Internal Audit Report

STUDENT HEALTH CENTER ELECTRONIC MEDICAL RECORDS SYSTEM

Report No. SC-12-10

September 2011

UC SANTA CRUZ

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INTERNAL AUDIT

IAS

ADVISORY SERVICES

September 30, 2011

ALMA SIFUENTES
Associate Vice Chancellor and Dean of Students

Re: Internal Audit No. SC-12-10 – Student Health Center - Electronic Medical Records System

Dear Alma,

Internal Audit & Advisory Services (IAS) has completed an audit of the Student Health Services' electronic medical records (EMR) system to determine the effectiveness of controls over the access, protection, and management of student medical information and compliance with applicable federal and university regulations. A copy of the report is attached and results are summarized on page 2, "I. EXECUTIVE SUMMARY".

The Student Medical Center's transition of student health records from paper to electronic is a significant undertaking in UCSC's efforts to modernize and improve its administration and protection of student medical information. The EMR is an evolving system requiring many change-management dynamics that challenge users and management to ensure the system continues to meet operational needs and regulatory compliance. SHS management has demonstrated it has programs in place to help ensure these challenges are met.

Our participation in this review effort was important in providing senior management with assurances over the system implementation efforts and in alerting operating management with observations and suggestions for improving controls and efficiencies within the EMR system.

Agreement was reached on all of the report's recommendations. Normal follow-up activity will be performed to verify completion of the agreements.

We would like to express our appreciation to the Student Health Center Executive Director and Business and Information System Coordinator for their cooperation and assistance during our review.

Sincerely,

Barry Long, Director
Internal Audit & Advisory Services

Attachment

Alma Sifuentes
September 30, 2011
Page Two

Distribution:

Coordinator Antonino
Principal Auditor Dougherty
Executive Director Knudtson
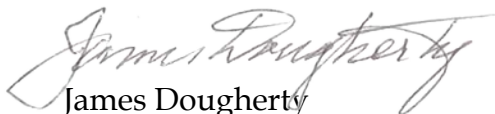Medical Director Malloy

UCSC Audit Committee:

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STUDENT HEALTH SERVICES
ELECTRONIC MEDICAL RECORDS SYSTEM

Report No. SC-12-10

September 2011

Approved:

James Dougherty
Principal Auditor

Barry Long, Director
Internal Audit & Advisory Services

UC SANTA CRUZ

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I.   EXECUTIVE SUMMARY

Internal Audit & Advisory Services (IAS) has completed an audit of the Student Health Services' electronic medical records (EMR) system to determine the effectiveness of controls over the access, protection, and management of student medical information and compliance with applicable federal and university regulations.

Overall, the EMR system was effectively implemented. This is a notable achievement, as the transition from a paper-based medical record to an electronic medical record must be addressed and managed on many different and complex levels: administratively, financially, culturally, technologically, and institutionally. Student Health Services (SHS) management and users we spoke to were in agreement that the system was worth the effort and expense to acquire, and provides operational efficiencies and effectiveness that surpass the paper medical records it replaced.

However, an EMR is an evolving system requiring many change-management dynamics that challenge users and management to ensure the system meets operational needs and regulatory compliance. SHS has management programs to help ensure these challenges are met. There were opportunities for improvement we addressed below.

The following issues requiring management corrective action were identified during the review:

A.   *The EMR (PnC) system did not have the functionality to automatically close open notes entered by the clinician after a specified period of time. As a result, the initial notes could be subsequently changed or deleted, and could not be preserved for review.*

B.   *SHS did not have a procedure to verify that an exceptional charting error did not result in a treatment error before the charting error was deleted.*

C.   *The EMR (PnC) backup procedure did not include a test of backup media reliability. Without this test, there is no assurance that complete and accurate information will be restored from backup media.*

D.   *The information system quarterly surveillance program has not yet been implemented; nor have its scope and methodology been fully defined.*

E.   *A documented record of actions for compliance with some areas of the HIPAA Security Rule is incomplete. Consequently, it is difficult for SHS management to monitor and provide assurance that such actions took place.*

Observations and related management corrective actions are described in greater detail in section III of this report.

II.   INTRODUCTION

A.   Purpose

The purpose of the audit was to conduct a post-implementation review of the Student Health Services electronic medical records system (EMR) and determine the effectiveness of controls over the access, protection, and management of student medical information and compliance with applicable federal and university regulations.

B.   Background

The UCSC Student Health Services (SHS) is the campus organization that provides health care to students. Its mission is to provide services which promote physical and emotional well being focused on the diverse needs of students.

The SHS departments are Medical Services; Counseling & Psychological Services (CAPS); Ancillary Services (Pharmacy, Laboratory, X-ray, Dietician, and Insurance & Billing); Business & Information Systems; and Student Health Outreach & Promotion. Its main center of operations is the Cowell Student Health Center; additionally there are CAPS offices in the colleges. The 2011 operating budget was $7,712,003; the main funding source for this budget was insurance revenue. According to the Permanent Staffing Roster for FY 2011, there were 57.19 FTE.

On March 20, 2006, the university signed a contract with Point and Click Solutions Inc. for an EMR system, named "Point and Click" (PnC). The cost that year for the products, services, and first year support was $170,000. The annual maintenance support from the second (2007) through the fifth year (2010) was a base cost of $36,640 plus a percentage increase of three percent. UCSC signed a new agreement with Point and Click Solutions for maintenance for the years 2011 through 2016, at a cost of $37,580 per year. The total of system costs and services through 2011 was $365,467. These costs were partially offset by savings once the paper medical records were replaced by electronic records. The medical records department was formerly staffed by a medical records administrator at 1.0 FTE and four medical records assistants totaling 3.5 FTE. The current medical records department consists of a medical records administrator who spends approximately half time or 0.5 FTE in medical records, and one medical records assistant at 1.0 FTE. Thus there was a savings of 3.0 FTE.

The PnC suit is composed of:

- OpenSchedule: a practice management system for registration, scheduling and billing and includes
    - Practice Management System software license
    - Licenses per workstations (20)
    - Registration interface
    - OpenCheckin (self check in kiosk – software only (2)
    - Email reminders (sends appt and HIPAA reminders)
- OpenChart: an order entry and electronic medical records (EMR) and includes
    - Clinical server software license
    - Additional client EMR licenses per workstation (45)
    - Quest Diagnostics lab interface
    - Propharm demographics (pharmacy) interface
    - OrchardSoft (laboratory) interface
- OpenCommunicator: patient web interface
    - Server software license
    - LDAP or Shibboleth patient authentication interface
    - Secure messaging module
    - Online Rx refill requests
    - Web appointments module
    - OpenEMF – web-based entrance medical forms
- Additional modules
    - OpenMeasures
    - OpenReport

PnC is a main-stream electronic medical records system employed widely in colleges and universities in the USA, including most campuses in the UC system. At UCSC, PnC replaced an electronic practice management system (Medical Manager) and a paper-based medical records system. It provides all of the same medical clinic operational features as Medical Manager, but in a much more elegant, user-friendly, Windows-based interface. The system is designed specifically with higher education medical clinics in mind and comes with many features that are unique to colleges and universities including term-based eligibility and insurance, compliance functionality for schools that have medical requirements as a condition of enrollment, registration interfaces and bursar exports that are easily configured for each particular site, group appointments and workshops, custom provider templates including medical and counseling-specific templates.

Use of the system is much more intuitive which has resulted in decreased training time and increased user aptitude. The system contains built in user-to-user instant messaging and user-to-user or user-to-patient secure messaging, which has facilitated more efficient communication between various department staff and greater documentation and accountability overall.

The area of greatest gain was in the electronic medical record functionality. Paper charts were replaced by electronic charts providing many improvements over the paper system including access to the chart by multiple staff; integration of the chart with other parts of the system including registration, scheduling, billing, reporting, messaging; ultimate flexibility to use assigned templates, switch to other custom templates as needed, or drop-in condition-specific sub-templates.

Generally, the transition from a paper-based medical record to an electronic medical record, such as PnC, must be addressed and managed on many different and complex levels: administratively, financially, culturally, technologically, and institutionally. An EMR consists of many components that work together to create the foundation of the legal medical record. These components may include, as PnC does, software applications such as computerized physician order entry; integration with laboratory, radiology, and pharmacy systems; an electronic document management system; or other solutions. The EMR journey is one that will evolve over many years, requiring many change-management dynamics that will challenge each of those involved with the transition process.

The implementation of PnC included its use for medical charting in January 2007. CAPS was the last SHS department to implement PnC. Psychiatric Services started using PnC in September 2010 for scheduling; charting started in April 2011 followed by all activity. Counseling was fully paperless in May 2011 starting with crisis services followed by counseling notes.

Clinicians we spoke to believed that overall, the PnC implementation was a successful endeavor that was worth the effort. Further, PnC, as a practice management system, is working without issue according to the Billing Office. For example, clinicians told us the system was helpful in many aspects of providing effective and high quality care, such as

- Ease of scheduling

- Legibility of entries

- Timely access to past chart entries including
  - Lab results
  - Medications
  - Refills

- o Referrals
- Communicating results of tests to patient in a timely manner
- Vastly easier to perform
  - o Quality management studies
  - o Peer audits
  - o Utilization
  - o Diagnosis reports
- Higher quality notes
- Fewer staff employed in filing records (Paper records are now mostly outside consultations or records that are scanned into individual patient case records and then shredded)
- Technical controls help assure quality of records
- Access controls ensure confidentiality
- Significant space savings at the Student Health Center

C. **Scope**

The scope of our review was focused on the implementation of PnC to determine if the system satisfied its use for medical records and as a practice management system, including providing adequate security for confidential information. Our determination was made by

- Interviews with SHS management and users of PnC;
- Demonstrations of how the system is actually used;
- Reviewing the quality management program; and
- Reviewing relevant documentation, including
  - o Standards for medical records, such the *UC Legal Medical Records Standards*, and the standards of the Accreditation Association for Ambulatory Health Care;
  - o American Health Information Management guidelines to prevent fraud;
  - o *SHS Policy and Procedures Manual*;
  - o PnC contract documents; and the
  - o *2011 HIPAA Security Rule Compliance Workbook*.

Our review did not include physical security of SHS information systems, as this was verified in the audit HIPAA Security Rule Compliance Governance, SC-11-55.

In addition, during our audit, a review of SHS was conducted by an outside insurance risk consulting firm, engaged by UC Risk Services at the request of the Regents. The stated charge of that engagement was to review health and counseling services provided to UC students. We did not have access to the review team and therefore the results of our SHS audit were generated independent from the work performed in that review.

D.   <u>Observations of Noteworthy Practices</u>

Quality Management Program
SHS has implemented a Quality Management Program, which provides an opportunity to ensure that standards regarding medical records are maintained within PnC, and issues regarding practice management and medical records are identified and addressed.

The scope of the Quality Management Program includes all activities that have a direct or indirect influence on the quality and outcome of clinical care, including medical and ancillary health services, administrative services, patient satisfaction, cost effectiveness of services, and risk management. The Program provides structure for conducting the peer review activities of the clinical staff, which includes the quality of clinical notes.

We reviewed documentation and forms describing this Program and meeting minutes to ensure that the Program was functioning as described.

In addition to the Quality Management Program, there is an Electronic Medical Records Committee that includes medical and CAPS management that meets regularly to address any pressing problems with the system; continuing development; and implementation of new features after major upgrades.

Further, there is a system-wide users group that periodically meets with the PnC vendor and provides mutual support.

III. OBSERVATIONS REQUIRING MANAGEMENT CORRECTIVE ACTION

A. Technical Controls for Open Notes

The EMR (PnC) system did not have the functionality to automatically close open notes entered by the clinician after a specified period of time. As a result, the initial notes could be subsequently changed or deleted, and could not be preserved for review.

PnC software should be enhanced to include functionality preventing clinician notes from remaining open beyond a specific time period.

Comments:
Clinical notes remain open until they are closed by the clinician's signoff. Once closed, the notes are locked; any changes to the notes must be made as an addendum, which is a separate attached entry to the note and must be electronically signed by the provider.

While open, the notes may be changed and/or sections completed, but without an indication of what changes are made. Clinician signoff is expected in a timely fashion, but it is possible that signoff can occur later than standards allow. PnC did not have a technical control that automatically closes open notes after a specified period of time. A risk that open notes brings is that a clinician could directly change a note (without creating an addendum) to avoid liability should a patient bring a complaint or suit against the Health Center and/or clinician should a diagnosis and/or treatment procedures prove to be inadequate or in error.

While PnC would show that the clinician entered the chart at a certain time, it would not capture what was changed at that time while the notes were in an open state. Not only would such a technical control reduce this risk, it would also provide management with a straight forward means to monitor compliance with its standards for timely signoff of notes.

According to the Information Systems Coordinator, PnC does not have such a technical control. He would have to request the PnC vendor to create this control as an enhancement to the application. Further, closed records provide the security of confidential information intended by California Senate Bill 850. This bill requires an electronic health or medical record system to automatically record and preserve any change or deletion of electronically stored medical information, and would require the record to include, among other things, the identity of the person who accessed and changed the medical information and the change that was made to the medical information. In our opinion, a request for this enhancement should be done.

The SHS Executive Director has informed us that a request for the enhancement of this application which would add this functionality was submitted to PnC, and a response was received that indicated that the application does not currently have the capability and that a request would be forwarded to their engineering department for consideration as an enhancement.

Agreements:
1. The Business and Information Systems Coordinator has discussed with the PnC vendor the enhancement of the PnC software, preventing clinical notes from remaining open beyond and specific period of time.

2. Student Health Services will update the SHS policy on the signoff of notes to include exceptions to the rule that signoff must occur within 24 hours of the encounter. This policy will include a monitoring function that will likely be performed by the medical records/system administrator and/or appropriate clinical manager. This policy will be updated and implemented by 11/01/2011.

B. Exceptional Charting Error Deletion

SHS did not have a procedure to verify that an exceptional charting error did not result in a treatment error before the charting error was deleted.

A procedure should be established to verify that an exceptional charting error did not result in a treatment error before the charting error is deleted.

Comments:
There is an exceptional charting error that SHS management deletes rather than having clinicians address it with an addendum to the record. This is when the provider mistakenly enters clinical notes in the wrong patient's record. SHS management justifies deleting the misplaced notes as they do not belong there. The deletion procedure requires the Information Systems Coordinator or the Medical Records System Administrator to meet with the provider to determine what happened. If they determine that the note was charted on the wrong patient, they print a copy of the note for their reference in charting on the correct patient, and then delete the note. The system asks for a reason for this action which they provide. The ability to delete the note is controlled by permissions that only select administrators have.

However, this procedure did not include a step to verify that the charting error did not result in a treatment error. If a treatment error occurred as a result of the charting error, and that error was deleted, the university could be exposed to additional legal and civil liabilities.

We were subsequently informed by the SHS Medical Director that a new chart deletion procedure has been developed, implemented, and added to the existing Medical Records Standards policy. The new policy reportedly requires that any request for chart note deletions follow a four step process, including; taking timely action to mitigate the harm once the error is recognized, and filing an incident report. Refer to Appendix A for an outline of the four step process included in the new chart deletion policy as described by the SHS Medical Director.

Agreement:
Student Health Services has developed and implemented a new chart deletion procedure and added it to the existing Medical Records Standards policy.

C.   **PnC Backup Media Testing**

The EMR (PnC) backup procedure did not include a test of backup media reliability. Without this test, there is no assurance that complete and accurate information will be restored from backup media.

The PnC backup media should be periodically tested for reliability.

Comments:
The contingency plan test conducted for PnC was a "failover" test. The failover test tests the PnC standby server, which is designed to backup the PnC production server.

Data from production is transferred to the standby server every 15 minutes to be SHS's most up-to-date data should the production server need to be restored. The last test, reported on 7/8/2011, verified that all data had been transmitted over to the standby server from the production server; the data was up to date; and was accessible. Till now, testing has not included a test of PnC backup media reliability.

Backups are made daily onto tape media and stored at a secure off-site facility (Iron Mountain). A test to verify that complete and accurate information can be restored from the backup media has not been performed from PnC backup tapes. This test has been performed successfully by ITS for the SHS lab system (Orchard Harvest) backup tapes. We recommend that the restoration of data from PnC backup tapes is performed.

We were subsequently informed that a request to test the restoration of PnC data from backup media was communicated to ITS on 9/28/2011.

Agreement:
The Business & Information Systems Coordinator will ensure a process similar to the Harvest lab and Propharm pharmacy restoration is evaluated and implemented during the upcoming backup testing cycle scheduled for 12/2011. Estimated closure date 01/31/2012.

D.   Information System Surveillance Program

The information system quarterly surveillance program has not yet been implemented; nor have its scope and methodology been fully defined.

The definition of the scope and methodology of the information system activity surveillance program should be completed and implemented.

Comments:
The HIPAA Security Rule requires an information system activity review. This involves procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports. Information Technology Services (ITS) is responsible for the implementation of logging and auditing on ITS-supported systems containing or accessing electronic protected health information. These include the SHS PnC database server, PnC standby server, PnC fileserver, Orchard Harvest database server, Kalos ProPharm database server, FileMaker database server, and Health Center workstations.

As part of its practice for compliance with this requirement, SHS stated in the *2001 HIPAA Security Rule Compliance Workbook*:

> *SHS reviews application access logs on an event-driven basis, and at least quarterly. The Health Center reviews PnC patient access logs as needed in response to privacy/security incident violations, when requested by management, and as part of quarterly surveillance program reviews.*

However, the information system quarterly surveillance program, which will consist of an internal audit of information system activity logs, has not yet been implemented; nor have the scope and methodology of these audits been fully defined.

Agreement:
The Business and Information System Coordinator will ensure that the scope and methodology of the quarterly surveillance program is developed and implemented by 10/15/2011, and the first quarterly surveillance audit is conducted in fall 2011. Estimated closure date 11/31/2011.

E.   Documentation of Actions for Compliance

A documented record of actions for compliance with some areas of the HIPAA Security Rule is incomplete. Consequently, it is difficult for SHS management to monitor and provide assurance that such actions took place.

Document timely actions taken to comply with these areas of HIPAA and periodically review this documentation to monitor compliance.

Comments:
Currently, there is good documentation for many critical aspects of the HIPAA security program including incident reporting, information system access/termination, logging of facility changes related to security and security awareness and training. However there were gaps in the process of documenting patient access requests and back-up testing.

SHS implements actions to comply with HIPAA, but does not always document what it does or when it does it. For example, we reviewed a log folder with 10 spreadsheets that captured log information, among which was the spreadsheet entitled "Patient Access Report Log." It was a new file with only a single row of information that was a sample rather than information on an actual patient request report. The Business and Information Systems Coordinator created this spreadsheet in response to an appreciation for the need to document patient access log review activity, so as to provide a means to monitor such activities.

We would like to encourage the full documentation of actions taken for compliance.

Agreement:
The Business and Information Systems Coordinator will improve documentation of actions for compliance in the areas of patient access report reviews and back-up testing to provide a record for management review by 12/ 31/ 2011.

Appendix A: Elements of New Chart Deletion Policy provided by SHS.

Source: SHS Executive Director:

"A new chart deletion procedure has been developed, implemented and added to the existing Medical Records Standards policy which requires that any request for chart note deletions follow the following steps:

*1. **Mitigate harm**. The first priority is to check to see if either patient involved in the documentation error suffered any harm as quickly as possible. This might include inappropriate injections, vaccinations, filled prescriptions, surgical procedure or radiation exposure, phlebotomy, lab tests, referrals or a delay in timely provision of these services to the correct patient. Taking timely action to mitigate harm is essential once the error is recognized.*

*2. **File an Incident Report**. After insuring the safety of both of the involved patients, an Incident Report should be initiated and forwarded to the Assistant to the Director for logging and review by the Risk Management Committee. A copy of the erroneous EMR entry should be printed and attached to the Incident Report, as well as reference to the correct patient SID #. If the error is caught prior to any resultant harm, an "Opportunity for Improvement" form should be completed with an attached copy of the erroneous note and the SID # of the correct patient. It is the responsibility of the staff member who made the documentation error to forward either the Incident Report or the "Opportunity for Improvement" form to the Assistant to the Director for reporting to the QM committee.*

*3. **Notify Health Information Management (HIM)**. The HIM administrators (Medical Records/System Administrator or Business and Information Systems Coordinator) should be notified the same day the erroneous entry is recognized. After review with the Medical Director, the HIM staff will print a copy of the erroneous entry for a Medical Records log and delete the erroneous entry from the EMR. The MRSA will facilitate the deletion of any resulting erroneous diagnoses, orders, billing, referrals, and secure messages in the EMR that may have resulted from the erroneous signed entry.*

*4. **Correct Documentation of the Encounter**. It is the responsibility of the clinician to transfer the contents of the erroneous entry into the correct patient's medical record, using the appropriate template with a diagnosis, encounter code and electronic signature on the same day the error is recognized. Use of copy and paste functions may lessen the time to transfer some of the information but some items such as vital signs may need to be entered manually. This staff member must also delete any resultant erroneous Problem List entries."*

<div align="center">***</div>