

AUDITOR'S REPORT

HARRIS HEALTH SYSTEM EPIC WILLOW PHARMACY SYSTEM OUTPATIENT PRESCRIPTION CONTROLS



January 28, 2016

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HARRIS COUNTY AUDITOR

January 28, 2016

Mr. George Masi
President and Chief Executive Officer
Harris Health System
2525 Holly Hall
Houston, Texas 77054

RE: Harris Health System Epic Willow Pharmacy System Outpatient Prescription Controls for the three months ended December 31, 2014

The Audit Services Department performed procedures relative to the Harris Health System (Harris Health) Epic Willow Pharmacy System Outpatient Prescription Controls for the three months ended December 31, 2014. The objective of the engagement was to evaluate critical operational and financial controls for filling outpatient prescriptions following implementation of the Epic Willow Outpatient Pharmacy System (Epic Willow). Our procedures included evaluating and selectively testing manual and automated controls for:

- Access to Epic Willow.
- Determining that outpatient prescriptions that are dispensed:
 - Are documented as prescribed and authorized by a qualified licensed professional in the medical record system.
 - Match the prescription documentation in the medical record system.
 - Are documented as verified by pharmacists in Epic Willow before they are dispensed.
- Determining outpatient prescriptions that are filled but not dispensed (i.e., cancelled, not picked up by the patient) are:
 - Identified, tracked, and monitored in Epic Willow.
 - Documented as not dispensed in the patients' pharmacy prescription records.
 - Returned to inventory stock timely.
 - Recorded as returned to inventory stock in the perpetual inventory records if controlled substances.
- Preventing prescriptions from being filled and dispensed at more than one location.

The engagement process included providing you with engagement and scope letters and conducting an entrance and exit conference with your personnel. The purpose of the letters and conferences were to explain the process, identify areas of concern, describe the procedures to be performed, discuss issues identified during the engagement, and solicit suggestions for resolving the issues. A draft report was provided to you and your personnel for review.

Mr. George Masi
President and Chief Executive Officer

The work performed required our staff to exercise judgment in completing the scope objectives. As the procedures were not a detailed inspection of all transactions, there is a risk that error or fraud was not detected during this engagement. Management therefore, retains the responsibility for the accuracy and completeness of their financial records and ensuring sufficient controls are in place to detect and prevent fraud.

The enclosed Auditor's Report presents the significant issues identified during our procedures, recommendations developed in conjunction with your staff, and any actions you have taken to implement the recommendations. Less significant issues and recommendations have been verbally communicated to your staff.

We appreciate the time and attention provided by you and your staff during this engagement.

Sincerely,



Barbara J. Schott
County Auditor

cc: Harris Health System Board of Managers
District Judges
County Judge Ed Emmett
Commissioners:
 R. Jack Cagle
 Jack Morman
 Steve Radack
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OVERVIEW

Outpatient pharmacy prescriptions for Harris Health patients are dispensed at Harris Health outpatient pharmacies located in hospitals, specialty care, and community health center locations. There were 585,004 outpatient prescriptions dispensed through Harris Health outpatient pharmacies during the three months ended December 31, 2014. The following table presents outpatient prescriptions dispensed by each of the outpatient pharmacies during the period:

Outpatient Pharmacy	Number of Prescriptions (Unaudited)		
	New	Refill	Total
Martin Luther King Jr. Health Center	30,540	27,600	58,140
El Franco Lee Health Center	35,013	19,504	54,517
Acres Home Health Center	28,589	16,688	45,277
Vallbona Health Center	25,747	17,929	43,676
Strawberry Health Center	24,419	16,743	41,162
Ben Taub General Hospital	32,127	8,649	40,776
Aldine Health Center	25,485	14,502	39,987
Gulfgate Health Center	21,734	16,800	38,534
Lyndon B. Johnson General Hospital	28,491	9,833	38,324
Northwest Health Center	21,717	15,431	37,148
Settegast Health Center	16,069	15,588	31,657
Casa de Amigos Health Center	17,376	13,388	30,764
Thomas Street Health Center	12,381	13,415	25,796
Baytown Health Center	17,175	8,334	25,509
E. A. "Squatty" Lyons Health Center	12,827	8,236	21,063
Smith Clinic	9,408	3,266	12,674
TOTAL	359,098	225,906	585,004

Source: Epic Willow

Outpatient prescriptions are filled from information transmitted to Pharmacists and Pharmacy Technicians through Epic Willow and Epic Willow documents and tracks prescriptions from when they are prescribed until they are dispensed to patients. Epic Willow was implemented at Harris Health in March 2014 and it is one of several healthcare clinical and financial software systems acquired by Harris Health from the clinical and patient information system vendor, Epic.

Harris Health prescriptions must be prescribed by Harris Health Qualified Licensed Professionals which are physicians, dentists, podiatrists, optometrists, and pharmacists. In addition, nurse practitioners and physician assistants can prescribe under a written protocol from a supervising physician. The outpatient pharmacies only fill or refill prescriptions prescribed by Harris Health Qualified Licensed Professionals, however, patients can choose to have their Harris Health prescriptions filled at a non-Harris Health outpatient pharmacy.

Prescriptions are ordered through Harris Health's electronic medical record system (EMR) by Qualified Licensed Professionals authorized to prescribe. Prescriptions are automatically sent to Epic Willow to be filled at an outpatient pharmacy after they are ordered.

Prescriptions ordered by nurse practitioners, physician assistants, and residents require documentation of an "authorizing" Qualified Licensed Professional by state law (nurse practitioners and physician assistants) or for billing purposes (residents). The identity of the Qualified Licensed Professional is either automatically populated in the EMR when the prescription is ordered, or the person ordering the prescription uses a drop down menu to select the appropriate Qualified Licensed Professional.

Depending on the Qualified Licensed Professional entering the prescription order, (or if a refill, the pharmacist or pharmacy technician entering the refill) a drop down menu may be displayed which allows selection of a "prescribing" Qualified Licensed Professional. The prescribing Qualified Licensed Professional selected appears as the prescriber on the label of the dispensed prescription.

Patients that receive prescriptions and want to have them filled or refilled can go to an outpatient pharmacy and wait, or they can order the prescription by telephone or using an interactive voice response system to be picked up later. Prescriptions that patients order for pick up the next day or later are routed to a Harris Health central pharmacy location where they are filled and packaged to be sent to the outpatient pharmacies for next day pick up by the patient.

Epic Willow has automated controls to ensure outpatient prescriptions are verified by a Pharmacist prior to dispensing, and to prevent prescriptions that have already been dispensed from being dispensed again at another Harris Health outpatient pharmacy.

Harris Health uses a retail pharmacy point-of-service cashiering system (Emporos) to record prescriptions that are dispensed to patients and any payments received. Emporos automatically updates the status of prescriptions picked up by patients to "dispensed" in Epic Willow through an electronic interface.

Patients have fourteen days to pick up their prescriptions or the prescribed pharmaceuticals are placed back into the inventory stock to fill other prescriptions. Prescriptions that are not picked up by patients or that are cancelled for other reasons are manually recorded in Epic Willow by pharmacy staff.

RESULTS

Based on procedures performed, controls for filling and dispensing outpatient pharmacy prescriptions were working effectively for the following activities:

- Prescriptions documented as dispensed in Epic Willow matched the documentation in the EMR.
- Prescriptions were documented as verified by pharmacists in Epic Willow before they were dispensed.
- Outpatient prescriptions filled but not dispensed were:
 - Identified, tracked, and monitored in Epic Willow.
 - Returned to inventory stock timely.
 - Recorded as returned to inventory stock in the perpetual inventory records if controlled substances.
- Controls prevented prescriptions from being filled and dispensed at more than one location.

Procedures also determined that critical controls for dispensing and documenting outpatient prescriptions need to be improved as follows:

- Ensure Pharmacists are trained to verify prescription status in Emporos before manually updating Epic Willow.
- Ensure that any temporary changes to Epic Willow made by the application service provider are made properly.
- Implement a process for periodically examining and updating prescribing and authorizing Qualified Licensed Professionals included on the drop down menus in the EMR.
- Implement, if feasible, system changes to limit the ability of personnel that record prescriptions to select incorrect prescribing Qualified Licensed Professionals.
- Periodically examine access provided to Qualified Licensed Professionals and Pharmacists to ensure it is appropriate for their job responsibilities.

These issues are discussed in more detail in the following Issues and Recommendations matrix.

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
<p>Updating Prescription Status</p>	<p>Pharmacists inspect a daily <i>Ready to Dispense but not Dispensed</i> report to identify prescriptions that have been filled but not picked up by patients. Prescriptions not picked up after 14 days are returned to the inventory stock and the status of the prescriptions in Epic Willow is manually updated to “cancelled”.</p> <p>Occasionally, a prescription is dispensed in Emporos, but the status is not updated in Epic Willow through the automatic electronic interface. However, in the interim, Pharmacists must inspect Emporos records to verify the status of prescriptions before updating Epic Willow.</p>	<p>Pharmacists do not always inspect Emporos records before updating the status of prescriptions in Epic Willow.</p> <p>As a result, for the three months ended December 31, 2014, the manually updated status in Epic Willow for 1 of 74 (1.3%) cancelled controlled substances prescriptions tested and 4 of 35 (11.4%) cancelled non-controlled substances prescriptions tested did not agree with Emporos.</p> <p>Not verifying the status of prescriptions in Emporos before updating Epic Willow increases the risk that dispensing information in Epic Willow will not be accurate and more refills than authorized could be dispensed to patients.</p>	<p>Outpatient Pharmacy Management should correct the dispensing records for the five prescriptions identified, documenting the reasons for the corrections. Also, additional training should occur to ensure all Pharmacists are trained to verify the status of prescriptions in Emporos before manually updating Epic Willow.</p>	<p>Complete – Management accepts this recommendation. The dispensing records for the five cited prescriptions have been corrected in Epic Willow Ambulatory. A 2-minute huddle was sent to the pharmacy staff on 10/26/15, reeducating them on the return to stock procedure and the manual assignment of the dispensed status.</p>

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
<p>Complying with Refill Statutory Requirements</p>	<p><i>Title 21 United States Code Control Substance Act, Section 829.</i> (Title 21) <i>Prescriptions</i>, states that “the refilling of a prescription for a controlled substance listed in Schedule II is prohibited”, and that “Schedule III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date on which the prescription was issued. Prescriptions for schedule V controlled substances may be refilled as authorized by the practitioner.”</p> <p>Epic Willow includes an automated control which prevents refills of controlled substances in excess of the limits established by Title 21.</p>	<p>The Epic Willow application service provider inadvertently deactivated the automated control that prevents excess refills for all controlled substances.</p> <p>As a result, of 36,452 controlled substance prescriptions dispensed during the three months ended December 31, 2014, 12 Schedule II prescriptions included authorizations for one or more refills and 4 Schedule III and IV prescriptions had authorizations for 6 or more refills, which did not comply with Title 21.</p> <p>After the issue was discussed with Outpatient Pharmacy Management, they informed us they reviewed activity for the above 16 prescriptions and no refills in excess of Title 21 limitations were filled at</p>	<p>Outpatient Pharmacy Management should implement a process for auditing, monitoring, and approving changes requested through the Epic Willow application service provider, such as submitting change requests through the Information Technology Change Control process.</p> <p>In addition, a review of controlled substance prescriptions that were issued after the audit period from January 1, 2015, until the automated control was reinstated (April 8, 2015) should be performed to determine whether refills authorized in excess of the refills allowed by Title 21 were actually filled. If any are identified, regulatory reporting should occur if needed.</p>	<p>Root Cause Resolved – One time occurrence due to the reclassification of Hydrocodone Combination Products from Schedule III to the more restrictive Schedule II on October 6, 2014.</p> <p>Management accepts this recommendation. A report of controlled substance prescriptions issued after the audit period from 1/1/2015 to 4/7/15 has been requested from IT on 10/26/15. Any prescriptions filled beyond the authorized refills allowed by Title 21 will be reported to regulatory agencies.</p> <p>IT, Pharmacy and Epic participate in scheduled weekly meetings to review issues and recommend change requests. The change request process is as follows:</p> <ol style="list-style-type: none"> 1) Set up the requested change in Epic REL (Release Cycle) and unit test

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
(Continued) Complying with Refill Statutory Requirements	On October 6, 2014, a controlled substance which Harris Health dispenses was changed by regulatory authorities from Schedule III to Schedule II. As a result, Outpatient Pharmacy Management requested that the Epic Willow application service provider temporarily disable the automated control to allow refills for prescriptions issued before October 6, 2014, for the controlled substance that changed.	a Harris Health outpatient pharmacy through March 30, 2015.		<ol style="list-style-type: none"> 2) Data Courier changes to Epic TST (Test) environment and perform full integration testing. 3) Sign off on the change control and schedule with CAB (Change Advisory Board) for approval. 4) Move to production and validate change in production.
Documenting Prescribers and Authorizers	<p>Qualified Licensed Professionals are credentialed through the Harris Health Physician Services Department and added to an electronic record (the SER) in the EMR by the Information Technology Department (IT).</p> <p>Practitioners included on the SER are also included</p>	<p>Controls do not adequately ensure the SER is accurate and that changes to the SER are made in accordance with stated procedures. As a result, during the three months ended December 31, 2014:</p> <ul style="list-style-type: none"> • 18 individuals without appropriate professional credentials were documented in the EMR 	<p>IT Management should review and make necessary corrections to the SER, and implement a process for ensuring the accuracy of the SER is maintained.</p> <p>In addition, consideration should be given to appointing someone familiar with medical practitioner credentialing to maintain the SER in</p>	<p>Resolution with project scheduled:</p> <p>Management accepts this recommendation. The Epic Clinical Team has been assigned to initiate a project to ensure that the accuracy of the SER (provider and Resource master file) is maintained. This will be a 90 days project, to scope, to make the necessary changes and test out all the</p>

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
<p>(Continued) Documenting Prescribers and Authorizers</p>	<p>on drop down menus in the EMR that are used in certain situations for documenting prescribing and/or authorizing Qualified Licensed Professionals for prescriptions.</p>	<p>as prescribing Qualified Licensed Professionals.</p> <ul style="list-style-type: none"> • 1 user identification code used for system testing (test ID) was selected as a prescribing and 3 test IDs were selected as authorizing Qualified Licensed Professionals. <p>In addition, 186 of 2,754 (6.8%) individuals selected as prescribers and 984 of 2,210 (44.5%) selected as authorizers during the 3 months should have been on the SER on January 21, 2015, but were not.</p> <p>Without adequate controls for maintaining the SER there is an increased risk of intentional or unintentional errors in documentation, causing incorrect prescribing records and/or violations of Texas State Board of Pharmacy rules.</p>	<p>accordance with formal written procedures (a SER Coordinator).</p>	<p>deliverables. This will also include setup of Policy and Procedures to help manage the SER records. The project is requested for approval to be started the 1st week of January 2016 and will include a request for a Coordinator position to facilitate and manage the correct use of SER records.</p>

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
<p>Selecting Prescribing Qualified Licensed Professionals</p>	<p>Some ordering Qualified Licensed Professionals can select a different Qualified Licensed Professional as prescribing from a drop down menu in the EMR. Although the EMR documents the ordering Qualified Licensed Professional, the Qualified Licensed Professional selected from the drop down menu will appear on the prescription label as prescribing.</p>	<p>Controls do not adequately prevent personnel from selecting an incorrect prescribing Qualified Licensed Professional from the drop down menu in the EMR.</p> <p>As a result, there is an increased risk of incorrect prescribing records in the EMR and/or violations of Texas State Board of Pharmacy rules.</p>	<p>Outpatient Pharmacy Management, in conjunction with Information Technology Management and the EMR application service provider, should determine whether computer application controls can be implemented that restrict selections available to personnel ordering the prescriptions in the EMR to select a prescribing Qualified Licensed Professional.</p>	<p>Ongoing Resolution by provider notification and education:</p> <p>Management accepts this recommendation. Epic has not provided application controls to restrict selections available to providers when ordering prescriptions and selecting the prescribing Qualified Licensed Professional. A request has been made to Epic on 10/28/15 to research and develop this functionality. To mitigate this risk, IT has requested a report on 10/28/2015 to identify any incidences where the logged-in user ID is different from the ordering provider ID. This report will be shared with Medical Staff Services for the purpose of continuing education for the providers.</p>

ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
Monitoring User Identification Codes	<p>Qualified Licensed Professionals and/or Pharmacists access the EMR and Epic Willow by logging on with their individual user identification codes (user IDs). The level of access provided is determined by their positions and the requirements of their job. Some Qualified Licensed Professionals and/or Pharmacist need more than one user ID because they have different jobs within Harris Health (for example, they serve as supplemental staff as well as a full time employee).</p>	<p>Controls do not adequately ensure that Qualified Licensed Professionals do not have more user IDs than needed. As of January 21, 2015, 81 of 2,898 (2.8%) Qualified Licensed Professionals and 173 of 569 (30.0%) Pharmacists had more than one user ID. Outpatient Pharmacy Management confirmed that some of the users did not require more than one user ID and some had user IDs that did not reflect their current positions.</p> <p>Not ensuring that all access provided to users reflects the requirements of their job increases the risk that the users will have an inappropriate level of access, which could result in inappropriate access to information or unauthorized transactions.</p>	<p>Outpatient Pharmacy Management, in conjunction with Information Technology Management, should develop a process for periodic examination and monitoring of the access provided to the Qualified Licensed Professionals and/or Pharmacists who have more than one user ID to ensure their access is appropriate for their job responsibilities. Any inappropriate access should be disabled.</p>	<p>Process development complete Management accepts this recommendation. A Duplicate ID report was delivered on 10/28/2015. IT will provide this report to Pharmacy and Medical Staff Services who will identify and submit to IT the IDs that should be deactivated. IT will deactivate the duplicate IDs.</p> <p>This report will be reviewed biannually and inappropriate access will be disabled.</p>

RISK ASSESSMENT AND SUMMARY OF RECOMMENDATIONS

The risk matrix below presents the assessed level of risk or exposure identified during our procedures. Inherent risk relates to factors that because of their nature cannot be controlled or mitigated by management. Inherent risk includes factors such as legislative changes, number and dollar amount of transactions processed and/or complex nature of transactions. Control risks relate to factors that can be influenced or controlled by management. Controls such as policies and procedures, electronic or manual approvals, system security access, and separation of job responsibilities may be instituted by management in order to mitigate control risk. Control risk is assessed during the planning phase in order to establish the nature, timing, and extent of testing and at the conclusion of the engagement in order to incorporate actions taken to implement our recommendations. The overall risk considers a combination of inherent and control risks.

Inherent Risk:	Control Risk:		Overall Risk:
<input checked="" type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low	Prior to Procedures	After Procedures	<input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low
	Needed Improvement	Needs Improvement	
Type of Procedures: Audit			
Purpose: To evaluate critical operational and financial controls for filling outpatient prescriptions following implementation of Epic Willow.			
Outstanding Audit Recommendations:			
Priority Rating:	Audit Recommendations: Outpatient Pharmacy		
1	Correct the dispensing records for the five prescriptions identified and ensure all Pharmacists are trained to verify the status of prescriptions in Emporos before manually updating Epic Willow.		
1	Implement a process for auditing, monitoring, and approving changes requested through the Epic Willow application service provider, such as submitting change requests through the Information Technology Change Control process. Review controlled substance prescriptions after the audit period for excess refills.		
1	Review and make necessary corrections to the SER, and implement a process for ensuring the accuracy of the SER is maintained. Consideration should be given to appointing someone familiar with medical practitioner credentialing to maintain the SER in accordance with formal written procedures (a SER Coordinator).		
1	Determine whether computer system controls can be implemented that restrict selections available to personnel ordering the prescriptions in the EMR to select a prescribing Qualified Licensed Professional.		
1	Develop a process for periodic examination and monitoring of access provided to the Qualified Licensed Professionals and/or Pharmacists who have more than one user ID to ensure their access is appropriate for their job responsibilities.		

Priority Rating	<ol style="list-style-type: none"><li data-bbox="342 196 1896 253">1. Implement immediately (30 – 90 days) – Serious internal control deficiencies; or recommendations to reduce costs, maximize revenues, or improve internal controls that can be easily implemented.<li data-bbox="342 256 1896 313">2. Work towards implementing (6 – 18 months) – Less serious internal control deficiencies, or recommendations that can not be implemented immediately because of constraints imposed on the department (i.e., budgetary, technological constraints, etc.).<li data-bbox="342 316 1896 373">3. Implement in the future (two – three years) – Recommendations that should be implemented, but that can not be implemented until significant and/or uncontrolled events occur (i.e., legislative changes, buy and install major systems, requires third party cooperation, etc.).
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