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***Subject: Epic Inpatient Pharmacy System Implementation  
AMAS Project 2011-17B***

Audit & Management Advisory Services (AMAS) has completed a review of the UCSD Health System (UCSDHS) EpicCare (Epic) Inpatient Pharmacy System (Willow). This report summarizes the results of our review.

### **Background**

UCSDHS has selected Epic as its primary clinical information system. Epic is a product of the Epic Systems Corporation of Verona, Wisconsin. The Epic application offers an integrated suite of healthcare software centered on a hierarchical object-oriented database system. All Epic applications leverage the same central database, which can be queried using built-in reporting tools for research and other analyses. Epic has been fully implemented in the UCSDHS ambulatory care environment as well as within inpatient patient care areas.

The UCSD Pharmacy transitioned from the Siemens Inpatient Pharmacy system to Epic for medication management in February 2011. Unlike the Siemens system, the Epic Willow Pharmacy Inpatient System module provides the functionality to manage medication ordering and administration processes by connecting pharmacists, physicians, nurses, and other healthcare professionals to a single order record. Medication orders entered into Epic interface directly to Willow for Pharmacist verification, and dispensing to a patient. Medication charge information is sent from Willow to the Financial Management System for processing to individual patient claims. Pharmacy staff have direct access to the patient medical record during the order verification process. Changes made by a Pharmacist are automatically updated and available for other users to view. Medication orders appear automatically on the electronic medication administration record (eMAR), a report that serves as a legal record of the drugs administered to a patient at a facility by a nurse or other healthcare professionals.

### **Audit Objective, Scope and Procedures**

The objectives of our review were to evaluate the post implementation management processes for the Willow Pharmacy Inpatient System, including the evaluation of risks identified during pre-implementation and the controls in place for mitigation (*Attachment A*). In addition, we

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evaluated the adequacy of the internal control structure in manual and electronic processes that helps to ensure data accuracy and completeness. In order to achieve project objectives, we performed the following audit procedures:

- Interviewed the Assistant Chief of Pharmacy, and the Director of Pharmacy Informatics;
- Attended the Willow Support meeting to review post implementation activities;
- Evaluated Epic drug pricing and price updates;
- Evaluated the review process for Epic medication charge data sent to the Financial Management System;
- Evaluated Post Implementation Survey responses for Epic users;
- Reviewed a listing of clinical reports used for monitoring and assessing various pharmacy information;
- Reviewed UCSD Medical Center Policy (MCP) documents; and
- Analyzed high risk activities and assessed mitigating controls for post implementation activities (*Attachment A*).

**Conclusion**

Based on our review procedures, we concluded that Willow post-implementation activities and processes were structured and thorough; and that medication management processes have been implemented as designed and operating effectively. The Pharmacy Epic Project Team continuously used a central repository for documentation storage, access and updates. Specifically, we noted that assessment documentation was robust; and that the systematic approach used to track and address implementation issues, and review business metrics for management reporting activities was comprehensive. Meetings were conducted with key personnel to identify and address high risk issues that may have impacted patient care and financial information. In addition, assessment surveys were conducted with Epic users to determine areas of focus for future enhancements.

To ensure that pharmacy business risks were considered during pre implementation activities, AMAS prepared a detailed risk assessment matrix, based on 10 key elements of inpatient pharmacy operations. We then assessed the controls that had been implemented to mitigate business risks (*Attachment A*). The controls reviewed were a combination of automated and manual procedures that were evaluated individually and in combination to assess their integrity. Seven of the ten key elements were determined to have a preliminary risk ranking of “high” during the pre implementation review. Those elements were then further evaluated to determine the effectiveness of the system and/or process controls in place after the implementation.

Based on the results of our post implementation review, we noted two areas for improvement specifically relating to medication reconciliation processes, requiring the revision and/or creation of policy and procedures. These issues are discussed in detail in the balance of this report.

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**Observations and Management Corrective Actions**

**A. Medication Dispense Reconciliation Process**

**Fully configured Dispense Reconciliation Reports did not contain all information needed to efficiently compare medications dispensed to medications administered.**

Medication dispense reconciliation is a process that compares each medication dose dispensed from Pyxis or another storage location with a related nurse administration entry. The California Code of Regulations, Title 22: Article 4, Section 75035 states: “Drugs shall be administered as prescribed, and shall be recorded in the patient’s health record,” and Section 75036.b requires: “A record of the drugs dispensed shall be entered in the patient’s health record.” A medication dispense reconciliation process will help to ensure compliance with these Title 22 documentation requirements.

We noted during our review that Epic offered the Epic *Dispense Reconciliation Report* (Report) to assist staff with completing the medication dispense process. Pharmacy was using this Report to identify and remediate drug dispensing discrepancies for controlled substances only. However, nursing staff assessed the initial version of the Report to determine whether the information it contained was adequate to complete a comprehensive, risk based review of all medication dispensing data, and found that it did not include all necessary information.

Health System management plans to implement a formal medication reconciliation process, which will identify how often medications, other than controlled substances, will be reviewed; how frequently the process will be performed; and which staff will be responsible. While processes and reports are being reviewed, Pharmacy and the Epic Team plan to improve Willow reporting functionality by assessing current reconciliation processes and re-configuring report format and content to ensure that a comprehensive, risk based medication reconciliation can be completed by associated hospital staff.

**Management Corrective Action:**

Pharmacy, Nursing and IT managements will collaborate to design a comprehensive medication reconciliation process, which will include a reconciliation of drug administration records to drug dispensing reports, to provide proper review and address discrepancies. Epic reporting tools will be revised, as needed, to support the process.

**B. Policies and Procedures**

**In some cases, MCPs related to Pharmacy operations had not been updated to reflect revised processes adopted during the Willow implementation. In addition, Pharmacy had not documented a medication return and re-stocking procedure.**

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When reviewing MCP's with reference to Pharmacy and medication related activities, AMAS noted that selected information contained in the policies required revision to include various new processes implemented during the Willow installation. The Pharmacy Epic Project Team performed a preliminary review of applicable MCPs and identified several areas that required amended language as a result of the Willow implementation. For example, MCP 327.2 *Medication Reconciliation* contained several references to manual processes, such as discharge order procedures and medication reconciliations, which are now being performed electronically within Epic.

We also noted that selected Pharmacy staff were responsible for monitoring medication distribution and return (restocking) processes, using system generated reports. However, a written internal procedure had not been created to provide guidelines for completing that process. Written procedures will help ensure that errors or omissions are identified and timely corrected.

**Management Corrective Actions:**

1. The Epic Project Team is working to review and amend MCP policy content as necessary.
2. In coordination with the evaluation of Finding A, Pharmacy management will develop a documented workflow and corresponding procedures for conducting medication distribution and re-stocking reconciliation, which will address the frequency and timing of those reviews.
3. Pharmacy processes will be documented and/or updated as MCPs are updated to ensure consistency.

AMAS appreciated the cooperation and assistance provided during this review. Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the corrective actions. At that time, we may need to perform additional audit procedures to validate that actions have been taken prior to closing the audit findings.

UC policy requires that all draft audit reports, both printed and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel or destroy them at this time.

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If you have any questions regarding this report, please contact me at (858) 534-3913 or by email at [shburke@ucsd.edu](mailto:shburke@ucsd.edu).

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**Epic Inpatient Pharmacy System Implementation  
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Risk Assessment Matrix  
Attachment A**

Key Element	Objectives	Inherent Risk(s) Identified	Preliminary Risk Ranking <sup>i</sup>	System and Process Controls Adopted During Implementation	Residual Risk
1. Patient Information	Ensure that essential patient information is obtained, readily available in useful form, and considered when dispensing medications.	Patient care information changes (inpatient to outpatient status, clinician, medical service, etc.) are not captured. Drugs can be dispensed without being administered to a patient. Administration records are not reconciled to dispensing reports to ensure the accuracy of drug administration documents.	<b>High</b>	The Dispense Reconciliation Report provided information on unreconciled dispenses as well as charge related information. A pharmacist staff member was identified to review reports and address discrepancies concerning controlled substances only. Nursing staff will eventually have the responsibility for reconciliation once reporting features have been configured, and reports can be built for each nursing station. Financial, Pharmacy and Nursing staff are emailed the report every two weeks for review.	<b>High (See Report Finding A)</b>
2. Drug Information	Ensure essential drug information is readily available in useful form and considered when dispensing medication. Practitioners are familiar with or are able to review, prior to dispensing, information about the product's known risks and hazards.	Information to assist with resolving questions regarding the safety of a prescription order is not available on a timely basis.	Medium	Hazardous drug warnings and other important administration information are displayed in Willow for all users. The Pharmacy website home page included relevant reference links. Management provides updated clinical information via printed materials.	<b>Low</b>
3. Communication of Drug Orders and Other Drug Information	Standardize and automate methods of communicating prescription orders and other drug information to minimize the risk for error.	Incomplete or ambiguous prescription information due to illegible handwriting. Typing mistakes, or poor fax quality; misread prescriptions; prescriber errors. Wrong drug. Wrong dose. Wrong route. No policy on how to resolve conflicts on potentially unsafe medication orders.	<b>High</b>	Medical Center Policy (MCP) 321.2, Pharmacist Prescribing Authority, addressed this issue. Willow preference lists and order sets guide the provider during the medication order selection process. Pharmacist validation is required for all Epic orders and overrides.	<b>Low</b>

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4. Drug Labeling, Packaging and Nomenclature	Develop strategies that minimize the possibility of errors with drug products that have similar or confusing labeling/packaging, and /or drug names that look or sound alike.	Faulty drug identification due to one or more medications that have look or sound alike names, mnemonics and/or packaging; lack of special precaution labels on high-alert medications.	Medium	As Technicians prepare medications, a Pharmacist reviews for accuracy and sign off. Labels that are generated electronically will display important high alert information automatically. There are numerous requests for build changes and development enhances with regard to labels. Enhancements will be implemented with a version upgrade in October, 2010.	<b>Medium</b>
5. Drug Standardization, Storage, and Distribution	Ensure that prescribed medications are accessible to patients and dispensed in a safe and secure manner. Medications and other necessary drug supplies are stored, dispensed, and returned to stock in a manner that reduces the likelihood of an error.	Medications are not returned to stock in a consistent manner that reduces the risk of an error.	<b>High</b>	Pharmacy staff process medication returned to stock using bar code scanners. Accountability for drugs originally dispensed by the Central Pharmacy is of particular importance because those items are charged when they are dispensed. A Dispense Reconciliation Report will be used to audit the activity. A written procedure is needed to ensure timely review and reconciliation.	<b>High (See Report Finding B)</b>
6. Environmental Factors, Workflow, and Staffing Patterns	Prepare and dispense medications in a safe and orderly environment that allows practitioners to remain focused on medication use without unnecessary distraction.	Staff workload and/or workflow are excessive, creating inefficiencies.	<b>High</b>	Pharmacy management has addressed the increase in net new workload resulting from the Willow implementation and associated go-live activities by adding personnel, and/or adjusting related job duties.	<b>Low</b>
7. Staff Competency and Education	Ensure Pharmacists and technicians receive sufficient training and orientation to the dispensing process and error prevention and undergo baseline and annual evaluation of knowledge and skill related to safe medication practices.	Insufficient validation of staff competency; system or process training. Lack of an effective orientation process. Staff are not trained for specific duties. Management does not provide feedback about errors and error prevention. Continuing education is not provided or completed.	<b>Low</b>	Epic online interactive classes continue to be available. Mandatory Epic training was conducted for Technicians and Pharmacists. Error reports were used for feedback. Medication errors were evaluated by using the Electronic Quality Variance Report (EQVR) system and tracing them to post implementation activities.	<b>Low</b>

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8. Drug Charging	Create and process accurate drug charges in the pharmacy system and interface them into the financial system.	Errors occur that lead to overcharging or undercharging for medications and errors are not identified or reconciled. Quality Assurance reports dealing with financial transactions within the system are not being reviewed.	High	A report will be generated that produces undercharge and overcharge data. Staff will review that report and reconcile all errors. A review of financial data sets is conducted to ensure that Epic configuration parameters are sending appropriate charges to the Financial Management System (FMS).	Medium
9. Pyxis Cutover	Verify that there is a bi-directional data flow from Siemens to Epic during the conversion process.	Errors occurred when entering Pyxis data into Epic. Configuration parameters are incorrect. Configuration parameters are not valid after the ADS console management messages are sent during the system cutover process.	High	Downstream process errors occurred shortly after implementation. Epic formulary data did not transfer properly to the Pyxis formulary database, creating the need for Pharmacists to manually input corrections, but the errors did not impact patient safety. This problem was corrected on March 24, 2011.	Low
10. Order Set Builds	Create patient order plans based on condition of the patient.	Epic orders sets are built based on existing Patient Care Information System (PCIS) information. New requests have not been completed.	High	Staff order sets were developed based on existing PCIS information and new requests. 72% of physician and residents agreed that order sets and preference lists for their area adequately met their needs.	Low

<sup>i</sup> Note: A risk level rating of "high" (noted in red) indicates internal controls that need to be enhanced in order to mitigate the risk noted.