

**UNIVERSITY OF CALIFORNIA, DAVIS  
INTERNAL AUDIT SERVICES**

**University of California, Davis Health System  
Blood Products Management  
Internal Audit Services Project #14-19**

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## MANAGEMENT SUMMARY

### BACKGROUND

Transfusion Medicine (Blood Bank) is part of the Clinical Laboratory in the Department of Pathology and Laboratory Medicine (Department). Blood Bank has 24 FTE and a FY2013 budget of \$34.3 million in revenues and \$14.7 million in expenses. Blood Bank's revenues come from fees for tests and procedures performed to match appropriate blood products to a patient. To improve efficiency, Blood Bank changed the methodology it uses to perform cross-match testing in FY2013. The new tests are priced lower than the previous tests, resulting in FY2013 revenues that were \$13.7 million (40%) lower than budgeted. Total FY2013 expenses for Blood Bank were \$13.8 million, approximately 7% less than budget. Most of Blood Bank's expenditures are for supplies. FY2013 blood products expenses equaled \$10.3 million, over 75% of total Blood Bank expenditures, including salaries and benefits.

Blood Bank has a contract with BloodSource to supply blood products. The contract calls for Blood Bank to prepay BloodSource a flat fee per month, and enables Blood Bank to return expired blood products for credit. BloodSource sends semi-monthly invoices that detail the actual products delivered and returned. BloodSource also sends a quarterly reconciliation report that compares the monthly prepayments to Blood Bank's actual usage. Department administrative staff verifies the invoiced and paid amounts in the report. To balance the account, BloodSource sends either an invoice or a check with the reconciliation report.

Blood Bank previously held their inventory of blood products on consignment from BloodSource. A contract amendment executed in March 2013 changed the terms of the agreement to transfer ownership of the blood to Blood Bank. However, their ability to return expired products for full credit remained unchanged.

Blood Bank uses a module of the Department's Laboratory Information System (LIS), to monitor blood products on hand and to receive patient orders from and transmit results to the health system electronic medical record system (EMR). Blood Bank is collaborating with Information Technology in creating a Transfusion Registry database that will help monitor and improve blood product utilization.

Blood Bank is accredited by the American Association of Blood Banks (AABB). The AABB has strict standards for accreditation and performs onsite inspections every two years to evaluate compliance. The FDA regulates blood, blood products and related equipment and inspects the Blood Bank facility at least every two years. Both of these inspections focus on the handling and storage of blood products, policies and protocols. The Transfusion Committee, consisting of physicians, residents and other medical staff involved in clinical operations, also oversees Blood Bank. The committee is charged with developing and recommending policies concerning transfusion of blood and blood constituents, ascertaining adherence to these policies, reviewing blood transfusions for proper utilization, and reviewing adverse reactions following transfusions. In addition, Blood Bank has established a Utilization Committee responsible for identifying internal projects and ideas to impact the utilization of blood products. The Blood Bank Continuous Quality Improvement

(BBCQI) committee and the Clinical Pathology Continuous Quality Improvement (CPCQI) committee oversee quality control and improvement monitoring activities for Blood Bank.

### **PURPOSE AND SCOPE**

We reviewed the financial and operational management processes of Blood Bank as part of our FY2014 audit plan. The purpose of the audit was to evaluate processes and procedures for monitoring and controlling blood products to ensure transactions are properly approved, recorded and appropriate, and to look for opportunities to improve economy and efficiency.

Our review covered Blood Bank transactions for FY 2013. We assessed the processes Blood Bank uses for ordering and receiving blood and blood products, maintaining the stored blood inventory, selecting vendors, and approving purchases and invoices. We reviewed relevant FDA, AABB, university and hospital policies and procedures and interviewed Blood Bank and department administrative personnel. We also spoke with UCD Medical Center representatives from Purchasing, Financial Services Administration, and Patient Financial Services. We tested the accuracy of Blood Bank's inventory records and reviewed a sample of operating transactions for accuracy and compliance with policy. We also tested a sample of patient charges for accuracy and completeness and reviewed implementation of Blood Bank's corrective actions in response to recent reviews by the AABB and the FDA. Finally, we examined the reports and procedures Blood Bank management uses to monitor operations.

### **CONCLUSION**

Blood Bank has well established processes and protocols to monitor and control blood products and testing and maintain a high-quality facility. We concluded that these processes are appropriate to control Blood Bank's daily operations. We also concluded that there are opportunities to improve inventory procedures and separation of duties, increase the effectiveness of invoice approvals and transaction reviews, enhance monitoring of corrective actions from accreditation and regulatory inspections, and improve document control.

Our observations and recommendations are presented in the body of this report along with corresponding management corrective actions.

## OBSERVATIONS, RECOMMENDATIONS, AND MANAGEMENT CORRECTIVE ACTIONS

### 1. BLOOD PRODUCT INVENTORY

#### **Inventory procedures should be implemented.**

Blood Bank has not performed a physical inventory of stored blood products, although the stored products have an average value of almost \$200,000. The blood products previously belonged to BloodSource and were sent to Blood Bank on consignment. As the owner of the products, BloodSource performed all physical inventories. In March 2013, the contract between BloodSource and UCDMC was amended to switch ownership of the products to Blood Bank, although Blood Bank's ability to return expired units for credit did not change.

UCD policy PPM 350-60 and UCDHS policy 2278 specify that all major supply inventories are to be verified by physical count on an annual basis, on or as close to June 30 as possible. Once the physical count is complete, the department head or designee must prepare a statement of inventory valuation addressed to the external auditors. Major supply inventories are defined as departmental inventories with a value in excess of \$50,000. The value of the blood stored by Blood Bank varies from day to day. However, tests during this audit calculated an average value over \$196,000, far exceeding the \$50,000 threshold of the policies.

A physical count of supply inventory serves to detect discrepancies in the electronic inventory record from errors or other loss. Failure to conduct the physical inventory increases the risk that errors or losses would go undetected, which could result in a shortage when products are needed.

#### **Recommendation**

Blood Bank should implement an annual physical inventory of its stored blood products.

#### **Management Corrective Actions**

The Department of Pathology will add the blood products to its inventory schedule. The next supply inventory is due by June 30 2014 and will include all blood products.

### 2. FINANCIAL REVIEW

#### **Expense monitoring could be improved.**

Invoices for blood products purchased and credited are approved without a detailed review. The Blood Bank supervisor does not verify the individual charges and credits before certifying that the BloodSource invoice is correct and all products listed were received.

The semi-monthly BloodSource invoices are over 65 pages long and contain hundreds of lines, including charges belonging to transplant and bone marrow recipient testing as well as Blood Bank charges and return credits. The Blood Bank supervisor reviews the summary of charges and credits and may occasionally check a charge, but does not routinely perform a more thorough

review. In addition, the Department has not performed general ledger reviews due to their belief they do not have proper separation of duties for an effective review. One of the analysts in the Department is the delegated purchaser, and the other processes the invoices. Therefore, neither has the necessary independence to do the monthly review of the general ledger.

The UC Accounting Manual sections A-000-7 and D-371-36 require a departmental receipt certification recorded on an invoice or a receiving report be obtained before Accounts Payable pays an invoice. To further monitor expenses, UCDHS Policy 1817 and UCD PPM 330-11 require that all departments use the general ledger review function to review and certify their ledgers monthly. These policies also state that departments should take appropriate action to correct all errors in the general ledger. Failure to provide adequate financial monitoring increases the risk that errors will go undetected, which can result in overpayments, missed credits and payments for items not received.

### **Recommendation**

Blood Bank should ensure that all invoiced units were received and returned units credited. In addition, Blood Bank should ensure that general ledger reviews are performed and certified and that any errors are promptly corrected in accordance with University policy.

### **Management Corrective Actions**

1. The Blood Bank supervisor will implement a review process by January 15, 2014 to compare a sample of invoiced charges with the products delivered to verify accuracy and to verify that all credits were posted .
2. General ledger reviews will be done per hospital policy, beginning with review of the November report, which will be completed by December 31, 2013.

## **3. SEPARATION OF DUTIES**

### **Separation of duties in cash receipts should be improved.**

When BloodSource sends a refund check to Blood Bank, at times a single staff member has possession of the check, prepares and approves the deposit and takes the deposit to the cashier.

UCD PPM 330-11 states departmental administrative duties shall be separated so that one person's work routinely serves as a complementary check on another's work, and no one person has complete control of a financial transaction. The current assignment of duties gives one staff member control over all parts of the deposit transaction. Failure to provide the proper separation of duties increases the risk that errors and/or irregularities will go undetected.

### **Recommendation**

Blood Bank should separate possession of the check, preparation of the deposit, and delivery to the cashier, or institute mitigating controls.

**Management Corrective Actions**

By January 15, 2014, the Department will instruct BloodSource to refund overpayments via electronic funds transfer beginning with the FY2014-Q1 reconciliation. In the event that BloodSource issues a paper check, the recipient in the Department will endorse the check and request a cash receipt document from the department's financial analyst. The financial analyst will forward the completed cash receipt document to the recipient who will then deliver both the check and the cash receipt document to the UCDHS Cashier.

**4. DOCUMENT CONTROL****Controls over versions of policies and protocols could be improved.**

There is no central repository that properly separates current and draft versions of Blood Bank policies and protocols. The policies and protocols are kept in several different network folders and in hard copy. Some hard copies have sticky notes and hand edits to indicate changes. Others were revised by a vote in a Transfusion Committee meeting without any other notice.

Blood Bank has numerous policies and protocols. Some are attached to UCD Medical Center policies, whereas others are only for internal purposes. The policies, and especially the protocols, change frequently as Blood Bank implements new research and best practices. Blood Bank has established folders for draft and approved policies and signing sheets where staff members attest they have read and understand revised policies and procedures and meeting minutes. However, the folders contain duplicate and out of date files, and no one verifies that all appropriate staff members have read the minutes and signed the attestation sheet. In addition, Blood Bank does not have a list of UCD Medical Center policies wherein Blood Bank policies are referenced or attached and is unable to ensure that all external copies are kept up to date.

AABB Standard 6.1.5 requires an accredited facility to have a process for document control that ensures the use and availability of only current and valid documents at all applicable sites. The existence of multiple versions of policies, procedures and protocols could lead to inefficient utilization of blood products or an error in patient treatment. In addition, the AABB has cited Blood Bank for violations of this standard. Continued violations could result in the loss of AABB accreditation.

**Recommendation**

Blood Bank should implement procedures to ensure all internal and external policies are current and to track and clearly separate current and draft versions of internal policies and protocols.

**Management Corrective Actions**

Blood Bank will make document control improvements in phases:

1. Beginning January 15, 2014 verify that staff members have read the policy changes and meeting minutes in a timely fashion ;
2. Verify all Blood Bank policies available in external departments are the current version by February 1, 2014;

3. Remove all old versions of the policies, procedures and protocols and change the most current versions to PDF format for protection by October 1, 2014;
4. Remove hand edits in policies by October 1, 2014;
5. Collaborate with Information Technology in implementing the On Base system for better electronic document control by December 31, 2014.

Progress will be monitored via communication between the Blood Bank supervisor and the department's chief administrative officer.

## 5. CORRECTIVE ACTION FOLLOW UP

### **Monitoring of corrective actions could be improved.**

Blood Bank has four open corrective actions from the December 2012 inspections by the AABB and FDA. Two corrective actions are overdue because Blood Bank has not completed the actions they told the agencies they would do immediately.

The Department's quality assurance manager and her staff do not monitor Blood Bank corrective actions. The quality control function in Blood Bank has developed as needed, and quality control duties have been assigned to available staff members without consideration of potential conflicts. The Blood Bank quality specialist is currently responsible for monitoring the completion of corrective actions resulting from inspections performed by the AABB and the FDA, and also works as a clinical laboratory scientist and reports to the Blood Bank supervisor, who is responsible for completing some corrective actions.

AABB Accreditation Standard 1.3 states that quality and operational procedures shall be developed and implemented to ensure that AABB standards are met. AABB Accreditation Standard 9.2 specifically addresses corrective actions, stating that the program should have a process for corrective action of deviations, nonconformances, and complaints relating to blood, blood components, perioperative products, critical materials, and services. University policy sets a precedent whereby an individual may not have oversight of the actions of anyone to whom he or she reports either directly or indirectly. An example is University of California Policy BUS-79, which forbids an employee from approving their own or a supervisor's expenses.

The current assignment of responsibilities requires the quality specialist to check the work of her own supervisor and could impair the effectiveness of the assurance process. Failure to complete corrective actions and ensure the Blood Bank meets AABB standards could put the Blood Bank's AABB accreditation at risk and lead to increased scrutiny by the FDA.

### **Recommendation**

Blood Bank should ensure effective, independent monitoring of the completion of corrective actions required by external regulatory entities.

### **Management Corrective Actions**

1. By January 15, 2014, the Department's Quality Assurance (QA) unit will develop a list of corrective actions and due dates for responses to external inspection findings beginning with the College of American Pathologists (CAP) self-inspection.

Supervisors will be responsible for establishing corrective actions, setting implementation dates, and providing feedback to QA when actions are complete or when a due date needs to be extended. QA will monitor implementation and follow up on overdue corrective actions.

2. The Department's QA manager will be added as a member of the BBCQI committee starting January 15, 2014.
3. All supervisors and specialists were reminded of their responsibility to notify the QA manager and bring to the applicable CQI meeting any significant QA issues on November 26, 2013.

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