Report to the
Office of Special Counsel
OSC File Number DI-11-3558

Department of Veterans Affairs
VA Texas Valley Coastal Bend Healthcare System
Harlingen, Texas

Veterans Health Administration
Washington, DC

Report Date: March 7, 2012

Executive Summary

The Deputy Undersecretary for Health for Operations and Management requested that a Fact Finding Team (Team) investigate a complaint lodged with the Office of Special Counsel by Richard Krugman, M.D. a whistleblower at the Department of Veterans Affairs, VA Texas Valley Coastal Bend Health Care System (VATVCBHCS) in Harlingen, Texas. The whistleblower provided the following broad categories of allegations: inadequate facilities at Harlingen Health Care Center; surgical staff hired but unable to practice; patient care concerns; discontinuation of patient records in advance of the Joint Commission visit; and outstanding VA debt to private providers compromising patient care. The Team conducted a site visit at the Health Care Center on February 8-9, 2012, following a telephonic and review of documents investigation completed on January 19, 2012.

Summary of Conclusions

Inadequate Facilities at Harlingen Health Care Center:

The allegation that the HCC lacked a Heating, Ventilation and Air Conditioning (HVAC) system adequate to control humidity in the operating theatre was not substantiated as the surgical unit is serviced by a dedicated HVAC system that is designed to control humidity in the operating theatre. The allegation that the HCC lacked back-up generators was not substantiated. The HCC is serviced by a 1,600 Kilowatt diesel fueled generator with automatic transfer switches. The generator is sufficiently sized to provide emergency electrical power to the HCC in the event that utility provided power is interrupted. The allegation that the HCC was poorly designed in that the distance between the operating rooms and recovery rooms was too great, and the 20 separate recovery room bays each had four walls, was not substantiated as the Surgical and Recovery areas are directly adjacent to each other on the third floor of the Harlingen HCC. VA Design Publications provide guidance with respect to functional relationships and their proximity to each other, but do not specifically address or limit distances. Furthermore, the VA Outpatient Clinic Guide Plate states that, "The Guide Plates are not intended to be project specific and are not meant to limit design opportunities". The allegation that the facility was unable to support any surgical procedures and perform sterilization of equipment was not substantiated as both the Surgical and SPD areas are served by AHU -1 (Air Handling Unit-1). AHU – 1 and the distribution system were designed to provide the required air exchanges per VA criteria as well as satisfying temperature and humidity requirements (refer to allegation # 1). In addition, the ventilation system in the Surgical Suites is configured to support a "sterile" operating field. The SPD area ventilation distribution system is designed to provide VA required air exchanges, temperature and humidity and room air balances (pressure relationships) between different functional spaces. The Harlingen HCC Sterile Processing Department did have steam, gas plasma and scope sterilizers which are capable of sterilizing the reusable medical equipment (RME) at the Harlingen clinic as well as a cart washer and sonic instrument cleaner.

Surgical Staff Hired but Unable to Practice:

The allegation that surgeons were hired but were unable to practice is not substantiated as shown by personal interviews with most of the surgeons named, review of employee records, review of credentialing and privileging records and a direct viewing of procedure rooms. While some minor findings were discovered, there is no evidence that the hiring practices at the facility, including timing of entrance on duty, titles granted, salary levels approved and alleged atrophy of surgical skills is present. Nor did the Team find any hiring practices there that constitute a violation of any law, rule, or regulation; or gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. The Team did find, however, that VHA Handbook 1100.19, November 14, 2008, *Credentialing and Privileging*, paragraph 6g was not followed when the facility did not require surgeons without recent surgery experience to undergo a Focused Professional Practice Evaluation (FPPE).

Patient Care Concerns:

The allegations about patient care concerns are not substantiated. Moreover, while the facility, similar to any health system (VA and private) has opportunities to improve in some areas, such as a more through process for tracking patient referrals, the Team did not find any systematic pattern of violations of any kind, or practices suggesting gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Discontinuation of Patient Records in Advance of the Joint Commission Visit:

The allegation that records were discontinued in advance of a Joint Commission visit is not substantiated. The facility was required to re-create a record system and took reasonable steps to do so in a manner that was oriented toward patient safety. No records were lost and consultations were discontinued for valid reasons, with clinician judgment guiding the entire process.

Outstanding VA Debt to Private Providers Compromises Patient Care:

This allegation was partially substantiated. The VATVCBHCS owes a substantial amount of money to fee providers in the community. The facility is working toward decreasing this amount, with the understanding that there will always be an outstanding debt pending, due to multiple issues as described in the findings. Still, the Team found the provisions of the Prompt Payment Act (PPA), 31 U.S.C. chapter 39, were not met when the provider bills were not paid within the time-frames specified in the contracts; however, appropriate remedy was provided when the amount of interest required was automatically added to the amount owed on issuance of payment.

The allegation that this debt has resulted in patient care being compromised is not substantiated. Reviews of medical records, documents, and interviews with multiple providers, leadership and administrative personnel responsible for the fee program did not reveal any instance where these payment issues resulted in patient care being compromised, any harm to any patient or in substantial or specific danger to public health or safety.

In conclusion, the team did not find gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. Any actions to be taken by the facility or Department as a result of this investigation are addressed in the recommendations of the report, which are repeated immediately below.

Summary of Recommendations

1. As new surgical procedures begin at the Ambulatory Surgery Center (ASC), surgeons without recent surgical experience should undergo focused professional practice evaluation while operating to ensure competence.

2. Future physician pay should be decided using pay tables consistent with the privileges they request.

3. The VATVCBHCS leadership indicated during interviews that they are working on a more comprehensive coordination of care process for fee-basis appointments and provider notification. It is recommended that this new process be implemented as soon as possible, and be coordinated with the national VHA effort to improve fee-basis processing.

4. Renewed efforts should be made to decrease the backlog of outstanding claims for fee-basis services.

5. Communication with community providers and health care systems should be continued/increased, including face-to-face meetings, status reports and development of a dispute resolution process to address, among other things, long standing debts.

6. VHA's Office of Compliance and Business Integrity should, in concert with the Integrated Ethics program, conduct a Focused Review of the facility and, if necessary and as appropriate, assist in implementing any identified corrective or improvement measures.

Report to the Office of Special Counsel

I. Summary of Allegations

The Deputy Undersecretary for Health for Operations and Management requested that a Fact Finding Team investigate a complaint lodged with the Office of Special Counsel by Richard Krugman, M.D. a whistleblower at the Department of Veterans Affairs, VA Texas Valley Coastal Bend Healthcare System (VATVCBHCS) in Harlingen, Texas. The whistleblower provided the following broad categories of allegations: inadequate facilities at Harlingen Healthcare Center; surgical staff hired but unable to practice; patient care concerns; discontinuation of patient records in advance of the Joint Commission visit; and outstanding VA debt to private providers compromising patient care. The Team conducted a site visit at the Healthcare Center on February 8-9, 2012, following a telephonic and review of documents investigation completed on January 19, 2012.

II. Facility Profile

The Texas Valley Coastal Bend Health Care System (VATVCBHCS) is comprised of the Harlingen Outpatient Clinic, the Health Care Center (HCC), the Corpus Christi Outpatient Clinic, the VA/DoD with Navy Health Clinic, the Laredo Outpatient Clinic, the McAllen Outpatient Clinic and a Mobile Medical Unit. The VATVCBHCS was officially activated as an independent VA Health Care System in October 2010 as the Department of Veterans Affairs newest VA Health Care System. The VISTA administrative packages and Computerized Patient Record System (CPRS) data transfer was activated on June 2, 2011. The HCC at Harlingen began operations in January 2011 for medical sub-specialty services with the surgery floor activating during the summer of 2011. It is anticipated that the HCC at Harlingen will provide the following medical and surgical specialties: Orthopedics, Urology, Gastroenterology, Infectious Disease, Dermatology, General Surgery, Pulmonology, Substance Abuse Treatment, Oncology, Neurology, Rheumatology, Ophthalmology/Optometry, Home and Community Based Care, Mental Health and Amputee Clinic/Prosthetics. The Center also provides ambulatory surgery with endoscopy/cystoscopy and has six operating rooms with Pre-operative (Pre-op) and post-anesthesia care units (PACU). The Specialty Care Unit (SCU) has 8 operating beds. The VATVCBHCS has a staff of 480 FTE, with 180 at the HCC.

III. Conduct of the Investigation

A Fact Finding Team consisting of two Network Chief Medical Officers (David S. Macpherson, M.D., Chief Medical Officer, VISN 4 and Gregg Parker, M.D., Chief Medical Officer, VISN 16) and a Chief of Staff (Kanan Chatterjee, M.D., Chief of Staff, Lebanon, VAMC), the Director of VHA Healthcare Engineering (John D. Stenger, CFM) and two Staff Engineers (Oleh Kowalskyj and Mark Fossett), an Associate Director (William Mills, Associate Director, Lebanon VAMC) and a HR Consultant (Clare M. Hajduk) conducted the site visit. The Team toured the HCC, interviewed individuals, and reviewed policies, procedures, and reports related to the allegations. A full list of the documents reviewed by the Fact Finding Team is in the Attachment. The Team held an entrance and exit briefing with HCC leadership.

During the site visit, the Team interviewed the following individuals in person (except as otherwise noted):

1. Richard Krugman, M.D., Whistleblower
2. (b) (6), Acting Director
3. (b) (6) Acting Associate Director
4. (b) (6) M.D, Chief of Staff
5. (b) (6) Associate Director for Patient Care Services/Nurse Executive
6. (b) (6) M.D., Acting Chief Surgery
7. (b) (6) M.D., Acting Associate Chief of Staff (ACOS) Primary Care and Chief Medical Officer (CMO) Corpus Christi Primary Care Clinic (telephonic)
8. (b) (6) M.D., Gastroenterologist
9. (b) (6) M.D., Ophthalmologist
10. (b) (6) VATVCBHCS Chief Facilities
11. (b) (6) VISN 17 Engineer
12. (b) (6) Operations Administrator HCC
13. (b) (6) Office of Construction and Facilities Management (CFM) Resident Engineer
14. (b) (6) Acting Chief, Human Resources
15. (b) (6) Credentialing Manager
16. (b) (6) VISN 17 Chief Financial Officer (CFO)
17. (b) (6) Chief, Medical Administration Service (MAS)
18. (b) (6) M.D., Ophthalmologist
19. (b) (6) M.D., Ophthalmologist
20. (b) (6) Infection Control Manager
21. (b) (6) HCC Building Developer Building Manager
22. Senior Vice President of Managed Care, Community Fee-Basis Health Care Provider
23. Systems Administrator, Community Fee-Basis Health Care Provider
24. Group Vice President, Community Fee-Basis Health Care Provider
25. (b) (6) Safety Officer
26. (b) (6) Chief Health Information Management System (HIMS)
27. (b) (6) Chief Health Information Officer (CHIO)
28. (b) (6) Administrative Officer to the Chief of Staff
29. (b) (6) M.D., CMO, Harlingen Outpatient Clinic
30. (b) (6) Developer
31. (b) (6) Architect

IV. Summary of Evidence Obtained from the Investigation

Inadequate Facilities at Harlingen Health Care Center (HCC)

Allegation #1:

The HCC surgical unit lacked a Heating, Ventilation, and Air Conditioning (HVAC) system adequate to control humidity in the operating theatre.

Findings

The Team found that the surgical theatre is served by a dedicated Heating, Ventilation, and Air Conditioning (HVAC) system. Technical data sheets for AHU-1 (Air Handling Unit-1) indicate that the unit was designed to VA specifications listed in the 2008 HVAC Design Manual, accounting for the local climatic conditions for where the HCC was constructed. In addition, the HVAC system includes monitoring and controls for humidification and temperature in the operating theatre. Humidification equipment serving AHU-1 and terminal units serving each of the operating rooms were observed.

Conclusion

This allegation was not substantiated, as the HCC surgical unit is served by a dedicated HVAC system that is designed to control humidity in the operating theatre.

Recommendations

None.

Allegation #2:

The HCC lacked back-up generators and power outages were frequent.

Findings

The Team found that the HCC is serviced by a 1,600 Kilowatt diesel fueled generator with automatic transfer switches that comprise the emergency electrical system (EES). The generator is sufficiently sized to provide electrical power to the HCC in the event that utility provided power is interrupted. The Team observed a test of the emergency electrical system at the HCC, demonstrating the successful generator start and subsequent transfer of generated power to the emergency electrical system.

Conclusion

This allegation is not substantiated. In addition, the frequency of "power outages" is irrelevant due to the fact the facility is served by a sufficient emergency electrical system, and that the reliability of the electrical utility provider is not within VA control.

Recommendations

None.

Allegation #3:

The facility was poorly designed in that the distance between the operating rooms and recovery rooms was too great, and the 20 separate recovery room bays each had four walls.

Findings

The Team observed that the surgery and recovery areas are directly adjacent to each other on the third floor of the Harlingen HCS. VA Design Publications provide guidance with respect to function relationships and their proximity to each other, but do not specifically address or limit distances. Furthermore, the VA Outpatient Clinic Guide Plate states that, "The Guide Plates are not intended to be project specific and are not meant to limit design opportunities. While plates are provided for a majority of space required in an Outpatient clinic, it is not possible to foresee all possible variations or future requirements. The project-specific space program shall be used as the basis for individual project design."

The Team observed that the architectural layout and design of the Post-Anesthesia Care Rooms (Recovery) utilizes separate "room bays" with multi-paneled sliding glass partitions that break away to the full width of the bay. This function is analogous to a traditional privacy curtain. In addition, the Team noted that there were 16 Post-Anesthesia Care Rooms – not 20 as stated.

Conclusion

This allegation was not substantiated.

Recommendations

None.

Allegation #4:

The HCC remains unable to support surgery or other procedures requiring a sterile environment because not all of the system changes have been implemented, including establishing a sterile operating theatre.

Findings

The Team determined that both the Surgical and Supply Processing & Distribution (SPD) areas are served by Air Handling Unit – 1 (AHU-1) and the distribution systems were designed to provide the required air exchange per VA criteria identified in the HVAC Design Manual, as well as satisfying temperature and humidity requirements (refer to allegation #1). In addition, the ventilation system in the surgical suites is configured to support a "sterile" operating field.

The SPD area ventilation distribution system is designed to provide VA required air exchanges, temperature and humidity and room air balances (pressure relationships) between different functional spaces.

The Team confirmed the presence of steam, gas plasma and scope sterilizers which are capable of sterilizing the reusable medical equipment (RME) at the Harlingen ASC as well as a cart washer and sonic instrument cleaner.

Conclusion

This allegation is not substantiated.

Recommendations

None.

Surgical Staff Hired but Unable to Practice

Allegation #5:

Physician Specialists were hired by TVCBHCS significantly in advance of the HCC's readiness for opening.

Findings

Hiring dates of physicians named by the whistleblower were verified using personnel files and further validated by interviews with the physicians listed below unless otherwise noted.

a (b) (6), M.D., an Ophthalmologist was hired on (b) (6), specializing in cataract surgery. Between February 2011 and the first cataract surgeries done at the HCC, he saw Veterans in the outpatient clinic area and assisted in equipment purchases and other operational start up for the ASC. At the time of his hire, this physician believed he would begin surgical work within a month or two of his start date. Instead, cataract surgery began approximately 11 months later. This Ophthalmologist's salary is $230,000 which is in line with ophthalmologists of his experience.

Summary and context: The allegation regarding this particular physician is partially substantiated. An eleven month delay from the time of hire of a cataract specialist to the first surgical procedure is too long. Some of the delays in start up of the ASC were related to uncontrollable events (i.e., Computerized Patient Record System (CPRS) transition, etc.). Mitigating this opinion is the fact that it can be challenging to recruit in the south Texas region and identifying a surgeon willing to work full time for the VA to perform a commonly needed service. Thus, when an opportunity to hire arises, it is reasonable to do so even if the timing is not optimal.

b. Another Ophthalmologist, (b) (6), M.D., was hired on (b) (6). This physician was hired to see Veterans in the outpatient clinic and neither performs nor intends to perform surgery in the ASC. He has continued to maintain his skills through practice in the clinic. This physician's salary is currently $237,500.

Summary: The allegation regarding this particular physician is not substantiated. He was hired in 2008 to perform ophthalmologist duties in the outpatient clinic and continues to do so to this date.

c. A physician specializing in Orthopedics, (b) (6), M.D., was hired on (b) (6). He has been employed by the VA for many years and was on board at the San Antonio VAMC prior to the VATVCBHCS separating from them. He is still a full-time VA employee with VATVCBHCS. His duty station is the Corpus Christi Outpatient Clinic, but he also conducts an Orthopedic Clinic in Harlingen every two weeks. He does not perform surgery in the ASC. His salary is currently $245,400.

Summary: Hiring too far in advance is not substantiated. This physician was a long standing VA employee who moved onto the VATVCBHCS staff when the facility separated from the San Antonio VAMC. Outpatient clinical service as provided by the orthopedic surgeon, despite lack of operative work, provides reasonable value to VHA.

d. (b) (6), M.D., a Gastroenterologist was hired on (b) (6). He was hired to establish an endoscopy service including upper and lower endoscopy (colonoscopy). Previous to this assignment this physician has been an employee of the VA for many years. Because of delays to begin this service at the HCC, he provided useful work and ongoing endoscopy services at the VA in San Antonio while at the same time helping the operational start of the services (outpatient clinic) at the HCC. He began providing endoscopy services in the late summer of 2011 with a growing workload of reasonable volume to date. This physician's salary is currently $252,500 which is in line with a gastroenterologist of his experience.

Summary: Hiring too far in advance is not substantiated. When delays in opening the endoscopy service occurred, reasonable and valuable other work was assigned that allowed this physician to maintain competency as a procedural gastroenterologist.

e. (b) (6), M.D., an Otolaryngologist (Ear, Nose and Throat – ENT) was hired on (b) (6). He had spent a long career in the private sector in the non-electronic medical record environment. He was found to be unable to keyboard and therefore use the VA electronic health records. Attempts at training did not improve his abilities and he resigned as of (b) (6). This physician was not available for interview. The total duration of employment for this physician who was found unable to keyboard could be viewed as too long. His salary was $246,500.

Summary: The allegation of hiring too far in advance was not substantiated. Outpatient clinic work by an ENT physician is quite valuable for Veteran care. The physician's inability to keyboard was not anticipated. Despite reasonable attempts to retrain, he was unable to perform

and resigned. The duration of employment, however, was too long, but represents efforts at remediation.

f. (b) (6), M.D., a Cardiothoracic Surgeon was hired on (b) (6) as the Chief of Surgery (ACOS for Surgery and Specialty Clinics). He had training and experience in both cardiothoracic and general surgery. He is considered a senior surgeon in the community and was hired to lead the development of the HCC surgical program. He was hired as a part-time physician (3 days per week) as he desired to maintain his private cardiothoracic surgery practice. After several months, he felt the time needed to devote to the VA was limiting his practice too much and elected to step down. He resigned on (b) (6). His salary was $300,000 which is less than usual salary for a cardiothoracic surgeon and pro-rated to his part-time status (total annual salary $225,000). Of note, the privileges requested and approved for this physician did not include cardiothoracic surgery procedures. This physician was not interviewed.

Summary: Hiring a senior surgeon known as a leader is a reasonable choice for the head of the developing surgical program and the time of his hiring was fully justifiable for the purpose of helping lead the ASC operation start up. There was no intent for him to perform cardiac surgery; however, there was intent for him to perform more minor general surgery.

Conclusion

While one physician was unable to practice for 11 months, the delay was reasonable due to uncontrollable events (Computerized Patient Record (CPRS) transfer) and recruitment issues as shown by personal interviews with most of the surgeons named, review of employee records, review of credentialing and privileging records, and direct viewing of procedure rooms. This allegation was partially substantiated.

Recommendations

None

Allegation #6:

VATVCBHCS leadership hired physicians in certain specialties, but in order to enhance their salaries or avoid licensing or certification problems, they were given titles that suggested they were performing other functions.

Findings

a. The whistleblower's title was changed from Associate Chief of Staff for Ambulatory Care to Associate Chief of Staff for Primary Care. His job duties were clearly defined in letters, e-mails and conversations with him and confirmed further in meetings with written documentation when his performance was less than satisfactory. His title was changed to more clearly identify his responsibilities. A title including the word "ambulatory" suggests oversight of all ambulatory

activities when his actual duties were confined to oversight of primary care and as needed, consultative work for the ACS.

Summary: The whistleblower's title change was reasonable and appropriate.

b. The whistleblower alleges he does not qualify for the position into which he was hired. He was hired to oversee primary care services from his stated experience of leading multispecialty groups of physicians. Thus, he was offered and accepted the position of Associate Chief of Staff for Ambulatory Care for his management and leadership skills, not his technical competency in a specific medical discipline. As quoted in the functional statement for his position, duties include responsibilities such as "the coordination and administration of patient care activities....the management of Primary Care and supervision of personnel...manages the operation of the service" along with other responsibilities commonly assigned to physician leaders. Counseling memos during his period of employment also provided clear detail as to his responsibilities. VHA Handbook 1100.19 does not limit Associate Chiefs of Staff to supervise physicians solely in their discipline. VHA Handbook 1100.19, paragraph 5.f states:

> (a) Physician service chiefs must be certified by an appropriate specialty board or possess comparable competence. For candidates not board certified or board certified in a specialty(ies) not appropriate for the assignment, the medical staff's Executive Committee affirmatively establishes and documents, through the privilege delineation process, that the person possesses comparable competence. If the service chief is not board certified, the Credentialing and Privileging file must contain documentation that the individual has been determined to be equally qualified based on experience and provider specific data. Appointment of service chiefs without board certification must comply with VHA policy for these appointments as appropriate.

Also noteworthy is that the Chief of Staff of the VATVCBHCS, (b) (6) , M.D., is a primary care physician; hence any clinical issues that were beyond the ACOS's capacity could be easily and competently judged by the Chief of Staff. Furthermore, the Chief of Staff was in the role of Chief Medical Officer (CMO) of a VA primary care site within the system prior to assuming the role of Chief of Staff and therefore was quite familiar with primary care operations.

Summary: The whistleblower is qualified for the role he assumed.

c. The whistleblower was required by the Chief of Staff (COS) to request privileges in Compensation and Pension (C&P), despite his lack of training. While his clinical background is uncommon for a physician performing C&P exams, these exams require skills only in obtaining historical information from Veterans, and performing a physical examination, and therefore could be done by a physician with past experience in anesthesiology with minimal further training. He was offered several training opportunities to gain the basic skills needed, but failed to complete the training.

Summary: It is reasonable for a COS to request an ACOS to obtain skills in C&P to assist in delivering these exams in a prompt manner for veterans.

d. The cardiothoracic surgeon, (b) (6) , M.D., was hired at a salary of $300,000 ($225,000 prorated for part-time status) commensurate with his role as Chief of Surgery. He was

given the title of ACOS for Surgery and Specialty Clinics as a leader of the stand up of the HCC. At the time of his hiring, too few medical specialties were hired to justify a separate Chief of Medicine; hence, he was given the role. This physician, despite not being an internist, was qualified to serve as a physician manager of a small number of medical or surgical specialists such as urology, ophthalmology or dermatology. There is no VHA Handbook or other document that prohibits supervision of one physician discipline of other physicians in other specialties. However, since he neither requested nor received privileges in cardiothoracic surgery, use of the pay table for cardiothoracic surgeons (Table 7, Tier 2) was not appropriate and (Table 4, Tier 3) for general surgeons would have been appropriate. Even within that pay table, this physician's salary was within an acceptable range.

Summary: This surgeon was not given a title to enhance his salary. He could function as a manager of physicians who were not cardiothoracic surgeons. His pay was commensurate with his responsibilities, experience and local market conditions although the wrong pay table was used for his salary determination.

Conclusion

There is no evidence of waste or fraud involved in the hiring practices of the facility as alleged by the whistleblower. The hiring practice at issue here concern the facility's timing of appointments, the titles granted tor appointed physicians, approved salary levels, and the competency and surgical skills of the physicians.

Recommendation

Future physician pay setting should be decided using pay tables consistent with the privileges they request.

Allegation #7:

It is alleged that because the facility was not able to support surgical specialties, the surgeons hired at the HCC were unable to perform surgery and/or were likely to lose surgical skills.

Findings

a. One ophthalmologist was hired approximately 11 months before resuming cataract surgery. Dr (b) (6) has extensive past experience as a cataract surgeon. He anticipated resumption of surgery within a few months of being hired; however, start up delays prevented him from operating. As of February 2012, he has successfully resumed surgery and performed six cataract extractions on the day of the fact finding. While his outcomes to date have been good, the facility should have instituted a system of observed or proctored procedures by another cataract surgeon from the community (if available) (Focused Professional Practice Evaluation (FPPE)) to assure patient safety. This physician was interviewed on the afternoon he performed cataract extractions.

Summary: Evidence that this physician had lost skill was not found, but the facility should have arranged for FPPE when he first resumed operating.

b. Another ophthalmologist mentioned by the whistleblower, (b) (6), M.D., sees veterans in the outpatient clinic and neither performs nor intends to perform surgery in the ASC. He continued to maintain skills through practice in the clinic. He was interviewed by the Team and reported these facts. Surgical privileges granted validate his report.

Summary: This ophthalmologist is not performing surgeries and continues to practice uninterrupted during his time at the HCC.

c. A part-time ophthalmologist, Dr. (b) (6) was hired on (b) (6) to practice ½ day per week and provide specialized retinal procedures. Initial retinal surgical procedures are planned to begin in February 2012. The whistleblower alleges that the types of procedures planned to be performed by this ophthalmologist are not performed in an ambulatory surgery setting but require inpatient or 23 hour observation settings. Per VHA Directive 2011-037, dated October 14, 2011, entitled *Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center* several types of surgery planned by the physician can be performed safely in an ambulatory surgery center such as the HCC. While patients with serious other medical diseases (heart, lung, etc.) may require 23 hour observation, these patients can be identified before surgery and the surgery performed at another site rather than the HCC. This ophthalmologist was interviewed during the course of the fact finding.

Summary: This ophthalmologist was hired to do procedures that can safely be done in an ambulatory surgery center and do not require inpatient care. Hence, her appointment was appropriate.

d. The cardiothoracic surgery skills of the cardiothoracic surgeon (b) (6), M.D were never intended to be used at the ASC as shown by his privilege request and privileges approved by the Chief of Staff. Some minor general surgical procedures were planned by him. This physician is not currently employed by the VA, so he was not interviewed; however, his past appointment, credentialing and privileging documents were reviewed.

Summary: This surgeon was hired for reasons other than performing cardiothoracic surgery.

e. The current Acting Chief of Surgery and Specialty Clinics, (b) (6), M.D., was hired on (b) (6). She is a general surgeon by trade. Prior to the opening of the ASC, she performed skin biopsies and other minor procedures in a procedure room on the second floor of the HCC. This room was observed and appeared to have been used with appropriate equipment. With the opening of the ASC she will perform more extensive general surgery that require more than local anesthesia. Removal of an elbow mass and a procedure on the anus was on the schedule during the fact finding visit. She was interviewed and her credentialing and privileging folder reviewed.

Summary: This surgeon has been performing biopsies in a second floor procedure room of the HCC and has patients scheduled for more complex general surgery as provided for in VHA Directive 2011-037 (identified above). The facility should consider FPPE for this general surgeon, factoring in the possible additional complexity and risk of procedures that nonetheless are considered minor in nature and able to safely be completed in an ambulatory surgery setting.

f. The issue with the ENT hired in (b) (6) was discussed previously in this report.

Conclusion

Although no atrophy of surgical skills is present, the facility should consider FPPE for the general surgeon. There was no waste, fraud, or abuse or risk to patient safety present.

Recommendation

As new surgical procedures begin at the ASC, surgeons without recent surgical experience should be observed operating to ensure competence.

Patient Care Concerns

Allegation #8:

It is alleged that in January or February 2011 (b) (6), M.D, the Chief of Staff and a former Director at VATVCBHCS ordered staff to cut by ten percent the number of specialty referrals of patients to private providers on a fee basis, for care not available at the facility. It is further alleged that requiring staff to cut specialty referrals by ten percent was arbitrary and ultimately harmful to patients who clearly needed medical care from the outside providers because it was not available within VATVCBHCS.

Findings

As background, VA is authorized under 38 U.S.C. § 1703 to contract with non-VA facilities to furnish hospital care and/or medical services to certain eligible veterans when VA facilities are either not capable of furnishing economical hospital care or medical services because of geographical inaccessibility or else are not capable of furnishing the care or services required. This authority, commonly referred to as "fee-basis" care, is in addition to VA's other contracting and "sharing" authorities (i.e., 38 U.S.C. §§§ 7409, 8111, 8153). By the terms of section 1703, VA cannot provide "fee-basis" care to an eligible veteran if VA determines it can provide the required care. Section 1703 also lists the veterans who are eligible to receive care under this section, the type of care, and the conditions for which they may receive non-VA care or services (e.g., service-connected conditions, hospital care for women veterans, etc.) Chiefly out of cost-control concerns, Congress has narrowly circumscribed the statutory eligibility criteria for fee-basis care. When appropriate and consistent with program requirements, providers will provide veterans with an individual authorization to obtain the specified care in the private sector at VA cost.

The Team verified that a goal to reduce fee basis costs by ten percent was a general goal of all of VISN 17, including the Harlingen Health Care System. The building of the HCC, which included space for specialty outpatient clinics and an ambulatory surgical center, reflects the facility's effort to provide care and services in-house that previously were referred for fee-basis care in the community. (The facility also seeks to limit referrals across the VA system by providing services in-house that would have otherwise been referred to the San Antonio VAMC). With respect to fee-basis care, the VATVCBHCS follows the standard VHA process for making and processing fee-basis care requests: the request is initiated by the clinician caring for the Veteran followed by approval or disapproval by a more senior clinician. Interviews with front line staff, including those who approve fee requests, (b) (6) , Chief, Medical Administration Service and (b) (6) , VISN 17 CFO, indicated that there was no mandate to disapprove fee requests. Rather, leadership at the facility identified areas with the highest fee-basis costs from prior years and identified interventions to decrease these costs while still ensuring good clinical care and exercising sound clinical judgment. For instance, data indicated that many fee-basis authorizations were indefinite in duration and therefore permitted more follow-up visits with the private-sector provider than were medically necessary. There is no medical literature evidence that a specific number of follow-up visits are required by specialists to improve medical outcomes. Therefore, efforts have been made by the facility to curb blanket, open-ended fee-basis authorizations for follow-up visits that lack sufficient medical justification. In all interviews with practicing clinicians, the Team asked if they had direct or indirect knowledge of any harm resulting to patients from the facility's efforts to reduce fee-basis program costs. No cases were identified or discovered during interviews and patient record reviews. Although it is alleged by the whistleblower that thousands of fee requests were not approved, the evidence is to the contrary. Specifically, the total spent by the facility for fee-basis care in Fiscal Year 2011 was $46,973,778 (comprised of 93,905 authorizations) compared to $33,781,416(comprised of 27,209 authorizations) in Fiscal Year 2010[1]

Conclusion

While the VATVCBHCS is focused on reducing costs related to fee-basis care, there is no evidence that the manner in which this is being undertaken is indiscriminant, unreasonable, or contrary to the standard of care. Providers are still required to exercise sound clinical judgment in determining whether the care or services required by their Veteran-patient is available in-house (or within the VA system) or instead suitable for referral under the fee-basis program.

Recommendation

None.

[1] Fiscal Year 2010 claims were obtained by separating those in the Coastal Bend area from San Antonio, as the TVCBHCS records were combined with the San Antonio records during part of the year.

Allegation #9:

It is alleged that VATVCBHCS lacked an adequate care management system to coordinate care between VA providers and fee-basis providers. The allegation further indicates that most patients referred for fee-basis care were never seen as the letter notifying the Veteran of approval of care was never received.

Findings

Clinicians providing care through referrals to fee-basis care, including those approving care, were interviewed regarding this allegation. The Team found that the VATVCBHCS has an established process to coordinate care. The fee-basis provider is required to give the referring clinician a hard copy report of the private clinical care results, which has been initialed by the non-VA provider. The report is then scanned into the VA electronic medical record and the Veteran's VA provider is notified electronically that the scanned document is available for review. Thus, providers receive two notifications of the fee-basis care results. While this process is not 100% reliable, there was evidence found in reviewed medical records that this process did occur. As to the second allegation, the Team found that the majority of fee-basis notification letters were received by veterans. This is underscored by the fact that the fee-basis program costs remain significant at the facility, indicating most veterans were aware of their ability to obtain the authorized care in the private sector. Also, no VA provider interviewed was aware of a significant number of patient complaints about this issue. Some providers acknowledged that incorrect Veteran addresses have led to incorrect mailings of their notice letters, but that this was not a common occurrence or a systemic problem. Indeed, providers at TVCBHCS appear not to be reticent about informing management of any perceived or actual delays in the provision of fee-basis care to their patients.

Conclusion

The allegation that the VATVCBHCS lacks an adequate system to coordinate care between fee-basis and VA providers was not substantiated. The Team also did not substantiate the allegation that the facility failed to provide veterans with notice they had been authorized to receive certain care through non-VA providers. While there likely were a few instances were letters were not received by patients (due to veteran address changes) the majority of patients were notified appropriately about their fee authorizations.

Recommendation

The VATVCBHCS leadership indicated during interviews that, on its own initiative, it has begun to develop a more comprehensive coordination of care process for fee basis appointments and provider notification. It is recommended that this new process be completed and implemented as soon as possible.

Allegation #10:

It is alleged that Veterans had difficulty locating private physicians willing to accept the VA fee referral.

Findings

Based on interviews with community hospital representatives, we found that a small number of private sector providers were refusing care for VA patients, including an orthopedic surgeon. Some VA providers stated that some patients do encounter physicians in the community who will not accept the VA referral because of delays in VA reimbursement. However, no VA provider stated their patients were unable to receive care as a result of those refusals; rather the veterans simply had to choose another private sector physician from whom to receive their care. Even in such cases, VA providers knew of no case resulting in a delay of necessary or urgent care to the Veteran.

Conclusion

This allegation was not substantiated.

Recommendations

None.

Allegation #11:

VATVCBHCS stopped sending patients for colonoscopies in the summer of 2010 because they could not afford non-VA providers and elected to use the Fecal Occult Blood Test (FOBT) instead of colonoscopies.

Findings

a. While a private sector gastroenterology contract was not renewed during this period, referrals for screening colonoscopies continued via the fee basis mechanism during this time. During Fiscal Year 2011, an average of 81 screening colonoscopies were conducted each month by private providers with a total of 977 for the entire fiscal year.

b. The VHA Directive, dated January 12, 2007, entitled *Colorectal Cancer Screening* states that:

Screening Options include:

(a) Home FOBT alone every year (three consecutive stool samples).
(b) Flexible sigmoidoscopy alone every 5 years
(c) Home FOBT every year combined with flexible sigmoidoscopy every 5 years
(d) Double contrast barium enema every 5 years
(e) Colonoscopy alone every 10 years

It states that "Each method has advantages and disadvantages but none has clearly been proven to be superior. The choice of specific screening strategy (absent medical contraindications to a particular method) needs to be based on patient preferences".

The Directive further requires the following action: "Veterans are informed about different options for colorectal cancer screening, including the option of no screening. They need to make a shared decision with their provider. This may be accomplished through a variety of methods, such as discussing one-on-one with the clinician, or providing a brochure or video about screening choices. The practitioner may recommend any one of the five screening options (identified above), but the veteran has the option of rejecting the recommended method and instead choosing one of the other four alternatives, or none".

In addition, the VHA National Center for Health Promotion and Disease Prevention has published a guidance document on colorectal cancer screening that states acceptable forms of screening are:

> Fecal Occult Blood Test (FOBT) annually with
> FDA approved guaiac-based (gFOBT);
>
> Or
>
> FDA approved fecal immunochemical (*i*FOBT/FIT);
> Sigmoidoscopy every 5 years with or without mid-interval FOBT
> Colonoscopy every 10 years

(http://vaww.prevention.va.gov/Clorectal Cancer Screening.asp)

The guidance further states that "There are multiple acceptable methods of CRC screening that have similar efficacies. These tests include gFOBT, *i*FOBT, sigmoidoscopy and colonoscopy".

When the use of either tool would be medically appropriate in a particular patient's case, the Veteran is given the choice of a FOBT versus colonoscopy. This is reasonable and in line with the medical literature. While colonoscopy is likely to detect more precancerous polyps or actual cancers, the procedure has inherent risks, including bowel perforation which is known to be more common in patients with significant medical co-morbidity. Thus, the benefit of more likely identification of pathology via colonoscopy is offset by inherent risks of the procedure, particularly in the population of Veterans who choose VA services, which is known to have a high disease burden. Contrary to the whistleblower's allegations, VATVCBHCS policy regarding colorectal cancer screening does not state that FOBT must be done first and providers interviewed did not indicate that such a mandate had been given to them. While a single e-mail provided by the whistleblower from a primary care clinical leader suggests FOBT *should* be done first, other clinical leaders and the Chief of Staff were emphatic that no policy exists which requires them to first use FOBT (or to require the completion of 3 tests before being able to order a colonoscopy) Again, VA providers are first and foremost required to adhere to the standard of care in this area and offer only what is clinically appropriate for the individual patient (with the

patient's full and informed consent) and there was no indication that the providers departed from the standard of care. On record review, however, no chart was found that indicated a Veteran was informed of his or her choice of type of screening tool. Complete documentation of all education and information given to patients is not required and the lack of it in the patient record does not suggest that the conversation/education did not take place. The number of screening colonoscopies has not changed significantly at VATVCBHCS, thus demonstrating that screening colonoscopy via referral to the private sector has continued unabated. Finally, the building of the HCC with a procedure clinic for the purpose of performing screening exams (including colonoscopy) demonstrates that the facility is dedicated to making the procedure available in-house to veterans.

Conclusion

These allegations were not substantiated.

Recommendation

None.

Discontinuation of Patient Records in Advance of the Joint Commission Visit

Allegation #12:

(b) (6), M.D., the Chief of Staff directed his administrative assistant, (b) (6), to alter the records of approximately 2000 VATVCBHCS patients, in order to conceal a backlog of patients who had not been seen for follow-up treatments. It is also alleged that the discontinuation of these records was to avoid a negative finding by the Joint Commission.

Findings

The VATVCBHCS was administratively separated from the San Antonio VA as of October 1, 2010. VA Information Technology (IT) directed VATVCBHCS to build new electronic medical records for its patients in their newly formed computer system. Almost all of these patients had received care through the larger system; hence, extensive electronic medical record data already existed. To create the new records at the facility level, VATVCBHCS implemented an elaborate process utilizing clinical staff to re-create the new records. Clinical staff were given time and dual monitors to do this work. Dual monitors were seen throughout the HCC and providers verified the time and labor of this work. A significant number of electronic consultations remained incompletely resolved after 90 days from the date of referral. (The actual number was approximately 1800, not the alleged 2000.) This appears due to a host of reasons that are largely administrative in nature, not clinical. For instance, most consultations remained unresolved or uncompleted because: 1) they were subjects of duplicate referrals; 2) they had not been closed administratively although the clinical care was in fact delivered; 3) they had not been closed because the Veteran failed to show either due to lack of interest or intervening health issues that obviated the need for the referral or resulted in the referral being contraindicated or deemed

unnecessary by the Veteran's provider. In those cases where staff could not find evidence that the specialty care was delivered per the consult request, the Veterans' primary care physician was notified and asked to make a determination as to whether the consult was still required. Thus, front-line clinicians, who are most familiar with their patients' care, were being asked to determine if new consultation requests would be entered in the new electronic health records system. Evidence provided by the whistleblower (copies of VA electronic medical records notes) and independent review of records by the Team demonstrated that this process has in fact occurred. To date, two consults out of the total of 1800 are still pending additional information. The facility here has chosen to both clean up older consultations by examining each record and by formally closing the old consults when there was evidence that the care had been delivered. There was no evidence to support the allegation that the facility's discontinuation of the consults at issue here resulted in harm or delay of needed (or urgent) care to patients. The Team discovered no cases where patients were adversely affected by the need to re-issue the consult request. Contrary to the allegation, we found that the consults were not flatly discontinued or done by blanket action. Lastly, we found no evidence that the discontinuation of consults was undertaken to hide delays in care from inspectors during an upcoming inspection by the Joint Commission.

Conclusion

This allegation was not substantiated.

Recommendations

None.

Allegation #13:

It is alleged that records were lost as a result of the process identified in allegation #12.

Findings

Based on interviews with front line providers and the Chief Health Information Officer, (b) (6) (b) (6) the facility has no knowledge of any records being lost. The process described above explains how a duplicate record has been created for each Veteran in the new electronic health record system of the newly established facility. Yet, this process merely duplicates information in the original parent facility's electronic record system. Records are never deleted from the prior system.

Conclusion

This allegation was not substantiated.

Recommendation

None.

Outstanding VA Debt to Private Providers Compromises Patient Care

Allegation #14:

Local private providers in the Texas Valley/Coastal Bend region are owed millions of dollars for providing fee-basis referrals under contracts with VATVCBHCS and that this debt compromises patient care.

Findings

As discussed above, when VA is not capable of providing the required care or providing the required care or services economically due to geographic inaccessibility, VA may authorize the Veteran in advance to receive the care through a private sector provider, pursuant to VA's Fee-Basis authority and implementing program rules. In cases involving the unauthorized provision of emergency treatment to veterans by non-VA providers, VA has authority to reimburse or pay for that treatment under 38 U.S.C. §§ 1725 (emergency treatment for non-service connected disabilities) and 1728 (emergency treatment for service-connected disabilities). In cases involving authorized fee-basis care or emergency care furnished for service-connected disabilities under 38 U.S.C. 1728, VA pays or makes reimbursement pursuant to the terms of VA's payment regulations codified at 38 CFR §§ 17.55 and 17.56. Payment or reimbursement of costs related to the provision of non-VA emergency treatment for non-service connected disabilities under 38 U.S.C. § 1725 is made pursuant to 38 CFR § 17.1005. Care provided outside of the fee-basis program under a sharing agreement or contract is paid in accordance with the terms of the negotiated agreement. Discussions with facility officials responsible for fee-basis payment/ reimbursement, (b) (6), Chief, Medical Administration Service and (b) (6), VISN 17 CFO, and the two largest community providers of fee-basis services indicated that there is a problem with untimely reimbursement and the billing/invoice process between the VA and the community providers. Identified problems include residual issues resulting from the separation from the San Antonio VAMC such as duplicate requests, incorrect tax identification numbers, questions about the usual and customary charges being requested, and claims under appeal. VATVCBHCS is using another VISN's billing office for the processing of payments, which should eliminate many of the identified problems. Leadership is also increasing the level of communication with community providers and the larger community healthcare systems that provide care to veterans on a contractual or fee-basis, addressing individual complaints as received, and reviewing outstanding accounts receivable on a daily basis. Most critical, the Team did not identify any harm to patient care as a result of the identified billing problems. All of the documents reviewed, including patient records, and interviews with both VA providers and leadership of community healthcare providers did not reveal any circumstance in which patient care was harmed or compromised in any manner by VA's failure to pay the non-VA providers in a timely fashion. Some fee-basis providers may have indicated to the VA or the community healthcare providers their desire to discontinue seeing Veteran patients because of delays in receiving VA reimbursements, we are unaware of

any occasion when those providers ever refused to see a VA patient. In almost every case, although they complained to the VA and/or the community healthcare system, they have continued to accept VA patients for service. Finally, fee-basis claim data as of February 2, 2012, shows that VATVCBHCS has recently processed over 14,000 claims, providing direct evidence that the facility is progressing in catching up on payment of old claims. We note that the provision of the Prompt Payment Act (PPA), 31 U.S.C., chapter 39 were not met when these bills were not paid within the timeframes specified in the contracts; however, appropriate remedy was provided when the amount of interest required was automatically added to the amount owed on issuance of payment. The PPA does not apply when there are errors on invoices submitted by contractors.

Conclusion

The allegation that VATVCBHCS owes a substantial amount of money to fee providers in the community was partially substantiated, but we found no evidence this issue has adversely affected veterans' access to care or receipt of quality care by non-VA providers. Review of medical records and documents and, interviews with multiple VA staff (including leadership, providers, and administrative personnel responsible for administering the fee-basis program) did not reveal any instance where these problems comprised patient care or prevented patients from receiving needed care in the community. Moreover, the facility is diligently working toward improving the timeliness of its payments to non-VA providers and continuing with its follow-up efforts to improve its billing and payment practices. Violations of the PPA for care furnished by contract when payments were not paid in the agreed upon timeframe was found; however, appropriate remedy was provided upon payment when the required interest was added.

Recommendations

1. Continued efforts should be made to decrease the backlog of outstanding claims for fee-basis services.

2. Communication with community providers and health care systems should be continued/increased, including face-to-face meetings, status reports and development of a dispute resolution process to address, among other things, long standing debts.

3. VHA's Office of Compliance and Business Integrity should, in concert with the Integrated Ethics program, conduct a Focused Review at the facility and, if necessary and as appropriate, assist in implementing any identified corrective or improvement measures.

IV. (Continued) Brief Summary of the Evidence Obtained from the Investigation

Inadequate Facilities at Harlingen Health Care Center:

The allegation that the HCC lacked a Heating, Ventilation and Air Conditioning (HVAC) system adequate to control humidity in the operating theatre was not substantiated as the surgical unit is serviced by a dedicated HVAC system that is designed to control humidity in the operating theatre. The allegation that the HCC lacked back-up generators was not substantiated. The HCC is serviced by a 1,600 Kilowatt diesel fueled generator with automatic transfer switches. The generator is sufficiently sized to provide emergency electrical power to the HCC in the event that utility provided power is interrupted. The allegation that the HCC was poorly designed in that the distance between the operating rooms and recovery rooms was too great, and the 20 separate recovery room bays each had four walls, was not substantiated as the Surgical and Recovery areas are directly adjacent to each other on the third floor of the Harlingen HCC. VA Design Publications provide guidance with respect to functional relationships and their proximity to each other, but do not specifically address or limit distances. Furthermore, the VA Outpatient Clinic Guide Plate states that, "The Guide Plates are not intended to be project specific and are not meant to limit design opportunities". The allegation that the facility was unable to support any surgical procedures and perform sterilization of equipment was not substantiated as both the Surgical and SPD areas are served by AHU -1. AHU – 1 and the distribution system were designed to provide the required air exchanges per VA criteria as well as satisfying temperature and humidity requirements (refer to allegation # 1). In addition, the ventilation system in the Surgical Suites is configured to support a "sterile" operating field. The SPD area ventilation distribution system is designed to provide VA required air exchanges, temperature and humidity and room air balances (pressure relationships) between different functional spaces. The Harlingen HCC Sterile Processing Department did have steam, gas plasma and scope sterilizers which are capable of sterilizing the reusable medical equipment (RME) at the Harlingen clinic as well as a cart washer and sonic instrument cleaner.

Surgical Staff Hired but Unable to Practice:

The allegation that surgeons were hired but were unable to practice is not substantiated as shown by personal interviews with most of the surgeons named, review of employee records, review of credentialing and privileging records and a direct viewing of procedure rooms. While some minor findings were discovered, there is no evidence that the hiring practices at the facility, including timing of entrance on duty, titles granted, salary levels approved and alleged atrophy of surgical skills is present. Nor did the Team find any hiring practices there that constitute a violation of any law, rule, or regulation; or gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Patient Care Concerns:

The allegation that records were discontinued in advance of a Joint Commission visit is not substantiated. The facility was required to re-create a record system and took reasonable steps to do so in a manner that was oriented toward patient safety. No records were lost and consultations were discontinued for valid reasons, with clinician judgment guiding the entire process.

Discontinuation of Patient Records in Advance of the Joint Commission Visit:

The allegation that records were discontinued in advance of a Joint Commission visit is not substantiated. The facility was required to recreate a record system and took reasonable steps to do so in a manner that was oriented toward patient safety. No records were lost and consultations that were discontinued were done so for valid reasons with clinician judgment guiding the process.

Outstanding VA Debt to Private Providers Compromises Patient Care:

The allegation that VATVCBHCS owes a substantial amount of money to fee providers in the community was partially substantiated, but we found no evidence this issue has adversely affected veterans' access to care or receipt of quality care by non-VA providers. Review of medical records and documents and, interviews with multiple VA staff (including leadership, providers, and administrative personnel responsible for administering the fee basis program) did not reveal any instance of these problems compromising patient care or preventing patients from receiving needed care in the community. Moreover, the facility is diligently working toward improving the timeliness of its payments to non-VA providers and continuing with its follow-up efforts to improve its billing and payment practices. Violations of the PPA for care furnished by contract when payments were not paid in the agreed upon timeframe was found; however, appropriate remedy was provided upon payment when the required interest was added.

V. A Listing of Any Violation or Apparent Violation of any Law, Rule or Regulation

After investigating the multiple allegations, the Team found the provisions of the Prompt Payment Act (PPA), 31 U.S.C. chapter 39, were not met when the provider bills were not paid within the time-frames specified in the contracts; however, appropriate remedy was provided when the amount of interest required was automatically added to the amount owed on issuance of payments.

While not a violation of law, rule, or regulation, the Team also found that VHA Handbook 1100.19, November 14, 2008, *Credentialing and Privileging*, paragraph 6g was not followed when the facility did not require surgeons without recent surgery experience to undergo a Focused Professional Practice Evaluation (FPPE).

The Team did not find gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

VI. Description of Any Actions to be Taken as a Result of the Investigation

Any actions to be taken by the facility or Department as a result of this investigation are addressed in the recommendation of the report, below.

1. As new surgical procedures begin at the ASC, surgeons without recent surgical experience should undergo focused professional practice evaluation while operating to ensure competence

2. Future physician pay should be decided using pay tables consistent with the privileges they request.

3. The VATVCBHCS leadership indicated during interviews that they are working on a more comprehensive coordination of care process for fee-basis appointments and provider notification. It is recommendation that this new process be implemented as soon as possible, but also coordinated with the national VHA effort to improve fee basis processing.

4. Renewed efforts should be made to decrease the backlog of outstanding claims for fee basis services.

5. Communication with community providers and health care systems should be continued/increased, including face-to-face meetings, status reports and development of a dispute resolution process to address, among other things, long standing debts.

6. VHA's Office of Compliance and Business Integrity should, in concert with the Integrated Ethics program, conduct a Focused Review of the facility and, if necessary and as appropriate, assist in implementing any identified corrective or improvement measures.

Attachment

Documents Reviewed

Schematics for Air Handling Unit-1 (AHU-1)

Plan excerpt from Approved Construction Drawing M5.1.1 dtd. 10/2/2009, AHU-1

Skyline Air Handling Unit Technical Data Sheet (AHU-1 30k), McQuay International, 13/10/2009, www.mcquay.com

HVAC Design Manual, dated February 2008, Department of Veterans Affairs, Office of Construction & Facilities Management, Facilities Quality Service

Emergency & Normal Power – Riser Diagrams, Harvey-Cleary Builders, dated 4/23/2010

Generator Technical Data Sheet, Kohler Power Systems, Model: 1600REOZMB

Electrical One-Line Diagram Generator Distribution

Typical OR Ceiling Ventilation – Plan View, Plan excerpt from Approved Drawing M3.31 dtd. 11/20/2009

Air Handling Unit AHU-1, Schematic excerpt from Approved Construction Drawing M9.1.4 dtd. 11/20/2009

Technical Data Sheet, AMSCO Evolution Steam Sterilizers

Technical Data Sheet, Sterrad 100NX Sterilizer

Technical Data Sheet, AMSCO Century Small Sterilizers

Technical Data Sheet, AMSCO Sonic Energy Console with Rinsing and Drying Systems

Technical Data Sheet, Medivators Advantage Plus Endoscope Reprocessor Model 2.0

Technical Data Sheet, Reliance 130L Load/Unload Modules

VA Outpatient Clinic Design Plates, Standards and Equipment Lists

VA Outpatient Clinic Functional Diagrams

Post Anesthesia Recovery Room Diagram

Design Contract Documents – delineation of applicable codes and standards

Construction Contract Documents – delineation of applicable codes and standards, applicable specifications for Electrical, HVAC, Steam Systems

Contract Documents for Commissioning Contractor

Approved As-Builts – Floor Plans

History of all Utility Systems Failures (by system) from October 2010 through January 31, 2012

VA Approved Submittals for: (A/E, Facility/RE) – approval sheets. Steam Generator and all associated safeties

Utilities System User Training Program PM 138-10-13

Hazard Reporting Program, Utility and Equipment SOP 07-15, 1/2/07

Preventative Maintenance of Equipment and Utility Systems SOP 07-05, 1/2/07

Engineering Service Utilities Criteria SOP 07-03, 1/2/07

Shutting Off Malfunctioning Critical Utilities and Who to Notify SOP 07-40, 1/2/07

Certificate of Occupancy from Authority Having Jurisdiction

Stamped Design and As-built Drawings by Registered Engineer

Completed HVAC Data Spreadsheet

Approved As-Builts – Ventilation Plans; for second and third floors

VA Approved Submittals (Showing Contractor and A/E reviews); HVAC Units (Supply air, Return air, Exhaust air) serving second and third floors

Temperature, Humidity, CFM Supply, CFM Return, CFM Exhaust, Relative Humidity histories from October 2010 through January 31, 2012 for the following areas: Ambulatory Surgery: Operatories, Cystoscopy, Service Corridors, Clean/Sterile Supply Storage, Dirty/Soiled Storage; Supply Processing & Distribution: Decontamination, Sterilization, Clean-Sterile Storage/Holding; Gastrointestinal (GI & GU): Procedure Rooms, Patient Prep and Post Holding, Scope Cleaning, Sterilization; Post Anesthesia Care Unit: Pre/Post OOP, Clean/Sterile Supply, Dirty/Soiled Storage

Quarterly Reports to EOC Committee on inspection, testing, and maintenance activities related to Heating, Air Conditioning, and Ventilation (HVAC) Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

Quarterly Reports to EOC Committee on program effectiveness and identified issues related to Heating, Air Conditioning, and Ventilation (HVAC) Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

Minutes from Joint Leadership Council summarizing the quarterly reports on inspection, testing, and maintenance activities related to Heating, Air Conditioning, and Ventilation (HVAC) Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

Minutes from Joint Leadership Council summarizing the quarterly reports on program effectiveness and identified issues related to Heating, Air Conditioning, and Ventilation (HVAC)

Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

Approved As-Builts – Emergency Electrical Systems Plans

VA Approved Submittals (Showing Contractor and A/E reviews): Generator Unit, Fuel System, Prime Mover, Transfer Switches, Cooling System

Environmental Permits

Risk Assessment for Essential Electrical System and associated components

Testing of the Systems Emergency Diesel Generators SOP 07-17, 1/2/07

Inspection, Testing and Alignment of Primary and Secondary Electrical Switchgear SOP 07-16, 1/2/07

Inspection and Testing of Electrical Receptacles and Grounding Systems SOP 07-21, 1/2/07

Emergency Electrical Plan SOP 07-07, 1/2/07

Generator-Prime Mover inspection and testing records from October 2010 through January 31, 2012

Transfer Switch Inspection and testing records from October 2010 through January 31, 2012

Quarterly Reports to EOC Committee on inspection, testing, and maintenance activities related to Emergency Electrical Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

Quarterly Reports to EOC Committee on program effectiveness and identified issues related to Emergency Electrical Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

Minutes from Joint Leadership Council summarizing the quarterly reports on inspection, testing, and maintenance activities related to Emergency Electrical Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

Minutes from Joint Leadership Council summarizing the quarterly reports on program effectiveness and identified issues related to Emergency Electrical Systems from October 2010 through January 31, 2012 (*ref. Utility Systems Management Plan 001-10-46*)

VHA Handbook 1100.19, November 14, 2008, *Credentialing and Privileging*

VHA Directive 2011-037, October 14, 2011, *Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center*

VHA Directive, January 12, 2007, *Colorectal Cancer Screening*

Organizational Chart, VA Texas Valley Coastal Bend Health Care System, Health Care Center at Harlingen

Organizational Chart, VA Texas Valley Coastal Bend Health Care System, Surgery & Specialty Service

The Joint Commission Summary of Findings, VA Texas Valley Coastal Bend Health Care System