



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

Office of Healthcare Inspections

Report No. 15-01432-264

Healthcare Inspection

Restraint Use, Failure To Provide Care, and Communication Concerns Bay Pines VA Healthcare System Bay Pines, Florida

April 13, 2016

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection at the request of Congressman Daniel Webster to assess the merit of allegations that staff inappropriately restrained a patient both physically and chemically; failed to provide anticoagulation medications (Coumadin), fluids, food, and nursing/medical care; and failed to effectively communicate with the patient's family at the Bay Pines Healthcare System (facility), Bay Pines, FL.

We found that the patient was not inappropriately restrained during a computed tomography (CT) scan. CT technicians placed straps during the procedure for patient safety and to avoid sudden patient movement.

We substantiated that during his Emergency Department (ED) and inpatient stay, the patient was physically restrained on three occasions due to his combativeness and attempts to interfere with medically necessary treatments. Nursing documentation of the use of restraints was consistent with facility policy; however, we did not find a physician's order for the episode of restraint use when in the ED. We also substantiated that the patient received antipsychotic medications for agitation in an effort to calm him and lessen the need for physical restraints. The patient became lethargic following dosing with the antipsychotic medication while an inpatient; he recovered once the medication was discontinued.

We did not substantiate that the patient failed to receive care. The patient was admitted to a constant observation room on a medical unit. Staff was continuously present in this room to immediately assist the patient if needed. The patient's electronic health record (EHR) contained required nursing assessment documentation that included assistance needed with meals; amount of food consumed; occasions when the patient refused to eat or drink; and entries from hospitalists and specialists that reflected daily interactions with the patient, cognitive assessments, and ongoing treatment plans.

We did not substantiate the allegation that the patient was not provided Coumadin because the facility did not have the medication in stock. The patient's medication administration records showed appropriate adjustments of the times and doses of Coumadin. Further, throughout the patient's stay the degree of blood anticoagulation was found to be within the desired range. Pharmacists, physicians, and nursing staff we interviewed told us that the facility has not had difficulty procuring Coumadin.

We substantiated that two patient advocates failed to act professionally when communicating with the patient's family. In one instance, a patient advocate failed to correctly identify the patient at issue, and in a second instance, a patient advocate terminated a facility staff/family meeting rather than facilitate the meeting to a successful conclusion for the family.

We did not substantiate the allegations that facility staff refused to release the patient's EHR to the family or that the EHR was altered. We found that facility staff released the patient's EHR to the family. We noted that the discharge documentation did not contain

all required elements. We determined that EHRs can be altered only in very limited circumstances, and those circumstances were not applicable in this case. We found that one of the hospitalists entered a note into the patient's EHR on 3 consecutive days indicating that he had conferred with a family member. When interviewed, the hospitalist stated that he spoke with the family member on only one occasion. As the phrases describing the family communication were identical, we believe this represents a copy/paste issue.

We substantiated that facility staff failed to effectively communicate with the patient's family on multiple occasions.

A qualitative review of the patient's non-VA care was not part of this inspection.

We recommended that the Facility Director ensure that:

- ED, CT Department, Patient Advocate, and 5B inpatient medical unit staff receive patient-centered care training and/or refresher training.
- A review of the patient advocates' actions, as described in this report, is conducted and action is taken as appropriate including providing guidance regarding the processing of patient/family concerns.
- Physician orders are entered into the EHR as required when restraints are used.
- Physician discharge notes contain all required elements, and documentation adequately reflects the patient's care and communication with family.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 18–21 for the Directors' comments.) We will follow up on the planned actions until they are completed.



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Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection at the request of Congressman Daniel Webster to assess the merit of allegations that staff inappropriately restrained a patient both physically and chemically; failed to provide anticoagulation medications (Coumadin), fluids, food, and nursing/medical care; and failed to effectively communicate with the patient's family at the Bay Pines VA Healthcare System (facility), Bay Pines, FL.

Background

The facility, part of Veterans Integrated Service Network (VISN) 8), comprises a medical center and eight community based outpatient clinics located in Bradenton, Lee County, Naples, Palm Harbor, Port Charlotte, St Petersburg, Sarasota, and Sebring, FL. The facility is a level 1A¹ teaching hospital with 186 acute inpatient beds, 121 community living center beds, and 99 mental health beds.

Patient-Centered Care Program. One of the Veterans Health Administration's (VHA) goals is to continuously improve patient and family satisfaction by promoting patient-centered care and excellent customer service.² Facility policy defines patient-centered care as health care that is delivered in a manner that works best for patients. In the patient-centered approach to health care, providers partner with patients and their family members to identify and satisfy the full range of patient needs and preferences. All employees are expected to be knowledgeable of the Patient-Centered Care Principles, which exemplify the basic expectation that patient care will be safe, accessible, and of the highest quality. Patients and families are full partners in care planning and delivery.³

Anticoagulation Monitoring. Anticoagulants such as Coumadin are commonly used for both the treatment and prevention of cardiac disease, cerebrovascular accident (stroke), and blood clots in both inpatient and outpatient settings. Although these medications can confer substantial benefits, their use or misuse carries a significant potential for patient harm. Subtherapeutic (low) levels can increase the risk of blood clotting complications while supratherapeutic (high) levels can increase the risk of bleeding complications. Laboratory monitoring is a key component of safe anticoagulant therapy management. A standardized laboratory test derived from blood clotting studies (the international normalized ratio or INR) is typically used to determine

¹ 2013 VHA Facility Quality and Safety Report Fiscal Year 2012 Data, December 2013, http://www.va.gov/HEALTH/docs/VHA_Quality_and_Safety_Report_2013.pdf. Accessed September 2, 2014. VA categorizes medical facilities at Levels 1a, 1b, 1c, 2, or 3. Level-1a facilities are the most complex and Level-3 facilities the least complex. Complexity levels are based on patient population, clinical services offered, educational and research missions, and administrative complexity.

² VHA Directive 2006-041. *Health Care Service Standards*, June 27, 2006. This Directive expired June 30, 2011 and has not yet been updated.

³ VA Healthcare Bay Pines Memorandum 516-10-00-010 *Patient-Centered Care Program*, May 2010.

the clotting tendency of blood for a patient receiving Coumadin therapy.⁴ When consulted, a facility pharmacist may monitor an inpatient's INR results and adjust times and doses of Coumadin to ensure that the degree of blood anticoagulation is within therapeutic range.⁵

Allegations. At the end of 2014, OIG received the following allegations:

- Computed Tomography (CT) staff inappropriately restrained a patient during a CT scan.
- The patient was inappropriately restrained, oversedated, and did not receive care after admission.
- The patient was not administered Coumadin.
- Two of the patient advocate staff failed to act professionally when dealing with the patient's family.
- The facility refused to release medical records,⁶ and the patient's medical records were altered as part of a cover-up.
- The facility failed to effectively communicate with the patient's family on multiple occasions.

Scope and Methodology

We interviewed the complainant prior to our site visit in early 2015, to clarify the allegations. We interviewed the facility Director, the Chief of Staff, Chief Hospitalist, Chief of Pharmacy, Chief of Radiology, Chief of the Business Office, and Chief of the Emergency Department (ED). In addition, we interviewed hospitalists, CT staff, nursing staff, social workers, ED staff, and patient advocate staff who were involved in the patient's care and/or interacted with the family. We interviewed the facility Privacy Officer, the Chief of Health Information Management, and the patient's family.

We reviewed relevant VHA and other governmental policies, The Joint Commission (JC) standards, and facility policies and procedures. We reviewed restraint/seclusion data, patient advocate data, bar code medication administration records, post-discharge non-VA medical records, and the patient's VA electronic health record (EHR). We toured the facility's CT suite, the inpatient medical unit's constant observation room, and the ED.

⁴ VHA Directive 2009-003. *Anticoagulation Therapy Management*, February 2, 2009. This Directive was rescinded but contains the same or similar language concerning the use of anticoagulants as the current one, VHA Directive 1033, *Anticoagulation Therapy Management*, July 29, 2015.

⁵ VHA Health Care Bay Pines. *Anticoagulation Management Program*, May 2014.

⁶ The complainant used the term medical records in the allegation however, for this report, the term electronic health record (EHR) will be used to designate medical records.

We **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. We **did not substantiate** allegations when the facts showed the allegations were unfounded. We **could not substantiate** allegations when there was no conclusive evidence to either sustain or refute the allegation.

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

Case Summary

The patient was a male in his late eighties. He lived with family members within 2 hours' drive from the facility. His pertinent medical diagnoses included atrial fibrillation (maintained on chronic Coumadin therapy), coronary artery disease, heart failure, a history of cardiac arrest with subsequent placement of an implantable cardiac defibrillator, orthostatic hypotension, essential tremor, and a history of falls. In early 2014, facility EHR entries indicated that the patient was having an "increasing dementia pattern with occasional outbursts of impulsive behavior...and poor interaction," becoming "agitated when there are new faces in the home." Though the patient's daily care was becoming more challenging with his decreased mobility and progressive dementia, the family strongly desired for him to continue living at home. By choice, he received most of his medical care through the private sector.

Several months later, a VHA neurologist assessed the patient during a regularly scheduled appointment and ordered a CT scan (with and without contrast) to evaluate changes in memory and cognition, among other signs/symptoms that could be indicative of increasing dementia.⁷ The CT scan, completed soon after the neurology clinic appointment, subsequently revealed no identifiable findings that correlated with the patient's progressive functional decline. The patient was released to his family and departed the facility to travel home.

Shortly thereafter, the family returned with the patient to the facility's ED. A family member informed ED staff that the patient was confused, combative, and violent in the car including screaming and hitting. Upon admission to the ED, the patient was attempting to hit staff with his belt. A nurse placed the patient in four-point⁸ restraints.⁹ Once in restraints, the patient was given a tranquilizing medication (medication #1) and became calmer and cooperative but remained confused. The family members departed the facility, indicating they would return the next day. Within 2 hours of the patient's admission to the ED, a nurse removed all restraints. A physician order authorizing the use of restraints in the ED was not entered into the EHR. Soon after the restraints were removed, the patient was admitted to the facility under observation status and transferred to a medical unit.¹⁰

⁷ Computed tomography (CT) of the head is a type of x-ray technology that creates virtual "slices" of a scanned area, creating more detailed assessment of internal structures. Intravenous contrast increases the radio-density of structures with a high amount of blood flow.

⁸VA Bay Pines Healthcare System. *Restraints and Seclusion Procedure*, March 5, 2010. Four point restraints is defined as both arms and both legs restrained with soft limb holders using cloth wristlets and anklets.

⁹ VA Bay Pines Healthcare System, *Restraints and Seclusion Memorandum 516-14-11-013*, August 2014.

Restraints may be applied or seclusion initiated based upon the registered nurse assessment of the patient who is demonstrating behavior immediately harmful to themselves or others. An order from a physician must be obtained within one hour of applying restraint or initiation of seclusion, and documented in the EHR.

¹⁰ Observation status means observing a patient for an extended period of time as an outpatient before admission as an inpatient.

Upon hospital admission (Day 1), the patient was initially non-combative and stable. He had several clinical findings suggesting relative dehydration¹¹ including a rapid heart rate, dry oral mucosa, an increase in serum creatinine,¹² and an elevated urine specific gravity.¹³ Due to periodic combativeness and resistance to the placement of an intravenous (IV) line, fluid administration was problematic for portions of the patient's hospitalization. However, by the second hospital day, the serum creatinine value returned to normal suggesting improvement in fluid balance.

Physical restraints were placed at the discretion of point-of-care nurses on two occasions during the patient's 6-day hospital stay. Once, two-point restraints were used, and once, four-point restraints were used. Physician orders authorizing the use of physical restraints were entered timely for each usage while in the hospital.

Throughout his hospitalization, the patient was in a nursing care status of "constant observation."¹⁴ Nursing assessments were documented daily and indicated that the patient received intravenous fluids for approximately the first 24 hours of his hospital stay, required assistance with some meals, and would occasionally refuse to eat or take his medications. Due to periods of agitation (pulling out the IV line and repeatedly removing an external urinary device) and combativeness, the physician ordered a medication that was used for the management of agitation (medication #2) as needed in an effort to calm the patient and lessen the possible need for physical restraints.¹⁵ The patient became lethargic following dosing with medication #2. VA caregivers documented that the drug was "probably contributing to his lethargy." On the second hospital day, the patient's primary inpatient caregiver, Hospitalist A,¹⁶ documented, "Assessment and Plan discussed with patient [sic] wife and she is in agreement"; the scope of discussion is not evident. On the third, fourth, and fifth hospital days, the covering physician, Hospitalist B, charted, "Assessment and Plan discussed with patient's wife and she is in agreement."

The patient received a dose of medication #2 early in the morning on Day 6. He was lethargic when the neurology team attempted to assess him approximately 5 and

¹¹ Dehydration is a condition that occurs when the loss of body fluids, mostly water, exceeds the amount taken in.

¹² Serum creatinine, a fairly reliable indicator of kidney function, measures a chemical waste molecule from muscle metabolism. Creatinine levels typically will rise with fluid deficit and return to baseline levels with fluid repletion. In this circumstance, serum creatinine levels were affected by fluid fluctuations rather than reflecting actual kidney failure.

¹³ Specific gravity of urine is a test used to help evaluate the body's water balance; significant elevations of urine specific gravity may be seen when a patient is dehydrated.

¹⁴ Facility Policy *Nursing Care Observation Levels*, June 28, 2011, p. 2-3. A patient requiring constant observation status (designated MO2) is admitted to a four-bed room with a staff member assigned to remain in the room and maintain visual observation of the patients at all times. The staff member is available to immediately assist and provide care to the patient.

¹⁵ According to Bar Code Medication Administration reports, medication #2 was ordered to be given every 12 hours as needed for agitation. The patient received the following doses of medication #2: Day 3 times two; Day 4 times three, and Day 6 times one.

¹⁶ A hospitalist is a physician who specializes in the care of patients admitted to the hospital.

9 hours later. However, in an EHR note, the neurologist discussed possible discharge the next day depending on the patient's mental status.

The following day, the patient's mental status was improved, and he was seen in consultation by a physical therapist to assess his functional capabilities. The physical therapist recommended that the patient would benefit from a transition period in a skilled nursing facility (SNF) prior to returning home. Hospitalist A discussed the patient's possible transfer to an SNF with a family member, but the family member indicated the patient was already participating in an outpatient physical therapy program and he/she wished to take him home. Approximately 2 hours after the physical therapist's evaluation, Hospitalist A released the patient for discharge stating that the patient was "responsive and alert," "dehydration resolved," and "per [family member], he is at baseline today."

Pharmacists monitored the patient's Coumadin therapy throughout his hospitalization. Although the patient declined the daily Coumadin dose on three of his six inpatient days, daily laboratory monitoring reflected the degree of blood anticoagulation was within the desired range. On the day of the patient's discharge, the pharmacist adjusted his Coumadin dose based on the results of his blood monitoring test results. A pharmacy counseling note at that time reflected education of two family members. A nurse's post-hospital telephone encounter with a family member on the day after discharge included the matter of Coumadin monitoring within 72 hours of discharge. At the family's preference, this follow-up was to be with the patient's non-VA provider. According to non-VA records we reviewed, the patient had several visits with his non-VA providers in the weeks following discharge from the facility for reasons to include ongoing management of Coumadin therapy. Approximately 2 months after discharge, the patient experienced a hemorrhagic stroke and died at a non-VA facility.

A qualitative review of the patient's non-VA care was not part of this inspection.

Inspection Results

Issue 1: Restraint Use

CT Department

We did not substantiate that CT staff inappropriately used physical restraints to complete a CT scan.

During a CT scan of the head, a Velcro® strap is applied to the patient's head for safety and to assist in avoiding sudden patient movement that may cause motion artifact in the imaging study. According to staff that we interviewed, a CT scan would not be performed on a patient who could not remain motionless during the exam, which only takes a few moments to obtain.

We relied on interviews and reports of contact from CT staff to gain an understanding of the following events. According to the family, the CT department is "ground zero" for

everything that happened. CT Technician A met the family and patient in the radiology waiting room and took the patient, in his wheelchair, to the procedure room. CT Technicians A and B assisted the patient from the wheelchair to the CT scanner table. Technician B stated that as they were starting an IV, the patient became agitated, stating he did not want to die. Technician A held the patient's hand and reassured him. A Velcro® safety strap was placed across the patient's forehead and secured. Technician A stated that the patient did not know where he was, nor did he understand the instructions given to him but was lying still on the CT scanner table. Technician B left the room to complete the first of two scans. Intravenous contrast was necessary for the second scan. Technician A remained beside the CT scanner table with the patient.

Technician B stated that after the contrast was administered, the patient became more agitated and began yelling, "I don't want to die." The scans took about 5 minutes to complete, during which time the patient continued to be agitated and became increasingly confused. Technician A stated that the patient did not refuse the scan at any time during the process. After completing the scan, Technician A reached across the table to loosen the Velcro® strap, and the patient grabbed the technician's arms. Technician A stated to the patient, "Sir you are hurting me." Technician C, who was in an adjacent area, heard the conversation and went to the CT scan room. By the time Technician C arrived, the patient had released his grip on Technician A. The three technicians moved the patient from the table to the wheelchair; the patient kicked off his shoes. As Technician C was trying to replace the shoes, the patient began to kick and hit Technician C. Technician B opened the door to the waiting area where the patient's family was waiting. The patient remained confused and disoriented. Immediately thereafter, the patient left the hospital with the family to return home.

We concluded that CT staff did not inappropriately restrain the patient during the CT scan. However, we found that CT staff did not explain to the family the challenges they had encountered with the patient during the scan or seek the family's assistance when the patient became confused and combative. See Issue 6 discussion concerning communication issues.

ED and Inpatient Medical Unit

A. Use of Physical Restraints

We substantiated that the patient was physically restrained on three occasions; however, we determined that facility staff followed policy when making the decision to restrain the patient and when taking care of the patient while restrained. We determined that facility staff did not document patient or family education when restraints were initiated or in use, and a physician's order for one episode of restraint use in the ED was not entered into the EHR.

Local policy requires that the use of restraints be limited to clinical situations involving imminent risk of harm to patients or others and prevention of dangerous behaviors

interfering with medically necessary treatment.¹⁷ A registered nurse (RN) may apply restraints based upon an assessment of the patient who is demonstrating such behavior. Immediate notification of the physician is required. A physician must initiate an order within 12 hours of the application of restraints. The physician must document his/her assessment of the patient whenever an order for restraints is written or renewed.

Qualified staff must assess the patient every 2 hours to ensure that the patient has no injury from the restraint; that the patient still requires the use of restraints; and that range of motion, skin care, elimination, and nutrition needs are addressed. Restraints must be discontinued as soon as it is possible to do so. Patients and their families are to be educated on the use or restraints.¹⁸

The first episode of restraint use was in the ED. The ED RN documented that the patient was confused and combative toward staff in the ED. The RN placed the patient in four-point soft restraints¹⁹ almost immediately after arrival. Soon thereafter, the ED provider ordered medication #1. The order for medication #1 was documented; however, we did not find an order for the restraints. Within 20 minutes of receiving medication #1, the ED nurse assessed the patient and wrote that the patient was calmer after receiving the medication. Approximately 2 hours after placing the restraints, the nurse removed the restraints as the patient was cooperative and confused but not combative.

The patient was transferred from the ED to a constant observation room on a medical unit, 5B. A few hours after arrival to 5B, he attempted to dislodge his IV and external urinary device, was combative towards staff, and refused his medications. Nursing staff documented that the patient was a risk to himself and others. The RN placed the patient in two-point restraints. The restraints were discontinued the next morning. Early in the morning on Day 3, the RN placed the patient in four-point restraints and documented:

This patient can be extremely combative and for the safety of the patient and the staff I would suggest he not be removed from the restraints unless there are at least 2 people for supervision. He is physically fit and very strong. I would also suggest he be given [medication #2] on regular bases (sic) instead of PRN.

The next morning, an RN documented that the patient was compliant with requests to remain in bed and discontinued the restraints.

We found physician orders for the two episodes of restraint use on 5B. Nursing and hospitalist documentation met the local policy requirements and addressed the reason

¹⁷ VA Healthcare System Bay Pines, Fl. VAHCS Memorandum 516-14-11-013, *Restraints and Seclusions*, August 2014.

¹⁸ *Ibid.*

¹⁹ Nursing Service *Restraints and Seclusion Procedures*. March 5, 2010. Soft restraints are made of cloth.

for restraints, the patient's reaction to the restraints, and the reason the restraints could not be discontinued.

We found no EHR documentation regarding family education on the use of restraints. We found documentation in a hospitalist note, "plan discussed with family"; however, the scope of discussion is not evident.

B. Use of Sedating Medications

We substantiated that the patient received a sedating medication once in the ED and a different medication ordered on an "as needed" basis for agitation while on the inpatient unit. He received a total of 6 doses of the medication for agitation.

After receiving medication #1 in the ED, the patient's agitation was relieved and his restraints were removed.

On Day 2, while on 5B, the patient became agitated and combative. In an effort to eliminate the need for restraints, his physician ordered medication #2 to help calm him. The patient became increasingly sedated while on the medication. The family visited the patient on Day 6, and found him to be very lethargic. Hospitalist A attributed the lethargy to a dose of medication #2 that the patient had received early that morning. The patient did not receive other doses of medication #2, became less lethargic over the next 24 hours, and was able to be discharged home the following day.

A family member stated that a staff member showed the family member a medication list containing an anti-anxiety medication and an anti-seizure medication that reportedly belonged to the patient. The family member further stated that the staff member said they (facility staff) were "drugging" the patient. The family was unable to identify the staff member. Review of the medication administration records indicated no order for, or administration of, the anti-anxiety or anti-seizure medication that the patient was purportedly receiving.

Issue 2: Failure To Provide Care

Patient Care

We did not substantiate that facility staff failed to provide care. The patient was admitted to a constant observation room. The EHR contained required nursing assessment documentation, including assistance needed with meals, amount of food consumed, occasions when the patient refused to eat or drink, refusal of medications, and activities of daily living such as the ability to feed himself and/or ambulate to the bathroom with or without assistance. EHR entries from hospitalists and specialists reflected daily interactions with the patient, cognitive assessments, ongoing treatment, and plan of care. We also reviewed unit 5B patient advocate data for 2 years and did not find evidence of patient/family complaints concerning the quality of nursing or provider care.

The complainant alleged that the patient lost a significant amount of weight during his admission, an indicator that he did not receive adequate nutrition. We could not substantiate the weight loss as we did not find any weights documented during his admission.

Coumadin Administration

We did not substantiate that the patient did not receive Coumadin during his hospitalization. The complainant stated that one of the nurses on the medical unit told the family that the patient was not given his Coumadin as ordered because the pharmacy did not have it in stock.

Pharmacists, physicians, and nursing staff we interviewed told us that the facility has not to their knowledge had difficulty procuring Coumadin and has never been without the medication. The patient's medication administration records showed appropriate adjustments of the times and doses of Coumadin. A template note in the EHR entitled *Inpatient Anticoagulation Follow-Up/Consult* that was completed daily by the pharmacist included:

- Indication for anticoagulation therapy
- Duration of therapy
- Desired INR range
- Laboratory data/date, time, and results of INR blood test
- Any pertinent changes to medication regimen
- Assessment that included if INR was therapeutic and whether the patient received the prescribed dose or refused the medication
- Plan/the prescribed dose, the ordered laboratory test, and the date and time for the next pharmacist anticoagulation follow-up consult note

Throughout the patient's stay, the degree of blood anticoagulation was found to be within the desired range.

Issue 3: Lack of Professionalism by Two Patient Advocate Staff

We substantiated that two patient advocate staff failed to act professionally when interacting with the patient's family.

A local policy entitled, *Processing Patient Concerns*, outlines an expectation that all staff are expected to exhibit courtesy, helpfulness, compassion, and concern toward patients and their families. The policy also requires "the patient advocate to assist the patient and family in seeking resolution to problems by acting on their behalf with individuals at all levels of the organization."²⁰

²⁰ VA Healthcare System Bay Pines Memorandum 516-09-090, *Processing Patient Concerns*, August 2009.

When family members visited the patient, they had concerns about the patient's care and met with Patient Advocate 1 to discuss their concerns. Patient Advocate 1 accessed the EHR to confirm the patient's enrollment and next of kin information in the VHA system. Patient Advocate 1 incorrectly accessed the record of a patient who had behavioral issues (Patient B). He mistakenly identified Patient B as the patient at issue (Patient A) and discussed Patient B's information with the family.

Patient Advocate 1 informed the family that Patient B's EHR was flagged for behavioral issues^{21,22} and that he/she personally had to call 911 to have Patient B removed from the facility campus. The family explained to the patient advocate that their family member, Patient A, was unable to drive and did not come to appointments unaccompanied.

Patient Advocate 1 told us that he had not properly checked Patient A's identifying information when accessing the EHR prior to speaking to the family. He subsequently identified and accessed the correct patient's EHR and forwarded the family's complaints to the appropriate department.

We determined Patient Advocate 1 failed to accurately identify the correct patient when speaking with the family. Family alleged that when discussing Patient B's behavioral issues and other concerns with them, Patient Advocate 1 failed to exhibit the courtesy, support, or helpfulness they had expected to receive from patient advocate staff.

Approximately 2.5 months after the patient's discharge from the facility, facility staff met with two family members after the family requested a meeting to discuss some concerns regarding the patient's care at the facility. The family members were accompanied by a family friend. Patient Advocate 2 and several clinicians²³ involved in the patient's care assembled for the meeting. Facility staff told us that such patient/family meetings were common and often successful in addressing patient and family concerns.

During introductions, the family friend identified himself as an attorney but indicated he was not acting as the family's legal representative. According to Patient Advocate 2, after learning the family friend was an attorney, he/she halted the meeting and instructed the attendees to not interact with the family or family friend while he/she left the room to seek advice from the facility's Privacy Officer and legal counsel.

The Privacy Officer advised Patient Advocate 2 that he/she was not aware of any policy, regulation, or precedent that prohibited family friends, who are also attorneys, from attending informal meetings to discuss patient care. The facility's legal counsel advised Patient Advocate 2 that in order to continue with the meeting, the spouse must have a Power of Attorney (POA) document and sign an additional document through regional

²¹ VHA Directive 2010-053, *Patient Record Flags*, December 3, 2010.

²² VA Healthcare System Bay Pines Memorandum 516-13-116-006, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, December 2013.

²³ Facility staff attendees included Supervisor of CT, Radiology Service, Chief Hospitalist, Unit 5B Assistant Nurse Manager, Chief, Health Administrative Services and a pharmacist.

counsel. Patient Advocate 2 returned to the meeting room and announced that the meeting was terminated. The complainant stated that the family and the friend volunteered to sign any necessary documents in order to continue the meeting. Patient Advocate 2 declined the request and asked the attendees and family to leave the meeting.

VHA policy requires a patient advocate to have certain competencies including the ability to assess the situation, utilize problem solving skills, crisis intervention, and effective communication that includes listening with the intention of understanding.²⁴

We determined Patient Advocate 2 failed to bring the meeting to a successful conclusion for the family. The family and friend volunteered to present and/or sign any necessary documents that would have allowed the meeting to continue. Patient Advocate 2 did not pursue that option but ended the meeting. Although the family friend indicated he was not present as the family's legal representative, Patient Advocate 2 stated that it was his/her belief that the family friend was at the meeting under false pretenses to conduct a fact finding for the family.

Issue 4: EHR Concerns

We did not substantiate the allegations that facility staff refused to release a copy of the patient's EHR record to the family or that the EHR was altered as part of a cover-up.

Release of Records

The process for granting release of information requests for copies of EHRs is outlined in VHA Handbook 1907.06, *Management of Release of Information*, January 18, 2013. Only information that "the Veteran has specified be released, to only those whom the Veteran has authorized or who have legal authority to receive such information" may be released. The documents may only be released after all applicable Federal laws, rules, and regulations regarding release of health information have been followed.²⁵

On the day of the patient's discharge from the facility, a family member spoke with the Chief of Health Information Management and requested a copy of the patient's EHR. After validating the family member's POA document, the Chief of Health Information Management agreed to mail the requested record within 3–4 days.

According to facility records, a copy of the patient's EHR was mailed to the address on file. According to the family, a copy of the patient's EHR was not received.

We compared the Release of Information request submitted by the family with the facility's mailing log and found that the addresses matched. The log also recorded which documents (EHR) were sent and the date they were sent. VA Directive 6609,

²⁴ VHA Handbook 1003.4 *VHA Patient Advocacy Program*, September 2, 2005. This VHA Handbook was scheduled for re-certification on or before the last working day of September 2010 but has not yet been recertified.

²⁵ VHA Handbook 1907.06, *Management of Release of Information*, January 22, 2013.

Mailing of Sensitive Information,²⁶ and VHA Directive 1907.1, *Health Information Management and Health Records*, do not require that the facility send a copy of the EHR by secure delivery or with package tracking. We determined that a copy of the EHR was sent by the facility, but we could not confirm that the family received the record. On the day the patient died, the family drove to the facility and requested and received a complete copy of the patient's EHR.

The complainant stated that when the family received and reviewed a copy of the EHR, they found what they perceived as discrepancies regarding admission dates and medication administration. The admission dates discrepancy may be explained in that the EHR contained two discharge summaries. One discharge summary covered the period when the patient was admitted under observation status. The second discharge summary covered the period after the patient was converted from observation status to inpatient admission until the day of discharge home. The family also questioned how the patient could have received medications without IV access and/or the ability to chew.²⁷ However, EHR entries indicate that the patient was able to take medications and receive nutrition via a mechanical diet.²⁸

VHA requires that the physician complete a discharge progress note or instruction sheet for each period of hospitalization. It must contain:

- Date and the type of discharge
- Diagnoses
- Recommendations relative to diet, exercise, and limit of disability
- Patient's condition on discharge
- Patient's place of disposition
- Recommendations for follow-up
- Patient education
- Discharge medication information²⁹

We found that EHR discharge summary documentation did not reflect the change in status from observation to admission, the patient's condition upon discharge, or all changes in medications.

Altered Records

The complainant further alleged that facility staff altered the patient's EHR. Changes to the EHR are allowed under very limited circumstances; however, these circumstances

²⁶ VA Directive 6609 *Mailing of Sensitive Personal Information* May 20, 2011.

²⁷ The family told us the patient could not chew because his dentures were on his bedside table when they came to visit, and not in his mouth.

²⁸ A mechanical diet includes foods that can be made easy to chew/swallow by using machines; foods may be blended, pureed, ground, or finely chopped.

²⁹ VHA Handbook 1907.01 *Health Information Management and Health Records*, July 22, 2014. This Directive was current at the time of the events in this report but has since been rescinded and replaced by VHA Handbook 1907.01 *Health Information Management and Health Records*, March 19, 2015.

are not applicable here. We reviewed the patient's EHR with an OIG Information Technology (IT) Specialist and found no instances in which the EHR had been altered.

Additional EHR Finding

We found that one of the hospitalists entered a note into the patient's EHR on 3 consecutive days indicating that he/she had conferred with a family member. When interviewed, the hospitalist stated that he/she spoke with the family member on only one occasion. As the phrases describing the family communication were identical, we believe this represents a copy/paste issue.³⁰

Issue 5: Communication

We substantiated that facility staff failed to effectively communicate with the patient's family on multiple occasions.

The facility patient-centered care policy specifies that employees be responsive and sensitive to the needs, preferences, and concerns of patients and strive to resolve patient/family concerns in a positive and timely manner. According to local policy, patient-centered health care is delivered in a compassionate and personalized manner and patients and their families are treated with dignity and respect.³¹

CT Department

Patient-centered care principles were not employed in the care of the patient at the time of the CT scan procedure. The complainant stated that when family members arrived in the CT scan area they told the technician that if the patient became agitated to come get them, and they would help with the patient. CT staff we interviewed told us they were able to complete the scan, despite the patient's increasing confused and agitated state, and did not ask the family for help in calming the patient. When the CT scan was completed and the patient became more agitated and combative during the discharge process, the CT staff did not involve and/or communicate with the family.

ED

While on the drive home from the facility, after the CT scan was completed, the patient became combative hitting a family member while he/she was driving. The family took the patient back to the facility ED. Upon arrival in the ED, the patient was physically restrained due to his continued combative behavior. According to the complainant, the ED staff did not inform the family that the patient was being restrained. The ED provider documented, "Plan: admission, psychiatric evaluation and medicine evaluation, placement, no family available at time of admission to discuss further per their request." The nurse who was facilitating the patient's admission obtained information regarding

³⁰Copy and paste are duplicating selected text or graphic(s) and inserting it in another location, leaving the original unchanged.

³¹ VA Healthcare Bay Pines Memorandum 516-10-00-010 *Patient- Centered Care Program*, May 2010.

the patient from the ED nurse. The nurse documented in his/her Initial Assessment Admission RN progress note that “the writer called phone number on file to speak to a family member to get questions answered but no answer.”

When interviewed, family members indicated they thought the patient would remain in the ED under observation. We did not find documentation in the EHR that ED staff notified the family when the patient was transferred to the inpatient unit.

Additionally, while one of the family members who had accompanied the patient to the hospital held a valid POA for the patient, facility staff could not produce documentation of signed³² consent by either the patient or the family member with POA for admission to the hospital.

Inpatient Medical Unit

The complainant told us that family members were not contacted consistently regarding changes in the patient’s condition or plan of care. When family members attempted to call, they were not able to receive information on the patient because they did not have a Patient Information Number (PIN).

The facility policy entitled *Patient Information Number (PIN)*³³ requires that all patients be provided with a PIN upon admission. The patient may disclose the PIN to persons who may receive patient information from facility staff after correctly identifying the assigned PIN. In the event a patient is incapable of making decisions, a person with a POA related to health care decision-making is provided the PIN. The complainant stated that the family member who held a valid POA for the patient did not receive a PIN. As a result, communication from nursing staff on the medical unit with the family was minimal, and the family was not actively involved with the patient’s nursing care.

The EHR contained multiple entries noting that the patient was incapable of answering questions without accompanying documentation of attempts to contact the family. We concluded that facility staff missed multiple opportunities to communicate effectively with the patient’s family.

Conclusions

We found that the patient was not inappropriately restrained during a CT scan. CT technicians placed straps during the CT study for patient safety and to avoid sudden patient movement.

We substantiated that during the patient’s ED and inpatient stay, the patient was physically restrained on three occasions due to his combativeness and attempts to

³² iMedConsent™ is a software package that supports electronic access, completion, electronically captured signature, and storage of documents, such as informed consent forms and advance directives.

³³ VA Healthcare Systems Bay Pine, Memorandum 516-14-136-017, *Patient Information Number (PIN)*, May 2014

interfere with medically necessary treatments. Nursing documentation of the use of restraints was consistent with facility policy; however, we did not find a physician's order for the episode of restraint use when in the ED. We also substantiated that the patient received antipsychotic medications for agitation in an effort to calm him and lessen the need for physical restraints. The patient became lethargic following dosing with the antipsychotic medication; he recovered once the medication was discontinued.

We did not substantiate that the patient failed to receive care. The patient was admitted to a constant observation room on a medical unit. Staff were continuously present in this room to immediately assist the patient if needed. The EHR contained required nursing assessment documentation and entries from hospitalists and specialists that reflected daily interactions with the patient, cognitive assessments, and ongoing treatment plans.

We did not substantiate the allegation that the patient was not provided Coumadin because the facility did not have the medication in stock. The patient's medication administration records showed appropriate adjustments of the times and doses of Coumadin. Further, throughout the patient's stay, the degree of blood anticoagulation was found to be within the desired range. Pharmacists, physicians and nursing staff we interviewed told us that the facility has not had difficulty procuring Coumadin.

We substantiated that two patient advocates failed to act professionally when communicating with the patient's family. In one instance, a patient advocate failed to correctly identify the patient at issue, and in a second instance, a patient advocate terminated a facility staff/family meeting rather than facilitating the meeting to a successful conclusion for the family.

We did not substantiate the allegations that facility staff refused to release copies of the patient's EHR to the family or that the EHRs were altered. We found that the facility released the records to the family. We noted that the discharge documentation did not contain all required elements. We determined that EHRs can be altered only in very limited circumstances, and those circumstances were not applicable in this case.

We found that one of the hospitalists entered a note into the patient's EHR on 3 consecutive days indicating that he had conferred with a family member. When interviewed, the hospitalist stated that he spoke with the family member on only one occasion. As the phrases describing the family communication were identical, we believe this represents a copy/paste issue.

We substantiated that facility staff failed to effectively communicate with the patient's family on multiple occasions.

Recommendations

1. We recommended that the Facility Director ensure that Emergency Department, Computed Tomography Department, Patient Advocate, and 5B inpatient medical unit staff receive patient-centered care training and/or refresher training.

2. We recommended that the Facility Director conduct a review of the patient advocates' actions as described in this report and take action as appropriate, including providing guidance regarding the processing of patient/family concerns.
3. We recommended that the Facility Director ensure that physician orders are entered into the electronic health record as required when restraints are used.
4. We recommended that the Facility Director ensure that physician discharge notes contain all required elements and documentation adequately reflects the patient's care and communication with family.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: March 2, 2016

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

Subj: Healthcare Inspection—Restraint Use, Failure To Provide Care, and Communication Concerns, Bay Pines VA Healthcare System, Bay Pines, Florida

To: Director, Washington DC Office of Healthcare Inspections (54DC)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed the draft report and concur with the report's recommendations. Attached are the Bay Pines VA Healthcare System's corrective action plans for recommendations 1–4.
2. Thank you for the opportunity to review the draft report. If you have any questions, please contact Ken Massingill, Chief, Quality Systems Service, at (727) 398-6661, extension 15507.

(original signed by:)

MIGUEL H. LAPUZ, M.D., MBA
Director, VA Sunshine Healthcare Network

System Director Comments

Department of Veterans Affairs

Memorandum

Date: March 2, 2016

From: Director, Bay Pines VA Healthcare System (516/00)

Subj: Healthcare Inspection—Restraint Use, Failure To Provide Care, Communication Concerns, Bay Pines VA Healthcare System, Bay Pines, Florida

To: Director, VA Sunshine Healthcare Network (10N8)

1. I have reviewed the draft report and concur with the report's recommendations. Attached is the Bay Pines VA Healthcare System's corrective action plan for recommendations 1 – 4.
2. Thank you for the opportunity to review the draft report. If you have any questions, please contact Mr. Ken Massingill, Chief, Quality Systems Service, at (727) 398-6661, extension 15507.

(original signed by:)
SUZANNE M. KLINKER
Director, Bay Pines VA Healthcare System

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the Facility Director ensure that Emergency Department, Computed Tomography Department, Patient Advocate, and 5B inpatient medical unit staff receive patient-centered care training and/or refresher training.

Concur

Target date for completion: May 27, 2016

Facility response: During fiscal year 2016, staff across the healthcare system will be afforded the opportunity to attend training/education regarding Veteran-centric care in the form of VA 101 training. Additionally, staff from the named departments will be required to complete Talent Management System (TMS) online course 1310158, "Customer Service Fundamentals: Building Rapport in Customer Relationships," by May 27, 2016. Compliance will be demonstrated by attestation by the units' leadership that TMS records have been verified to ensure appropriate staff have completed the assigned course.

Recommendation 2. We recommended that the Facility Director conduct a review of the patient advocates' actions as described in this report and take action as appropriate including providing guidance regarding the processing of patient/family concerns.

Concur

Target date for completion: May 27, 2016

Facility response: Patient Advocates' Office staff will receive additional patient-centered care training inclusive of refresher elements of patient advocacy expectations. This training need was coordinated with and will be presented by the VHA Office of Patient Centered Care (OPCC) by May 27, 2016.

Recommendation 3. We recommended that the Facility Director ensure that physician orders are entered into the electronic health record as required when restraints are used.

Concur

Target date for completion: May 27, 2016

Appendix C

Facility response: Emergency Department (ED) leadership will conduct 100% review of all episodes of restraint use for thirty days occurring in the ED ensuring all required elements are present. Findings of the review will be reported to leadership with actions to correct deficiencies.

Recommendation 4. We recommended that the Facility Director ensure that physician discharge notes contain all required elements and documentation adequately reflects the patient's care and communication with family.

Concur

Target date for completion: May 27, 2016

Facility response: The Chief of Staff will remind leadership of all services having staff duties that prepare discharge notes of the importance of completing all required elements and including communication with the Veteran and family as appropriate. Service leadership will perform random chart reviews for a period not less than three months to ensure discharge notes meet expectations. Findings of the reviews will be reported to leadership and when necessary, actions to correct any noted deficiencies will be developed and tracked.

OIG Contact and Staff Acknowledgments

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