

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY			STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
S000000	<p>This visit was for the investigation of a State complaint.</p> <p>Complaint Number: IN00112700 Substantiated: State deficiencies related to the allegations are cited</p> <p>Facility Number: 005015</p> <p>Date of Survey: 01/02/2013</p> <p>Surveyor: Sandra Nolfi, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 02/22/13</p>	S000000			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY			STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
S000946	<p>410 IAC 15-1.5-6 NURSING SERVICE 410 IAC 15-1.5-7 (c)(4)</p> <p>(c) Drugs and biologicals shall be prepared for administration and administered as follows:</p> <p>(4) In accordance with the signed written orders of the practitioner or practitioners responsible for the patient's care. When verbal or telephone orders are used they shall be accepted only by personnel that are authorized to do so by the medical staff rules.</p> <p>Based on medical record review, policy and procedure review, and interview, the facility failed to ensure medications were administered according to physician's orders for 1 of 1 patients who had an order for home medication use (#P5).</p> <p>Findings included:</p> <p>1. The medical record for patient #P5 indicated the patient was seen in the ED (Emergency Department) on 07/16/12 for persistent vomiting and was admitted to 3 South at 11:06 AM under Medicare Observation status. The "Admission Medication Reconciliation Form and New Medication Orders" form listed all of the medications the patient was taking at home and the physician indicated whether or not the medications were to be continued while in the hospital. The</p>	S000946	<p><u>Question 1 – Description of actions our facility took to correct the deficient practice for all patients</u> The practice that led to the deficiency was remedied prior to ISDH survey of 1/2/13 with the application of our new electronic medical record program titled 'EPIC' that was implemented on August 4, 2012. EPIC has eliminated the risk of duplicating medication orders, ensuring all medications, including home medications, are administered according to physician orders. <u>Question 2 – Description of system changes our facility made to ensure the deficient practice does not recur</u> The deficiency occurred in the legacy pharmacy system Horizons Meds Manager (HMM). In this system the patient's home medications were entered using a non-formulary shell which allowed the pharmacist to type in the</p>	01/03/2013	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013	
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY				STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>physician signed the form at 01:50 PM on 07/16/12 and indicated all of the medications that were to be continued, including Lamotrigine (Lamictal) 300 mg. take 1.5 tablets at 4 PM daily. The admission documentation indicated the patients own medications were sent home.</p> <p>The "Physician's Orders" form indicated an order from the physician at 0645 on 07/17/12, "May use patient's home meds as needed". The MAR (Medication Administration Report) indicated Lamotrigine 300 mg.=3 once a day was transcribed at 15:00 on 07/16/12. The form also had Lamotrigine 200 mg. Tab. 1.5 dose at bedtime transcribed at 22:00 on 07/17/12. A notation with this dose indicated "Patient taking own meds. Verified by pharmacy 7/17/12." The form indicated Lamotrigine 300 mg.=3 was given at 16:54 on 07/16/12 and 07/17/12 and Lamotrigine 200 mg. Tab. 1.5 dose at bedtime was given at 21:29 on 07/17/12, when the physician order was only for daily.</p> <p>2. The facility policy "Medication Reconciliation", last reviewed 12/09, indicated, "6. The Admission Medication Reconciliation Report will serve as a physician order form."</p> <p>3. The facility policy "Home Medication</p>		<p>name of the drug, dose, route, frequency and print a barcode. Unfortunately, this non-formulary shell did not screen for duplications, allergies or drug interactions. So when the patient's home medication of Lamotrigine was entered using the non-formulary shell it did not give the pharmacist a warning that there was a previous order in the system for Lamotrigine. This resulted in two orders in the system with different administration times and the patient received an extra dose. HMM was sun-downed when we went live with EPIC on 8/4/12. In EPIC there is no non-formulary shell so if there is a duplicate drug entered the physician and the pharmacist will receive a warning of the duplication. SEE ATTACHED COPY OF EPIC SCREENSHOT 'Medication Warnings'. Question 3 – Description of how corrective actions are monitored and title of responsible party Medication Errors are reported through our online event reporting system; Risk Monitor Pro. We will continue to monitor medication errors as follows · Medication errors along with all incident reports are reviewed daily by the Risk Management Coordinator. · Risk Monitor Pro generates an automatic electronic alert to Pharmacy that a medication error has occurred. Pharmacy reviews all reports upon notification. ·</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013	
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY				STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>Use for Medicare Observation Patient", last reviewed 08/03/12, indicated, "Authorized hospital personnel shall administer patient medication. ...IV. Procedure: A. Patient to sign 'Home Medication' form F.9200.23. B. Physician will authorize use of patient's home medications. C. Nurse collects all home medications brought to hospital and send immediately to pharmacy for verification and bar coding. D. Pharmacy will return bar coded home medications to nursing unit for storage in appropriate designated area. E. Nurse will administer patient's home medications via EPIC, bar code system." The policy did not address how to document the medications were brought in and sent to pharmacy for verification.</p> <p>4. At 1:15 PM on 01/02/13, staff member #N2 who navigated the EMR (Electronic Medical Record), confirmed the medical record findings and confirmed there weren't two different orders for the Lamotrigine.</p> <p>5. At 2:10 PM on 01/02/13, the director of pharmacy, staff member #N5, was interviewed. He/she indicated he/she was not at the facility in July, but described the process for using home medications. He/she indicated it appeared that the physician order for Lamotrigine was</p>		<p>The Patient Safety Oversight Team meets bi-monthly, reviewing all patient safety occurrences including medication errors, taking appropriate action as indicated. · The Medication Safety Committee meets monthly, also reviewing all medication errors, forwarding any medication safety recommendations to the Corporate Medication Safety Committee for best practice standard review. · Responsible Party: Hospital Pharmacy Director</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 01/02/2013
--	---	--	---

NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY	STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360
--	--

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	transcribed on 07/16/12, then again on 07/17/12 when the patient's home medications were received since the MAR documentation indicated the home meds were verified by pharmacy on 7/17/12. He/she indicated the first order should have been discontinued and the system that is in use now would alert pharmacy to avoid a similar problem.			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013	
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY				STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
S001014	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7(c)</p> <p>(c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals.</p> <p>Based on policy and procedure review and interview, the facility failed to ensure their policies regarding the use of home medications were specific regarding documentation of, monitoring of, and return of the medications.</p> <p>Findings included:</p> <p>1. The facility policy "Home Medication Use for Medicare Observation Patient", last reviewed 08/03/12, indicated, "Authorized hospital personnel shall administer patient medication. ...IV. Procedure: A. Patient to sign 'Home Medication' form F.9200.23. B. Physician will authorize use of patient's home medications. C. Nurse collects all home medications brought to hospital and send immediately to pharmacy for verification and bar coding. D. Pharmacy will return bar coded home medications to nursing unit for storage in appropriate designated area. E. Nurse</p>	S001014	<p><u>Question 1 – Description of actions our facility took to correct the deficient practice for all patients.</u> The practice that led to the deficiency was changed. A hospital policy and procedure has been updated/revised to ensure that Medications brought from home that cannot be sent home with a family member or responsible party are documented in the patient's medical record (EPIC) and are securely stored until time of discharge. Additional process changes were made to monitor for home medications that need to be returned at time of discharge in order to provide a secondary mechanism for compliance. SEE ATTACHMENT A (Pharmacy Policy #7300.0013) <u>Question 2 – Description of system changes our facility made to ensure the deficient practice does not recur</u> At the time of admission, when it is determined that the home medications cannot be sent home, there were</p>	05/09/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY			STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>will administer patient's home medications via EPIC, bar code system." The policy did not address how to document the medications were brought in, sent to pharmacy, or returned to the patient upon dismissal.</p> <p>2. At 1:15 PM on 01/02/13, staff member #N2 confirmed none of the pharmacy policies or discharge forms addressed how to ensure home medications used in the hospital for the patient were returned to the patient upon discharge or how nursing documentation verified the process was followed. He/she indicated the area marked "Valuables/Meds" on the discharge form referred to medications that were secured while the patient was hospitalized, not home medications administered during the hospitalization.</p>		<p>processes put in place for logging the medications stored and to alert the discharging nurse of medications that need to be returned to the patient. A supplementary process has been added for auditing of the home medications stored on the unit. To ensure staff compliance with Pharmacy Policy & Procedure #7300.0013, a mandatory CBT (computer based training) training module has been created to review appropriate procedure for documenting, securing, delivering, and returning home medications. SEE ATTACHMENT B (FSAHMC Patient Home Medications.pptx) For controlled substances. Nursing will now log controlled substances on the Belongings List in EPIC. Medications will be placed in a Valuables Envelope. Medications should be counted by nursing along with the patient or patient representative, quantity recorded on the valuables envelope, and both parties should initial. Claim ticket needs to indicate medications are in pharmacy. Medications will be brought to pharmacy by a nurse. If pharmacy is closed, the medications will be stored securely on the nursing unit until pharmacy opens. Valuable claim ticket will be stored in the patient's hard chart. Pharmacy will store the medications securely until the patient is</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY			STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
			<p>discharged. Upon discharge the belongings list will be reviewed to ensure all medications and belongings are returned. To obtain the medications at the time of patient discharge, nursing will bring the claim ticket to pharmacy and match the envelope number to the claim ticket number. The sealed envelope will be returned to the patient or patient representative. Nursing and patient or representative will count the quantity of medication to be returned to the patient. Patient or representative will sign the After Visit Summary (AVS) acknowledging that all medications have been returned.</p> <p><u>For Non-Controlled Substances</u>, Nursing will log non-controlled substances on the Belongings List in Epic. Medications will be placed in a Valuables Envelope. Medications will be stored securely on the nursing unit in designated locked area. The valuable claim ticket will be stored in the patient's hard chart. Upon discharge the belongings list will be reviewed to ensure all medications and belongings are returned to patient upon discharge. Patient or representative will sign on the AVS acknowledging that all medications have been returned. There will be a log kept in the medication storage area on each unit that will list the patients that have medications stored on the unit and/or in pharmacy. This log</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY			STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
			<p>will be audited daily and compared with the anticipated discharge list. Staff member auditing the log will alert the nurse that there are medications stored that need to be returned to the patient. For medications identified still on the unit for any discharged patient, the staff member auditing the log will follow the process for notifying the patient as outlined in policy. <u>Question 3 – Description of how corrective actions are monitored and title of responsible party</u> The following steps will be taken to monitor the effectiveness of the corrective actions and need for additional process change/education. · Education Department will monitor compliance with mandatory CBT and will provide Clinical Managers, Directors, Chief Nursing Officer, and VP of Service Line Excellence reports on completion status · The Home Medication Storage Unit Log will be audited daily by the Health Unit Coordinators · The Manager or designee will use the Home Medication Storage Unit log to complete a monthly chart audit of patients with stored home medications. The charts will be monitored for compliance with the new processes. Additional education will be provided as determined by the chart audits. · The Clinical Managers will review the policy changes with the staff during their department meetings. The managers will provide copies</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150015	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 01/02/2013
NAME OF PROVIDER OR SUPPLIER FRANCISCAN ST ANTHONY HEALTH - MICHIGAN CITY			STREET ADDRESS, CITY, STATE, ZIP CODE 301 W HOMER ST MICHIGAN CITY, IN 46360		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
			of their agendas and attendance logs to the VP of Service Line Excellence. Responsible Party: Director, Med-Surg/Women's Health Services SEE ATTACHMENTS: C Excerpt from Board of Pharmacy Regulations 2012 – Page 62 D (Home Medication Storage Unit Log) and E (Home Medication Storage Monthly Audit Log)		