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***Subject:*** ***Epic Inpatient Pharmacy System Implementation***
***AMAS Project 2011-17A***
***Interim Report***

Audit & Management Advisory Services (AMAS) has completed a pre-implementation review of the UCSD Health System (UCSDHS) EpicCare (Epic) Inpatient Pharmacy System (Willow). This interim report provides a summary of the work performed to date, and our preliminary conclusions.

## Background

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

UCSD Pharmacy currently uses the Siemens Inpatient Pharmacy system for medication management and will fully transition to the Epic Willow module in February 2011. The Siemens system interfaces with the following major hospital systems:

- The Siemens Patient Care Information System (PCIS), which includes the Computerized Physician Order Entry module (CPOE) to receive and approve mediation orders;
- The Medication Administration module (MAK) to provide automated validation of inpatient medication administration;
- The Pyxis automated dispensing cabinet system; and,
- UCSDHS Financial Management System (FMS) to submit inpatient medication charges.

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 will interface directly to Willow for Pharmacist verification, and dispensing to a patient. Pharmacy staff will have direct access to the patient medical record during the order verification process. Changes made by a Pharmacist will automatically be updated and available for other

users to view. Medication orders will also 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.

Because Epic Inpatient system has integrated the functionality provided by CPOE and MAK, Willow system interfaces will vary as identified in ***Attachment A***.

## Audit Objective, Scope and Procedures

The objectives of our review were to evaluate the implementation management processes for the Willow Pharmacy Inpatient System, including the major data interfaces to other systems (***Attachment A***), and to ensure data accuracy and completeness through inclusion of an adequate internal control structure in manual and electronic processes. In order to achieve project objectives, we performed the following audit procedures:

- Analyzed the portion of the Epic Vendor Contract pertaining to the Willow implementation;
- Interviewed key personnel associated with the project including the Assistant Chief of Pharmacy, the Associate Director of Inpatient Pharmacy Operations, a Pharmacy Financial Analyst; the Director of Pharmacy Informatics and an Epic Informatics Pharmacist;
- Obtained detailed information regarding Pharmacy billing processes and Willow integration;
- Evaluated the Epic data structure for drug pricing and price updates;
- Attended the Epic Finance meeting regarding the billing process for Pharmacy charges;
- Reviewed the Epic medication charge process flow;
- Evaluated the process used to build the Epic user interface for ordering, filling and dispensing medications;
- Evaluated the process flows for current and proposed medication orders;
- Reviewed a listing of clinical reports used for monitoring and assessing various pharmacy information; and,
- Completed a detailed risk assessment for both pre and post implementation activities (***Attachment B***).

## Conclusion and Supporting Comments

Based on our review procedures, we concluded that Willow pre-implementation activities and processes were structured and comprehensive. The Pharmacy Epic Project Team created a central repository for documentation storage, access and updates. Specifically, we noted that system development documentation was robust, and system development plans were realistic. Recurring meetings were conducted with key personnel to specifically address high risk areas that may have impact on the implementation timeline. As a result, the original implementation date of December 7, 2010 was rescheduled to February 27, 2011 to allow additional time to address those high risk areas and identify concrete solutions necessary for a successful implementation.

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 manual and automated controls that were planned or had been implemented to mitigate business risks (***Attachment B***). 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." These elements will be further evaluated in the post implementation phase of this review to determine whether the system or process controls in place are effective.

Audit & Management Advisory Services appreciated the cooperation and assistance provided during the initial phase of this review. AMAS plans to perform additional review procedures to assess pre and post implementation activities beginning in January 2011. Applicable Medical Center Policies (MCPs) will also be reviewed at that time to ensure that they reflect current practices.

UC policy requires that all draft audit reports, both printed (copied on tan paper for ease of identification) 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.

If you have any questions regarding this report, please call me at (858) 534-3617.

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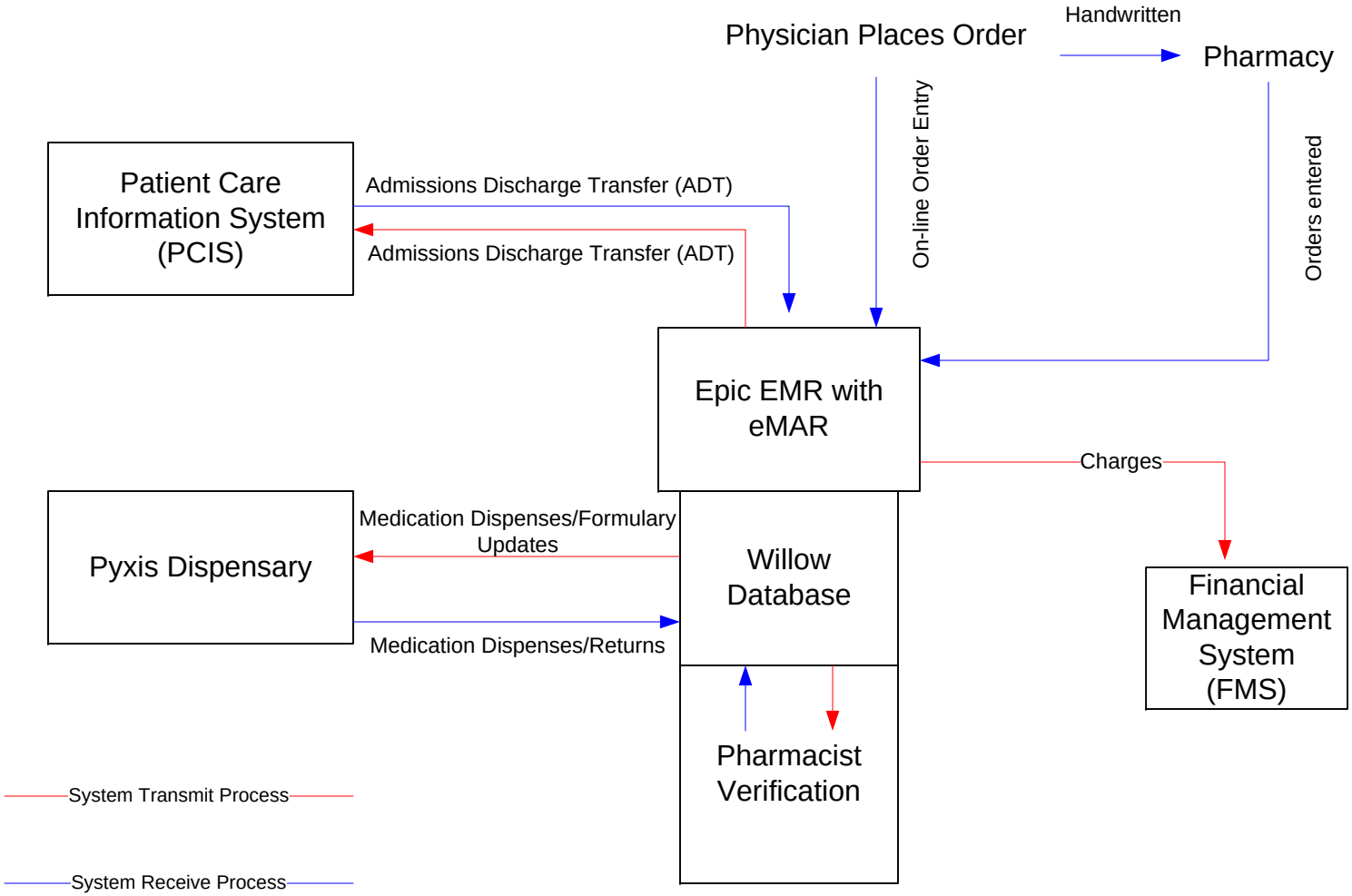
## External Systems Interface to Epic/Willow



***Epic Inpatient Pharmacy System Implementation***
***Audit Management Advisory Services Project 2010-17A***
***Risk Assessment Matrix***
***Attachment B***

| Key Element | Objectives | Risk Identified | Controls Identified | Preliminary Risk Assessment |
|---|---|---|---|---|
| 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 drug administration documents. | The Willow Medication Reconciliation Navigator will provide access to medication reconciliation process. The Dispense Reconciliation Report will provide information on unreconciled dispenses as well as charge related information. Staff have been identified to review reports and address discrepancies. | **High** |
| 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. | Hazardous drug warnings and other important administration information will be displayed in Willow for all users. The Pharmacy website home page includes relevant reference links. Management will provide updated clinical information via printed materials. | **Medium** |
| 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. | Medical Center Policy (MCP) 321.2, Pharmacist Prescribing Authority, addresses this issue. Willow preference lists and order sets will guide the provider during the medication order selection process. Pharmacist validation will be required for all Epic orders and overrides. | **High** |
| 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 mediations that have look or sound alike names, mnemonics and/or packaging; lack of special precaution labels on high-alert medications. | When Technicians prepare medication, a Pharmacist will review for accuracy and sign off. Labels that are generated electronically will display important high alert information automatically. The current Hazardous Drug Policy, MCP 323.1C, addresses oversight responsibility. | **Medium** |
| 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. | Outdated, recalled and discontinued drug products may not be removed from current inventory, and secured away from current stock. | Nurses will return all Pyxis dispensed drugs back into Pyxis. Returns of items dispensed by the Central Pharmacy will be of particular importance because those items will be charged when they are dispensed. A dispense reconciliation report will be used to audit the activity. Training will be in place to emphasis the return process. | **High** |
| 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. | Pharmacy management is addressing the increase in net new workload that will result from the Willow implementation and associated go-live activities. | **High** |
| 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. | Epic online interactive classes are available. An Epic "play" environment is available on shared clinical workstations to provide staff a place to work with the new system. Mandatory Epic training is available for Technicians and Pharmacists. Error reports will be available for feedback. Management will follow the Medication Error Reduction Plan, which states that all errors will be reviewed. Severe errors will be evaluated using a root cause analysis approach that involves Physicians, Nurses, Pharmacists and Compliance. | **Low** |
| 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. | A report will be generated that produces undercharge and overcharge data. Staff will review that report and reconcile all errors. Epic configuration parameters will send appropriate charges to the Financial Management System (FMS). Corresponding policies and procedures will be developed or updated. | **High** |
| 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. | Pyxis databases will be reviewed for accuracy prior to implementation to verify that appropriate configuration parameters are in place and erroneous configurations are corrected. Each action is tested. Corresponding policies and procedures will be developed or updated. | **High** |
| 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. | Staff order sets have been developed based on existing PCIS information and new requests. A clinical review will be completed for all order sets. Pharmacy management will ensure that all order sets are built and properly tested prior to go live. | **High** |

Note: A preliminary risk level rating of "high" (noted in red) does not indicate that the controls in place are insufficient or ineffective.
However, in these cases additional testing is warranted to validate that the control procedures are operating as designed, and effective to mitigate the risk noted.