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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____ | X3) DATE SURVEY COMPLETED 06/06/2016 |
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| NAME OF PROVIDER OR SUPPLIER HEARTH AT SYCAMORE VILLAGE LLC | STREET ADDRESS, CITY, STATE, ZIP CODE 611 W COUNTY LINE RD S FORT WAYNE, IN 46814 |
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| R 0000 Bldg. 00 | <p>This visit was for a State Residential Licensure Survey.</p> <p>Survey date: June 2, 3 & 6, 2016</p> <p>Facility number: 011804 Provider number: 011804 AIM number: N/A</p> <p>Census bed type: Residential: 106 Total: 106</p> <p>Census payor type: Other: 106 Total: 106</p> <p>Sample: Residential sample: 7</p> <p>These deficiencies reflect state findings cited in accordance with 410 IAC 16.2-5.</p> <p>QR completed on June 8, 2016 by 17934.</p> | R 0000 | The statements made in this Plan of Correction are not an admission to, nor constitute an agreement nor does it constitute an agreement with the alleged deficiencies herein. To remain in compliance with all federal and state regulations, the community has taken or is planning to take the actions set forth in the following plan of correction. All deficiencies cited have been or are to be corrected by the date or dates indicated. | |
| R 0121 Bldg. 00 | <p>410 IAC 16.2-5-1.4(f)(1-4) Personnel - Noncompliance (f) A health screen shall be required for each employee of a facility prior to resident contact. The screen shall include a tuberculin skin test, using the Mantoux method (5 TU, PPD), unless a previously</p> | | | |

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.

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| | <p>positive reaction can be documented. The result shall be recorded in millimeters of induration with the date given, date read, and by whom administered. The facility must assure the following:</p> <p>(1) At the time of employment, or within one (1) month prior to employment, and at least annually thereafter, employees and nonpaid personnel of facilities shall be screened for tuberculosis. The first tuberculin skin test must be read prior to the employee starting work. For health care workers who have not had a documented negative tuberculin skin test result during the preceding twelve (12) months, the baseline tuberculin skin testing should employ the two-step method. If the first step is negative, a second test should be performed one (1) to three (3) weeks after the first step. The frequency of repeat testing will depend on the risk of infection with tuberculosis.</p> <p>(2) All employees who have a positive reaction to the skin test shall be required to have a chest x-ray and other physical and laboratory examinations in order to complete a diagnosis.</p> <p>(3) The facility shall maintain a health record of each employee that includes reports of all employment-related health screenings.</p> <p>(4) An employee with symptoms or signs of active disease, (symptoms suggestive of active tuberculosis, including, but not limited to, cough, fever, night sweats, and weight loss) shall not be permitted to work until tuberculosis is ruled out.</p> <p>Based on interview and record review, the facility failed to ensure tuberculin skin testing was completed for 7 of 10 staff at hire (Cook #20, Certified Nursing Assistant (CNA) #21, Food Service Director #22, Wellness Director</p> | R 0121 | <p>1. A first step and second step tuberculin skin test has been performed for employees #20, #21, #22, #23, #24, #25, #26, #27 including steps to accurately administer, read and record the testing. 2. Business Office</p> | 07/06/2016 |

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| | <p>Keepsake Village #23, Server #24, Executive Director #25, and Qualified Medication Assistant (QMA) #26).</p> <p>Findings include:</p> <p>A review of the facility personnel records began on 6/6/16 at 10:00 a.m. and indicated the following:</p> <p>Cook #20 (start date of 12-3-15) had a first tuberculin (TB) skin test read on 11/22/15. A second TB skin test was administered on 12/10/15 but documentation was lacking of the test ever being read.</p> <p>CNA #21 (start date of 1-12-16) had a TB skin test read on 1/7/16. Documentation was lacking of a negative TB skin test during the prior 12 months or a second step TB skin test performed and read.</p> <p>Food Service Director #22 (start date of 9-28-15) had documentation on the physical examination form of "had TB test 9/21/15" but documentation was lacking of the results of the skin test. A TB skin test was administered on 6/3/16 and read on 6/6/16.</p> <p>Wellness Director Keepsake Village #23 (start date of 10-12-15) had a TB skin test</p> | | <p>Manager has conducted an audit of all employee files to identify any other employees who do not have a complete and/or timely tuberculin test performed per state regulations. For any noncompliant employees, a tuberculin test will be immediately performed including steps to accurately administer, read and record the testing. 3. Regional Operations Manager will train Executive Director and Business Office Manager on June 28, 2016 regarding state regulations for accurate completion of tuberculin screening for employees. Business Office Manager will be responsible for ensuring that new employees have been screened for tuberculosis prior to starting work to include a first step tuberculin skin test that has been performed, read and recorded accurately. Business Office Manager will utilize a tracking system for new employees to ensure that those who do not have a documented negative tuberculin skin test during the preceding twelve months have a second test performed one to three weeks after the first step, including steps to accurately administer, read and record the testing. 4. Executive Director will monitor new employee records and the TB tracking system to ensure that all steps of the tuberculin testing are being completed accurately. These audits will be conducted twice</p> | |

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| | <p>read on 10/11/15. Documentation was lacking of a second TB test having been performed.</p> <p>Server #24 (start date of 12-23-15) had a TB skin test read on 12-3-15. Documentation was lacking of a second TB skin test having been performed.</p> <p>Executive Director #25 (start date of 5-16-16) had one TB test performed on 5/25/16, but documentation was lacking of the test having been read. Documentation was lacking of a TB skin test read prior to starting work and a second step TB skin test having been performed.</p> <p>QMA #26 (start date of 3-23-16) had a TB skin test performed on 3/15/16. Documentation was lacking of the test having been read or a second TB skin test having been performed.</p> <p>On 6/6/16 at 3:50 p.m., the Business Office Manager #27 was interviewed. She indicated she was responsible to ensure new employees received their TB skin tests and also to have them read. She indicated she was given this responsibility 2 to 3 weeks ago. Business Office Manager #27 indicated a TB certified nurse administered the TB skin test to employees. She further indicated</p> | | <p>weekly x4weeks; weekly x 4 weeks and monthly thereafter. Results of these audits will be reviewed by the QA Committee, who will establish the threshold of compliance and make further recommendations accordingly.</p> | |

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| R 0148 Bldg. 00 | <p>upon employees accepting a job offer by the facility, the employee was to have received a TB skin test performed and read. The Business Office Manager #27 indicated when employees did not get the TB skin test read as required, the employee would have to had the TB skin test repeated. She indicated employees were required to have a two step TB skin test performed upon hire. The Business Office Manager #27 also indicated the Food Service Director #22 had an initial TB skin test administered on 6/3/16 and read on 6/6/16, even though the date he began working at the facility was on 9-28-15.</p> <p>On 6/6/16 at 4:14 p.m., the Wellness Director of Keepsake Village #23 provided a policy and procedure for "Pre-Employment Physical" dated 9/27/11. The policy included, but was not limited to, the following: "The physical exam must include a test for Tuberculosis."</p> <p>410 IAC 16.2-5-1.5(e)(1-4) Sanitation and Safety Standards - Deficiency (e) The facility shall maintain buildings, grounds, and equipment in a clean condition, in good repair, and free of hazards</p> | | | |

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| | <p>that may adversely affect the health and welfare of the residents or the public as follows:</p> <p>(1) Each facility shall establish and implement a written program for maintenance to ensure the continued upkeep of the facility.</p> <p>(2) The electrical system, including appliances, cords, switches, alternate power sources, fire alarm and detection systems, shall be maintained to guarantee safe functioning and compliance with state electrical codes.</p> <p>(3) All plumbing shall function properly and comply with state plumbing codes.</p> <p>(4) At least yearly, heating and ventilating systems shall be inspected.</p> <p>Based on observation, interview and record review, the facility failed to ensure hazardous chemicals were maintained in a safe and secure manner in 2 of 2 memory units, Keepsake Village North and South. This had the potential to affect 10 confused and independently mobile residents on the 2 units.</p> <p>Findings include:</p> <p>An observation in the Keepsake Village North unit on 6-2-2016 at 4:09 p.m., indicated the laundry room door was not secured. The door was observed to have a lock, but the door was observed not to be closed to engage the lock. The laundry room was observed to be unattended. Inside the laundry room, the following were observed:</p> | R 0148 | <p>1- Our immediate action was to secure all doors. Doors were inspected immediately to evaluate proper functioning of the door closers. The maintenance supervisor and assistance conducted a full house audit of all areas of the community that would contain hazardous chemicals to ensure the areas were secure. 2- Keepsake Village residents identified as confused and independently mobile have the potential to be affected by these deficient practices. On Keepsake South the nursing station doors and the Kitchen doors have been secured and staff have been inserviced with daily reminders to keep these doors locked when they are not present. In addition the kitchen cabinets were inspected and hazardous items were removed immediately. Additional</p> | 07/06/2016 |

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| | <p>A shelf inside the door was located approximately 6 feet from the ground with 2 containers of spray starch (a 22 ounce and a 20 ounce spray bottle), a quart spray bottle of tropical breeze neutralizer and a 21.5 ounce bottle of "brand name" stain remover.</p> <p>A shelf located above the folding table had a 12 ounce bottle of stain remover and 3 containers of liquid laundry soap (50 ounce, 315 ounce and a 169.5 ounce sized containers).</p> <p>An observation while in the laundry room on 6-2-2016 at 4:10 p.m., indicated QMA #6 entered the laundry room and turned and walked out of the laundry room without ensuring the laundry room door was secured.</p> <p>An observation of the unattended nurse station on 6-2-2016 at 4:11 p.m., indicated a large container of germicidal wipes were found in a cabinet which was not secured. There were no locks observed on any of the cabinet doors at the accessible nurse's station.</p> <p>All the above chemicals had "Keep out of Reach of Children" on the labels.</p> <p>An observation on the Keepsake Village South on 6-2-2016 at 4:18 p.m., indicated</p> | | <p>keys were made and distributed to staff for the kitchen in which they now wear on their person.</p> <p>On Keepsake North the nursing station cabinets were inspected and hazardous items were removed. Staff has been in serviced with daily reminders to keep all areas of the nurses' station free of hazardous items. The laundry door lock has been replaced with a storage room lock and self closing hinges in order to ensure that the door locks and latches. Staff have been in serviced with daily reminders on the importance of keeping the laundry door locked when they are working outside the laundry room/nursing station area. 3-The Wellness Directors and Executive Director will conduct inservice training which will begin on June 24th through July 5th for all staff on the guidelines pertaining to maintaining a community that is free of hazards that may adversely affect the health and welfare of our residents. 4-The Executive Director and/or Designee will round daily for two weeks, three times per week for the next 2 weeks and monthly thereafter in order to monitor that Keepsake Village is free of hazards that may adversely affect the residents. Evaluate progress with the safety committee quarterly. Results of these audits will be reviewed by the safety Committee, who will establish the threshold of</p> | |

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| | <p>the nurse's office door was opened and the office was unattended.</p> <p>A 32 ounce pump bottle of cocoa butter lotion was observed on the counter with "Keep out of Reach of Children" and "If swallowed get medical help or contact poison control center right away" on the label.</p> <p>Further observation indicated several upper cabinets were accessible and had no locks to secure the doors. Inside the cabinets, the following were observed:</p> <p>A 100 tablet bottle of acetaminophen 325 milligrams, a 90 tablet bottle of extra strength antacid, a 4 ounce can of hair spray, a 1 ounce bottle of hand sanitizer, a large container of germicidal wipes, a 16 ounce bottle of hydrogen peroxide and a spray bottle with 18 ounces of concentrated laundry air freshener. Each container had "Keep out of reach of children" on the label.</p> <p>An observation while in the unattended nursing office in the Keepsake Village South memory unit on 6-2-2016 at 4:21 p.m., indicated LPN #7 entered the nursing office. LPN #7 indicated she needed to clock in and left the nursing office without securing the door. At 4:24 p.m., while still in the unattended and accessible nursing office, CNA #8</p> | | compliance and make further recommendations accordingly. | |

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| | <p>entered the office. CNA #8 was interviewed at this time and she indicated the nursing office door was usually locked.</p> <p>An observation in the hallway outside the nursing office on the Keepsake Village South memory unit on 6-2-2016 at 4:25 p.m., indicated a resident was ambulating independently with her walker.</p> <p>An observation in the Keepsake Village South kitchen on 6-6-2016 at 11:08 a.m., indicated the kitchen door was not secured. The door handle had a lock but the door was not shut tight. Inside the kitchen, the cabinet doors and drawers each had locks. Upon closer inspection, none of the kitchen cabinet doors and drawers were locked. An observation in a drawer indicated 20 packets of thermometer probe cleaning squares. In 2 other drawers, a total of three 8 ounce pump bottles of hand sanitizer were observed. Both products had "Keep out of reach of children" and "If swallowed, get medical help or contact Poison Control Center right away" on the labels.</p> <p>An interview with the Director of Food Services on 6-6-2016 at 11:30 a.m., indicated the staff were not very good about locking the kitchen door (in Keepsake Village South) and he</p> | | | |

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| R 0273 Bldg. 00 | <p>indicated the kitchen door should have been secured.</p> <p>An interview with the Executive Director on 6-6-2016 at 2:15 p.m., indicated the laundry room door in Keepsake Village North and the nursing office door in Keepsake Village South should have both been secured.</p> <p>On 6-6-2016 at 3:05 p.m., the Executive Director indicated there were 6 confused and independently mobile residents in Keepsake Village South and 4 confused and independently mobile residents in Keepsake Village North. Further interview with the Executive Director, indicated the facility did not have a policy on chemical storage. The Executive Director indicated, "we just know that we are to keep them (chemicals) locked up."</p> <p>410 IAC 16.2-5-5.1(f) Food and Nutritional Services - Deficiency (f) All food preparation and serving areas (excluding areas in residents ' units) are maintained in accordance with state and</p> | | | |

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| | <p>local sanitation and safe food handling standards, including 410 IAC 7-24. Based on observation, interview and record review, the facility failed to ensure food was labeled and securely stored with open dates identified, expired food products were discarded, handwashing or hand hygiene was done at appropriate times, serving utensils were used appropriately, plates and bowls were protected from contamination, dome covers were washed and sanitized after resident use. These deficiencies affected 3 of 3 dining rooms with the potential to affect the 106 residents who ate their meals at the facility.</p> <p>Findings include:</p> <p>An observation in the facility kitchen with the Director of Food Services on 6-2-2016 from 10:20 a.m. to 10:46 a.m., indicated the following:</p> <p>Inside the walk in refrigerator, there was an opened, unidentified bag of meat found on a shelf. The Director of Food Services indicated the contents were diced chicken and the bag should have been secured, labeled and dated.</p> <p>Inside a reach in (bread) refrigerator, there were 6 assorted drink bottles and an unlabeled insulated lunch bag. The</p> | R 0273 | <p>1- Our immediate action included discarding the food items that were opened and unlabeled. 2-All residents have the potential to be affected by these deficient practices. The Food Service Director conducted training and review of policies and procedures with the food service staff on 6.10.16. Topics reviewed included: Hand Washing; Glove Use; Food Storage; Food Safety; non-food storage; food receiving and storage policy. 3-The Executive Director/Food Service Director will conduct training with nursing, food services, administrative and activities staff regarding the following: Hand Washing-proper hand washing procedure with return demonstration; and the proper ways to handle dishware/utensils while serving; Food Storage; Food Safety; non-food storage; food receiving and storage policy. Training will begin on June 24th through July 5th. 4-The Food Service Director and or designee will conduct observations of the meal service process to ensure food is being served under sanitary conditions. Observations will be conducted three times per week for 4 weeks; once a week for the next 4 weeks; and monthly thereafter. The Food Service Director will ensure the staff is following the proper food storage procedures 2</p> | 07/06/2016 | | | |

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| | <p>Director of Food Services indicated the employees stored their personal drinks and food on the bottom shelf of the reach in refrigerator.</p> <p>Inside an ice cream cooler, there were two opened 5 gallon containers of ice cream (butter pecan and mint chip) stored without being covered or dated when opened.</p> <p>An observation in the Keepsake Village North memory unit kitchen on 6-2-2016 at 11:45 a.m., indicated an opened coffee creamer container and a partially used foil wrapped package of unsalted butter did not have open dates on them. Further observation in the freezer, indicated an opened and covered 5 gallon container of cookies and cream ice cream was not labeled when opened. An undated notice was posted on the front of the refrigerator and indicated the following: "...any and all products that go into this refrigerator needs to be labeled with 1. what is it 2. when it was received/or filled 3. when it was opened...."</p> <p>An observation in the Keepsake Village South memory unit kitchen on 6-6-2016 at 11:08 a.m., indicated the following:</p> <p>A cart with a stack of plates and 2 stacks of bowls were observed to be sitting right</p> | | <p>times per week for the first month and weekly thereafter. Results of these meal service observations will be reviewed by the QA committee, who will establish the threshold of compliance and make further recommendations accordingly.</p> | |

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| | <p>side up in the kitchen area without being protected from contamination. An interview with the Director of Food Services on 6-6-2016 at 11:30 a.m., indicated the dishes will be used for lunch and usually had parchment paper covering them when transported from the main kitchen.</p> <p>Further observation of the Keepsake Village South memory unit kitchen, indicated the following:</p> <p>Inside a cabinet above the sink, there was an opened and unsecured package of marshmallows without an open date on the package and a 12 ounce, opened, partially used bottle of sugar free syrup with "Keep refrigerated after opening" on the label.</p> <p>A unopened box of apple juice concentrate was found under the juice machine with a use by date of 5-14-2016.</p> <p>A cabinet labeled "baking supplies" located under the oven had an opened, unsealed 14 ounce partially used package of coconut with a sell by date of "May 12, 2015 and an opened date of "1-12" written on the package. A 6 ounce opened and partially used, unsealed package of walnut pieces had an opened date of "12-2" and an unreadable sell by</p> | | | |

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| | <p>or use by date. There were 2 sealed, clear packages of white powder, not stored in the original container. There was not a use by or sell by date on either package and only 1 package had legible printing identifying the contents "cream cheese fill [sic]." An opened, partially used 5 pound paper bag of sugar was observed to not be sealed securely. An opened and partially used 16 ounce bottle of white distilled vinegar was observed to have a "best by date of 3-13-2013." Four, unopened 1 cup packages of shortening with a use by date of "Aug. 6, 2011" on the labels were observed in the cabinet. An unopened package of microwave popcorn with a "sell by date 12-29-15" and an opened box of hot cocoa mix with 11 individual packets inside had a "sell by date 5-5-2016" were also inside the cabinet.</p> <p>An interview with the Director of Food Services on 6-6-2016 at 11:30 a.m., indicated he was unaware the items in this kitchen were not securely stored and some were out of date.</p> <p>An observation of the Keepsake Village North lunch meal on 6-2-2016, indicated the following:</p> <p>At 11:52 a.m., the Dining Room Supervisor #3 used his gloved hand to</p> | | | |

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| | <p>pick up the hamburger and hot dog buns and placed them on the plates for the 12 residents that ate lunch on this day.</p> <p>At 12:05 p.m., Activities #4 was observed to enter the dining room and without washing her hands or using hand hygiene, and served a resident their lunch meal.</p> <p>An observation of the Main dining room on 6-3-2016, indicated the following:</p> <p>At 11:44 a.m., Server #2 used her right hand to brush her hair back by her right brow and without washing her hands or using hand hygiene, she obtained a cup and filled it with soup and served it to a resident.</p> <p>At 11:45 a.m., Server #2 was observed to touch the braid on the back of her head twice and without washing her hands or performing hand hygiene, she served 2 residents their drinks.</p> <p>An observation in the hallway between the main dining room and the main kitchen on 6-6-2016 at 11:50 a.m., indicated Server #1 was carrying a stack of 10-12 dome covers (used to cover plated food in transport) turned upside down on a tray from the main dining room to the kitchen. Once in the kitchen,</p> | | | |

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| | <p>Server #1 placed the dome covers in the holder by where the plates were being covered. Server #1 was observed to use 2 of the dome covers she had just brought to the kitchen, to cover 2 plates, carried them to the dining room and served 2 residents their lunch.</p> <p>An interview with the Dining Room Supervisor on 6-6-2016 at 11:54 a.m., indicated the dome covers brought back from the main dining room should have been taken to the dishwasher to be washed and sanitized prior to using them again. An interview with the Director of Food Services at this time, indicated he was unaware staff were re-using the dome covers without having been washed.</p> <p>An interview with Server #1 on 6-6-2016 at 11:56 a.m., indicated she had taken the used dome covers to the kitchen and re-used them without getting them washed. She indicated she would only get the dome covers washed if there was food on them. Further interview with Server #1, indicated she was unaware the dome covers had to be washed after each use.</p> <p>An observation of the Keepsake Village South lunch meal on 6-6-2016 indicated 20 residents were in the dining room to</p> | | | |

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| | <p>be served. The following was observed:</p> <p>At 11:59 a.m., Server #5 was observed to bring the insulated cart into the kitchen and began to take the temperature of the food without washing his hands first.</p> <p>At 12:16 p.m., Server #5 was observed to use his gloved hand to pick up the breadsticks and cornbread being served to the residents for lunch.</p> <p>At 12:20 p.m., Server #5 placed a set of tongs in the breadstick container, but at 12:25 p.m., he was observed to pick up the breadstick with his gloved hand while the tongs were right there.</p> <p>At 12:35 p.m., Server #5 opened a package of buns and obtained 2 buns with his gloved hand and placed them on 2 residents plates.</p> <p>An interview with the Dining Room Supervisor on 6-6-2016 at 12:40 p.m., indicated the breadsticks, cornbread and buns should have been picked up with tongs or serving utensils.</p> <p>A current policy dated 1-6-2016 and titled "Storage of Food in Refrigeration" was provided by the Director of Dining Services on 6-6-2016 at 4:30 p.m. and indicated "...all containers must be</p> | | | |

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| R 0298 | <p>labeled with the contents and date food item was placed in storage...employee food items may not be stored in any refrigerator or freezer in the main kitchen...."</p> <p>A current policy dated 1-6-2016 and titled "Food Safety" was provided by the Director of Dining Services on 6-6-2016 at 4:30 p.m., and indicated "...all staff will be aware of proper handling and storage of dirty and clean utensils and service and production equipment...all food service staff will wash their hands upon entering the kitchen...."</p> <p>A current policy dated 3-10-2016 and titled "Hand washing" was provided by the Director of Dining Services on 6-6-2016 at 4:30 p.m., and indicated "...hands are washed before, during and after preparing food...after blowing your nose, coughing, sneezing...."</p> <p>410 IAC 16.2-5-6(c)(2) Pharmaceutical Services - Deficiency</p> | | | | |

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| Bldg. 00 | <p>(2) A consultant pharmacist shall be employed, or under contract, and shall:</p> <p>(A) be responsible for the duties as specified in 856 IAC 1-7;</p> <p>(B) review the drug handling and storage practices in the facility;</p> <p>(C) provide consultation on methods and procedures of ordering, storing, administering, and disposing of drugs as well as medication record keeping;</p> <p>(D) report, in writing, to the administrator or his or her designee any irregularities in dispensing or administration of drugs; and</p> <p>(E) review the drug regimen of each resident receiving these services at least once every sixty (60) days.</p> <p>Based on observation, interview and record review, the facility failed to ensure expired medications were removed from the medication cart for Resident #8, medicated treatments were labeled with a resident's and physician's names, opened dates labeled on multi use medications and medications were stored at the recommended temperature for 1 of 5 medication carts (Keepsake Village South) and 3 of 3 treatment carts (Keepsake Village North and South and Assisted Living) and 2 of 3 medication storage rooms refrigerators (Assisted Living and Keepsake Village North). This practice had the potential to affect 83 of 106 residents whose medications were administered by the facility.</p> <p>Findings include:</p> | R 0298 | <p>1. The undated eye drops, expired insulin for Resident #8, unlabeled tube of Aloe Vista protective ointment, unlabeled tube of denture adhesive cream, unlabeled tube of Bacitracin, unlabeled tube of pain relieving cream and unlabeled tube of calmoseptine ointment that were identified during the survey have been discarded and replaced. The EDK and insulin that had been improperly stored were discarded and replaced. The unlabeled/undated chocolate nutritional drink and unlabeled bottles of Dermal Wound Cleaner identified during the survey were discarded. The refrigerated plastic bags of medications that had been identified during the survey as having gotten wet were discarded/replaced. The vial of Aplisol that had no year indicated with the open date was discarded. The medication</p> | 07/06/2016 |

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| | <p>1. An observation of the medication cart on Keepsake Village South (a secured memory unit) with QMA #11 on 6/6/16 at 2:15 p.m., indicated the following:</p> <p>Ilevro 0.3% Ophth (ophthalmic) Drop (eye drop for inflammation and pain) with a Rx (prescription) filled date of 10/21/15 was not labeled with an opened date. QMA #11 indicated she did not know when the eye drops were opened and also indicated the eye drops should have been labeled with the date the bottle was opened.</p> <p>Humulin R U-100 Insulin for Resident #8 was labeled with an open date of 4/27/16. QMA # 11 indicated the insulin expired 1 month after the open date and indicated the insulin should not have been used. QMA #11 was observed to check the overflow insulin stored in the refrigerator and indicated the expired vial of Humulin Insulin was the only vial for the resident. QMA #11 further indicated QMA's do not administer insulin and indicated only the nurse administered insulin to the residents.</p> <p>During the observation of the treatment cart for Keepsake Village South on 6/6/16 at 2:30 p.m. with QMA #11, a 2 ounce tube of Aloe Vista Protective Ointment was opened but was not labeled</p> | | <p>refrigerator on Keepsake North has been replaced. 2. All refrigerators used for storage of medications and nutrition were inspected during the survey with actions taken as noted above. 3. Wellness Directors will provide training to all nurses and QMA's utilizing both facility and pharmacy policies regarding storage of medications, storage and use of injectable medications and refrigerator temperature logs beginning on June 24,2016 to be completed by July 5, 2016. As a point of clarification, our pharmacy policy does include the acceptable temperature range for medication/nutrition refrigerators but we will update our facility policy to include this same information. Wellness Directors have instituted a new facility practice for nurses/QMA's to complete weekly checks of all medication carts and medication refrigerators to ensure items are labeled and stored appropriately and not expired. Nurses/QMA's will continue our facility practice to check and document temperatures of all medication/nutrition refrigerators daily to ensure temperatures are within acceptable ranges. 4. Wellness Directors will inspect medication/nutrition refrigerators, medication carts and refrigerator temperature logs three times per week x4 weeks and weekly thereafter to ensure proper medication storage and labeling.</p> | |

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| | <p>with a resident's name or room number. QMA #11 indicated she did not know which resident the Aloe Vista belonged.</p> <p>Review of Resident #8's clinical record provided by the Wellness Director of Keepsake Villages on 6/6/16 at 4:10 p.m., indicated the following:</p> <p>Resident #8's diagnoses included but were not limited to: Diabetes, Hypertension, Dementia, Anemia, Hyperlipidemia, Left Heel Ulcer.</p> <p>The Physician/Prescribe Telephone Order, signed by the nurse on 3/1/16 and the Prescriber on 3/8/16 indicated, "...Humulin R per Sliding Scale: 151-200 = 1 unit, 201-250 = 2 units, 251-300 = 3 units, 301-350 = 4 units, > (greater than) 400 call MD, Give Sub Q (subcutaneous) with accuchecks (test for blood sugar)...."</p> <p>The MARS (Medication Administration Record Sheet) for Resident #8 indicated the expired Humulin R Insulin was given 22 times for a total of 29 units given since expiration on 5/25/16 through 6/6/16 at 11:53 a.m.</p> <p>2. An observation of the treatment cart for Assisted Living on 6/6/16 at 3:00</p> | | Results of these audits will be reviewed by the QA Committee, who will establish the threshold of compliance and make further recommendations accordingly. | |

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| | <p>p.m. with Nurse #12, indicated the following:</p> <p>A 2.4 ounce tube of [Brand] Denture Adhesive Cream was opened and was not labeled with a resident's name or room number.</p> <p>A 1 ounce tube of Bacitracin with Zinc Ointment was opened and was not labeled with a resident's name or room number.</p> <p>A 2.7 ounce tube of [Brand] Pain Relieving Cream was not labeled with a resident's name or room number.</p> <p>A 4 ounce tube of Calmoseptine Ointment with an opened date of 3/18/16 was not labeled with a resident's name or room number.</p> <p>An interview with Nurse #12 on 6/6/16 at 3:05 p.m., indicated the ointments and creams in the treatment cart should have been labeled with a resident's name and room number, a physician's name and open dates. She indicated the treatment creams and ointments will be discarded and reordered.</p> <p>An observation of the Assisted Living Medication Room refrigerator used for storage of medications and nutrition on</p> | | | |

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| | <p>6/6/16 at 3:10 p.m. with Nurse #12, indicated the following</p> <p>One opened, 8 ounce bottle of [Brand] Rich Chocolate Nutritional Drink with a room number written on the cap. The nutritional drink was not labeled with a resident's name or an opened date.</p> <p>The medication/nutrition refrigerator was observed the to have a small freezer compartment with a clear plastic door. In the freezer was stored the facility's EDK (Extra Drug Kit) Box from the Pharmacy. The EDK was shut with a blue zip lock tag and the EDK box was covered with ice chunks and ice crystals. The EDK was labeled with the contents in the box and the label was visible without opening the box. The EDK contained the following medications: one, 10 ml (milliliter) vial of Novolog (insulin), one 10 ml vial of Novolin 70/30 (insulin), one 10 ml vial of Humalog Mix 75/25 (insulin), one 10 ml vial of Novolin N (insulin), one 10 ml vial of Lantus (insulin), one 10 ml vial of Novolin R (insulin) with an expiration date of 5-16, four doses of Lorazepam 2 mg (milligram)/ 1 ml with expiration of 5-16 and 4 Promethazine (treatment for nausea/vomiting/motion sickness and acts as an antihistamine) Suppositories 12.5 mg. Also in the freezer</p> | | | |

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| | <p>compartment was a box of Novolog Insulin that was frozen to the bottom of the freezer and the box was covered with ice crystals, with the Rx label on the sealed box.</p> <p>An interview with Nurse #12 on 6/6/16 at 3:15 p.m., indicated the EDK and insulin should not have been stored in the freezer.</p> <p>An Interview with Wellness Director of Assisted Living on 6/6/16 at 3:20 p.m., indicated she did not know who would have put the EDK and insulin in the freezer. She indicated she would need to call the pharmacy and have the medications replaced at the cost of the facility because the medications were not to be in the freezer.</p> <p>3. An observation of the treatment cart on Keepsake Village North (a secured memory care unit) on 6/6/16 at 3:30 p.m. with QMA #13, indicated the following:</p> <p>Two opened and used 16 fluid ounce spray bottles of [Brands] Dermal Wound Cleaner were in the bottom drawer of the treatment cart. Both spray bottles of the Dermal Wound Cleanser were not labeled with a resident's name, a physician's name or an opened date.</p> | | | |

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| | <p>An interview with QMA #13 on 6/6/16 at 3:35 p.m., indicated the wound cleanser spray must have been a stock item and was used on various residents when it was ordered by the physician.</p> <p>During an observation of the Keepsake Village North's medication room with QMA #13 on 6/6/16 at 3:40 p.m., the following was observed:</p> <p>The medication refrigerator's thermometer read 50 degrees F (Fahrenheit, a measurement of temperature) and was verified by QMA #13. The refrigerator's freezer was melting and dripping down onto a white plastic tray containing 5 plastic zip-lock bags with Rx medication in them. The Rx labels were adhered to the plastic bags. The plastic bags were wet and sat in a pool of water that had dripped down from the melting ice in the freezer. The following medications were stored in the refrigerator: Three plastic bags contained a bottle of Latanoprost Sol 0.005%, all with a blue label, "REFRIGERATE" adhered to the plastic bag, one plastic bag contained 12 suppositories of Acetaminophen 650 mg Suppository, with a blue label, "REFRIGERATE" adhered to the plastic bag, one plastic bag's Rx label was wet and the medication name and directions were not</p> | | | |

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| | <p>legible, a bag contained Bisacodyl Suppositories and a plastic bag containing 1 vial of Aplisol Inj 5/0.1 ml (injection to test for tuberculosis) with an opened date of 2/2, with no year labeled and a blue label "REFRIGERATE" adhered to the plastic bag.</p> <p>An observation of QMA #13 indicated she dried the water off of the plastic bags and tray and placed the medications back into the warm refrigerator on the white plastic tray lined with a paper towel.</p> <p>An interview with QMA # 13 at 3:45 p.m. indicated the freezer was not working properly and she would place a work requisition for maintenance to check the refrigerator freezer.</p> <p>An interview with Wellness Director of Keepsake Villages on 6/6/16 at 4:15 p.m., indicated the insulin should have been labeled with an opened date and also indicated the insulin expired one month after the open date. She also indicated it was the responsibility of the nurse to label the insulin with an open date and the nurse was to check to see if the insulin was expired before administering the insulin to a resident.</p> <p>An interview with Maintenance Supervisor on 6/6/16 at 4:25 p.m.,</p> | | | |

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| | <p>indicated he checked the refrigerator in the medication room on Keepsake Village North and indicated the freezer was in the defrosting mode and explained the reason why the refrigerator temperature was 50 degrees F. He also indicated it was not unusual for the freezer to heat up to defrost. He further indicated the refrigerator had started to cool down.</p> <p>On 6/6/16 at 4:40 p.m., the Wellness Director of Keepsake Villages provided the current facility policy, titled, Vials and Ampules of Injectable Medications, with effective date of January 2007. The policy indicated, "...Vials and ampules of injectable medications are used in accordance with the manufacturer's recommendations or the provider pharmacy's directions for storage, use and disposal....The date opened and the initials of the first person to use the vial are recorded on multidose vials on the vial label or an accessory label affixed for that purpose....Medication in multidose vials may be used until the manufacturer's expiration date if unopened. Once opened, insulins may be used for 28 days and other multidose vials may be used for 30 days (unless manufacturer's guidelines state otherwise) if inspection reveals no problems during that time...."</p> | | | |

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| | <p>On 6/6/16 at 4:40 p.m., the Wellness Director of Keepsake Villages provided the current facility policy, titled, Medication Storage (Non Narcotic), with approval dated 9/27/11. The policy indicated, "...Medication that requires refrigeration will be kept in a small refrigerator in the nursing area..."</p> <p>On 6/6/1 at 4:40 p.m., the Wellness Director of Keepsake Villages provided the current facility policy, titled, Refrigerator Temperature Log, with approval date of 4/29/13. The policy indicated, "...1. Each refrigerator has its own refrigerator thermometer....2. The temperature of the refrigerators are checked daily....3. The temperature is recorded on Refrigerator Temperature Log....4. If the temperatures are out of desired range maintenance is contacted for repair/replacement...." The facility policy did not include the the acceptable temperature range for the refrigerators.</p> | | | |

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

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