

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/08/2014
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 185154	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/27/2014
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NAME OF PROVIDER OR SUPPLIER HOME OF THE INNOCENTS	STREET ADDRESS, CITY, STATE, ZIP CODE 1100 EAST MARKET STREET LOUISVILLE, KY 40206
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(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
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F 000 INITIAL COMMENTS

A Standard Survey was conducted 03/25/14 through 03/27/14. Deficiencies cited during the standard survey with the highest scope and severity of an "E". A Life Safety Code Survey was conducted 03/25/14. There were no deficiencies cited related to the Life Safety Code Survey.

This was a Nursing Home Initiative survey with entrance on Tuesday, 03/25/14 at 7:50 AM.

F 431 483.60(b), (d), (e) DRUG RECORDS, SS=E LABEL/STORE DRUGS & BIOLOGICALS

The facility must employ or obtain the services of a licensed pharmacist who establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the

F 000

"This Plan of Correction is prepared and submitted pursuant to Federal and State law. This Plan of Correction does not constitute an admission of, or agreement to, any alleged deficiencies or to any statement, findings, facts, or conclusions that form the basis of the alleged deficiencies. This facility reserves the right to challenge the alleged deficiencies and any statements, findings, facts, or conclusions that form the basis of the alleged deficiencies in any legal proceeding".

F 431 F Tag 431 PHARMACY SERVICES 4-21-14

The statement of deficiency indicated several unlicensed individuals were observed working in the medication room on Sunshine Lane and were not directly supervised by a licensed staff person. Further interviews revealed unauthorized individuals including the Director of Environmental Services / Material Management and Unit Secretaries had keys allowing access to the medication rooms. This allowed access to unlocked medications located in the medication refrigerator and storage shelving. Locks were placed on the medication refrigerators on March 27, 2014 by Maintenance Manager, Bob Defazio and Maintenance Technician, Mike Moss to safeguard refrigerated prescribed medications on each of the five cottages housing resident medications. Staff members of Environmental Services, Materials

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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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.

APPROVED

MAY - 6 2014

If continuation sheet Page 1 of 7
OFFICE OF INSPECTOR GENERAL
DIVISION OF HEALTH CARE FACILITIES AND SERVICES

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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F 431 Continued From page 1

Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

This REQUIREMENT is not met as evidenced by:
Based on observation, interview and review of the facility's storage of medications policy, it was determined the facility failed to ensure physician ordered medications were secured and only accessible to licensed personnel. The facility failed to secure physician ordered medication in five (5) of five (5) medication rooms. The medication rooms on Maple, Sunshine, Zephyr, Ocean and Rain Forest had refrigerators unlocked with physician ordered medications.

The findings include:

Review of the facility's Storage of Medication Policy, provided on 03/27/14, effective date 03/27/14, revealed medications and biologicals are stored safely, securely and properly following the manufacturer's recommendations or those of the supplier. The medication supply would be accessible only to licensed nursing personnel, pharmacy personnel or staff members lawfully authorized to administer medications.

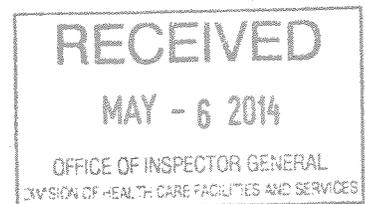
Observation of the medication room on the Sunshine Unit, on 03/25/14 at 1:35 PM, revealed a closed door to the medication room and a mop bucket sitting in the hall way outside of the medication room. A lone staff member was seen

F 431

Management, Health Information Management / Medical Records, Nursing Staff and Pharmacy Staff that were on duty during the hours of 0800 and 1800 on March 27, 2014 and March 28, 2014 were verbally reminded of the policy that indicates "medication supply would be accessible only to licensed nursing personnel, pharmacy personnel or staff members lawfully authorized to administer medications" by Karen Bender, DON, April Raddish, DCS and Jeff Lewis, Administrator. Staffs from the above identified departments were instructed by Karen Bender, DON and April Raddish, DCS on March 27th and 28th 2014 that whenever access was necessary, an approved individual must be present in the room at all times thus eliminating the potential for other residents to be affected by the same deficient practice. A walk-thru survey was conducted by Karen Bender, DON and April Raddish, DCS on March 31, 2014 to determine other areas that may have been affected by the same alleged deficient practice. We determined that the Clinical Supervisor's Office and the Lab Room intermittently contain unlocked medications and thus access should be restricted.

Systemic changes made to ensure that the deficient practice will not recur in the KCPCC included changing the key cores on April 17th and April 18th, 2014 by Mike Moss, Maintenance Technician of each medication room, Clinical

F-431



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F 431 Continued From page 2

through the window mopping the floor in the medication room with the door closed. A second staff was in the hallway. A medication refrigerator was seen in the medication room without a locking mechanism attached.

Observation with the Director of Environmental Services/Central Supply, on 03/25/14 at 1:37 PM, revealed Heparin Flush was stored on the shelves in the medication room. The medication refrigerator had physician prescribed medications and did not have a locking mechanism to secure the medications.

Observation of the Director of Environmental Services (DES), on 03/25/14 at 1:50 PM, revealed she directed a staff member of housekeeping to clean the medication room as the medication room door was unlocked and propped open to the hallway on the Sunshine unit. The staff member left her housekeeping cart at the entrance door. The housekeeping staff was in the medication room unsupervised while the DES was at the nurse's station counter.

Interview with the Director of Environmental Services/Central Supply and Supervisor of Environmental Services, on 3/25/14 at 1:37 PM, revealed an unlicensed staff could be in the medication and supply room with two (2) persons observing. The Director of Environmental Services reported she had a key to the room to let staff in for cleaning and stocking when the nurses are busy. She stated that she had a set of keys to allow staff in and out of the central supply room. She stated the nurse was busy so she let the Supervisor of Environmental services in to mop the room. She stated this was the same for all of the medication/storage rooms on each unit

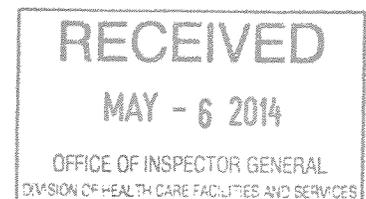
F 431

Supervisor's Office and Lab Room thus limiting previous access as indicated above. Keys to the new key cores were distributed on April 18, 2014 by Karen Bender, DON, to licensed nursing personnel and pharmacy personnel ensuring accessibility by approved individuals only.

The procedure Medication Storage in the Facility ID1 Storage of Medications was revised on April 16, 2014 by April Raddish, DCS, to indicate the requirement of a licensed individual to be present in the medication room at all times when an unlicensed individual requires access to the room for purposes of stocking, cleaning or medication transcription. (See Attachment A)

KCPCC Staff, Materials Management Staff and Pharmacy Staff were made aware of changes to the procedure and to the requirements for accessibility to medication rooms by unlicensed individuals through email distribution of the revised procedure to ensure that these solutions are sustained on April 18, 2014 by Susan Sanford, Staff Development Coordinator. (See Attachment B)

Access to Medication Rooms, Clinical Supervisor's Office and the Lab Room by unlicensed individuals shall be monitored on an ongoing basis during Infection Control Rounds that occur monthly and are conducted by one or more of the following individuals:



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F 431 Continued From page 3

served. She reported she served Maple Way, Sunshine, Ocean, Zephyr and Rain Forest. The room was for medication storage and the central supply room. The Supervisor of Environmental Services stated there must be two (2) people present when a staff was cleaning in the room. He stated it was ok for the observer to be in the hallway while the other was mopping the floor.

Interview with the Unit Secretary, on 03/25/14 at 2:00 PM, revealed she had a key to the medication/storage rooms for each of the units she worked on. She stated her key unlocked the medication rooms on Maple, Sunshine and Ocean Units.

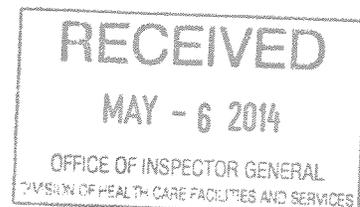
Interview with Registered Nurse (RN) #2, on 03/27/14 at 10:40 AM, revealed housekeeping staff had been let in the medication room for cleaning purposes. She had not always stayed with the staff during busy times on the unit.

Interview with the Director of Nursing, on 03/27/14 at 10:50 AM, revealed the narcotics were double locked on the medication carts. She reported the Unit Secretaries had access to the medication/supply room so they could retrieve the medication administration records (MAR) to update them as needed. She stated they had never had locks on the refrigerators; however, when narcotics were delivered by pharmacy they were in a locked box and attached to the bar in the refrigerator and the door is locked to the room. She stated the licensed staff was responsible for the room and only licensed staff such as pharmacy and nursing was allowed access to the medications. She stated the Unit Secretaries and Housekeeping staff was not authorized to have access to the medications.

F 431

Karen Bender, DON, Madelyn Pressey, Vice President of Quality Improvement, RN Clinical Supervisors and David McDonald, CFO. Infection Control Rounds findings related to limiting access to medication storage areas will be reported quarterly to the Risk Management Committee and Quality Improvement Committee. (See Attachment C)

In an effort to ensure the above solutions are sustained into the future, Kathy Masterson, Director of Environmental Services and Materials Management, Todd Padgett, Supervisor of Laundry and Environmental Services and Toni Knierem, Health Information Management Coordinator shall include the requirement for limiting accessibility to medication rooms, Clinical Supervisor's Office and the Lab Room in orientation of new employees in these respective departments. Staff will be reminded of the access limitations to medication storage areas during All Staff Meetings conducted by Jeff Lewis, Administrator and during Materials / Environmental Services / Laundry Department Meetings conducted by Kathy Masterson, Director of Environmental Services and Materials Management quarterly over the next 12 months. Minutes to these meetings will be distributed to those individuals unable to attend the meetings and reported to the Quality Improvement Committee.



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F 431 Continued From page 4
She stated there should be two (2) staff present in the medication room when an unlicensed staff was present. She reported this function was the same for all units in the facility.

F 520 483.75(o)(1) QAA
SS=E COMMITTEE-MEMBERS/MEET
QUARTERLY/PLANS

A facility must maintain a quality assessment and assurance committee consisting of the director of nursing services; a physician designated by the facility; and at least 3 other members of the facility's staff.

The quality assessment and assurance committee meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and develops and implements appropriate plans of action to correct identified quality deficiencies.

A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.

Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

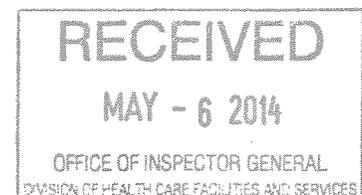
This REQUIREMENT is not met as evidenced by:
Based on interview and review of the facility's Quality Assessment and Assurance (QAA) policy

F 431 F Tag 520 COMMITTEE - MEMBERS / MEET QUARTERLY / PLANS

F 520 The facility will ensure appropriate record is kept quarterly to identify all attendees and members of the Quality Improvement Committee. Marilyn Mayes, Administrative Assistant to Quality Improvement developed a new sign in sheet on 4/11/14. A recording process will be implemented at the next QI Committee meeting on 5/15/14 that requires signatures of all participants to ensure irrefutable recording of all attendees. The QI Administrative Assistant will take three strategic measures to remind members of the time and date of the Quality Improvement Meetings.

- Implement a sign-in sheet with the printed names of committee members on the left side of the paper and require the members' signature on the right side of the paper to include the Medical Director. (See Attachment D)
- The QI Administrative Assistant will distribute the Quality Improvement packet which includes the minutes, agenda, previous actions, new business for discussion and the date and time of the next meeting to all members of the committee, including the Medical Director, one week prior to the meeting. This serves as a reminder of the date and time the meeting will occur.

4-21-14



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F 520 Continued From page 5
and attendance record, it was determined the facility failed to ensure the Medical Director attended quarterly for two (2) of the last three (3) quarterly committee meetings. The Medical Director was not in attendance at the quarterly QAA meetings, on 11/21/13 and 02/20/14, as identified on the committee membership attendance record.

The findings include:

Review of the facility's Performance Improvement Policy, Continuous Quality Improvement Plan, effective date August 1998, and revised January 2006, revealed the facility established a Continuous Quality Improvement Program to operate under the policies of the Board of Directors and in accordance with the organizations's mission, vision and values.

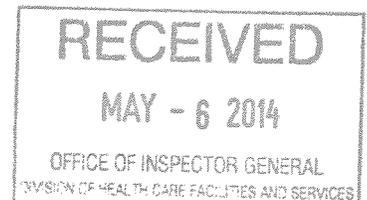
Review of the facility's Performance and Quality Improvement (PQI) Plan, dated 2010-2011, and identified as still current by the Vice President of Quality Assurance, revealed the program directors/supervisors submit quality monitoring reports quarterly to the Vice President for Quality Improvement(QI/QA). Quarterly the multidisciplinary group reviews the data and makes recommendation to management. The committee has the responsibility to receive and review all PQI activities. The committee meets quarterly and membership included the Medical Director.

Review of the facility's QAA Committee attendance record, dated 11/21/13, revealed the Medical Director was not in attendance.

Review of the facility's QAA Committee

F 520

- On 4/18/14, the KCPCC Administrative Assistant, Debbie VanMeter, posted a reminder on the Physician's Calendar which is located in the Physician's office with the date, time and location of the upcoming Quality Improvement Committee meetings thru the end of the year as a constant reminder of when the Quality Improvement Committee meetings will be held.
- The QI Administrative Assistant will distribute a copy of the meeting minutes following each committee meeting. If the physician was unable to attend, the physician will review and sign the minutes indicating acknowledgment of the content of the meeting and return the packet to the Vice President of Quality Improvement, Madelyn Pressey. This will be implemented at any point the physician is unable to attend.
- A meeting was held 4/11/14 with Jeff Lewis, KCPCC Administrator and Heather Huxol, KCPCC Medical Director to discuss the importance of her /and or one of the attending physicians regular attendance to the Quality Improvement Committee meeting. At that time, she informed me that she was late to the February 20, 2014 Q.I. committee meeting nevertheless she was present. (See Attachment E) We also discussed the new sign in sheet that was



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F 520 Continued From page 6
attendance record, dated 02/20/14, revealed the Medical Director was not in attendance.

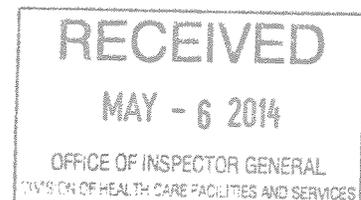
Interview with the Vice President for Quality Improvement (QI/QA), on 3/27/14 at 2:24 PM, revealed QI/QA met quarterly. She stated the Medical Director was required to attend the QA meetings quarterly. She identified the past three (3) quarterly QA meetings, since the last survey, occurred on 08/15/14, 11/21/13 and on 02/20/14. Upon review of the attendance record for the committee membership, she stated the Medical Director did not attend the QA quarterly meeting, on 11/21/13 and on 02/20/14. She reported the purpose of the Medical Director's attendance to the QA committee meeting was to ensure the Medical Director monitored all the programs and to ensure the programs were reviewed medically. Further interview revealed the facility had not discussed the last two meetings with the Medical Director.

Interview with the Administrator, on 03/27/14 at 2:25 PM, revealed the facility conducted a quarterly QA committee. He reported the committee consisted of the Director of Nurses and the Medical Director plus other department heads. He stated, they had a new Medical Director that was still onboarding with the program; however, had not attended the last two meetings. He reported the prior Medical Director was still active to meet the needs of the facility; however had not attended the last two meetings either. He stated he was aware the Medical Director was to attend the QA committee at least quarterly.

F 520

developed to allow all committee members to document their attendance at the meeting. I asked that she or the attending physicians sign the sheet at the meeting to begin 5/15/14. In the event a physician is unable to attend, I asked that Dr. Heather Huxol read and sign the minutes for the meeting and return them to Madelyn Pressey Vice President of Quality Improvement to verify that she received the content of the meeting. We agreed on this plan to ensure involvement of the Medical Director in the Quality Improvement Committee.

- Jeff Lewis, KCPCC Administrator will review the sign in sheet with the QI Administrative Assistant following each QI Meeting to ensure the Medical Director or attending physician regularly attends the Quality Improvement Committee meeting.



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K 000	<p>INITIAL COMMENTS</p> <p>CFR: 42 CFR 483.70(a)</p> <p>BUILDING: 01</p> <p>PLAN APPROVAL: 2003, 2010</p> <p>SURVEY UNDER: 2000 New</p> <p>FACILITY TYPE: SNF/NF</p> <p>TYPE OF STRUCTURE: The original 2003 building is a one (1) story structure with a partial basement. The 2010 building addition is a two (2) story structure with a full basement, Construction Type II Protected.</p> <p>SMOKE COMPARTMENTS: Seven (7) smoke compartments.</p> <p>FIRE BARRIER: The non-certified facility and the Skilled Nursing Facility were separated by a two-hour fire barrier.</p> <p>FIRE ALARM: Complete fire alarm system with heat and smoke detectors.</p> <p>SPRINKLER SYSTEM: Complete automatic, wet sprinkler system, hydraulically designed</p> <p>GENERATOR: Type II, 750 KW generator. Fuel source is diesel.</p> <p>An abbreviated, Short Form, Life Safety Code survey was conducted on 03/25/14. The Home of the Innocents was found to be in compliance with the Requirements for Participation in Medicare</p>	K 000		4-21-14

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *[Signature]* TITLE *Admin / VP* (X6) DATE *5-5-14*

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OFFICE OF HEALTH CARE COMPLIANCE SERVICES
If continuation sheet Page 1 of 2

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K 000	Continued From page 1 and Medicaid in accordance with Title 42, Code of Federal Regulations, 483.70 (a) et seq. (Life Safety from Fire).	K 000		

