychiatry unit and found the conditions intolerable. The patient asked to be discharged and left against medical advice the day after admission. The patient was scheduled to meet with Psychiatrist 2 three days later.

The patient presented to the scheduled appointment, reported that the amitriptyline had been reduced to 275 mg per day on the inpatient psychiatry unit, and that the patient had further reduced it of his/her own accord to 200 mg per day along with reducing diazepam to 15 mg per day. Psychiatrist 2 advised the patient to continue diazepam at 15 mg per day and to take 200 mg per day of amitriptyline for two–three weeks, next, decrease to 175 mg per day for one week, and then decrease to 150 mg per day. Psychiatrist 2 prescribed a replacement antidepressant (Antidepressant 3) for the amitriptyline and an antihistamine for anxiety. Psychiatrist 2 instructed the patient to return to the clinic in one to two months.

After three weeks, the patient returned to the clinic and reported not being able to tolerate the medication taper; a slower taper was ordered. Psychiatrist 2 prescribed 265 mg amitriptyline per day with a decrease of 12.5 mg per day every three–four weeks as tolerated. Psychiatrist 2 also increased diazepam to 20 mg per day as the patient requested. Psychiatrist 2 discontinued Antidepressant 3 with a plan to re-start it after the amitriptyline dose was lower. The patient was to return in two months.

At a return visit in early 2016, the patient reported doing generally well except for fatigue. The patient had reduced the amitriptyline to 212.5 mg per day and denied side effects. Approximately two weeks later, the PCP evaluated the patient as part of a routine checkup. The patient reported being "on a very high dose [of amitriptyline] and is weaning off right now with the psychiatrist." The patient further described concerns about being tachycardic and metoprolol being ordered to

bring the heart rate down. The PCP documented that the “[p]atient seems to be very much upset. Patient would like to get off most...medications.” The West Lafayette CBOC PCP documented a normal heart exam and vital signs that day and did not order any evaluations of cardiac functioning.

Five weeks later, the patient was treated for a dog bite at the Indianapolis VAMC and reported taking 125 mg per day of amitriptyline. An ECG completed that day was within normal limits with no notation of the 2012 ECG finding of non-specific intra-ventricular conduction delay.

Approximately two weeks later, the patient met with Psychiatrist 2 and reported successfully reducing the amitriptyline dose to 150 mg per day. Psychiatrist 2 noted that the patient “spent a good amount of time, talking about...resentment of being on a high dose of amitriptyline for over 20 years. [The patient] was unable to tell me for certain where this medication was initially started... Vet is not willing to commence another antidepressant at this time.” Psychiatrist 2 did not initiate Antidepressant 3 as was planned in the prior visit. Psychiatrist 2 continued diazepam at 20 mg per day and discontinued the previously ordered antihistamine as the patient reported stopping it. The patient was to return in two months.

Prior to the scheduled visit, the patient presented to the Indianapolis VAMC ED and reported distress over unsuccessful efforts to taper off amitriptyline. The patient reported taking 125–150 mg per day. Initially, the patient requested to transfer care to Indianapolis VAMC. However, the patient “refused” the provider’s offered treatment plan to start Antidepressant 3 and reduce amitriptyline, and left the ED. An amitriptyline blood level performed at the patient’s request was below the therapeutic reference level (subtherapeutic).<sup>61</sup> An ECG was within normal limits with no notation of the non-specific intra-ventricular conduction delay.

The next day, the patient phoned the West Lafayette CBOC Mental Health Clinic and requested Antidepressant 3 be ordered because the current dose of 125 mg per day of amitriptyline was not doing as well as the patient had hoped. The PA provided the requested prescription for Antidepressant 3 and the patient was to follow up with Psychiatrist 2 in nine days. As scheduled, the patient presented to Psychiatrist 2, who described the patient’s mood as stable. The patient reported taking 125 mg per day amitriptyline and not taking Antidepressant 3 regularly. Psychiatrist 2 increased the diazepam to 30 mg per day. The patient was to return in three months.

Approximately six weeks later, the patient phoned the West Lafayette CBOC Mental Health Clinic and requested that Psychiatrist 2 prescribe pain medication to address pain that the patient attributed to weaning off of amitriptyline. Psychiatrist 2 told West Lafayette CBOC staff to advise the patient to contact the PCP. However, the nurse’s attempts to contact the patient by

---

<sup>61</sup> A subtherapeutic dose is a dose “below what is used for treating disease or producing an optimal therapeutic effect.” Merriam-Webster, <https://www.merriam-webster.com/dictionary/subtherapeutic>. (The website was accessed on July 9, 2018.)

telephone or leave a voicemail were unsuccessful. At the time of the next regularly scheduled visit, the Mental Health PA saw the patient. The patient remained on 130 mg per day dose of amitriptyline. The patient reported chest pain and palpitations at a lower dose. The patient complained of nightmares and panic attacks, and noted “trembling on the inside at all times.” The patient wanted to only follow up with Psychiatrist 2 in the future. The PA did not order any testing or cardiology follow-up.

Approximately two weeks later, the patient and the patient's significant other met with Psychiatrist 2. Psychiatrist 2 noted that the patient's significant other talked about an article “regarding amitriptyline cardiotoxicity. I advised that veteran make an appointment with [veteran's] PC [primary care] provider—which [veteran] agreed.” Psychiatrist 2 initiated Antidepressant 2 “as adjunct for depression,” continued amitriptyline and diazepam as before, and advised the patient to stop reducing the amitriptyline dosage. A follow-up appointment was to be scheduled for approximately two months later. Psychiatrist 2 included the PCP as an additional signer and the PCP acknowledged receipt. Four days later, a medical support assistant documented “[w]riter attempted to contact veteran to schedule an appointment with [veteran's] primary care provider...Pt [patient] to discuss cardiotoxicity with pcp per note. A HIPAA compliant message was not able to be left for the veteran because [veteran's] phone was not taking calls. A letter will be mailed asking the veteran to schedule an appointment” with the PCP.

One month later, the patient met with the PCP who noted the patient was reporting an issue with the amitriptyline and documented “I informed [the patient] that this is a matter that needs to be discussed with the prescribing physician and instructed [the patient] to make an appointment with mental health immediately after this office visit to discuss this with mental health specialist. [The patient] expressed understanding and agreement.” The PCP wrote “[m]edications reviewed and renewed/modified as appropriate. Indications, usage, and possible side effects discussed. Questions and concerns were addressed to patient's satisfaction and updated medication list provided.” The PCP documented a normal heart exam, well controlled hypertension, and the patient's declination to undergo additional blood tests. The PCP did not request a cardiology consult, include Psychiatrist 2 as an additional signer, or document any collaborative attempt or plan.

In early 2017, the patient met with Psychiatrist 2 and reported increased anxiety and cessation of smoking cigarettes. The patient also reported increasing the amitriptyline to 150 mg per day two months earlier and stopping Antidepressant 2. In a visit with Psychiatrist 2 a few weeks later, the patient described displeasure with the process of obtaining a letter from the system to assist the patient in being excused from court testimony. That day, the patient's mood was depressed, and

Psychiatrist 2 added Antidepressant 3 to the treatment regimen.<sup>62</sup> Psychiatrist 2 advised the patient to follow up in two–three months with the mental health PA, or earlier if needed.

After some scheduling complications, the patient met with another West Lafayette CBOC psychiatrist (Psychiatrist 3) approximately three months later. At that meeting, the patient expressed concerns about perceived cardiac issues. Psychiatrist 3 documented the patient stated the metoprolol avoided “a baseline heart rate of 180–200. Talked about frustration that no experts anywhere have known what to do to help [the] heart problems and that trying to lower [the] Amitriptylene [sic] below 150 mg has made [the] cardiac problems worse.” Psychiatrist 3 did not order additional testing or cardiology follow-up.<sup>63</sup>

### **The Patient's Care at the Indianapolis VAMC<sup>64</sup>**

At a visit three months later, Psychiatrist 3 noted that the patient reduced the amitriptyline to 150 mg and the patient was feeling “worse than a year ago because of trying to lower[the] Amitriptylene [sic].” Psychiatrist 3 diagnosed the patient with depression, mood disorder due to heart condition, and possible mild cognitive impairment. At the next visit, approximately four months later, the patient scored in the high moderate severity level on the MoCA. Psychiatrist 3 diagnosed the patient with “[m]ood disorder due to heart condition, post concussional syndrome,<sup>65</sup> medication toxicity” and “[o]rganic brain syndrome unspecified (Impairment of short-term memory, attention, language, visuospatial)” in addition to the major depression and mood disorder due to heart condition diagnoses. The patient declined Psychiatrist 3's offer for neuropsychological testing or another medication. In mid-2018, Psychiatrist 3 documented the patient's risk factors for cognitive impairment that included [a] history of head injury and “1990–2016 Amitriptylene [sic] 300 mg HS [at bedtime].” Psychiatrist 3 also noted that the patient's “26–27 years” high doses of amitriptyline caused tachycardia and [the patient's] trying to reduce it below 150 mg makes the tachycardia worse. As of mid-2018, no VA provider had referred the patient for additional cardiology testing or evaluation.

---

<sup>62</sup> Psychiatrist 2 reported no longer working at the West Lafayette CBOC after early 2017.

<sup>63</sup> Shortly thereafter, the West Lafayette CBOC was realigned under the Indianapolis VAMC, but the clinical staff remained the same.

<sup>64</sup> The West Lafayette CBOC was aligned under the Indianapolis VAMC at this time.

<sup>65</sup> Psychiatrist 3's diagnosis of post concussional syndrome (or traumatic brain injury) was in response to the Patient's report of a head injury as a result of a motor vehicle accident many years prior.

## Inspection Results

### Issue 1: Medication Risks and Benefits

The OIG substantiated that the patient was prescribed 300 mg of amitriptyline, and VHA providers failed to explain that this dosing was higher than the drug labeling maximum for outpatients and the risks of the high dosage. Specifically, the OIG team found that the Orlando VAMC ordering provider did not document notifying the patient of a 2012 abnormal ECG or follow up with additional evaluation to assess and discuss the potential that amitriptyline contributed to the abnormality. Although VHA providers generally documented risk and benefit discussions for medications as required, none documented specific discussions about risk and benefits related to the high dose of amitriptyline.

Beginning in the early 1990s, private non-VA providers prescribed the patient amitriptyline and reportedly increased the dosing to reach 300 mg per day by the sixth week. The patient initiated VHA care in 2012; VHA providers continued to prescribe 300 mg of amitriptyline daily as initiated by private non-VA providers. The patient told the OIG team that VHA providers did not tell the patient about the high dose and that the patient should not be taking as high of a dose as was prescribed. Throughout the years of VHA care, the patient intermittently expressed concerns about the effectiveness and negative effects of amitriptyline, particularly the risk of cardiac toxicity, and that providers at each of the three VHA facilities offered tapering plans to reduce the dosage and initiate different antidepressant medications. (See Table 1.) When interviewed, Psychiatrist 2 recalled expressing concern about the maximum dose of amitriptyline to the patient but was not sure if they discussed the cardiac risks.

At the patient's initial 2012 PCP appointment, the PCP ordered an ECG and results indicated a non-specific intra-ventricular conduction delay, which may have reflected a toxic effect from amitriptyline. The OIG found no evidence that the PCP documented notifying the patient of this abnormal result, as required.<sup>66</sup>

As one component of a patient's informed consent process, providers must describe the known benefits and expected risks of a recommended treatment.<sup>67</sup> Providers are required to obtain repeat informed consent when there are significant changes in the treatment plan or in the patient's condition or diagnosis that would be expected to alter the patient's original informed treatment consent.<sup>68</sup> The OIG team identified 25 of 38 mental health prescribers' notes included a general statement that the provider and the patient discussed medication risk and benefits. In two of the 25 notes, the statement included that amitriptyline risks and benefits were discussed

---

<sup>66</sup> VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009, rescinded October 7, 2015.

<sup>67</sup> VHA Handbook 1004.01.

<sup>68</sup> VHA Handbook 1004.01.

specifically. As required, all eight visits that included a change in amitriptyline dosage also included a general statement of risk and benefits. In the 13 notes that did not include a risks and benefits discussion, the provider did not change the patient's amitriptyline dosage or diagnosis.

As required by system policy, it is the usual course of business, according to the system pharmacy staff, to provide patients with standard written information (Guide) about amitriptyline with each filled amitriptyline prescription.<sup>69</sup> The Guide provided to the patient did not include information about risks of off-label dosage use. However, guidance included warnings, how to use the medication, and side effects. To reduce the risk of side effects, the Guide advised following the provider's instructions carefully, not increasing the dose, and not stopping the medication without consulting a provider. The Guide further advised that amitriptyline should be continued even when improvements are noticeable because some conditions may become worse when the medication is suddenly stopped. Additionally, the Guide stated that the medication is prescribed because the provider judged that the benefit is greater than the risks of side effects.

## Issue 2: Medication Toxicity Effects

The OIG was unable to substantiate or not substantiate that the patient experienced tachycardia or short-term memory loss as a result of taking amitriptyline because of other possible causes for these conditions. However, the OIG team found that providers did not follow up with further medical evaluation related to the patient's risk factors, cardiac symptoms, and expressed cardiac concerns. The OIG team found that VHA providers took action regarding the patient's reported memory concerns.

### Tachycardia

The patient's tachycardia had multiple potential causes including history of heart disease, other medical conditions, and smoking. However, the OIG team found that providers did not inform the patient of a 2012 abnormal ECG or follow up with further cardiac evaluation. Although the patient reported a history of cardiac disease, risk factors, and cardiac symptoms throughout the course of the VHA care, providers did not refer the patient for a medical evaluation of cardiac functioning. See Table 1 for VHA care related to the patient's cardiac symptoms and amitriptyline concerns. Additionally, except for once in 2016 at the patient's request, providers did not order blood tests to determine levels of amitriptyline or its metabolites including a time when the patient's levels could have been increased as a result of having stopped smoking cigarettes. The OIG team also found that the provider who ordered the mid-2016 blood test did not notify the patient that the results indicated a subtherapeutic level of amitriptyline. Further, the OIG team found that in 2017, the patient did not receive follow-up to expressed cardiac concerns due to a failure to collaborate between Psychiatrist 2 and a system PCP.

---

<sup>69</sup> VA Illiana Health Care System, Medical Center Memorandum Number 119-15, *Medication Management*, September 2017.

**Table 1: VHA Care Related to Cardiac Symptoms and Amitriptyline Concerns  
Late 2012–Mid-2018**

Year	VHA Location	VHA Care Related to Cardiac Symptoms and Amitriptyline Concerns
2012 (Late)	Orlando VAMC	PCP ordered ECG: abnormal with a non-specific intra-ventricular conduction delay; amitriptyline 300 mg per day prescribed by private non-VA providers; Psychiatrist 1 continued prescription; the patient reported concerns about effectiveness of amitriptyline
2013 (Early)	Orlando VAMC	Event 1–NP 1 set goal to titrate off amitriptyline; noted the 2012 abnormal ECG Event 2–NP1 initiated decreased dosage of amitriptyline Event 3–Patient told NP 1 about not decreasing dosage due to depression symptoms
2014 (Through-out)	Indianapolis VAMC	Event 1–CNS 1 refilled amitriptyline 300 mg per day Event 2–Patient reported benefit from amitriptyline, reported “dry mouth” as side effect, requested continuation, and declined CNS 2’s offer to try a different medication” Event 3–Patient reported reduced amitriptyline dosage not effective; CNS 2 prescribed 300 mg per day Event 4–Patient declined CNS 2’s taper schedule
2015 (Late)	System	Event 1–Patient reported becoming ill when tried to stop amitriptyline; admitted to inpatient; amitriptyline reduced to 275 mg per day with taper schedule; Patient reduced to 200 mg per day; Psychiatrist 2 advised taper schedule Event 2–Patient reported not being able to tolerate the taper and agreed to a slower taper
2016 (Through-out)	System	Event 1–Patient reduced the amitriptyline to 212.5 mg per day and denied side effects Event 2–Patient told the CBOC PCP that the amitriptyline caused tachycardia; 212.5 mg amitriptyline per day; PCP documented a normal heart exam and vital signs
	Indianapolis VAMC	Event 3–Evaluation for a dog bite; Patient at 125 mg of amitriptyline per day, normal ECG Event 4–ED visit related to the patient’s distress over unsuccessful efforts to taper off amitriptyline; 125 mg of amitriptyline per day; normal ECG; subtherapeutic amitriptyline blood level
	System	Event 5–Patient reported not doing well on 125 mg of amitriptyline per day; Psychiatrist 2 increased diazepam Event 6–Patient reported pain caused by weaning off of amitriptyline; nurse unable to reach the patient to say that Psychiatrist 2 advised contacting a PCP Event 7–Patient reported chest pain/palpitations when below 130 mg amitriptyline per day Event 8 –Psychiatrist 2 advised the patient to discuss concerns about cardiotoxicity due to amitriptyline with PCP Event 9–PCP referred the patient back to Psychiatrist 2 to discuss “an issue with the amitriptyline”
2017 (Early to Mid)	System	Event 1–Patient told Psychiatrist 2 about increasing amitriptyline to 150 mg per day two months prior; Patient reported ceasing cigarette smoking Event 2–Psychiatrist 3 documented the patient was frustrated about not getting help with cardiac problems and that trying to lower amitriptyline below 150 mg worsened the cardiac problems
	Indianapolis VAMC	Event 1–Patient told Psychiatrist 3 about reducing amitriptyline dosage from 175 mg to 150 mg; feels worse because of trying to lower medication Event 2–Psychiatrist 3 diagnosed the patient with mood disorder due to heart condition, medication toxicity
2018 (Mid)	Indianapolis VAMC	Event 1–Psychiatrist 3 noted that the patient’s “26–27 years” high doses of amitriptyline caused tachycardia and trying to reduce it below 150 mg makes the tachycardia worse.

Source: VA OIG analysis of the patient’s EHR

In 2012, the patient presented to the Orlando VAMC with multiple cardiac diagnoses including hypertension, a history of “sinus tachycardia-controlled on Metoprolol,” and coronary artery disease with a history of myocardial infarction. Other medical conditions that were risk factors for cardiac illness included type 2 diabetes, chronic obstructive pulmonary disease, and tobacco use. Although the patient's abnormal ECG might have reflected a toxic effect of amitriptyline, the PCP and mental health providers (Psychiatrist 1 and NP 1) did not order blood tests for drug levels or its metabolites, follow-up ECGs, or additional cardiac evaluations. Further, there is no EHR documentation that Orlando VAMC providers informed the patient of the abnormal ECG.

VHA mental health staff assessed the patient's pulse and blood pressure at eight (25 percent) of the 32 mental health prescriber outpatient visits from late 2012 to mid-2018. Of the eight vital sign readings, the patient's blood pressure was elevated three times and staff did not document any follow-up testing. Psychiatrist 2 reported checking the patient's vital signs at appointments, but vital signs are only documented in one of the 10 applicable visits. Additionally, when interviewed by the OIG team, Psychiatrist 2 recalled referring the patient to cardiology and for an ECG, but the OIG found no evidence in the patient's EHR that documented those actions were taken.

In response to the patient's concerns, providers discussed and planned decreased dosages of amitriptyline. However, the patient experienced increased depression symptoms or physical illness when the dosage was decreased, and in 2015, the patient agreed to a system inpatient admission to manage withdrawal that initiated a successful taper of the amitriptyline dosage.

In early 2016, the patient decreased the amitriptyline dosage to 125 mg per day. During an inpatient admission at the Indianapolis VAMC in early 2016, and an Indianapolis VAMC ED visit in mid-2016, the patient was taking 125 mg per day of amitriptyline. The ECG performed during the 2016 ED visit showed no abnormalities. Unlike the 2012 ECG when the patient was taking 300 mg of amitriptyline per day, the ECGs had no notation of a non-specific intra-ventricular conduction delay. A mid-2016 amitriptyline blood level, performed at the patient's request, indicated the medication was at a subtherapeutic blood level. Although the subtherapeutic dose may have reflected a need for dose adjustment or other medication changes to treat the patient's depression more effectively, the OIG team did not find evidence that the ordering provider informed the patient of this test result.

In late 2016, the patient reported chest pain and heart palpitations after lowering the amitriptyline dosage below 130 mg per day. The system mental health PA documented that the patient would continue diazepam 10 mg three times daily as needed for anxiety during the period of amitriptyline weaning. Also in late 2016, Psychiatrist 2 advised the patient to discuss concerns about cardiotoxicity with the PCP and informed the PCP through the EHR. At a late 2016 appointment, the PCP referred the patient back to Psychiatrist 2 to discuss the amitriptyline. The OIG team did not find evidence of consultation or collaboration between Psychiatrist 2 and the PCP to respond to the patient's questions and concerns.

In early 2017, the patient told Psychiatrist 2 about increasing the amitriptyline dosage to 150 mg per day and ceasing smoking cigarettes. Although tobacco cessation could impact the efficacy of amitriptyline, Psychiatrist 2 did not order blood tests to measure drug or metabolite levels.<sup>70</sup>

At a mid-2017, private non-VA PCP appointment, the patient complained of occasional palpitations. The PCP noted that the patient “saw cardiology and psych [iatry]...regarding high dose Amitriptyline and side effects, but, no resolution.” The PCP documented the plan to find another psychiatric opinion regarding the “Amitriptyline dose potential safety and cardiac side effects onn [sic] rhythm.” At a later 2017 visit, the PCP wrote that the patient was exhibiting tremors due to withdrawal from amitriptyline that was being lowered by the VA.

Psychiatrist 3 documented the patient's frustration about not getting help with the cardiac problems and concerns that amitriptyline had harmed his/her heart. In late 2017, Psychiatrist 3 listed additional conditions that could be responsible for depression including “mood disorder due to heart condition, post concussional syndrome, medication toxicity.” Psychiatrist 3 did not offer the patient a referral for cardiac testing at any visits.

In early 2018, the patient's private non-VA PCP documented that the patient had a normal treadmill stress test and an upcoming appointment with a cardiologist. Additionally, to address the patient's near fainting (near syncope<sup>71</sup>) episodes, the PCP ordered a head computerized tomography scan and recommended an appointment with a neurologist. At a later 2018 appointment, the PCP noted the patient's cardiac comorbid conditions (hypertension, post-myocardial infarction) and other cardiac risk factors. The PCP referred the patient to a cardiologist to evaluate and treat.

Psychiatrist 3 told the OIG team that caution was necessary in prescribing TCAs for patients with “heart issues” due to cardiac risks. Psychiatrist 3 reported awareness of the patient's two normal ECGs (2016) and acknowledged not following up with additional medical evaluation or referral to cardiology. In response to the OIG team's questions, Psychiatrist 3 also reported a plan to review the patient's amitriptyline level to determine if the level was still subtherapeutic, inform the patient about the prior subtherapeutic blood level, and offer an ECG. However, at the patient's next visit, Psychiatrist 3 did not follow up on those actions.

## Short-Term Memory Loss

The patient's memory problems had multiple potential causes including depression and anxiety disorders, diazepam usage, and a history of head injury. The OIG team found that VHA providers took action regarding to the patient's reported memory concerns. (See Table 2.)

---

<sup>70</sup> Prescribers' Digital Reference, “Amitriptyline Hydrochloride - Drug Summary.”

<sup>71</sup> Syncope is the “loss of consciousness resulting from insufficient blood flow to the brain.” Miriam-Webster, <https://www.merriam-webster.com/dictionary/syncope>. 2018. (This website was accessed on June 26, 2018.)

Depression and anxiety disorders can negatively affect memory. The patient was diagnosed with depression and anxiety for approximately 20 years prior to the beginning of the patient's VHA care in 2012. Additionally, beginning prior to and throughout the years of VHA care, the patient was prescribed diazepam which can cause memory impairment.<sup>72</sup> In an interview with the OIG team, Psychiatrist 2 reported concern about the patient's high dose of diazepam because of the negative impact on memory.

Immediately after the patient's 2015 inpatient admission, Psychiatrist 2 and the patient reduced the diazepam to 15 mg per day (down from 30 mg per day) as well as the tapering schedule for the amitriptyline dosage. The patient did not complain of memory problems again until early 2017, and at that time Psychiatrist 2 referred the patient for a neuropsychological evaluation. However, the patient declined the referral and Psychiatrist 3's subsequent offers for a neuropsychology evaluation.

Per the patient's provided medical records, in spring 2017, a private non-VA PCP referred the patient to a non-VA neurology practice. To evaluate the patient's memory disturbance, the neurologist ordered electroencephalography and blood tests.<sup>73</sup> The electroencephalography and blood test results were normal. In mid-2017, the patient scored in the high moderate severity level of cognitive impairment on the MoCA. The neurology provider concluded that the patient's cognitive functioning was affected by the dosing of amitriptyline, as well as by the history of many psychiatric interventional treatments and a concussion.

In late 2017, Psychiatrist 3 noted the patient's short-term memory was getting worse, completed the MoCA, and diagnosed organic brain syndrome unspecified. One month later, the patient declined Psychiatrist 3's offers for neuropsychological testing or other medication. In mid-2018, Psychiatrist 3 documented the patient's risk factors for cognitive impairment including a history of head injuries and use of amitriptyline 300 mg per day from "1990–2016."

---

<sup>72</sup> Memory impairment may occur as an adverse reaction to diazepam. Prescribers' Digital Reference, "Diazepam - Drug Summary," <http://www.pdr.net/drug-summary/Valium-diazepam-2100.1196>, 2018. (The website was accessed on June 13, 2018.)

<sup>73</sup> An electroencephalography is a test that determines changes in brain activity useful in diagnosing brain disorders. Mayo Clinic, "EEG (electroencephalography)," <https://www.mayoclinic.org/tests-procedures/eeg/about/pac-20393875>, May 16, 2018. (The website was accessed on June 13, 2018.)

**Table 2: VHA Care Related to Short-Term Memory  
Late 2012–Mid-2018**

Year	VHA Location	VHA Care Related to Short-Term Memory and Amitriptyline Concerns
2013 (Early)	Orlando VAMC	NP ordered a computerized tomography scan to assess for potential brain conditions impacting memory; scan results were normal
2015 (Late)	System	The patient reported “having increasing problems with memory issues and is losing [patient’s] train of thought when...talking to people.” In consultation with Psychiatrist 2, the PA arranged for an inpatient admission to discontinue the medications
2017 (Early to Mid)	System	Event 1–Psychiatrist 2 entered a neuropsychology consult in response to the patient’s memory complaints Event 2–Patient canceled the scheduled neuropsychological evaluation and did not wish to pursue the evaluation
(Late)	Indianapolis VAMC	Event 1–Psychiatrist 3 administered the MoCA, and the patient scored in the high moderate severity level; documented that the patient’s short-term memory was getting worse and added the diagnoses of “post concussional syndrome” and “organic brain syndrome unspecified (Impairment of short-term memory, attention, language, visuospatial).” Event 2–Patient declined neuropsychological testing and other medication
2018 (Mid)	Indianapolis VAMC	Psychiatrist 3 documented risk factors for cognitive impairment including history of head injury, long-term use of high dosage (300 mg per day) of amitriptyline

Source: VAOIG analysis of the patient’s EHR

### Issue 3: System Director Response to Congressional Inquiry

The OIG substantiated that the January 3, 2017, System Director’s response to Senator Donnelly was not timely and included inaccurate information. In the response, the System Director stated that providers reduced the patient’s amitriptyline dosage by more than 50 percent during the patient’s 2015 inpatient psychiatry unit admission. However, the patient’s dosage was decreased gradually during and after the admission, and in early 2016, the patient reported reaching over a 50 percent reduction. Additionally, the patient informed the OIG team that while the congressional response asserted that the patient was satisfied with the mental health care that was provided, the patient never expressed satisfaction as claimed. The OIG also found that the Service Preparer may not have consulted with Psychiatrist 2 in preparation of the response and that system administrative staff did not retain background documentation, as required by system policy. Further, the System Director’s response exceeded the VHA mandated 30-day time frame for responding to congressional mail.<sup>74</sup>

<sup>74</sup> VHA Directive 2012-017, *Veterans Health Administration Correspondence Management*, June 25, 2012, expired June 30, 2017, and has not been updated.

Senator Donnelly sent a letter dated September 29, 2016, to the system patient representative on behalf of the patient and requested a review of the patient's request for an inpatient program to discontinue amitriptyline. The letter included the patient's written concerns about the VHA medical care, including amitriptyline overmedication, cardiac conditions, and cognitive dysfunction.

The system Chief, Quality Management told the OIG that the System Director's secretary administratively logged the congressional correspondence into the internal tracking system on November 10, 2016, and assigned the subject congressional inquiry to the Chief, CBOC with a due date of November 21, 2016. The Chief assigned a CBOC administrative employee, who had limited experience in responding to congressional inquiries, to be the Service Preparer.

In preparation of the response, the Service Preparer recalled reaching out to the CBOC mental health nurse. The mental health nurse reportedly advised the Service Preparer to contact Psychiatrist 2 (the patient's treating mental health provider at that time) for further information. However, when Psychiatrist 2 was interviewed, the OIG team was told that Psychiatrist 2 did not discuss the congressional inquiry with the Service Preparer.

The Service Preparer reportedly spoke with the patient by phone on December 27, 2016. The Chief, Quality Management told the OIG that the system's tracking system reflected that the Chief, CBOC forwarded the response to the Director's office on December 27, and the System Director's response to Senator Donnelly was dated January 3, 2017, which was 54 days after the inquiry was assigned to the service.<sup>75</sup>

The OIG team's review of the EHR documentation confirmed that the System Director's letter regarding the patient's inpatient admission amitriptyline dose reduction was inaccurate. Additionally, the Acting Chief of Staff who reviewed and approved the draft response and Psychiatrist 2 told the OIG team that the information in the letter regarding the amitriptyline dose reduction was inaccurate.

Table 3 includes the information that the System Director provided to Senator Donnelly and the findings of the OIG team.

---

<sup>75</sup> Although Senator Donnelly's inquiry letter was dated September 29, 2016, system staff logged in the internal tracking system on November 10, 2016. The OIG team used the November 10 date as Day 1 for calculation of response time.

**Table 3: Inconsistent Information between System Director’s Response to Congressional Inquiry and OIG Findings**

System Director’s Response	OIG Finding
<p><b>“During this admission, [the patient’s] Amitriptyline dosage was reduced by more than 50%.”</b></p>	<p>Psychiatrist 2 prescribed amitriptyline 300 mg per day from late 2014, up to the patient’s inpatient psychiatry admission. Upon admission Psychiatrist 2 decreased the dosage to 275 mg per day (a decrease of eight percent). The patient was discharged the next day.</p>
<p><b>“[In 2016] the Community Based Outpatient Clinic (CBOC) Administrative Officer contacted [the patient] to discuss his concerns regarding his medications. [the patient] is at a tolerable maintenance dose and is satisfied with his mental health care.”</b></p>	<p>The CBOC Administrative Officer (Service Preparer) reportedly spoke with the patient to discuss concerns and took notes but discarded the notes after drafting the response. The patient told the OIG team that being satisfied with the treatment received was never expressed to the Administrative Officer or other System staff. The patient discussed asking for help and they were not helping</p>

Sources: The patient’s EHR, VA OIG Interviews

The OIG team was unable to confirm that the patient reported to the CBOC Administrative Officer (Service Preparer) that “[the medication] is at a tolerable maintenance dose and is satisfied with [his/her] mental health care,” as indicated in the System Director’s congressional response. The OIG team identified several factors that indicated the patient was not satisfied with treatment:

- The patient discussed unhappiness in the letter to Senator Donnelly with many aspects of care, including the medication regimen.
- The mental health nurse reported that the patient was unhappy about the medication.
- The patient told the OIG team that being satisfied with the care received was never expressed during the phone call with the Service Preparer.
- During the patient’s PCP appointment just three weeks prior to the System Director’s response, the patient reported an ongoing concern about amitriptyline.

System policy requires the Service Preparer to submit the draft response to the Director’s office in a folder containing the response and background information, and to retain documentation per VHA’s record retention rules. The OIG found that the Service Preparer told the OIG team that all paperwork used to prepare the response was destroyed. This was contrary to system policy.

## Conclusion

The OIG team reviewed the patient's EHR for the period of care from late 2012 through mid-2018 at the Lake Baldwin CBOC under the Orlando VAMC, the Indianapolis VAMC, the West Lafayette CBOC, and the system. The OIG substantiated that the patient was prescribed 300 mg of amitriptyline, and VHA providers failed to explain that this dosing was higher than the drug labeling maximum for outpatients and the risks of the high dosage. Specifically, the OIG team found that the Orlando VAMC ordering provider did not document informing the patient of a 2012 abnormal ECG or follow up with additional evaluation to assess and discuss the potential that amitriptyline contributed to the abnormality. Although VHA providers generally documented risk and benefit discussions for medications as required, none documented specific discussions about risk and benefits related to the high dose of amitriptyline.

The OIG was unable to substantiate or not substantiate that the patient experienced tachycardia as a result of taking amitriptyline because of other potential causes such as the patient's history of heart disease, other medical conditions, and smoking. However, the OIG team found that providers did not inform the patient of a 2012 abnormal ECG or follow up with further cardiac evaluation. Although the patient reported a history of cardiac disease, risk factors, and cardiac symptoms, VHA providers did not refer the patient for a medical evaluation of cardiac functioning. Additionally, except for once in mid-2016 at the patient's request, providers did not order blood tests to determine levels of amitriptyline or its metabolites including a time when the patient's levels could have been increased as a result of having stopped smoking cigarettes. The OIG team also found that the provider who ordered the mid-2016 blood test did not notify the patient that the results indicated a subtherapeutic level of amitriptyline. Further, the OIG team found that in 2017, the patient did not receive follow-up to expressed cardiac concerns due to a failed collaboration between Psychiatrist 2 and a system PCP.

The OIG was unable to substantiate or not substantiate that the patient experienced short-term memory loss as a result of taking amitriptyline because of other potential existing causes for memory problems such as depression and anxiety disorders, diazepam usage, and a history of head injury. The OIG team found that at various points over the years from late 2012 through mid-2018, VHA providers took action regarding the patient's reported memory concerns.

The OIG substantiated that the January 3, 2017, System Director's response to Senator Donnelly was not timely and included inaccurate information. In the response, the System Director stated that providers reduced the patient's amitriptyline dosage by more than 50 percent during the patient's 2015 inpatient psychiatry unit admission. However, the patient's dosage was decreased gradually during and after the admission, and in early 2016, the patient reported reaching over a 50 percent reduction. Additionally, the patient informed the OIG team that being satisfied with mental health care received was never expressed as asserted in the response. The OIG also found that the Service Preparer may not have consulted with Psychiatrist 2 in preparation of the response and that system administrative staff did not retain background documentation, as

required by system policy. Further, the System Director's response exceeded the VHA mandated 30-day time frame for responding to congressional mail.

The OIG made eight recommendations.

## **Recommendations 1–8**

1. The Orlando VA Medical Center Director evaluates the care of the subject patient with respect to the patient's cardiac complaints and takes action, as appropriate, including clinical disclosure.
2. The Orlando VA Medical Center Director verifies staff compliance with Veterans Health Administration policies related to patient notification of electrocardiogram test results and follow-up as clinically indicated.
3. The Richard L. Roudebush VA Medical Center Director evaluates the care of the subject patient with respect to the patient's cardiac complaints and takes action, as appropriate, including clinical disclosure.
4. The Richard L. Roudebush VA Medical Center Director verifies staff compliance with Veterans Health Administration policies related to patient notification of medication blood level test results and follow-up as clinically indicated.
5. The VA Illiana Health Care System Director evaluates the care of the subject patient with respect to the patient's cardiac complaints and takes action, as appropriate, including clinical disclosure.
6. The VA Illiana Health Care System Director strengthens processes for effective clinical consultation and follow-up between mental health and collaborating primary care providers.
7. The VA Illiana Health Care System Director strengthens the processes for congressional inquiry response to ensure response timeliness, clinical information accuracy, and records retention, as required.
8. The VA Illiana Health Care System Director evaluates staff actions and approval processes in the preparation of the letter to Senator Donnelly, and takes appropriate administrative action, if indicated.

## Appendix A: Executive in Charge Comments

### Department of Veterans Affairs Memorandum

Date: November 20, 2018

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Concerns Related to the Management of a Patient's Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System, Danville, Illinois; Orlando Florida; Indianapolis, Indiana and Danville, Illinois

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft of your case review of the care a Veteran received at three Veterans Affairs (VA) Medical Centers. I appreciate the extensive work the Office of Inspector General (OIG) has done on this review, however, I do not concur with all of its conclusions. Most importantly, the Veteran described in this report experienced no harm from care in VHA. This patient received compassionate, attentive, evidence-based, and clinically appropriate care.
2. Importantly, the Veterans Health Administration (VHA) needs the Inspector General to conduct significant reviews of VHA's national health care system to help us improve care for all Veterans. A retroactive health record review of a single patient, while using substantial resources, is not transferrable nationwide and does not provide the Agency with substantive recommendations for improvement.
3. VHA finds the patient record adequately documents that the patient consented to the medical treatment plan. Dosing of Amitriptyline was within published standards and clinical guidelines for therapeutic effect is evidence-based health care. According to Cochrane Library Systematic Review, Amitriptyline versus placebo for major depressive disorder,<sup>76</sup> the therapeutic dose of Amitriptyline is 25-300 mg per day; consistent with the dosing for the subject patient. The VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder (April 2016),<sup>77</sup> in alignment with published reports, establishes the maximum dose per day at 300 mg. As with all clinical treatments, providers must obtain and document that the patient provided oral informed consent in the health record, which they did. When the patient experienced some of the many expected side effects from the medication, clinical providers at all three sites appropriately adjusted medication dosing to balance side effect tolerance with

---

<sup>76</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009138.pub2/full>.

<sup>77</sup> <https://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf>.

therapeutic effect. These actions demonstrate expected patient centered care and shared decision-making between the patient and providers.

4. VHA disagrees with OIG's mischaracterization of the normal electrocardiogram (ECG) from [redacted]<sup>78</sup> 2012. The patient was promptly informed of the normal ECG as well as the follow up normal ECGs over time. VHA's National Program Director for Cardiology reviewed the OIG's concerns regarding the 2012 electrocardiogram and provided the following expert opinion:

I would non-concur with the OIG conclusion that management of the patient was inappropriate, related to an abnormal Electrocardiogram (ECG) noted on [redacted] 2012, and concurrent use of amitriptyline. The OIG [draft] report states that the Primary Care Provider (PCP), and presumably the computerized interpretation of the (ECG) (which is quite accurate in the area of cardiac intervals like PR, QRS, and QT intervals) did not indicate an abnormal conduction time on the ECG. A subsequent cardiologist overread of the ECG was determined to show a non-specific intra-ventricular conduction delay (IVCD). Subsequent ECGs obtained on [redacted] 2016, and on [redacted] 2016, while the patient remained on amitriptyline, were normal without IVCD noted. On [redacted] 2017, the patient was seen by a non-VA primary care provider and it was stated that the patient had seen a private cardiologist regarding concerns of amitriptyline use and cardiac effects, yet "no resolution" is noted indicating that the private cardiologist did not see fit to perform further testing or to change the amitriptyline dose due to cardiac concerns. During a [redacted] 2018 visit, the patient's non-VA primary care provider also noted that the patient underwent a treadmill cardiac stress test which was normal.

Based on my review of the OIG report, I feel that the cardiac management of the patient surrounding the question of toxicity from amitriptyline was appropriate and within the standard of care. Findings of IVCD on ECG testing are often subjective and the clinical significance is unclear when the QRS interval remains less than 120 milliseconds (msec) as was the case with the [redacted] 2012 ECG. A QRS interval of greater than 120 msec would be determined a bundle branch block and would almost always be detected via computerized ECG reading algorithms. That was not the case with this patient. Subsequent normal ECGs while still on amitriptyline further mitigate the claim that the drug caused ongoing

---

<sup>78</sup> All instances of redacted information are pursuant to 5 U.S.C. § 552a(b) (2013) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936.

cardiac toxic effects. It would be more meaningful to know that the QRS duration had significantly changed over time, or that it exceeded 120 msec, however that was not the case in this patient or is not mentioned in the OIG report. Regarding the patient's complaints of tachycardia, those complaints could likely be due to other confounding issues, and heart rates recorded by Richard L. Roudebush VA were normal with the few exceptions being explained by acute noncardiac medical issues.

5. The draft report discloses a great deal of personal health information protected by the Health Insurance Portability and Accountability Act of 1996 Privacy Rule which needs to be redacted to protect Veterans' rights to privacy.

6. With respect to the response to Senator Donnelly: regrettably, the administrative staff who prepared the letter inadvertently misstated the inpatient treatment plan to reduce the Amitriptyline dose by 50 percent over time. This is an unfortunate, but an understandable mistake for a non-clinical person. The commentary regarding the patient's satisfaction is more concerning and could be interpreted as misleading. Certainly, the site should improve its response and concurrence process for Congressional requests.

7. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO OIG Accountability Liaison at [VHAI\\_OEI\\_DMRSAction@va.gov](mailto:VHAI_OEI_DMRSAction@va.gov).

*//original signed by://*

Richard A. Stone, M.D.

Attachments

## Appendix B: VISN 8 Director Comments

### Department of Veterans Affairs Memorandum

Date: October 4, 2018

From: Director, VISN 8—VA Sunshine Healthcare Network (10N8)

Subj: Healthcare Inspection—Concerns Related to the Management of a Patient's Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System, Danville, Illinois: Orlando Florida; Indianapolis, Indiana and Danville, Illinois

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

1. We appreciate the Office of Inspector General's oversight which focuses on events that occurred at the Orlando VA Healthcare System (OVAHCS), Orlando, Florida. Since the OIG's site visit, comprehensive review of the Veteran's care and treatment at the OVAHCS has been completed. Opportunities to enhance healthcare delivery have been completed despite not finding mismanagement of the Veterans medication management as was alleged.

2. I have reviewed the Healthcare System Director's action plan and projected completion dates and I concur. VISN 8 will assist the Healthcare System's leadership in reaching full compliance in a timely manner.

*(Original signed by:)*

Miguel H. LaPuz, M.D., MBA  
Director, VA Sunshine Healthcare Network (VISN 8)

## Appendix C: Orlando VA Medical Center Director Comments

### Department of Veterans Affairs Memorandum

Date: October 4, 2018

From: Director, Orlando VA Healthcare System (675/00)<sup>79</sup>

Subj: Healthcare Inspection — Concerns Related to the Management of a Patient's Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System, Danville, Illinois: Orlando Florida; Indianapolis, Indiana and Danville, Illinois

To: Director, VA Sunshine Healthcare Network (VISN 8)

1. Thank you for the opportunity to review the draft report and recommendations from a medical record review of the care provided at the Orlando VA Healthcare System (OVAHCS). I have reviewed and concur with the recommendations. However, we disagree with the allegation that there was mismanagement of this patient's medication during the [redacted] time span starting [redacted] 2012 when the patient was under the care of the OVAHCS. At the time of the initial primary care appointment, the patient gave a history of Amitriptyline use for 20 years that was still being managed by a non-VA provider. A same day face-to-face consultation with a psychologist and same day telephonic consultation with a psychiatrist were provided to address depression with an attempt to gradually adjust the medication regimen. Changes in the medication regimen were repeatedly attempted by providers at OVAHCS, with non-compliance by the patient. Amitriptyline at a 300 mg dose is considered a "usual dose" in several psychiatric references and does not require additional informed consent as was implied in the report. The EKG from [redacted] 2012 has been subsequently reviewed and compared to the two EKGs read as normal in 2016 and found to demonstrate no clinically significant difference. Finally, there is no conclusive evidence that Amitriptyline resulted in cardiac and neurological damage since there were many other risk factors, co-morbidities and treatments (e.g. electroconvulsive therapies) that are much more probable causes of these findings.

2. A response to the recommendations with additional details is submitted along with this document.

---

<sup>79</sup> The name of the facility per <https://www.orlando.va.gov/> is Orlando VA Medical Center.

*(Original signed by:)*

*Lisa L. Zacher, MD, Chief of Staff for*

Timothy W. Liezert

Director, Orlando VA Healthcare System

## Comments to OIG's Report

### Recommendation 1

The Orlando VA Medical Center Director evaluates the care of the subject patient with respect to the patient's cardiac complaints and takes action, as appropriate, including clinical disclosure.

Concur.

Target date for completion: August 24, 2018

### Director Comments

A thorough comprehensive review of the subject patient's care at the Orlando VA Medical Center (OVAMC) was conducted by subject matter experts including the Chief of Staff, Pharmacy Supervisor, and Section Chief of Cardiology on August 24, 2018. These subject matter experts reviewed the patient's entire care received at the Orlando VA Medical Center including history, presenting symptoms, medications, and electrocardiogram (EKG). Based on the history, current vital signs, and EKG, it was determined that care, treatment and referrals were appropriate and no disclosures indicated.

The case review findings were that the patient's EKG was within acceptable range considering the patient's self-report of a myocardial infarction in 2007 and recent favorable report of coronary angiogram. The EKG was obtained at the time of the appointment for "HTN and anxiety," not because of drug monitoring. Requirements for amitriptyline are to do a baseline EKG when care is started, but then, no specific EKG monitoring is required. The EKG was obtained during the first visit to the OVAMC on [redacted] 2012 at 10:58 a.m. The physician noted that "The patient was notified of test results in person." The physician signed this note at 11:06 a.m. If there is a major abnormality, the EKG printout will clearly state "ABNORMAL" in large letters at the top of the report. The EKG software is programmed to overcall findings. This particular EKG was read several hours later by a cardiologist who apparently did not edit or clarify significance of a "nonspecific intraventricular delay" (IVCD), and added the poor r wave progression. Up-to-Date reference states that "Cardiologists use the term IVCD in different contexts, creating potential confusion among some specialists and non-specialists." The EKG was subsequently reviewed by three independent cardiologists, blinded and read as normal (the poor r-wave progression was also felt to be an over-call). Even when given the history of amitriptyline use and dosage, these three cardiologists would not have treated this EKG as an abnormal test result. We subsequently obtained EKGs from the Indianapolis VA obtained in [redacted] 2016 and compared them to the 2012 EKG. Our Acting Chief of Cardiology stated he did not "appreciate a clinically-significant difference between those EKGs." The only variability was that the HR in 2012 was 71, compared to 92 and 95 in 2016.

After the initial review by the primary care provider, several other providers also reviewed this nonspecific EKG finding and did not find it clinically relevant. As the report later points out, there are other etiologies for the patient's cardiac disease, including tachycardia and memory loss. Also not mentioned in the report is that this Veteran had just had a complete cardiac workup, to include a cardiac catheterization, that the patient describes as normal in [redacted] 2012 (two months prior to this initial primary care appointment). The patient was advised to obtain a Release of Information form (ROI) and to obtain non-VA records for review, and did not follow through on this request. The [redacted] 2012 EKG was done for hypertension and anxiety and demonstrated normal sinus rhythm with a heart rate of 71. The patient did not report any chest pain and had a normal blood pressure and pulse. Later, a mental health provider also reviewed and documented the QT interval on the EKG as normal. A prolonged QT interval is more consistent with amitriptyline toxicity.

This Veteran was seen by psychology and then also telephonically by a psychiatrist on day one of the intake. A review of this case by the Chief of Cardiology did not find any reason for a cardiac consultation at the time of the initial visit or subsequent visits to the Orlando VAMC. After a thorough review of the care and treatment, no disclosures are indicated. We request closure of this recommendation.

**OIG Update:** The OIG considers this recommendation open to allow the submission of documentation to support closure.

## **Recommendation 2**

The Orlando VA Medical Center Director verifies staff compliance with Veterans Health Administration policies related to patient notification of electrocardiogram test results and follow-up as clinically indicated.

Concur.

Target date for completion: September 4, 2018

## **Director Comments**

On clinical case review the documentation in CPRS reflects the following: The provider documented that all test results were reviewed with the patient. This documentation was written after the EKG ([redacted] 2012) was obtained in the clinic. It was printed and handed to the physician at 10:58 a.m. The documentation on [redacted] 2012 at 11:06 a.m. stated that "the patient was notified of test results in person." The note further documents the lab tests that will require follow-up. The cardiologist did an over-read of the EKG later that same evening, however the EKG was not flagged either by the computer read or by the cardiologist as being abnormal; rather it showed some non-specific findings. Three additional cardiologists separately reviewed the EKG in a blinded fashion and read it as normal. Based on an EKG that was not

identified as abnormal, there would have been no additional follow-up required. This reflects compliance to the Directive to notify patients of test results. Directive 1088 (Documentation for Outpatient Test Results) requires “documentation in CPRS...in response to critical, urgent, and clinically significant test results that require therapeutic intervention or action.” Education to providers on the Directive and Policy on notification of test results was reviewed on Training Day, September 4, 2018 by the Chief Informatics Officer and Chief of Staff. We request closure of this recommendation.

**OIG Update:** The OIG considers this recommendation open to allow the submission of documentation to support closure.

## Appendix D: VISN 10 Director Comments

### Department of Veterans Affairs Memorandum

Date: October 9, 2018

From: Acting Network Director, VISN 10 (10N10)

Subj: Healthcare Inspection—Concerns Related to the Management of a Patient's Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System, Danville, Illinois

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

1. Please find attached a review and response to the Healthcare Inspection Report. I concur with the Medical Center Director's response.
2. If you have any questions, please contact Jane Johnson, VISN 10 Quality Management Officer at (513) 247-2838.

*(Original signed by:)*

Denise M. Deitzen  
Acting Network Director, VISN 10 (10N10)

## Appendix E: Richard L. Roudebush VA Medical Center Director Comments

### Department of Veterans Affairs Memorandum

Date: October 9, 2018  
From: Director, Richard L. Roudebush VA Medical Center (583/00)  
Subj: Healthcare Inspection—Concerns Related to the Management of a Patient's Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System, Danville, Illinois  
To: Director, VA Healthcare System (VISN 10)

1. It is appreciated that the OIG serves a verifiably beneficial role in the oversight of the VHA. I am not able to concur with the report as a whole. The report does not reflect mismanagement of patient's medication, but rather the process of addressing the complex needs of a patient who receives care from multiple private and VHA sites of care.
2. The allegations of the toxic cardiac effects of Amitriptyline are based on tachycardia and one *non-specific* finding at the Orlando VAMC, which is not substantiated at the R.L. Roudebush VAMC. No clinical evidence of tachycardia was demonstrated during any visit to the Roudebush VA. Additionally, there were two normal EKGs that did not demonstrate non-specific intraventricular conduction delay.
3. It is significant to note the patient had a very extensive history of medication management changes without physician supervision and was frequently noted to be self adjusting medications and dosages. This is a confounding factor in the care and ultimately the patient's well being, but is not reflective of the actual medication management practices of the VHA sites of care. Unfortunately, the patient's own handling of this medication regime was not mentioned in the report.
4. In conclusion, I do not concur with the premises posited in this report. I do believe that in complex care situations, we can continue to improve and refine our coordination efforts within the VA and the private sector.
5. As Medical Center Director, I can be contacted at 317-988-2206 if there are additional questions or if further clarification is needed.

*(Original signed by:)*

J. Brian Hancock, MD, FACEP, FACHE, VHA-CM

## Comments to OIG's Report

### Recommendation 3

The Richard L. Roudebush VA Medical Center Director evaluates the care of the subject patient (the patient) with respect to the patient's cardiac complaints and takes action, as appropriate, including clinical disclosure.

Concur-in-principle.

Target date for completion: N/A

### Director Comments

The R.L. Roudebush VA is committed to the highest standards of medication safety, and has many facility policies in place to address this recommendation. It is believed that erroneous data has contributed to this recommendation; if tachycardia (which is the alleged cardiac symptom) is part of the constellation of symptoms upon which this recommendation is based, enclosed is a full list of measured and documented heart rates at the facility. In the time period of [redacted] 2013-2018, there were 20 documented heart rates, with 4 (20%) meeting the definition of tachycardia (American Heart Association guidance). Additionally, two ER visits generated two EKGs that were documented as normal sinus rhythm with a QTC of 447 and 452 (normal).

[redacted]

There are four instances of tachycardia which are all explained by anxiety or pain, and during which the patient was on less than or equal to 150mg Amitriptyline / day as documented in Table 1 of the OIG report.

[redacted] 2016–Patient was admitted for a dog bite and required inpatient hospitalization.

[redacted] 2017–Patient in a psychiatric crisis state and agitated.

[redacted] 2018–Patient was on 150mg/day of Amitriptyline during a psychiatry medication management visit. Taking less caused tachycardia and 'palpitations' per the patient.

[redacted] 2018–Patient was on 150mg/day of Amitriptyline during a psychiatry medication management visit. Taking less caused tachycardia and 'palpitations' per the patient.

Because there are two normal EKGs and the fact that occasional tachycardia could be explained by factors other than being on high dose Amitriptyline (which the patient was not on since 2016), there would be no clinical indication to obtain a cardiology consult. Since there was no error in the management of the medication by the R. L. Roudebush VAMC, there would be no need for a clinical disclosure. We request closure of this recommendation due to documented clinical data that contradicts the recommended course of action.

**OIG Update:** The OIG considers this recommendation open to allow the submission of documentation to support closure.

## **Recommendation 4**

The Richard L. Roudebush VA Medical Center Director verifies staff compliance with Veterans Health Administration policies related to patient notification of medication blood level test results and follow-up as clinically indicated.

Concur.

Target date for completion: January 31, 2019

## **Director Comments**

The facility agrees with the reporting of normal values to the patient within 14 days (VHA Directive 1088, *Communicating Test Results to Providers and Patients*). The patient had requested an amitriptyline level on [redacted] 2016. The patient was counseled that this would lead to a subtherapeutic level. The patient subsequently eloped from the ED. This created complexity as most laboratory work is completed on-site and communicated at the end of the ED visit, but this particular lab was sent off-site for performance. The test results returned five days later during a period of time in which the patient was unable to be contacted for follow-up (after repeated attempts) and had rescheduled at Illiana.

The facility will continue to uphold high standards of patient notification. Off-site labs have a lag time because they are sent from the facility for performance and the result returns days to weeks later. This list will be reviewed and Emergency Department providers will be re-educated on VHA Directive 1088 requirements by October 31, 2018 regarding the timeframe of test result notification. After education, we will monitor the communication of all off-site test results for ninety days ending January 31, 2019.

## Appendix F: VISN 12 Director Comments

### Department of Veterans Affairs Memorandum

Date: September 26, 2018

From: Director, VA Great Lakes Health Care System (VISN 12)

Subj: Healthcare Inspection— Concerns Related to the Management of a Patient's Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System

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

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Healthcare Inspection, Concerns Related to the Management of a Patient's Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System.
2. After careful review, we did not find mismanagement of the care provided as indicated in the report. The care was appropriate and without any adverse outcomes.
3. Although there were no adverse outcomes or mismanagement in the care provided, we acknowledge that the consult process between services could be enhanced to achieve a greater quality of care to patients.
4. VA Illiana Health Care System will enhance the process for responses to congressional inquiries.
5. I can be contacted at 708-492-3900 if there are additional questions or if further clarification is needed.

*(Original signed by:)*

Renee Oshinski  
Director, VA Great Lakes Health Care System (VISN 12)

## Appendix G: VA Illiana Health Care System Director Comments

### Department of Veterans Affairs Memorandum

Date: September 27, 2018  
From: Acting Director, VA Illiana Health Care System (VAIHCS) (550/00)  
Subj: Healthcare Inspection — Concerns Related to the Management of a  
Patient's Medication at Three VA Medical Centers and Inaccurate Response  
to a Congressional Inquiry.  
To: Director, VISN 12 VA Great Lakes Health Care System (10N)

1. A thorough clinical review was conducted on the care provided to the Veteran from [redacted] 2014 to [redacted] 2017 and it was determined that the standard of care was met. There was no evidence of an adverse event or outcome. Based on the clinical review, the care provided to this Veteran would not indicate the need for a clinical disclosure.
2. VA Illiana Health Care System is committed to providing exceptional care and will strengthen clinical consultation between mental health and primary care providers. This action will further enhance patient safety and high quality care we provide to our Veterans.
3. If additional information is needed, please contact my office at (217) 554-5072.

*(Original signed by:)*

*Diana Carranza, Associate Director for*

Kelley A. Sermak

Acting Director, VA Illiana Health Care System

## Comments to OIG's Report

### Recommendation 5

The VA Illiana Health Care System Director evaluates the care of the subject patient with respect to the patient's cardiac complaints and takes action, as appropriate, including clinical disclosure.

Concur in principle.

Target date for completion: Completed.

### Director Comments

The patient's care has been evaluated by the Chief of Community Based Outpatient Clinics and Chief of Quality Management Service in response to the patient's cardiac complaints and care at VA Illiana Health Care System (VAIHCS). The Veteran was initially seen at VAIHCS on [redacted] 2014. The care at VAIHCS included mental health and primary care. The Veteran's care was found to be appropriate and there was no mismanagement of care identified or need for clinical disclosure. The review noted:

- The reported purpose of metoprolol, was initially stated for hypertension and later changed to tachycardia. The change to tachycardia coincided proximally in timing with claims of cardiotoxicity from amitriptyline and proximally in time to the significant other's having read this as a potential adverse effect in a publication.
- During the Veteran's four years of care at VAIHCS, there has never been a hypertensive reading during visits and there has never been documentation of a measured tachycardia.
- The Veteran self-reported symptoms of palpitations which could be attributed to an underlying diagnosis of anxiety.
- At the time the Veteran was treated at VAIHCS there was no objective evidence for significant cardiac pathology in this patient of any etiology.

**OIG Update:** The OIG considers this recommendation open to allow the submission of documentation to support closure.

### Recommendation 6

The VA Illiana Health Care System Director strengthens processes for effective clinical consultation and follow-up between mental health and collaborating primary care providers.

Concur.

Target date for completion: October 1, 2018

## Director Comments

There was no adverse outcome or mismanagement of care for this Veteran. However, to enhance communication and coordination in the future, VAIHCS will implement a hand off tool using a Situation, Background, Assessment, Recommendation (SBAR) communication model that facilitates care coordination between primary care and mental health service.

**OIG Update:** The OIG considers this recommendation open to allow the submission of documentation to support closure.

## Recommendation 7

The VA Illiana Health Care System Director strengthens the processes for congressional inquiry response to ensure response timeliness, clinical information accuracy, and records retention, as required.

Concur.

Target date for completion: September 24, 2018

## Director Comments

Senator Donnelly's office will be contacted on September 24, 2018 to clarify the content of the correspondence identified in this report.

The VA Illiana Health Care System (VAIHCS) Director has strengthened the processes for controlled correspondences. An updated Standard Operating Procedures (SOP) on Controlled Correspondence is in place. Updates to the SOP include requirements for specific timeframes of response preparation to Congressional offices to ensure the Congressional inquiries receive a reply in a timely manner, review process by VAIHCS Service Chief and Executive Leadership Team as well as required Report of Contact (ROC) and record retention of related documents. Education of the amended SOP for Administrative staff, Service Chiefs and Executive Leadership has been completed.

**OIG Update:** The OIG considers this recommendation open to allow the submission of documentation to support closure.

## Recommendation 8

The VA Illiana Health Care System Director evaluates staff actions and approval processes in the preparation of the letter to Senator Donnelly, and takes appropriate administrative action, if indicated.

Concur.

Target date for completion: October 31, 2018

## Director Comments

The Associate Chief of Staff for Ambulatory Care has met with Human Resources staff regarding potential administrative action to be taken. A fact finding will be conducted by the Associate Chief of Staff for Ambulatory Care into staff actions and approval process of the correspondence in question. Upon completion of the fact finding, appropriate administrative action will be determined.

**OIG Update:** The OIG considers this recommendation open to allow the submission of documentation to support closure.

## 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	Terri Julian, PhD, Director Lisa Barnes, MSW Joseph Giries, MHA Alison Loughran, JD, BSN Alan Mallinger, MD Vanessa Masullo, MD
-----------------	--

---

Other Contributors	Stephanie Beres, MSN, MHA Elizabeth Bullock Jonathan Ginsberg, JD Kathy Gudgell, JD, RN Patrice Marcarelli, MD Natalie Sadow, MBA
--------------------	--

## Report Distribution

### VA Distribution

Office of the Secretary  
Veterans Health Administration  
Assistant Secretaries  
General Counsel  
Director, VA Sunshine Healthcare Network (VISN 8)  
Director, Orlando VA Medical Center (675/00)  
Director, VA Healthcare System (VISN 10)  
Director, Richard L. Roudebush VA Medical Center (583/00)  
Director, VA Great Lakes Health Care System (10N12)  
Director, VA Illiana Health Care System (550/00)

### Non-VA Distribution

House Committee on Veterans' Affairs  
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and  
Related Agencies  
House Committee on Oversight and Government 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  
Illinois: Tammy Duckworth, Richard J. Durbin  
Indiana: Mike Braun, Todd Young  
Florida: Marco Rubio, Rick Scott  
U.S. House of Representatives  
Illinois: Rodney Davis, Adam Kinzinger, John M. Shimkus  
Indiana: Jim Baird, Susan W. Brooks, André Carson, Trey Hollingsworth, Greg Pence  
Florida: Val Demings, Stephanie Murphy, Bill Posey, Darren Soto, Ross Spano,  
Michael Waltz, Daniel Webster

*The OIG has federal oversight authority to review the programs and operations of VA medical facilities. OIG inspectors review 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.*

**OIG reports are available at [www.va.gov/oig](http://www.va.gov/oig).**