



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

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**Healthcare Inspection**

**Alleged Quality of Care Issues  
James A. Haley Veterans Hospital  
Tampa, Florida  
and  
Bay Pines VA Health Care System  
Bay Pines, Florida**

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## Executive Summary

The purpose of the review was to investigate allegations that a patient received poor care at both the James A. Haley Veterans Hospital (JAHVH) in Tampa and the Bay Pines VA Health Care System (BPVAHCS) in Bay Pines, FL. The complainant alleged that JAHVH providers: (1) declined to perform a myectomy; (2) prescribed a high dose of anti-anxiety medication, did not tell him about the side effects, and did nothing to address his complaints; and (3) prescribed a medication for headaches but did not tell him about the side effects. He also alleged that BPVAHCS providers: (4) did not adequately sedate him for an endoscopic procedure; (5) used unsterile endoscopy equipment, which caused him to develop a urinary tract infection (UTI); (6) did not provide appropriate equipment or treatment for his injured ankle during a visit to the emergency department (ED); (7) prescribed a “research” medication that he did not consent to, and did not tell him about potential side effects; and (8) routinely cancelled his mental health clinic appointments.

After our interview, the patient withdrew his complaint that JAHVH providers declined to perform a myectomy; we did not evaluate this issue further. While we confirmed that providers prescribed a dosage of venlafaxine that slightly exceeded the manufacturer’s recommended guidelines, we found that the dosage was within a usual range prescribed by mental health providers. We did not substantiate the patient’s allegations that he received inadequate counseling on medication side effects or that providers did nothing when he complained about negative side effects. Documentation reflects that, in general, providers discussed and addressed side effects. We could not confirm or refute the patient’s allegations that he received inadequate sedation during an endoscopic procedure or that an unsterile endoscope caused him to develop a UTI. The patient previously complained about a visit to the BPVAHCS ED; that complaint had already been reviewed and addressed by health care system staff. Our evaluation did not disclose any new facts about the ED visit. We did not substantiate the allegation that the patient was given a research medication he did not consent to, and we could not confirm or refute the allegation that he was not counseled about its side effects. While we confirmed that at the time of our interview, the patient had not seen his mental health therapist for more than 2 months, we found that he, not the clinic, had cancelled the previous appointment. We made no recommendations.



**DEPARTMENT OF VETERANS AFFAIRS**  
**Office of Inspector General**  
**Washington, DC 20420**

**TO:** Director, VA Sunshine Network (10N8)

**SUBJECT:** Healthcare Inspection – Alleged Quality of Care Issues, James A. Haley Veterans Hospital, Tampa, FL, and Bay Pines VA Health Care System, Bay Pines, FL

## **Purpose**

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an evaluation in response to allegations that a patient received poor care at the James A. Haley Veterans Hospital (JAHVH) in Tampa, FL, and the Bay Pines VA Health Care System (BPVAHCS) in Bay Pines, FL.

## **Background**

The JAHVH and the BPVAHCS are large tertiary care facilities that provide medical, surgical, mental health, rehabilitative, and nursing home care services to veterans in central and south-central Florida. The two facilities are located 36 miles apart and are part of Veterans Integrated Service Network (VISN) 8.

In February 2007, the complainant contacted Congressman C. W. Bill Young and requested investigation into (1) medication issues (including education and side effects) and (2) a recent visit to the BPVAHCS emergency department (ED) for an ankle injury. In July 2007, the BPVAHCS Director responded to the complaint and reported that there was no evidence that medications prescribed by VA providers caused the patient to develop tardive dyskinesia<sup>1</sup> or that staff did not provide adequate education about medication side effects. However, the Director confirmed that, in response to the patient's visit and subsequent complaint, ED staff received training on the appropriate use of prosthetic devices used to stabilize fractured bones.

In September 2007, the complainant contacted Congressman Young's office reporting his dissatisfaction with the BPVAHCS Director's response. He repeated his complaints of February 2007 and alleged additional patient care issues at both the JAHVH and the

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<sup>1</sup> A neurological disorder characterized by involuntary facial or extremity movements that are caused by long term use of some antipsychotic medications.

BPVAHCS. While this complaint letter appeared to criticize JAHVH providers for improperly prescribing antipsychotic medications that caused the patient's tardive dyskinesia, the patient did not voice this complaint when we met with him. We prompted him several times, but he advised us that this was not a concern. We did not evaluate this complaint any further. The complainant outlined several other allegations for our review.

The patient has received care at the JAHVH since early 2005. He alleged that JAHVH providers:

- Declined to perform a myectomy (in this case, removal of excess skin and muscle from the eyelids).
- Prescribed a high dose of venlafaxine (for anxiety) and did not tell him about the side effects and did nothing to address his complaints.
- Prescribed indomethacin (to prevent migraine headaches) but did not tell him that gastrointestinal (GI) bleeding is a potential side effect.

The patient transferred his primary and mental health care to the BPVAHCS in early 2006. He alleged that BPVAHCS providers:

- Did not give him adequate sedation and he “woke up” in the middle of an endoscopy<sup>2</sup> procedure.
- Used unsterile endoscopy equipment, which caused him to develop a urinary tract infection (UTI).
- Did not provide appropriate equipment or treatment for his injured ankle during a visit to the ED.
- Prescribed a “research” medication (Primidone)<sup>3</sup> that he did not consent to, and did not tell him about potential side effects.
- Routinely cancelled his clinic appointments, and as a result, he had not seen his mental health therapist “in months.”

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<sup>2</sup> Minimally invasive procedure that involves inserting a tube (endoscope) inside the body to look at different internal organs.

<sup>3</sup> An anticonvulsant medication used to control seizure activity.

## Scope and Methodology

We interviewed the patient and his wife in person in early December 2007, to clarify the specific issues outlined in his complaint; we also had continuing communication with him throughout our review. We reviewed the patient's medical record and JAHVH and BPVAHCS policies. We also interviewed clinical staff from both facilities that had knowledge of the patient and his concerns.

This review was performed in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

## Case Summary

The patient is a non service-connected veteran in his late 40's with a primary medical history that includes depression, anxiety, obesity, non-insulin dependent diabetes mellitus, gastroesophageal reflux disease,<sup>4</sup> familial tremor,<sup>5</sup> hyperlipidemia,<sup>6</sup> and sleep apnea. During our interview, the patient reported that in 2004 and early 2005 he was diagnosed with bipolar disorder, blepharospasm,<sup>7</sup> and migraine headaches by private sector physicians. He was treated in the private sector until he re-enrolled<sup>8</sup> for VA healthcare in early 2005.

Approximately 2 weeks after enrollment, the patient saw a JAHVH primary care provider. The medical record shows that the patient was taking citalopram (for depression), risperidone (for bipolar disorder), clonazepam (for anxiety), and propranolol (to prevent migraines) as prescribed by his private-sector physicians. During this appointment, the primary care provider ordered laboratory tests and added a cholesterol-lowering drug to the patient's existing medication regimen. The patient was referred to the mental health and weight management clinics, and was advised to follow-up with his primary care provider in 4 months. Over the next year, the patient had appointments with his JAHVH primary care provider, psychiatrist, ophthalmologist, social worker, and weight-management nurse. He also contacted the VISN-Telecare (nurse advice) line to report some medical and mental health concerns. A year after enrolling for VA care at JAHVH, in early 2006, he transferred his medical and mental health care to the BPVAHCS, as it was located closer to his home. He continued to see the ophthalmologist at JAHVH for treatment of his blepharospasm.

The patient saw his BPVAHCS primary care provider later that month. During the appointment, the provider ordered laboratory tests and a series of diagnostic studies to

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<sup>4</sup> Occurs when the lower esophageal sphincter (the valve separating the esophagus and stomach) does not close properly, allowing acid to back up into the esophagus.

<sup>5</sup> A neurologic disorder that runs in families and results in shaking (tremors).

<sup>6</sup> High cholesterol.

<sup>7</sup> Involuntary blinking or eyelid twitching.

<sup>8</sup> He had been seen several times at a VA outpatient clinic in 2002.

evaluate the patient's migraine headaches and a recent episode of dizziness. The patient was referred to the mental health, neurology, GI, pharmacy, and sleep clinics. The patient continues to be routinely followed by BPVAHCS primary care, mental health, and weight management providers.

## **Inspection Results**

### **Issue 1: Patient Care at the JAHVH**

#### Myectomy Procedure.

Although the patient initially alleged that his JAHVH ophthalmologist declined to perform a myectomy, he informed us in mid December 2007 that he was not currently seeking a myectomy. The patient has been receiving FDA-approved Botox injections about every 2–3 months for blepharospasm dating back to August 2005. Botox causes partial paralysis of some facial muscles, which can relieve the tics and twitching that characterizes blepharospasm. The patient most recently had Botox injections in mid December 2007 and mid February 2008, and noted that the injections effectively relieve his symptoms for about 2 months. Therefore, he is not seeking surgical intervention at this time. The patient has a follow-up appointment with the JAHVH ophthalmologist in April 2008. We did not evaluate this issue further.

#### Venlafaxine Prescription.

While we confirmed that providers prescribed a dosage of venlafaxine that slightly exceeded the manufacturer's recommended guidelines, we found that the dosage was within a usual range prescribed by mental health providers. We did not substantiate the allegation that the patient's psychiatrists did not provide education about venlafaxine's side effects. The medical record did not specifically reflect that the patient was counseled about potential side effects. However, the record is replete with documentation that the patient was given opportunities to discuss his medications and was asked about side effects. We also did not substantiate the allegation that providers ignored his complaint of negative side effects as a result of taking the high dose of venlafaxine.

The patient was treated with venlafaxine from May 2005 through April 2006. During the approximately 1 year that the patient was taking venlafaxine, he received increasing dosages to control his anxiety and depression, and during each clinic appointment, the JAHVH psychiatrist documented that the patient was asked about side effects. In our review of the patient's medical record, we found that:

- In early May 2005, the patient presented to the ambulatory care clinic complaining of a rash. The JAHVH primary care physician consulted with a psychiatrist and recommended that the patient taper off the citalopram (a possible cause of the

rash) and prescribed another antidepressant medication, venlafaxine. The patient's initial dosage was 37.5 mg for 5 days, which was increased to 75 mg on day 6.

- In late May, a JAHVH psychiatrist diagnosed the patient with major depression, dysthymic disorder,<sup>9</sup> and generalized anxiety disorder. His venlafaxine was increased to 150 mg daily. He denied medication side effects.
- In mid June, the patient was seen for an outpatient mental health appointment. The patient complained of ongoing depression and anxiety with multiple psychosocial stressors and poor sleep. The patient denied side effects. The psychiatrist discontinued the risperidone and prescribed quetiapine, an atypical antipsychotic medication. His venlafaxine was increased to 225 mg per day.
- In August, the patient reported feeling depressed and over-sedated, and noted that the venlafaxine was not working. As sedation is more commonly seen with use of quetiapine or clonazepam, the JAHVH psychiatrist decreased the dosages of these two medicines. He increased the venlafaxine to 300 mg daily. During a follow-up appointment the following week, the patient reported resolution of this complaint. The psychiatrist noted that the patient was given an opportunity to ask questions about his medications, illness, and treatment.
- In September, the patient reported that his depression and anxiety had improved significantly. He stated that his familial tremor had worsened but he did not attribute this to a side effect from his psychiatric medication.
- In November, the patient presented twice to the JAHVH psychiatric ED complaining of increased anxiety and depression, and reported that his medications were not effective. No medication changes were made during those visits. The patient did not complain of side effects.
- In December, the patient denied that he was experiencing negative side effects from his medications. The psychiatrist noted, "I discussed with pt [patient] that this dose is above the FDA [Food and Drug Administration]-recommended guidelines and educated him on the associated risk. He states that he desires to continue this med [medication] at this dose and agrees to call the clinic with side effects. Also educated pt on discontinuation syndrome, recommended against stopping this med abruptly."

In early 2006, the patient transferred his care to the BPVAHCS.

- Later that month, the patient was evaluated by a psychiatrist in conjunction with his primary care visit. He complained of a 70-pound weight gain,<sup>10</sup> loss of libido, and increasing irritability. He was scheduled for a mental health clinic appointment.
- A month later, the patient told his psychiatrist that his venlafaxine caused side effects including weight gain, right hand tremor, and increased blood pressure.

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<sup>9</sup> Chronic depressed mood lasting more than 2 years.

<sup>10</sup> Records show a 20-pound weight gain between April 2005 and April 2006.



The patient reported that he had started to taper off his venlafaxine dosage. His new psychiatrist recommended that he continue to gradually taper off the venlafaxine. The patient telephoned the clinic on April 23 to report that he discontinued the medication.

We found that while the patient was receiving mental health services at the JAHVH, he complained about a negative side effect (over-sedation) only once. The psychiatrist adjusted his medications and the condition resolved within 8 days. After the patient transferred his care to the BPVAHCS, he complained about several side effects. He had already begun to taper off his venlafaxine, and the BPVAHCS psychiatrist concurred with that plan. We concluded that both the JAHVH and BPVAHCS psychiatrists adequately discussed and addressed side effects that were brought to their attention.

While it is technically accurate that the manufacturer's guidelines for venlafaxine recommend a dose range up to 225 mg per day, it is not unusual for mental health providers to prescribe up to 300 mg per day for some patients. The patient was appropriately followed in the mental health clinic and was advised to call the clinic should he experience negative side effects.

#### Indomethacin Prescription.

We did not substantiate the patient's allegation that a provider prescribed indomethacin but did not tell him that a potential side effect is GI bleeding. In October 2005, a neurologist in the Pain Management Headache Clinic ordered a magnetic resonance imaging test and prescribed indomethacin to treat the patient's migraine headaches. The neurologist's progress note reflects that he warned the patient that indomethacin could cause GI distress and to discontinue the medication if he experienced this side effect.

Although GI bleeding is a potential side effect of indomethacin, we found no evidence that the patient complained of bleeding, vomiting blood, or GI distress. Laboratory tests and other clinical studies completed during the 6 months he was taking the medication were not indicative of internal bleeding. The patient did develop ankle edema (swelling), a potential side effect of indomethacin. The provider promptly discontinued the indomethacin and the condition resolved.

#### Pharmacy Education about Medication Side Effects.

While it appeared that the JAHVH and BPVAHCS providers were attentive to the patient's concerns about medication side effects, we also considered whether Pharmacy Service provided educational opportunities and materials to the patient along with his newly prescribed medications. According to the Chief of Pharmacy Service, the JAHVH does not have a policy outlining patient education requirements related to medications. However, VA Handbook 1108.05 states that, "A licensed pharmacist or designee must offer prescription education to patients and/or caregivers on all prescriptions dispensed

from the outpatient pharmacy. Patient education must be provided at the inception of any new therapeutic agent.” Subsequent prescriptions of the same medications do not require patient education. The Chief of Pharmacy told us that patients should receive this education (either verbal or written) regardless of whether the prescription is filled at the JAHVH pharmacy or mailed by the consolidated mail-out pharmacy (CMOP).

The patient’s first venlafaxine prescription was filled at the JAHVH pharmacy, which would have allowed the pharmacist to provide both verbal medication counseling and an informational pamphlet. We could not confirm, however, that this was actually done, as there is no mechanism to retrieve patient education information for a prescription filled 2 years ago.

All of the patient’s indomethacin prescriptions were mailed from the CMOP. While the CMOP should have included an informational pamphlet (to include side effects) with the first indomethacin shipment, we also had no way to confirm that this was done. The patient told us that he routinely receives and reads the enclosed educational materials, but he reported that he had not seen information about side effects.

## **Issue 2: Patient Care at the BPVAHCS**

### Endoscopic Procedures.

We could not confirm or refute the allegation that the patient “woke up” in the middle of an endoscopic procedure and was told that he could not be sedated any more because of low blood pressure.

The patient had a colonoscopy and esophagogastroduodenoscopy<sup>11</sup> (EGD) in June 2006. Because these procedures can be uncomfortable, patients are usually sedated with a combination of pain killers and anti-anxiety medications. Patients who receive conscious sedation can speak and respond to verbal cues throughout the procedure and can communicate any discomfort they experience to the provider. Frequently, amnesia may erase any memory of the procedure.<sup>12</sup>

The patient was evaluated by anesthesia staff prior to the colonoscopy and EGD. He received 100 micrograms (mcg) of Fentanyl and 10 milligrams (mg) of Versed intravenously prior to the procedures; both were appropriate dosages based on his physical assessment. Anesthesia monitoring forms reflect that the patient’s heart rate and blood pressure remained stable (slightly low but at his baseline) throughout the procedures, and his pain scores were consistently “0.” All of these were indications that the medications were having the desired sedative effect. Had the patient “woken up,” it is likely that his heart rate, blood pressure, and pain score would have increased in

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<sup>11</sup> Diagnostic endoscopic procedures that visualize the lower part of the GI tract (colonoscopy) and upper part of the GI tract (EGD).

<sup>12</sup> American Association of Nurse Anesthetists, [www.aana.com](http://www.aana.com).

response to the pain and anxiety associated with the procedures. The medical record reflected that the patient “tolerated the procedure without difficulty.”

We also determined that the Quality Management office had no record of this alleged incident. Usually, unexpected events that negatively impact patient care (such as inadequate anesthesia) prompt staff to complete a patient incident report.

#### Urinary Tract Infection.

We could not confirm or refute the allegation that the patient developed a UTI from unsterile endoscopy equipment. UTIs develop when bacteria, usually *escherichia coli* (E. coli), which normally lives in the colon, enter the urethra. In males, the length of the urethra and distance from the rectum (where the endoscope is inserted) makes it unlikely that the bacteria could have been transmitted from one location to the other. Laboratory testing confirmed the patient’s UTI, and he was appropriately treated with antibiotics.

#### ED Visit.

The patient originally complained about this visit in his February 2007 letter to Congressman Young; in July, the BPVAHCS Director responded to the complaint. Our review did not disclose any new facts.

We could not confirm or refute the allegation that the patient did not receive appropriate treatment for his injured ankle while at the BPVAHCS’ ED. The patient’s description of the event differed from documentation in the medical record. In response to the patient’s initial complaint, however, facility managers had taken action to educate ED staff about the proper fitting and use of prosthetic devices designed to stabilize fractures.

We could not confirm or refute the allegation that on the day in question, the patient had to walk to Radiology because there were no wheelchairs in the ED. In general, medical centers try to keep wheelchairs available at several locations throughout the hospital. When wheelchairs are not available, customer service representatives will locate chairs upon request.

#### Primidone Prescription.

We did not substantiate the allegation that the patient was given a research medication to which he did not consent. Primidone is not a research medication; it is an anticonvulsant medication that also has an off-label<sup>13</sup> but commonly accepted use in the treatment of tremors. Early in his blepharospasm treatment, the patient had only short term response to Botox and was referred to a BPVAHCS neurologist to explore other options. The

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<sup>13</sup> Prescribing of medications to treat conditions not specifically approved by the Food and Drug Administration. Off-label use is a legal and common practice in the United States.

neurologist prescribed Cogentin,<sup>14</sup> but the patient stopped taking it because it was not effective and it made him drowsy.

The Neurology pharmacist evaluated the patient in October 2006 and discussed the case with the neurologist. The patient was started on low dose Primidone (50 mg twice per day) as adjunct treatment for his blepharospasm. The patient was scheduled to return to see the pharmacist in 2 months for evaluation of medication effectiveness. However, in early November, the patient contacted the VISN–Telcare line to report that the Primidone had caused nausea, vomiting, and dizziness and that he had stopped taking the medication. The patient was told to go to the ED if his symptoms persisted.

We could not confirm or refute the allegation that his provider did not tell him about the side effects. Neither the neurologist nor the pharmacist explicitly documented that they counseled the patient about side effects of Primidone.

#### Cancelled Therapy Appointments.

At the time of our interview in early December 2007, the patient had not seen his mental health therapist (a clinical social worker) for more than 2 months. The patient's most recent therapy appointment was late September. It appears, however, that the patient (rather than the clinic) cancelled his appointment scheduled for November. Consequently, we did not find evidence that the BPVAHCS routinely cancelled his mental health appointments.

He was then rescheduled for December 24; however, this appointment was cancelled when the President unexpectedly gave all Federal employees the day off. That appointment was rescheduled for the first week of January 2008; the patient did see his psychiatrist then. The psychiatrist commented in her progress note that the patient would like an appointment with his therapist before mid March, his next routinely scheduled appointment. The therapist contacted the patient and suggested that he attend a Transition support group in late February; they also agreed to maintain his individual therapy appointment in mid March.

## **Conclusion**

After our interview, the patient told us that his Botox injections for blepharospasm were effective, and he withdrew his complaint about the myectomy. We did not evaluate this issue further. While we confirmed that providers prescribed a dosage of venlafaxine that exceeded recommended guidelines, we found that the dosage was within a usual range prescribed by mental health providers. We did not substantiate the patient's allegations that he received inadequate counseling on medication side effects or that providers did

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<sup>14</sup> Used in the treatment of Parkinson's Disease and to control movement side effects of antipsychotic drugs. It improves muscle control and decreases stiffness and tremors.

nothing when he complained about negative side effects. Documentation reflects that, in general, providers discussed and addressed side effects. We could not confirm or refute the patient's allegations that he received inadequate sedation during an endoscopic procedure or that an unsterile endoscope caused him to develop a UTI. The patient previously complained about a visit to the BPVAHCS ED; that complaint had already been reviewed and addressed by health care system staff. Our evaluation did not disclose any new facts about the ED visit. We did not substantiate the allegation that the patient was given a research medication he did not consent to, and we could not confirm or refute the allegation that he was not counseled about its side effects. While we confirmed that the patient had not seen his therapist for more than 2 months at the time of our interview, we found that he, not the clinic, had cancelled the most recent appointment. We made no recommendations.

## **Comments**

The VISN and Medical Center Directors agreed with our findings. No follow-up actions are planned.

*(original signed by:)*  
JOHN D. DAIGH, JR., M.D.  
Assistant Inspector General for  
Healthcare Inspections

## OIG Contact and Staff Acknowledgments

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Acknowledgments	David Griffith Michael Shepherd, M.D.
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