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KULA HOSPITAL	100 KEOKEA PLACE KULA, HI 96790

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4 000	11-94.1 Initial Comments A relicensure survey was completed at the facility on April 21, 2017. At the time of entrance the census included 63 residents.	4 000		
4 088	11-94.1-16(a) Governing body and management (a) Each facility shall have an organized governing body, or designated persons functioning as the governing body, that has overall responsibility for the conduct of all activities. The facility shall maintain methods of administrative management that assure that the requirements of this section are met. This Statute is not met as evidenced by: Based on record review, interviews and review of the facility's policies and procedures, the facility failed to ensure it is administered in a manner that enables it to use its resources effectively and efficiently in order for the residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being and failed to maintain an effective quality assessment and assurance (QA&A) committee which included analyses of identified performance improvement activities, including specific standards for quality of care and related outcomes for their residents. Findings include: 1) There is non-compliance with this regulation based on the deficient findings/outcomes in the areas of Resident Assessment, Quality of Care with substandard quality of care and harm for R #77, Quality of Life, Nursing Services and Pharmacy services. This is evidenced and cross-referenced at F157, F221, F279, F280, F281, F323, F334, F353, F371, F425, F431, F441 and F520. Inclusive are the survey	4 088	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: As a director result of the initial feedback and interviews during the initial phase of our licensure survey, the Administrator, Director of Nursing, and Medical Director met to discuss our needs to assure the provision of quality care to our residents as the priority over transition activities. It was determined that we needed to bring together all of our department heads to discuss our need to focus on our core obligations to provide safety quality care to our residents through a Quality Assurance and Performance Improvement framework. We held a QA/PI meeting on April 17, 2017 and shared elements for improvement that had up to that time had been identified during the survey. This was presented in a summary format with further verbal explanation during the meeting. Department heads were asked to look at the needs of the residents in their respective units and their own identified areas for improvement to develop unit-based measures for QA/PI. The expectation is that through collaboration with leadership the department heads would develop indicators for improvement to begin processes for monitoring and changes to improve care delivery. Another QA/PI was held on April 25, 2017 to further discuss the survey findings and preliminary plans for correction, along with the initial development of a PI team with focus on communication amongst the caregivers regarding status / need changes for residents.	4/17/2017 4/25/2017

KM 5/17/17

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4 088	Continued From page 1 observations, interviews, record reviews, and reviews of the facility's policies and procedures. Per interview with the NHA on the morning of 4/21/17, he acknowledged the preliminary survey findings and stated that aside from the transition period the long term care unit is going through, he attributes the lack of an effective QAPI (quality assurance and performance improvement) program to have been a factor that may have prevented the facility to have identified these care related issues found by the State Agency. The NHA also stated they have taken steps to remedy how quality improvement measures and policy making will be addressed by their governing body in the future. 2) On 04/13/2017 at 10:22 AM, an interview with the NHA, DON and Staff #122 was done. They were asked about their quality assurance/performance improvement (QAPI) plan and what quality care areas were being reviewed. The DON stated each department attends their QAPI meetings to discuss department specific PI projects. The DON said they also review the Casper Report and what their "triggers" were. The NHA stated they also reviewed their audits on documentation, such as the prior survey's bathing citation as an example. The NHA said the nurse managers were actively involved in the audits as well. The DON and NHA concurred however, that most of their PI work has been focused on the transition process with their facility to transfer management to a new entity effective 7/1/17. Despite knowing the needs of the long term care unit and the need to maintain the quality of care, they both acknowledged their focus has been directed on the lack of staffing related to the transition. The NHA said their QAPI meetings entailed more of a review of the Casper Report in aggregate and were general	4 088	HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the organizations failure to ensure that the facility is administered in a manner that enables it to use its resources effectively and efficiently in order for the residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being and to maintain an effective quality assessment and assurance committee which included analysis of identified performance improvement activities, including specific standards for quality of care and related outcomes for our residents. WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: The QA/PI Committee will be sharing progress, including PI team actions routinely at the Quality Committee of the Maui Region Board, which in turn rolls into the Maui Region Board as a whole to perform the function of oversight. We have scheduled the survey findings, plans of corrections, and revised Quality Assurance / Performance Improvement and Infection Prevention and Control Plans reported to the Quality Committee of the Maui Region Board, and requesting the Plans acceptance and presentation to the entire Maui Region Board for approval.	5/16/2017

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4 088	Continued From page 2 discussions about their dashboard. They acknowledged the State Agency's preliminary quality concerns found during the survey, but yet were unable to demonstrate they had identified similar concerns, or any new concerns using their own PI methodology to demonstrate an effective PI program. Thus, based on the State Agency's clinical outcomes and quality concerns, the facility failed to demonstrate areas of quality performance improvement measures, including the identification of, or monitoring the effect of any implemented changes and with improvements to their action plans. The facility's primary focus has been on the transition process, however, the outcomes found in the areas such as Resident Assessment and Quality of Care was not identified in their on-going quality improvement process. Cross-reference to findings at F157, F221, F279, F280, F281, F323, F334, F353, F371, F425, F431, F441 and F490.	4 088	HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: The QA/PI Committee will be sharing progress routinely at the Quality Committee of the Maui Region Board, which in turn rolls into the Maui Region Board as a whole to perform the function of oversight of proper facility administration of responsibilities. Our new Quality Assurance / Performance Improvement and Infection Prevention and Control Plans have been invigorated and require the organization to report on progress of the plans goals and initiatives to the Board in order to allow for appropriate governance. We will be meeting monthly for a joint QA/PI and IC meeting to evaluate our progress on meeting our QA/PI and IC goals. We will also be reporting progress to the Quality Committee of the Maui Region Board monthly. WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: As a direct result of the initial feedback and interviews during the initial phase of our licensure survey, the Administrator, Director of Nursing, and Medical Director met to discuss our needs to assure the provision of quality care to our residents as the priority over transition activities. It was determined that we needed to bring together all of our department heads to discuss our need to focus on our core obligations to provide safety quality care to our residents through a Quality Assurance and Performance Improvement framework. We held a QA/PI meeting on April 17, 2017 and shared elements for improvement that had up to that time had been identified during the survey. This was presented in a summary format with further verbal explanation during the meeting. Department heads were asked to look at the needs of the residents in their respective units and their own identified areas for improvement to develop unit-based measures for QA/PI. The expectation is that through collaboration with leadership the department heads would develop indicators for improvement to begin processes for monitoring and changes to improve care delivery. Another QA/PI was held on April 25, 2017 to further discuss the survey findings and preliminary plans for correction, along with the initial development of a PI team with focus on communication amongst the caregivers regarding status / need changes for residents.	5/16/2017 5/23/2017 4/17/2017 4/25/2017
4 089	11-94.1-16(b) Governing body and management (b) The facility shall ensure that: (1) Staff sufficient in number and qualifications shall be on duty twenty-four hours a day to carry out the policies, responsibilities, assessed care needs of the residents and program of the facility; and (2) The numbers and categories of personnel shall be determined by the number, acuity level, and needs of residents. This Statute is not met as evidenced by:	4 089		

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4 089	Continued From page 3 Based on record review, interviews and review of the facility's policies and procedures, the facility failed to ensure it is administered in a manner that enables it to use its resources effectively and efficiently in order for the residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Finding includes: There is non-compliance with this regulation based on the deficient findings/outcomes in the areas of Resident Assessment, Quality of Care with substandard quality of care and harm for R #77, Quality of Life, Nursing Services and Pharmacy services. This is evidenced and cross-referenced at F157, F221, F279, F280, F281, F323, F334, F353, F371, F425, F431, F441 and F520. Inclusive are the survey observations, interviews, record reviews, and reviews of the facility's policies and procedures. Per interview with the NHA on the morning of 4/21/17, he acknowledged the preliminary survey findings and stated that aside from the transition period the long term care unit is going through, he attributes the lack of an effective QAPI (quality assurance and performance improvement) program to have been a factor that may have prevented the facility to have identified these care related issues found by the State Agency. The NHA also stated they have taken steps to remedy how quality improvement measures and policy making will be addressed by their governing body in the future.	4 089	HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the organizations deficient practice of failing to ensure that it is administered in a manner that enables it to use its resources effectively and efficiently in order for the residents to attain or maintain their highest practicable physical, mental and psychosocial well-being. WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: The QA/PI Committee will be sharing progress, including PI team actions routinely at the Quality Committee of the Maui Region Board, which in turn rolls into the Maui Region Board as a whole to perform the function of oversight. We have scheduled the survey findings, plans of corrections, and revised Quality Assurance / Performance Improvement and Infection Prevention and Control Plans reported to the Quality Committee of the Maui Region Board, and requesting the Plans acceptance and presentation to the entire Maui Region Board for approval. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: The QA/PI Committee will be sharing progress routinely at the Quality Committee of the Maui Region Board, which in turn rolls into the Maui Region Board as a whole to perform the function of oversight of proper facility administration of responsibilities. Our new Quality Assurance / Performance Improvement and Infection Prevention and Control Plans have been invigorated and require the organization to report on progress of the plans goals and initiatives to the Board in order to allow for appropriate governance. We will be meeting monthly for a joint QA/PI and IC meeting to evaluate our progress on meeting our QA/PI and IC goals.	5/16/2017 5/16/2017
4 136	11-94.1-30 Resident care The facility shall have written policies and procedures that address all aspects of resident	4 136		5/23/2017

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4 136	Continued From page 4 care needs to assist the resident to attain and maintain the highest practicable health and medical status, including but not limited to: (1) Respiratory care including ventilator use; (2) Dialysis; (3) Skin care and prevention of skin breakdown; (4) Nutrition and hydration; (5) Fall prevention; (6) Use of restraints; (7) Communication; and (8) Care that addresses appropriate growth and development when the facility provides care to infants, children, and youth. This Statute is not met as evidenced by: Based on observations, record review and interview with staff members, the facility failed to ensure a resident, Resident #63 was free from a physical restraint andto ensure the resident environment remains as free from accident hazards as is possible; and each resident receives adequate supervision and assistance to prevent accidents for 1 of 23 residents (Resident #77) in the Stage 2 sample. Findings include: 1) On 4/10/17 at 11:30 A.M. observed Resident #63 in the activity room. The resident was seated in a wheel chair with a gait belt looped through the bars on the sides of the wheelchair and buckled across her lap. Subsequent observation at 11:42 A.M. found the gait belt still buckled across the resident's lap. At 12:21 P.M. Resident #63 was observed eating lunch at a table with the gait belt still affixed to her wheelchair. On the morning of 4/11/17 Resident #63 was observed eating her breakfast in the activity/dining room,	4 136	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1) The inappropriate use of the gait belt ended during the survey upon identification / discussion. The Physician Orders, Assessments, and Care Plan for resident 63 were reviewed by the Nurse Manager with the Director of Nursing on 4/11/2017 and appropriate changes made. The Nurse Manager counseled both licensed and non-licensed nursing staff with regard to the inappropriate use of restraints and deviation from the care plan for the resident. 2) The care plan for R#77 had been revised at the time of the survey but after the fall with injury. Current resident care plans are being reviewed through the Inter-Disciplinary Team meetings on a scheduled frequency and will include a review of pertinent medical and considerations that require care plan monitoring and interventions – changes will be made as identified through this and with changes in resident condition. The staff that performed the assessment was counseled on making modifications to the written care plan as necessary in real-time based on her assessments. This point was discussed with all disciplines as an expectation at the Quality Assurance / Performance Improvement meeting on 4/17/17. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practices of 1) not ensuring that residents are free of restraint without an appropriate physician order, assessment, and plan of care and 2) adequately develop and implement a comprehensive and person-centered care plan to help prevent a fall injury	4/11/2017 4/17/2017

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4 136	Continued From page 5 the gait belt was affixed to her wheelchair. Subsequent observation at 10:06 A.M. found the resident watching the entertainment. The resident was seated on a bench in the front row. On 4/11/17 at 2:22 P.M. observed Resident #63 asking Staff Member #110 to take her back to the room. Resident #63 was seated in a wheelchair and observed to be wearing a seat belt that was buckled in the front. Resident #63 was observed to self-propel the wheelchair with her feet. The seat belt was removed by the staff member, Resident #63 was observed to stand and walk to the bathroom independently. The resident stood in front of the toilet and started pulling her pants down; at this time, the staff member requested to have the door closed. Second observation at 3:06 P.M. found Resident #63 ambulating on the unit with the assistance of a staff member. Observation from 3:14 P.M. through 3:34 P.M. found Resident #63 propelling herself in the wheelchair around the unit. The seat belt was applied. On 4/12/17 at 8:03 A.M. Resident #63 was observed eating breakfast in the activity/dining room, the seat belt was not applied and there was no gait belt looped across her lap. Subsequent observation at 9:04 A.M. found the resident's seat belt was affixed. A record review done on the morning of 4/12/17 found a physician's order for the month of April 2017 included an order for front buckle seat belt and tab alarm while in wheelchair for safety and positioning, dated 1/20/17. Further review found a "Restraint/Device Assessment/Rap Review" dated 1/20/17 for bed rails and front buckle belt. The reason for the use of device is dementia with anxiety and left foot weakness secondary to TIA,	4 136	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: 1) A meeting with the Director of Nursing, QA/PI RN, Medical Director, and Administrator was held to review the policy & procedure "Restraint Use in Long Term Care" 510-110-01. It found it to be appropriate. After discussion, the decision was made to work with our Nursing Education Coordinator to develop a staff competency (5/17/17) on the proper use of restraints as outlined in the current policy & procedure. The use of the competency will begin on 5/23/17. In addition to the competency training, Nurse Managers will be performing and documenting visual audits no less than three days per week to assess for inappropriate use of items that could constitute a restraint without the proper order, assessment, and care planning. 2) A process improvement team has been established with the focus on communication amongst the caregivers regarding status / need changes for residents. The team is looking at a multi-prong approach including 1 - how shift to shift report is conducted, 2 - easily summarized plans of care, 3 - status change notices posted within the unit, 4 - restraints orders / types notices posted within the unit, 5 - the initial care plan creation with the Pre-Admission nurse and nurse manager, 6 - a standard set of more frequent assessments of the resident for the initial period after admission, and 7 - a one-week post-admission IDT care planning meeting to revise and take in staff observations. The intent is to allow staff a quick way to view the care plan for the residents, pass on changes in resident needs / care planning interventions shift:shift, and standardize the initial care plan creation for new admissions with interventions to provide safety for residents while resident becomes acquainted with the facility and then staff acquainted with the resident. Nurse managers will be interviewing staff involved in the care of residents to assess their familiarity with the residents care needs.	5/17/2017 5/23/2017 5/11/2017 4/25/2017

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4 136	Continued From page 6 gait instability. The form documents that the device is a restraint; however, the team checked that the front buckle belt is not a restraint because the: resident can ask to have it removed; resident can remove it on his/her own; and resident cannot get up on his/her own so is not being restrained. There is no documentation of an assessment for the use of a gait belt to be looped through the sides of the wheelchair as a possible restraint. A review of the Minimum Data Set for significant change with an assessment reference date of 1/9/17 codes daily use of trunk restraint. In Section G. Activities of Daily Living Assistance, Resident #63 was coded as requiring extensive assistance with two person physical assist for transfer (how resident moves between surfaces including to or from: bed, chair, wheelchair, standing position) and walk in room and corridor as being totally dependent with one person physical assist. A review of the care plan for restraint was updated on 1/20/17 for the use of front buckle belt. The interventions included: when restraint in use, check q 1 hour and release q 2 hours and inspect skin, circulation and movement; release restraint during activities as appropriate; monitor resident's response to restraint; reposition q 2 hours and as needed; and ambulate with 2 person assistance as tolerated. On 4/12/17 at 1:31 P.M. an interview was conducted with Staff Member #155. The observation of the use of the gait belt looped through the side bars across the resident's lap was shared with the staff member. The staff member reviewed the physician order and confirmed there is no order for the use of the gait belt; however, there is an order for front buckle seat belt and tab alarm. Subsequently an	4 136	HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: 1) Nurse Managers will meet no less than monthly for the next 3 months to discuss audit results, compliance, and opportunities for further staff education to clarify compliance expectations. The aggregate results will be compiled by our Quality RN and shared / discussed as a scheduled report at our Quality Assurance / Performance Improvement meeting. 2) The care planning of the resident will be monitored by the nurse managers and the Director of Nursing through documentation of the care plan and notice of status changes and evaluation dates performed by staff for their findings inclusion in the care plan with modifications as needed. The one-week re-assessment care planning meeting completion will be a monitor reported at the monthly nurse manager meeting and trended across the facility by the Quality RN – these items and the progress of implementations by the PI team. Those implementations will focus on a rapid-cycle change approach that are expected to be modified and evolve as we work towards a system that "sticks" and assures that staff are knowledgeable about the residents for which they provide care. These results will also be reported at the QA/PI meetings	5/11/2017 5/23/2017 5/23/2017

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interview was conducted with Staff Member #85. The staff member reported the gait belt is not used to be looped over the resident's lap, the gait belt is kept in the resident's wheel chair for tactile purposes. The staff member further reported the gait belt is not to be used to loop across the resident's lap and the use of the gait belt is to assist the resident to ambulate.

On 4/12/17 at 1:44 P.M. concurrent observation of the resident was done with Staff Member #155. The resident was asked to unbuckle the seat belt, the resident grabbed the buckle and stated that it was stuck. Resident #63 was unable to remove the front belt buckle.

An interview was done with Staff Member #112 on 4/12/17 at 1:40 P.M. The observation of the use of the gait belt was shared with the staff member. The staff member commented that the gait belt was utilized as a restraint and it should not be used in that manner. An interview was conducted with the staff member providing direct care, Staff Member #28 on 4/11/17. The staff member reported the gait belt is not to be used across the resident's lap, the gait belt is kept in the wheel chair so the resident can "play with it". The staff member denied applying the gait belt to the wheelchair and stated it may have been the night staff that applied the gait belt to the wheel chair.

The facility failed to ensure Resident #63 was free of a physical restraint as evidenced by the use of a gait belt looped through the bars on the sides of the wheelchair and over the resident's lap without an assessment and plan of care.

2) A Stage 2 review was done based on an incident report (IR) involving a fall related injury

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sustained by Resident #77 (R #77). The facility's self-reported IR stated the resident's 3/25/17 fall appeared to have "...more affected her shoulder which was already affected by the cva. She is forgetful at times and does not remember to use the call bell. She does not realize that the left side of her body does not support her anymore. What interventions were implemented after the incident/event to prevent further injury? Immediate measures: 1:1 supervision while in bed and visual supervision when out of bed. Toileting at least every 2 hours with the goal of working on promoting continence, PT/OT have done initial evaluations with resident on 3/23-24 and will be working with resident to increase physical capabilities which will help with all aspects of care and comfort."

On site review found R #77 was admitted to the facility on 3/21/17 from the hospital with several diagnoses including left sided weakness with an inability to perform activities of daily living (ADLs), frequent falls, removal of a frontal brain tumor, subacute stroke with dysphagia, and anemia. The resident's chart review found her admission included rehabilitation services (physical and occupational therapy) and that she has confusion. The resident's unwitnessed fall occurred on 3/25/17 in her room, and at the time of the incident, she stated she wanted to go to the bathroom.

As a result of the fall, R #77 sustained a left shoulder subluxation (dislocation) injury. The emergency department noted it was a difficult reduction of the shoulder injury and she was given a left arm sling to stay on for at least 7 days. Observation of the resident on 4/12/17 at 10:16 AM in the hallway found she still required the use of a sling. The resident was being

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4 136	Continued From page 9	4 136		

assisted by nurses aides with Staff #13 instructing them how to apply a new cross-over type of sling to support her left shoulder/arm. The resident allowed the sling to be applied and spoke very few words to the staff in her native dialect.

Chart review of the 3/24/17 therapy evaluation by Staff #13 found her assessment of the resident included, "decreased mobility + ADL safety + independence, impaired cognition/safety awareness with impulsiveness and difficulty communicating. She remains aware of the need to toilet, sits for at least several minutes unsupported..." Staff #13's plan was to recommend supporting R #77's left upper extremity at all times, to respond as quickly as possible to her requests to toilet, provide two staff assistance for putting on briefs, and provide program and training for staff to maximize the resident's ADL safety, independence, mobility and quality of life.

On 04/12/2017 at 2:04 PM, an interview of Staff #13 was done regarding her 3/24/17 evaluation of the resident. She was asked how she communicated her plan to the line staff caring for the resident. Staff #13 replied that if things need to be known immediately, she went directly to a nurse's aide or the nurse. She said if they were not available, she would document it on a sheet for the next shift to get it communicated forward, or speak with the head nurse to communicate it as quickly as possible and do a care plan update. She acknowledged she could update the care plan as well. Staff #13 recalled speaking to a licensed staff about the toileting and transfer for this resident and how important it was for staff to stabilize "the other side as she (the resident) really doesn't put any weight on the other side and her ankle on the left side is unstable and

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4 136	Continued From page 10 can't put weight on it to transfer." Staff #13 thought it may have been added or implemented to the basic care plan and said nursing typically would put it in right away and that the resident came in with a history of falls. Staff #13 acknowledged the resident sustained the fall with injury on 3/25/17 at 4:30 AM, the day after her evaluation was done with the recommendations/plan. She also said she understood where the "handing off" of communication may not have been in the basic care plan prior to the injury occurring. Staff #13 was informed that her plan/recommendations were not found in the care plan, which could have potentially prevented an injurious fall from occurring. She said her entry on 3/24/17 was about therapy and the IDT care plan (on 4/4/17) included additional interventions, but acknowledged that it was done after the resident's 3/25/17 fall injury occurred. On 04/12/2017 at 2:48 PM, interview of Staff #55 was done. She affirmed she completed the IR because the DON was on leave. She said the family said R #77 "fell all the time at home." She also said the emergency room physician said R #77's shoulder dislocation was a difficult reduction. Staff #55 said she would have to look to see if she discussed it with the nurse manager at the time, but the nurse manager "should have incorporated it into the resident's care plan." Staff #55 acknowledged there should have been something more put in place and that Staff #13's assessment should have been part of it. She acknowledged as Staff #13 is also a licensed professional, her expectation was the staff "speak in terms of a communication hand off" and "some of these things would have been added to the care plan."	4 136		

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4 136	Continued From page 11 Further review of the post-fall investigation report revealed some of the contributing factors to R #77's fall included the resident's inability to ambulate by herself (stand/pivot), that she was non-English speaking with a lack of safety awareness, she had a condition (tumor excision) resulting in left sided weakness, neurological memory loss causing her to forget she has the left sided weakness, an inability to remember to use her call light, and, that her bed alarm although activated on the bed, had not been activated on the display board. It also noted a lack of staff guidance related to "points of communication/exchange" (i.e., handoffs/shift reports). In addition, this resident on admission was noted with a history of frequent falls and Staff #55 stated this in her interview. Yet, these assessments were not done until after R #77 suffered the injurious fall to her left shoulder, causing injury to an already weakened left side. During an interview with the Nursing Home Administrator (NHA) and the Director of Nursing (DON) on 04/13/2017 at 10:22 AM, the DON acknowledged that harm due to the resident's fall with injury, occurred for this resident. During an interview with the Medical Director on 4/21/17 at 8:30 AM, she stated the communication piece was something they are looking to improve, and mentioned the SBAR method as an example on how to improve communication amongst the staff. The facility failed to fully assess the resident's known pre-disposition to frequent falls concomitant with her clinical condition/status on admission. There was an additional failure in communicating Staff #13's plan/recommendations and failure to immediately implement interventions into the resident's care plan to assure staff would be alerted to the	4 136		

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4 136	Continued From page 12 resident's care needs. This failure may have contributed to the resident's subsequent fall and left shoulder injury on 3/25/17.	4 136		
4 148	11-94.1-39(a) Nursing services (a) Each facility shall have nursing staff sufficient in number and qualifications to meet the nursing needs of the residents. There shall be at least one registered nurse at work full-time on the day shift, for eight consecutive hours, seven days a week, and at least one licensed nurse at work on the evening and night shifts, unless otherwise determined by the department. This Statute is not met as evidenced by: Based on observations, record reviews, interviews, and facility policy reviews, the facility failed to provide sufficient nursing staff based on the staff's inability to provide the necessary care and services based on the resident assessments to ensure each resident is able to reach their highest practicable physical, mental and psychosocial well-being. Findings include: During the interview with the NHA and DON on 04/13/2017 at 10:22 AM, the NHA agreed they have had a staffing problem such that per the DON, the need for coverage was so great, due to the transition and sick calls. The DON also said they were often "short 38%" of their staff. The NHA said by not having a quality nurse position filled for about 1.5 years, they have seen "doubling up of responsibilities" with their remaining staff, which has "led to a lack of identification of opportunities" (for improvement)	4 148	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: Nursing managers, including the Director of Nursing and the QA/IC RN met to discuss areas for improvement of staff performance in order to assure the provision of sufficient nursing care for resident well-being. Through this they identified the need for staff competencies in the areas of restraints and department managers for appropriate restraint usage and pressure ulcers staging. Beyond this there was the need to improve communication amongst care givers due to both the use of travel nurses and float staff to support gaps in employed staffing. There was a commitment by the Nursing Managers and leadership to utilize rapid-cycle change strategies and the performance improvement methodology of Plan Do Check Act (PDCA) o support staff in the succeeding in our mission to provide our residents with quality care. Emphasis was placed on not focusing solely on a singular solution but complimentary strategies – as such it was identified that there was an opportunity to attain more uniformity between the units to support staff that work throughout the hospital – an example of this was some units had their medication refrigerator log in a binder at the nursing station, while another had it on the refrigerator itself – such disparity could be a causative factor in floating staff to not succeed in the appropriate monitoring of temperature ranges and thus assure proper medication storage. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk from the deficient practice of failing to provide sufficient nursing staff to provide the necessary care and services based on the resident assessments to ensure that each resident is able to reach their highest practicable physical, mental, and psychosocial well-being.	4/17/2017 4/25/2017 5/11/2017

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4 148	Continued From page 13 and they have "become more reactive than proactive." The NHA also said it included the communication piece as well. The DON further stated with a 13 week turnover interval for the "travelers" (out of state travel nurses and nurses aides), there was less consistency in the delivery of care to their residents. She stated "the real issues" thus were not being addressed. The cumulative findings in the areas of Resident Rights, Resident Behavior and Facility Practice, Quality of Care, Quality of Life and Pharmacy Services demonstrates widespread concerns, including harm and substandard quality of care, which are interdisciplinary and includes nursing and administrative services. This deficiency is directly related to the lack of an effective quality assurance and assessment program, to which it is cross-referenced at F520. It is also evidenced and cross-referenced to the survey findings at F157, F221, F279, F280, F281, F323, F334, F371, F425, F431, F441 and F490.	4 148	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: As noted above the nursing managers will be working with nursing leadership and progressing with measures to meet goals and monitor progress. We have targeted competencies to begin by 5/25/2017. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: The QA/PI Committee will be sharing progress routinely at the Quality Committee of the Maui Region Board, which in turn rolls into the Maui Region Board as a whole to perform the function of oversight of proper facility administration of responsibilities. We will be meeting monthly for a joint QA/PI and IC meeting to evaluate our progress on meeting our QA/PI and IC goals.	5/25/2017 5/16/2017 5/23/2017
4 149	11-94.1-39(b) Nursing services (b) Nursing services shall include but are not limited to the following: (1) A comprehensive nursing assessment of each resident and the development and implementation of a plan of care within five days of admission. The nursing plan of care shall be developed in conjunction with the physician's admission physical examination and initial orders. A nursing plan of care shall be integrated with an overall plan of care developed by an interdisciplinary team no later than the twenty- first day after, or simultaneously, with the initial interdisciplinary care plan	4 149		

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4 149	Continued From page 14 conference; (2) Written nursing observations and summaries of the resident's status recorded, as appropriate, due to changes in the resident's condition, but no less than quarterly; and (3) Ongoing evaluation and monitoring of direct care staff to ensure quality resident care is provided. This Statute is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure it developed and implemented a comprehensive, person-centered care plan for 1 of 23 residents (Resident #12), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs identified in the comprehensive assessment in the Stage 2 sample. Finding includes: Resident #12 (R #12) was admitted to the facility from an acute setting as her cardiac status had stabilized. R #12's admission was for ongoing medical management and rehabilitation services (physical and occupational therapy) due to severe weakness related to her hospitalization. Some of her diagnoses included a gastrointestinal bleed with anemia, hypertension, congestive heart failure (CHF) and chronic kidney disease. Observation of R #12 revealed the resident was arousable but lethargic. A family interview revealed the resident had a recent exacerbation of her CHF symptoms with noted edema (swelling). A review of R #12's clinical chart	4 149	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: A Congestive Heart Failure care plan for resident #12was developed on 4/13/17 and placed in the resident's medical record. It was revised on 4/17/17 when MD ordered medication and EKG. It was reviewed again on 4/26/17 and revised on 5/8/17 to include fluid restriction orders. The care plan is comprehensive, person-centered, and reflect the findings of the resident assessments. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to adequately develop and implement a comprehensive and person-centered care plan. Current resident care plans are being reviewed through the Inter-Disciplinary Team meetings on a scheduled frequency and will include a review of pertinent medical and considerations that require care plan monitoring and interventions – changes will be made as identified through this and with changes in resident condition.	4/13/2017 4/17/2017 4/26/2017 5/8/2017

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4 149	Continued From page 15 of her CHF symptoms with noted edema (swelling). A review of R #12's clinical chart found a 3/31/17 nursing note which documented upon assessment, the resident was "noted to be diaphoretic and lethargic. Arousable but generalized lethargy...Noted increased irregular HR (heart rate) in the 120s and BP 110/79." The record revealed the attending physician was notified and ordered a stat EKG, which was done at 10:10 AM on 3/31/17. Per the attending physician's 3/31/17 note, she assessed the resident as having sinus tachycardia with wheeze, questionable asthma as symptoms were recurrent, and ordered oxygen as needed. The physician also ordered a new inhalation medication (Budesonide) twice daily for 5 days and noted the resident's history of CHF and positive fluid retention, and "consider checking of BNP...". The lab tests drawn on 4/3/17 included a basic metabolic panel and a B-Natriuretic Peptide (BNP) level. The BNP was significantly elevated at 908 pg/mL (normal <100), compared to the resident's 1/23/17 BNP result of 385 and compared to other BNP levels. A 4/2/17 entry by the on-call physician found R #12 was assessed to have CHF, pulmonary edema and mild hypoxia. Orders were given for a one time Lasix dose and to increase the resident's routine daily Lasix dose to 20 mg. Additional orders included increasing the oxygen to 2 Liters/min by nasal prong, to check the resident's oxygen saturation (O2 sat) level every shift and to report to the physician if the O2 sat was 90 or less. Daily weights x 5 days were also ordered and a 4/2/17 nursing entry stated R #12 had a weight gain of "at least 2.5# (pounds)" and observed with increased facial and bilateral hand edema.	4 149	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: The development and review of resident the care plans occurs upon admission, as needed with changes, and at regularly scheduled inter-disciplinary team meeting. The current policy "Notification of Changes in Resident Condition" 510-105-01 was reviewed by Nursing, the Medical Director, and the Administrator and modified to be appropriate guidance for staff. It also includes a Notice of Change Checklist that includes the steps staff takes during the immediate timeframe when such an event would occur. The checklist includes notation as to who was notified (preference is the first listed – if unable then document why and attempts), when, and care plan changes made as a result. Nurse Managers are in the process of reviewing the policy with licensed staff for compliance (expect completion by 5/24/2017), while the Medical Director is doing so with Medical Staff. On a daily basis, the Nurse Managers and Nursing Administration round on the units to discuss resident care needs, assess interventions effectiveness, and the need for care plan modification – this would also include a review of steps that staff have taken, including proper notification protocols. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Nurse Managers will meet no less than monthly for the next 3 months to discuss audit results, compliance, and opportunities for further staff education to clarify compliance expectations. The aggregate results will be compiled by our Quality RN and shared / discussed as a scheduled report at our Quality Assurance / Performance Improvement meeting.	5/10/2017 5/11/2017 5/24/2017 5/11/2017 5/23/2017

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4 149	Continued From page 16 A concurrent chart review of the resident's care plans was done with Staff #58 on 04/13/2017 at 8:06 AM. During the interview with Staff #58, he stated with regard to the resident's CHF, the attending physician knew of the resident's BNP level and adjusted R #12's medications. He also acknowledged daily weights for five days were ordered. Staff #58 verified there was no care plan developed for the resident's CHF but that it was important to have one based on the resident's diagnosis of CHF and her recent CHF exacerbation. Staff #58 said, "It is every nurse's responsibility to develop a care plan" and affirmed a care plan for it was not done. The facility failed to develop a care plan for a resident with a known history of CHF and during a recent exacerbation of CHF symptoms.	4 149		
4 151	11-94.1-39(d) Nursing services (d) Should drug or medication administration be delegated pursuant to chapter 16-89, subchapter 15, there shall be documented evidence of a training program, individuals receiving training, and ongoing monitoring and evaluation to assess compliance with requirements. This Statute is not met as evidenced by: Based on observation, record review, staff interview and policy review, the facility failed to ensure the services being provided meet professional standards of quality according to accepted standards of clinical practice for 2 of 23 residents (Residents #43 and #76) in the Stage 2 sample.	4 151		

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4 151	Continued From page 17 Findings include: 1) During Resident #43 (R #43's) room observation on 4/10/17 at 2:42 PM, it was noted that she received enteral nutrition via G-tube feedings (GTF). The enteral nutrition (EN) bag that was hanging on the IV pole but not being infused at the time was Fibersource HN. On the bag's label, it had the resident's handwritten name as initials. It was also dated 4/10/17 and "370 cc/hr" written on it. There was no start time written on the label when the initial EN infusion began. R #43's physician's order for her GTF was as follows: "12/16/15 Fibersource HN at 370 ml over 1 hour 3x/day to provide 1110 ml daily - flush with 100 ml of water before and after tube feedings (0500, 1200, 1800)." Review of the facility's policy on "Enteral Tubes" was provided on 4/12/17, but it did not address how the EN formula bags were to be labeled. On 04/13/2017 at 7:25 AM, a room observation was done with Staff #108 for R #43. The resident's EN bag that was hanging on the IV pole had the resident's handwritten name as initials, and "4/12 1300" on it. Staff #108 said, "It's missing the feeding order." Staff #108 further said their policy says the EN bag should be labeled with the amount of the flow rate on it. Staff #108 stated, "it's not acceptable," and also verified the way staff had labeled the EN bag per surveyor's 4/10/17 observation by omitting the start time was not acceptable. The State Agency references the American Society for Parenteral and Enteral Nutrition (ASPEN), The Journal of Parenteral and Enteral Nutritional Practice Recommendations,	4 151	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1) The administration of the enteral nutrition (EN) feeding for R43 and other residents receiving EN feedings was modified on 4/13/2017 to be compliant with the expectation of labeling of the EN bag to include the resident's name, date / time of infusion start and flow rate of volume over time as directed by the physician's order. 2) The review of resident 76 was a closed record. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to ensure that services provided meet professional standards of quality for clinical practices.	4/13/2017

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4 151	Continued From page 18 Bankhead, R., et al., Mar 12, 2009, pp. 129-130: "D. Labeling of Enteral Nutrition...Practice Recommendations...3. All EN labels in any healthcare environment shall express clearly and accurately what the patient is receiving at any time...4. The EN label should be compared with the EN order for accuracy and hang time or beyond-use date before administration." For R #43, there was a failure by staff to label the EN bag following acceptable standards of clinical practice as the labeling did not include the start times according to the physician's order and the actual rate as 370 ml over 1 hour with the water flush before and after. 2) On 4/20/2017 a record review found the following conflicting documentation for Resident #76: 12/14/2016 admission: "Skin Assessment: superficial open area overlying coccyx; no surrounding erythema or discharge, excoriation and erythema in the coccyx 0.5 cm x 0.5 cm dry; 12/18/2016 EZ graph "Stage 2, 1 cm x 1 cm to coccyx, open area red/flaky skin." physician notified obtained order for Mepilex boarder till physician can evaluate.; 12/21/2016 "glueteal excoriation almost completely closed", physician order to discontinue Mepilex boarder was documented. On 4/11/2017 at 3:15 PM interviewed Staff #14. Staff #14 was asked if Resident #76 was admitted with a pressure ulcer and if the ulcer had become a Stage 2 in 4 days then healed in 3 days. Staff #14 stated "the doctor codes the ulcers, nurses are not trained to do the assessment". A concurrent record review was done with Staff # 14, who stated "looks like Res #76 came in with an excoriation, a nurse assessed it and called it a Stage 2 then when the doctor came in he correctly called it a healed excoriation. This may have been an error on the staging by the nurse". A review of the facility	4 151	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: 1) The process of labeling of the EN bag with the resident's name, date / time of infusion start and flow rate of volume over time as directed by the physician's order began 4/13/2017 for all resident's receiving this service. The policy and procedure 300-110-01 is being finalized this week. Education with licensed nursing staff about the finalized policy and procedure will be completed on 5/17/17. Nurse Managers will be performing and documenting visual audits no three days per week to assess for the appropriate labeling of EN bags. 2) After discussion, the decision was made to work with our Nursing Education Coordinator to develop a staff competency by 5/25/17 on the proper assessment and staging of pressure ulcers. The intent is to begin its use with nursing care 5/25/2017. In the event of a newly identified pressure ulcer or skin condition of concern, the nurse manager will join staff in the assessment and staging of the area prior to documentation, physician notification, and care planning. On a basis of no less than weekly, nurse managers that oversee residents with known pressure ulcers will re-assess the resident's skin to verify appropriate staging and documentation. In both of these instances the manager will provide real-time education and feedback to staff, and note accuracy of assessments as part of the monthly nurse managers meeting and QAPI reporting. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Nurse Managers will meet no less than monthly for the next 3 months to discuss audit results, compliance, and opportunities for further staff education to clarify compliance expectations. The aggregate results will be compiled by our Quality RN and shared / discussed as a scheduled report at our Quality Assurance / Performance Improvement meeting.	4/13/2017 5/17/2017 5/25/2017 5/3/2017 5/11/2017

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4 151	Continued From page 19 guideline for staging found that nurses are able to do pressure ulcer assessment using the National Pressure Ulcer Advisor Panel, Feb 2007, 8th edition, found in the Clinical Nursing Skills Basic to Advanced Skills by Smith Duel, Martin. Incorrect pressure ulcer staging may potentially cause unnecessary treatment delivery to the resident.	4 151		
4 152	11-94.1-39(e) Nursing services (e) There shall be a policies and procedures manual that is kept current and consistent with current nursing and medical practices and approved by the medical advisor or director and the person responsible for nursing procedures. The policies and procedures shall include but not be limited to: (1) Written procedures for personnel to follow in an emergency including: (A) Care of the resident; (B) Notification of the attending physician and other persons responsible for the resident; and (C) Arrangements for transportation, hospitalization, or other appropriate services; (2) All treatment and care provided relative to the resident's needs and requirements for documentation; and (3) Medication or drug administration procedures that clearly define drug administration process, documentation, and authorized	4 152	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: The current policy "Notification of Changes in Resident Condition" 510-105-01 was reviewed by Nursing, the Medical Director, and the Administrator and modified to be appropriate guidance for staff to contact the person of record for notification when a change of resident condition occurs and modify the care plan. Nurse Managers are in the process of reviewing the policy with licensed staff for compliance, while the Medical Director is doing so with Medical Staff. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to notify their representative when a change in their status occurs.	5/5/2017 5/8/2017

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4 152	Continued From page 20 This Statute is not met as evidenced by: Based on clinical record review and interviews, the facility failed to immediately notify the resident's representatives when there was a significant change in the resident's physical condition and health status for 1 of 23 residents (Resident #12) in the Stage 2 sample. Finding includes: During a confidential family interview on 04/11/2017 at 10:31 AM, a family member stated he/she is the person who would be notified of a change in condition involving Resident #12 (R #12). The family member stated there had been a recent change in R #12's health condition. The family member stated he/she had not been promptly notified by staff caring for R #12 of the laboratory tests and an electrocardiogram (EKG) that had been ordered. The family member further said the tests were ordered about a week ago on a Friday, and when he/she came to visit R #12 on Sunday, the resident "was going through" an exacerbation of her congestive heart failure (CHF). The family member stated the resident was also found to have swelling (edma) of her face and hands. During a follow-up confidential interview on 04/12/2017 at 9:02 AM, the family member said, "I knew (the resident) was quite lethargic but not aware of the labs and EKG." The family member also said there was a decline in the resident's condition and by that Sunday, 4/2/17, the on call physician was called to assess R #12. The family member stated although another family member "is the primary contact (he/she) asked for me (this family member) to be contacted first" due to	4 152	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: The current policy "Notification of Changes in Resident Condition" 510-105-01 was reviewed by Nursing, the Medical Director, and the Administrator and modified to be appropriate guidance for staff. It also includes a Notice of Change Checklist that includes the steps staff takes during the immediate time frame when such an event would occur. The checklist includes notation as to who was notified (preference is the first listed – if unable then document why and attempts), when, and care plan changes made as a result. Nurse Managers are in the process of reviewing the policy with licensed staff for compliance, while the Medical Director is doing so with Medical Staff. On a daily basis, the Nurse Managers and Nursing Administration round on the units to discuss resident care needs, assess interventions effectiveness, and the need for care plan modification – this would also include a review of steps that staff have taken, including proper notification protocols. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Nurse Managers will meet no less than monthly for the next 3 months to discuss audit results, compliance, and opportunities for further staff education to clarify compliance expectations. The aggregate results will be compiled by our Quality RN and shared / discussed as a scheduled report at our Quality Assurance / Performance Improvement meeting.	5/10/2017 5/24/2017 5/11/2017 5/23/2017

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4 152	Continued From page 21 a language barrier. The resident's clinical chart documents this family member to be the first person the facility is to call on the resident's contact list. The family member re-verified that no staff informed him/her of the labs and EKG and change in the resident's condition. On 04/13/2017 at 8:06 AM, an interview with Staff #58 was done. Staff #58 said R #12's CHF "gets more complicated," but confirmed that when an EKG and labs are ordered, the family is to be notified. Staff #58 verified based on his chart review, there was no clinical documentation by Staff #100 to show that R #12's family member who is to be contacted first had been notified. Staff #58 said it was important that it be documented, but that it had not been done. The facility failed to immediately notify/contact the family member listed as the first person to contact regarding a change in the resident's condition and the ordered clinical tests.	4 152		
4 159	11-94.1-41(a) Storage and handling of food (a) All food shall be procured, stored, prepared, distributed, and served under sanitary conditions. (1) Dry or staple food items shall be stored above the floor in a ventilated room not subject to seepage or wastewater backflow, or contamination by condensation, leakages, rodents, or vermin; and (2) Perishable foods shall be stored at the proper temperatures to conserve nutritive value and prevent spoilage.	4 159		

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4 159	Continued From page 22 This Statute is not met as evidenced by: Based on observations, staff interviews and facility policy review, the facility failed to maintain a walk in refrigerator and walk in freezer to ensure proper food storage. Findings include: An initial tour of the kitchen on the morning of 4/10/17 at approximately 9:30 A.M. found a walk-in refrigerator and the walk in freezer both of which didn't latch when the door was left to shut on it's own. When shutting the door, the door did not completely shut until a staff member pressed it against the door frame. The top edge of the refrigerator door appeared uneven, sloping downward from left to right. At the top of the door, the space between the left side of the walk in refrigerator door and the refrigerator door frame had a gap of approximately 2 inches and narrowed toward the bottom to approximately 0.75 inches. The temperatures for the walk in refrigerator were maintained at or below 41 degrees. However, the possibility for the temperature to rise above 41 degrees was high based on the necessity for the the staff to push the door shut. In addition to the walk in refrigerator, the walk in freezer also did not latch when the the door was left to shut on it's own. A sign was taped to the freezer door to remind staff to push the door shut. When shutting the freezer door, the door did not completely shut until a staff member pressed it against the door frame. The edge of the freezer door appeared uneven, sloping downward from left to right. At the top of the door, the space between the left side of the walk in freezer door and the freezer door frame had a gap of approximately 2 inches and narrowed toward the	4 159	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: During the survey and thereafter until the issue is resolved, Dietary staff were reminded to assess with each use - adequate closure of the walk-in refrigerator and freezer to maintain compliance with standards relating to closure. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to maintain the walk-in freezer and walk-in refrigerator to ensure proper food storage. WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: An assessment of repair work was completed on 4/26/2017. After a requested onsite evaluation, a vendor provided a quote for repairs to the walk-in refrigerator and freezer to maintain compliance with standards. The vendor reported that the parts needed for repair arrived on 5/11/2017. The vendor anticipates complete repairs by 5/19/2017. The Maintenance Supervisor and Dietician will be monitoring the effectiveness of the repairs to the doors and status of temperatures in the respective walk-ins – action will be taken with staff and the vendor as necessary to assure compliance. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: The status of the repair work and trending of temperature log findings will be shared at the QA/PI meeting, along with actions taken as necessary to remedy variances.	4/12/2017 4/26/2017 5/11/2017 5/19/2017 5/23/2017

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4 159	Continued From page 23 bottom to approximately 1 inch. A gray strip around the freezer door was loose at the corner. The Maintenance staff re-glued the gray strip until it was permanently fixed. Additionally, the floor was wet under the door to the walk in freezer. Staff #12 reported that she thought the wetness was from condensation. The temperatures for the walk in freezer were maintained at or below 0 degrees. However, the possibility for the temperature to rise above 0 degrees was high based on the necessity for the staff to push the door shut. A review of the walk in refrigerator and walk in freezer temperature logs on the morning of 4/13/17 revealed the temperature levels for March and April 2017 were maintained within acceptable ranges. The foods in the freezer were frozen solid without any thaw. An interview of Staff #12 on the morning of 4/12/17 revealed the facility was aware that the walk in refrigerator and walk in freezer doors were not working properly. Staff #12 further noted the kitchen staff taped a sign to the walk in freezer door indicating the door was malfunctioning for an unspecified amount of time. As of survey date, 4/13/17, the facility had not contracted a vendor to assess the doors of the walk in refrigerator and walk in freezer. A review of the facility's policy titled, "Food Storage and Preparation" with revision date of 10/2015 revealed, "(11) Preventive refrigerator, freezer, and ice machine maintenance to be provided routinely and as needed by contacting food service supervisor." The facility failed to maintain the doors for one of the walk in refrigerators and the walk in freezer.	4 159		

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4 172	11-94.1-42(j) Physician services (j) Each resident shall receive age-appropriate immunizations or vaccinations including but not limited to pneumococcal and annual influenza vaccines and any necessary immunizations following the recommendations of the Advisory Committee of Immunization Practices unless otherwise contraindicated, or refused by the resident, legal guardian, or surrogate. All immunizations provided shall be documented in each resident's medical record. This Statute is not met as evidenced by: Based on record review, interview with staff members and review of the facility's policy and procedure, the facility failed to ensure 5 (Residents #70, #63, #34, #56 and #57) of 5 residents sampled for immunization had the opportunity to refuse the influenza vaccine. The resident's medical record does not include documentation that the resident or resident's representative was provided with education regarding the benefits and potential side effects of the influenza immunization and the resident received the immunization or refused the vaccination. Findings include: On 4/10/17 the facility provided a copy of the the policy and procedures for "Vaccination Pneumococcal and Influenza Inpatient Protocol". The procedure includes if a resident is indicated for the vaccine, the facility will provide the :Vaccine Information Statement (VIS) and will review the appropriate VIS with the resident prior to the administration of the vaccine. The required documentation includes: patient/family education; the date of administration of the	4 172	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: The policy, procedure, and accompanying form for admission assessment of vaccination status, seasonal influenza immunization, and pneumococcal immunization consent were revised on 5/11/17. It includes staff documentation of resident or resident's representative education on benefits and potential side effects of the immunization, along with the documentation of their receipt or refusal of it. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to meet their rights to receive education on benefits and potential side effects of the immunization, along with the documentation of their consent to receive or refusal of it.	5/11/2017

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4 172	Continued From page 25 pneumococcal vaccine; amount and dosage given; the site of injection; the vaccine manufacturer; the lot number of the vaccine used; the expiration date of the vaccine; and signature of licensed nurse administering the vaccine. The policy did not include provision for the resident or resident's representative to refuse immunization. On 4/13/17 at 9:00 A.M. an interview was conducted with the Director of Nursing (DON) and Staff Member #122. The staff members reported the process for immunizations include sending a letter to the resident or resident's representative to offer the vaccine with the VIS attached. The letters are sent out in October and November. Staff Member #122 provided a sample of the immunization packet that is sent to the resident or resident's representative. The letter was reviewed during the interview which notifies the resident or resident's representative that "All residents at [facility name] are scheduled to receive: flu vaccine annually; tetanus/diphtheria vaccine - given every 10 years, or as medically necessary; tetanus/diphtheria/peruses (Tdap) - given one time for adults 65 years or older; and pneumococcal (a type of pneumonia) - given at age 65 with a second for those people aged 65 and older who got their first does under the age of 65 if five or more years have passed. The letter also documents that the physician has ordered these vaccines and will administer as ordered unless contraindicated. There was no information related to declination of the vaccines. Upon review of this letter, the DON stated the letter informs the recipient of the letter of the right to refuse the vaccines. Staff Member #122 reviewed the letter and confirmed there is no information regarding declining administration of the vaccines. Staff Member #122 reviewed the VIS documents in the packet and found the	4 172	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: The Quality / Infection Control RN will be coordinating the review of new admission's vaccination status assessments, the development of a facility-wide matrix of pneumococcal status for boosters, and the seasonal implementation of influenza immunization assessments, offering of and declination of administration. Feedback will be provided to the nurse manager and staff involved for each instance of non-compliance with documentation requirements. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Results of audits will be reported at each Quality Assurance / Performance Improvement meeting – as part of our infection prevention and control efforts the results of and strategies for compliance with new admission assessments, acceptance or declination of immunization, status of pneumococcal booster scheduling, and seasonal influenza rates – along with documentation compliance.	5/23/2017

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information statement for the Tdap vaccine was dated 2/24/2015 which indicates the date when the form was updated, acknowledging the form may have been revised since 2015 and the facility may not be providing the most current information (VIS) related to vaccines.

The inconsistent process for the five sampled residents was shared during this interview. The inconsistencies included letters that were not dated, letters that were dated and not signed, no documentation education was provided to the resident or resident's representative and no opportunity for the resident to refuse the immunization. Staff Member #122 commented the facility will "definitely tighten the process" for immunizing the residents.

1) On 4/11/17 an interview and concurrent record review was done for Resident #63 with Staff Member #155. Staff Member #155 confirmed the resident received the flu vaccine on 10/7/16 and the pneumovax on 6/18/16. The staff member reported the resident or representative is provided with information regarding the vaccine on admission then once a year the resident or representative is contacted. The staff member reported staff members are to document in the progress note that education was provided. The staff member referred to the "Interdisciplinary Patient/Resident and Family Teaching Record" form that documents education was provided to the resident or resident's representative. The staff member could not find documentation on the form that education was provided to the resident and/or representative. The staff member also reviewed the progress note and confirmed there was no documentation in the progress notes related to education and there was no documentation that the resident

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4 172	Continued From page 27 and/or representative had an opportunity to decline the vaccine. Further review found a letter dated 6/15/16 regarding vaccines informing residents that vaccines (annual influenza vaccine, tetanus/diphtheria and peruses and a pneumococcal vaccine) will be ordered by their physician. Also noted was an enclosed "CDC Fact Sheets". This letter was not signed by the Acting DON. This letter was not the same letter that was included in the packet provided by the DON and Staff Member #122. There was documentation of a second letter dated 7/19/16 which was signed by the Acting DON. The letters sent to the resident or resident's representative did not include information to refuse vaccines. 2) On 4/12/17 at 8:52 A.M. an interview and concurrent record review was done for Resident #34 with Staff Member #155. The review found a letter dated 6/15/16 regarding vaccines that will be ordered by the physician which was not signed by the Acting DON. There was another letter dated 7/19/16 which was signed by the Acting DON. The letter in the resident's medical record was not the same letter provided by the staff members during the interview. Subsequently, Staff Member #155 found the "Interdisciplinary Patient/Resident and Family Teaching Record" which documents on 6/30/16, 8/30/16 and 9/8/16 education was provided regarding vaccinations to the resident. The documentation on this form consisted of the staff member writing the number "8" for vaccinations in the topic/learning objectives column. There was no progress note to document the specifics of the education that was provided. A review of the physician's order for April 2017 documents the flu vaccine was administered on 105/16 and pneumovax on	4 172		

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4 172	Continued From page 28 6/18/16. There was no documentation that the resident had an opportunity to refuse the vaccine. 3) A review of Resident #70's medical record on the morning of 4/11/17 at 2:55 P.M. revealed she received the Influenza vaccine for the 2016 flu season on 10/5/16. The documentation regarding the vaccine was incomplete and did not show how the facility discussed the risks and benefits with Resident #70's Power of Attorney (POA) for receiving the flu vaccine. An interview of the Nurse Manager on the afternoon of 4/11/17 at 2:55 P.M. revealed the facility did not educate the POA for the risks/benefits of the Influenza vaccine. 4) On 4/12/17, a chart review of Resident #56's (R #56) immunization status for influenza and pneumococcal vaccines was done. There was no clinical documentation to show the resident or the resident's representative received the vaccine information statements, including the benefits and risks of both immunizations, and the administration or the refusal of, or medical contraindications to the vaccines. In addition, the vaccine information statements (VIS) forms sent out were for the 2015 year, and not the current year for 2016. On 04/13/2017 at 7:21 AM, Staff #108 confirmed for R #56, she had received verbal consent from the resident's guardian to administer the vaccines. Staff #108 verified however, there was no documentation in the resident's progress notes about the verbal consent. Staff #108 also said the teaching record the facility used to chart when the VIS was sent out was a process being done on every unit. She acknowledged both the consent and/or declination had to be documented, but that it was not done.	4 172		

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4 172	Continued From page 29 5) In the morning of 4/15/2016 a concurrent record review was done with Staff #58 for Resident #57. Res #57 received an influenza vaccine in 2016. Staff #58 was asked to show evidence of the influenza vaccine education provided to resident #57 or POA prior to administration of the vaccine. Staff #58 showed a facility paper in the resident record with a checkmark to topic #8 "verbal paperwork sent to family 7/20/16". When asked for evidence for consent for immunization. Staff #58 stated a telephone call was made to the resident's son around that time and the "son agreed to the vaccine for the resident". There was no written evidence provided by staff for consent for vaccination or education on side effects and benefits of the vaccine. Failure to provide documented education on the vaccine side effects and benefits; and consent to vaccinate prior to vaccination potentially violates the resident's informed consent rights.	4 172		
4 185	11-94.1-46(b) Pharmaceutical services (b) A facility shall have a current pharmacy policy manual consistent with current pharmaceutical practices developed and approved by the pharmacist, medical director/medical advisor, and director of nursing that: (1) Includes policies and procedures, and defines the functions and responsibilities relating to pharmacy services, including the safe administration and handling of all drugs and self-administration of drugs. Policies and procedures shall include pharmacy functions and responsibilities, formulary, storage,	4 185		

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4 185	Continued From page 30 administration, documentation, verbal and telephone orders, authorized personnel, recordkeeping, and disposal of drugs; (2) Is reviewed at least every two years and revised as necessary to keep abreast of current developments in overall drug usage; and (3) Has a drug recall procedure that can be readily implemented. This Statute is not met as evidenced by: Based on observation, interviews, and policy review the facility failed to provide pharmaceutical services to meet the needs of each resident. Findings include: 1) On 4/10/2017 at 11:50 AM observed an IV bag hanging for Resident #44. The IV bag was not labeled with a resident's name or dated. At 12:00 PM interviewed Staff #116 regarding the unlabeled IV bag. Staff #116 agreed the bag hanging should be labeled. Staff #116 shared Resident #44 receives TPN nourishment through her PICC line and after the TPN is infused an IV bag is hung until the line is flushed. Staff #116 brought out an unopened IV bag to show that the pharmacy label is attached to the outside plastic wrap of the IV bag, when the bags are opened the pharmacy label is discarded. Unlabeled medications has the potential for medication errors. 2) On 4/12/2017 at 8:13 AM observed an unlocked treatment cart with one drawer pulled out resting in the hall outside of the dining hall. The opened drawer contained ointments. There was no staff seen near or around the opened	4 185	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1)The administration of the TPN for R44 was modified on 4/10/2017 to be compliant with the expectation of appropriate labeling of the resident's name, date / time of infusion start and flow rate of volume over time as directed by the physician's order, 2) the treatment cart without a lock is no longer used in the hallway and is left in a room that is locked when unattended as of 4/13/2017. Staff were reminded 4/13/17 regarding the requirement to maintain the storage of medications in a locked compartment at all times. 3) The policy and procedure for controlled substance disposal was modified with consultation with our contracted pharmacy service on 5/12/2017 to assure compliance. Staff education about this new process began on 5/15/2017, 4) All medications with risk of compromise as determined by the manufacturer and our contracted consultative pharmacy service were disposed of on 4/13/2017. The medication refrigerator policy and log was corrected with collaboration from our contracted consultative pharmacy to note the correct temperature range to be kept between 36° to 46° Fahrenheit on 4/26/2017. The new log includes further detail of actions to be taken when a temperature is noted as out of range, which includes contacting maintenance and also the contracted pharmacy to determine whether the medications within the refrigerator were compromised and need to be removed from use, and 5) Out-dated Pharmerica policy and procedure manuals were removed from the nursing units on 4/13/2017. The reviewed and revised Pharmacy p&p are available online and staff education as to their location has been ongoing – a reminder of their location being posted on the nursing unit computer monitors was sent 5/15/2017.	4/10/2017 4/13/2017 5/12/2017 5/15/2017 4/13/2017 4/26/2017 4/13/2017 5/15/2017

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4 185	Continued From page 31 cart. Shortly after observed Staff # 116 came out of the dining room. Staff #116 was asked about the unattended, unlocked treatment cart with the treatment drawer opened. Staff #116 stated she went to check a resident and had left the cart unlocked. Staff #116 agreed the cart should have been locked. Unlocked treatment carts has the potential for medication loss and misuse. 3) On 4/12/2017 at 10:40 AM interviewed Staff #116 regarding the procedure for discarding discontinued narcotics. Staff #116 stated that liquid narcotics are disposed into the drain and the controlled pills are discarded into the sharps container. The policy for disposal of discontinued narcotics was provided by Staff #116 and reviewed. The policy dated 12/12 stated: "1. The director of nursing and the consultant pharmacist will monitor for compliance with federal and state laws and regulations regarding the disposal of medications. The nursing care center should maintain approved containers to separate and securely store different types of pharmaceutical waste until it is scheduled for pick up. b. Authorized personnel who have access to medications should deposit pharmaceutical waste in the appropriately labeled container. Each container used to collect, separate and store each type of pharmaceutical waste will be labeled with the type of waste to be stored in the container. 2. Controlled Substances listed in Schedules II, III, IV and V remaining in the nursing care center after the order has been discontinued are retained in the nursing care center - until destroyed as outlined by state regulation. a. Transfer to a container for release to a pharmaceutical waste contractor, was checked off on the policy. At 1:36 PM the same day interviewed the DON regarding nursing practice for disposal of discontinued resident	4 185	HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to ensure that quality pharmaceutical services are rendered to meet the needs of each resident.	

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4 185	Continued From page 32 narcotics. The DON shared the policy for disposal of controlled drugs used on the nursing floors dated 12/12 is old, a new policy dated 5/16 is on line but has not been changed in the PharMerica policy binders used by the nursing staff. At 1:41 PM the same day interviewed Staff #108 regarding disposal of narcotics procedure. Staff #108 stated the narcotics are popped out of the blister pack and thrown into the sharps container, sometimes the pills are crushed. The liquid narcotics are poured onto a paper towel and discarded. Later that afternoon contacted the pharmacist consult (Staff #181) for the facility. When asked the recommendation and policy for disposal of controlled medications at the facility Staff #181 shared, the pharmacist does not have a role in narcotics disposal, once the medication leaves the pharmacy it belongs to the resident, nothing is returned to the pharmacy. Upon request from the facility pharmacy can advise the facility on discarding controlled medication. When informed about the practice of throwing away discontinued narcotics in the sharps containers or down the drain Staff #181 stated, "we don't look at that; we are more concerned with out of date drugs." A review of the pharmacy contract titled 'Hawaii Health Systems Corporation Agreement for Goods or Services Based Upon Competitive Sealed Proposals" states 2.12 Provide experienced, trained Geriatric Consultant Pharmacist to perform the following services: As per CMS requirements provide assistance with tracking, destroying; and reconciling unused controlled substances." Failure to provide pharmacy consultative services for discontinued controlled substances may potentially provide opportunity for misuse of controlled discontinued substances. 4) On 4/12/2017 at 10:40 AM reviewed the	4 185	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: 1) The nurse managers of units with residents receiving intravenous infusions will perform audits of no less than twice weekly to assess staff compliance with labeling requirements. 2) An alternate cart with a lock was selected and is being ordered as a replacement. 3) In collaboration with our contracted consultative pharmacy service, an alternate method of secure controlled substance disposal was identified. A procurement action has been taken and the order placed on 5/8/2017 for a liquid, patch, and solid controlled substance secured container system for each nursing unit. Once obtained, the revised policy and procedure will be finalized in conjunction with the contract pharmacy. 2-4)All nurse managers will audit compliance with the 1) locking of treatment carts, 2) proper disposal of controlled substances, and 3) temperature adequacy of medication refrigerators through their respective logs - no less than twice weekly. Audits on cart locking and temperature management began 4/13/2017. Audits on controlled substance disposal began 5/15/2017. Actions as necessary shall be taken to assure compliance – status reports will be made to the Director of Nursing for each instance of non-compliance. 5) The reviewed and revised Pharmacy p&p are available online and staff education as to their location has been ongoing – a reminder of their location being posted on the nursing unit computer monitors was sent 5/15/2017. A hard copy of this is also available in the Nursing Office.	4/13/2017 5/15/2017 5/8/2017 4/13/2017 5/15/2017 5/15/2017

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4 185	Continued From page 33 temperature log on the 3rd floor of the facility. The log titled "MEDS Refrigerator/Freezer Temperature Log" was printed "REFRIGERATOR STANDARD: 33 degrees - 40 degrees FAHRENHEIT". The recorded refrigerator temperatures for April 2017 was found to be documented at 34 degrees on April 7 and April 8, and at 35 degrees on April 12, 2017. The refrigerator contained some of the following medications and amounts: Calcitonin Salmon Nasal Solution 1 box; Cathflor Activase a 2 mg vial; Biscodyl Suppository 13 packets; Acetaminophen Suppository 10 packets; Octreotide 50 mcg one box; Ativan vials, 4 bags with 5, 3, 5, and 5 vials per bag. The printed manufacturers label recommended temperature storage at 36 - 46 degrees for the Octreotide, Calcitonin Salmon Nasal Solution and Ativan. The temperature log was concurrently reviewed with Staff #116. Staff #116 provided a printed copy of the facility policy titled, "Refrigerator/Freezer Temperature control and Maintenance. Purpose: To maintain proper temperatures for food safety and potency of medications". The policy stated: "Refrigerator standard range if 33 degrees to 40 degrees Fahrenheit". On the same day at approximately 11:06 AM the temperature logs for the 4th and 2nd floors were reviewed. Observed that all the units were using the same standard log with the incorrect temperature range of 33 to 40 degrees Fahrenheit. The refrigerator on the second floor was observed to have the following medications and amounts: Pneumococcal vaccine premeasured syringes one box; Calcitonin Salmon Nasal Spray 1 box; Influenza premeasured syringes 1 box; Tetanus 2 vials, and Ativan 3 vials. On 4/12/2017 at 1:49 PM	4 185	HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Compliance with TPN labeling, treatment cart locking, controlled substance disposal, and maintenance of medication refrigerator temperatures will be reporting at the QA/PI meeting, along with actions taken to assure compliance. Revisions to pharmacy policy and procedures will be updated online and shared with staff for education.	5/23/2017

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4 185	Continued From page 34 pharmacy consultant (Staff #181) was interviewed by phone and asked about the effect of the drug temperature being at 35 degrees when the manufacturers recommendation is at 36 degrees. Staff #181 stated, "one degree is not going to matter, even if the package says 36 degrees, it is OK". When asked if the manufacturer could be consulted for the medications found on the 2nd and 3rd floors stored below the manufacturers recommendation, Staff #181 stated a call would be made to the manufacturer but a response would not be available for a few days due to the time zones. Later that afternoon interviewed the DON regarding the discrepancy on the facility medication temperature log, the facility policy for refrigerated medications for storage range of 33 - 40 degrees versus the manufactures recommendation for refrigerated medications to be stored at 36 - 46 degrees. Also the concern for the efficacy of the medications stored out of temperature range. The DON shared the policy and logs were revised on 12/2016. Requested copies of the temperature logs for the past 4 months from January 2017 to April 2017 from all the nursing units for review. On 4/13/2017 at 3:49 AM contacted the drug manufactuers Merck, for the Pneumococcal vaccine; Phizer for the Ativan vials; and Sagent Pharmaceuticals for the Octreotide vial. Each manufacturer interviewed was asked about the efficacy of the drug when stored below the recommended 36 - 46 degrees. Ativan stored below 36 degrees had no information or recommendations of use. The Octreotide drug stability studies indicated the drug was stable up to 3 months under the accelerated conditions. Accelerated conditions are described as below 36 degrees. The Pneumococcal vaccine efficacy	4 185		

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4 185	Continued From page 35 was determined by the total number of hours kept below the manufacturers recommended temperature. On 4/13/2017 at 7:30 AM obtained from the DON the collection of medication refrigerator temperature logs from January 2017 to April 2017 for the entire facility, which had been requested from the DON on 4/12/2017. The following temp logs provided were missing: 4 North - missing April 2017 and January 2017; 3rd floor - missing March 2017. Review of the 2nd floor refrigerator log found that the Pneumococcal vaccine had been stored below 36 degrees for 216 hours from Jan - April 2017. At 7:48 AM spoke to the Merck manufacturer consultant by phone regarding the 216 hours the Pneumococal vaccine was stored below 36 degrees. Per the manufacturers recommendation, given the number of hours kept below 36 degrees the recommendation was not to administer the vaccine to any patients and remove the vaccine from inventory. The manufactures advise was shared with Staff #108 and the DON. Review of the facility policy for "potency of medications" titled "Refrigerator/Freezer Temperature control and Maintenance" date effective 12/2016 found that the policy was not signed as approved and reviewed by a PharMerica consultant. Review of the contract agreement between HHSC and the Pharmacy Corporation of America states: 2.0 Contractor Requirements. The contractor shall provide "Long Term Care Pharmacy services" pursuant to the provisions specified below: 2.1 Provide the facility with a comprehensive range of professional pharmaceutical services related to the use, storage, distribution and administration of medicines."	4 185		

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4 185	Continued From page 36 Failure to properly label medication; failure to secure and lock treatment cart inventory; inconsistency of nursing staff practice in the proper disposal of controlled drugs; failure to update the pharmMerica binder used on the floors by nursing staff on the disposal of controlled drugs; and failure to provide consultative pharmaceutical service for policy development and review in the area of medications stored in refrigerator/freezer has the potential for pharmaceutical errors.	4 185		
4 194	11-94.1-46(k) Pharmaceutical services (k) Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. This Statute is not met as evidenced by: Based on observations, interviews, and policy reviews the facility failed to utilize the pharmacy for consultation services on all aspects of the provision of pharmacy services in the facility. Findings includes: 1) On 4/12/2017 at 10:40 AM interviewed Staff #116 regarding the procedure for discarding discontinued narcotics. Staff #116 stated that liquid narcotics are disposed into the drain and the controlled pills are discarded into the sharps container. The policy for disposal of discontinued narcotics was provided by Staff #116 and reviewed. The policy dated 12/12 stated: "1. The director of nursing and the consultant pharmacist will monitor for compliance with federal and state laws and regulations regarding	4 194	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1) The policy and procedure for controlled substance disposal was modified with collaboration from our contracted consultative pharmacy on 5/12/2017 to assure compliance. Staff education about this new process began on 5/15/2017. 2) Out-dated Pharmerica policy and procedure manuals were removed from the nursing units on 4/13/17. The reviewed and revised Pharmacy p&p are available online and staff education as to their location has been ongoing – a reminder of their location being posted on the nursing unit computer monitors was sent 5/15/2017. A hard copy of this is also available in the Nursing Office.	5/12/2017 5/15/2017 4/13/2017 5/15/2017

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4 194	Continued From page 37 the disposal of medications. The nursing care center should maintain approved containers to separate and securely store different types of pharmaceutical waste until it is scheduled for pick up. b. Authorized personnel who have access to medications should deposit pharmaceutical waste in the appropriately labeled container. Each container used to collect, separate and store each type of pharmaceutical waste will be labeled with the type of waste to be stored in the container. 2. Controlled Substances listed in Schedules II, III, IV and V remaining in the nursing care center after the order has been discontinued are retained in the nursing care center - until destroyed as outlined by state regulation. a. Transfer to a container for release to a pharmaceutical waste contractor, was checked off on the policy. At 1:36 PM the same day interviewed the DON regarding nursing practice for disposal of discontinued resident narcotics. The DON shared the policy for disposal of controlled drugs used on the nursing floors dated 12/12 is old, a new policy dated 5/16 is on line but has not been changed in the PharMerica policy binders used by the nursing staff. At 1:41 PM the same day interviewed Staff #108 regarding disposal of narcotics procedure. Staff #108 stated the narcotics are popped out of the blister pack and thrown into the sharps container, sometimes the pills are crushed. The liquid narcotics are poured onto a paper towel and discarded. Later that afternoon contacted the pharmacist consult (Staff #181) for the facility. When asked the recommendation and policy for disposal of controlled medications at the facility Staff #181 shared, the pharmacist does not have a role in narcotics disposal, once the medication leaves the pharmacy it belongs to the resident, nothing is returned to the pharmacy. Upon request from the facility pharmacy can advise the	4 194	HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to utilize the pharmacy for consultative services on all aspects of pharmaceutical services in the facility. WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: 1) Nurse managers will be reviewing controlled substance disposal logs with staff no less than twice weekly and quizzing staff on accurate knowledge of the proper methods. Audits on controlled substance disposal began 5/15/2017. Actions as necessary shall be taken to assure compliance – status reports will be made to the Director of Nursing for each instance of non-compliance. In collaboration with our contracted consultative pharmacy service, an alternate method of secure controlled substance disposal was identified. A procurement action has been taken and the order placed on 5/8/2017 for a liquid, patch, and solid controlled substance secured container system for each nursing unit. Once obtained, the revised policy and procedure will be finalized in conjunction with the contract pharmacy. The contracted pharmacy will begin reviewing controlled substance disposal logs for compliance with regulatory compliance 5/16/2017 2) The reviewed and revised Pharmacy p&p are available online and staff education as to their location has been ongoing – a reminder of their location being posted on the nursing unit computer monitors was sent 5/15/2017. A hard copy of this is also available in the Nursing Office.	5/15/2017 5/8/2017 5/16/2017 5/15/2017

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4 194	Continued From page 38 facility on discarding controlled medication. When informed about the practice of throwing away discontinued narcotics in the sharps containers or down the drain Staff #181 stated, "we don't look at that; we are more concerned with out of date drugs." A review of the pharmacy contract titled 'Hawaii Health Systems Corporation Agreement for Goods or Services Based Upon Competitive Sealed Proposals" states 2.12 Provide experienced, trained Geriatric Consultant Pharmacist to perform the following services: As per CMS requirements provide assistance with tracking, destroying; and reconciling unused controlled substances." Failure to provide pharmacy consultative services for discontinued controlled substances may potentially provide opportunity for misuse of controlled discontinued substances. 2) On 4/12/2017 at 10:40 AM reviewed the temperature log on the 3rd floor of the facility. The log titled "MEDS Refrigerator/Freezer Temperature Log" was printed "REFRIGERATOR STANDARD: 33 degrees - 40 degrees FAHRENHEIT". The recorded refrigerator temperatures for April 2017 was found to be documented at 34 degrees on April 7 and April 8, and at 35 degrees on April 12, 2017. The refrigerator contained some of the following medications and amounts: Calcitonin Salmon Nasal Solution 1 box; Cathflor Activase a 2 mg vial; Biscodyl Suppository 13 packets; Acetaminophen Suppository 10 packets; Octreotide 50 mcg one box; Ativan vials, 4 bags with 5, 3, 5, and 5 vials per bag. The printed manufacturers label recommended temperature storage at 36 - 46 degrees for the Octreotide, Calcitonin Salmon Nasal Solution and Ativan. The temperature log was concurrently reviewed with Staff #116. Staff #116 provided a printed	4 194	HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Nurse Managers will meet no less than monthly for the next 3 months to discuss audit results, compliance, and opportunities for further staff education to clarify compliance expectations. The aggregate results will be compiled by our Quality RN and shared / discussed as a scheduled report at our Quality Assurance / Performance Improvement meeting. Revisions to pharmacy policy and procedures will be updated online and shared with staff for education.	5/23/2017

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KULA HOSPITAL	100 KEOKEA PLACE KULA, HI 96790

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4 194	Continued From page 39 copy of the facility policy titled, "Refrigerator/Freezer Temperature control and Maintenance. The policy stated: "Refrigerator standard range if 33 degrees to 40 degrees Fahrenheit". On the same day at approximately 11:06 AM the temperature logs for the 4th and 2nd floors were reviewed. Observed that all the units were using the same standard log with the incorrect temperature range of 33 to 40 degrees Fahrenheit. The refrigerator on the second floor was observed to have the following medications and amounts: pneumococcal vaccine premeasured syringes one box; Calcitonin Salmon Nasal Spray 1 box; Influenza premeasured syringes 1 box; Tetanus 2 vials, and Ativan 3 vials. On 4/12/2017 at 1:49 PM pharmacy consultant (Staff #181) was interviewed by phone and asked about the effect of the drug temperature being at 35 degrees when the manufacturers recommendation is at 36 degrees. Staff #181 stated, "one degree is not going to matter, even if the package says 36 degrees, it is OK". When asked if the manufacturer could be consulted for the medications found on the 2nd and 3rd floors stored below the manufacturers recommendation, Staff #181 stated a call would be made to the manufacturer but a response would not be available for a few days due to the time zones. Later that afternoon interviewed the DON regarding the discrepancy on the facility medication temperature log, the facility policy for refrigerated medications for storage range of 33 - 40 degrees versus the manufactures recommendation for refrigerated medications to be stored at 36 - 46 degrees. Also the concern for the efficacy of the medications stored out of temperature range. The DON shared the policy	4 194		

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4 194	Continued From page 40	4 194		

and logs were revised on 12/2016. Requested copies of the temperature logs for the past 4 months from January 2017 to April 2017 from all the nursing units for review.

On 4/13/2017 at 3:49 AM contacted the drug manufacturers Merck, for the pneumococcal vaccine; Phizer for the Ativan vials; and Sagent Pharmaceuticals for the Octreotide vial. Each manufacturer interviewed was asked about the efficacy of the drug when stored below the recommended 36 - 46 degrees. Ativan stored below 36 degrees had no information or recommendations of use. The Octreotide drug stability studies indicated the drug was stable up to 3 months under the accelerated conditions. Accelerated conditions are described as below 36 degrees. The pneumococcal vaccine efficacy was determined by the total number of hours kept below the manufacturers recommended temperature.

On 4/13/2017 at 7:30 AM obtained from the DON the collection of medication refrigerator temperature logs from January 2017 to April 2017 for the entire facility, which had been requested from the DON on 4/12/2017. The following temp logs provided were missing: 4 North - missing April 2017 and January 2017; 3rd floor - missing March 2017. Review of the 2nd floor refrigerator log found that the pneumococcal vaccine had been stored below 36 degrees for 216 hours from Jan - April 2017. At 7:48 AM spoke to the Merck manufacturer consultant by phone regarding the 216 hours the pneumococcal vaccine was stored below 36 degrees. Per the manufacturers recommendation, given the number of hours kept below 36 degrees the recommendation was not to administer the vaccine to any patients and remove the vaccine from inventory. The

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4 194	Continued From page 41 manufactures advise was shared with Staff #108 and the DON. Review of the facility policy for "potency of medications" titled "Refrigerator/Freezer Temperature control and Maintenance" date effective 12/2016 found that the policy was not signed as approved and reviewed by a PharMerica consultant. Review of the contract agreement between HHSC and the Pharmacy Corporation of America states: 2.0 Contractor Requirements. The contractor shall provide "Long Term Care Pharmacy services" pursuant to the provisions specified below: 2.1 Provide the facility with a comprehensive range of professional pharmaceutical services related to the use, storage, distribution and administration of medicines." Inconsistency of nursing staff practice in the proper disposal of controlled drugs; failure to update the PharMerica binder used on the floors by nursing staff on the disposal of controlled drugs; and failure to provide consultative pharmaceutical service for policy development and review in the area of medications stored in refrigerator/freezer has the potential for pharmaceutical errors.	4 194		
4 195	11-94.1-46(l) Pharmaceutical services (l) All drugs, including drugs that are stored in a refrigerator, shall be kept under lock and key, except when authorized personnel are in attendance. The facility shall be in compliance with all security requirements of federal and state laws as they relate to storerooms and pharmacies.	4 195		

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4 195	Continued From page 42 This Statute is not met as evidenced by: Based on observations, interviews, and policy reviews the facility failed to utilize the pharmacy for consultation services on all aspects of the provision of pharmacy services in the facility. Findings includes: 1) On 4/12/2017 at 10:40 AM interviewed Staff #116 regarding the procedure for discarding discontinued narcotics. Staff #116 stated that liquid narcotics are disposed into the drain and the controlled pills are discarded into the sharps container. The policy for disposal of discontinued narcotics was provided by Staff #116 and reviewed. The policy dated 12/12 stated: "1. The director of nursing and the consultant pharmacist will monitor for compliance with federal and state laws and regulations regarding the disposal of medications. The nursing care center should maintain approved containers to separate and securely store different types of pharmaceutical waste until it is scheduled for pick up. b. Authorized personnel who have access to medications should deposit pharmaceutical waste in the appropriately labeled container. Each container used to collect, separate and store each type of pharmaceutical waste will be labeled with the type of waste to be stored in the container. 2. Controlled Substances listed in Schedules II, III, IV and V remaining in the nursing care center after the order has been discontinued are retained in the nursing care center - until destroyed as outlined by state regulation. a. Transfer to a container for release to a pharmaceutical waste contractor, was checked off on the policy. At 1:36 PM the same day interviewed the DON regarding nursing practice for disposal of discontinued resident	4 195	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1) The policy and procedure for controlled substance disposal was modified in collaboration with our contracted consultative pharmacy on 5/12/2017 to assure compliance. Staff education about this new process began on 5/15/2017, 2) All medications with risk of compromise as determined by the manufacturer and our contracted consultative pharmacy service were disposed of on 4/13/2017. The medication refrigerator policy and log was corrected and signed with collaboration from our contracted consultative pharmacy to note the correct temperature range to be kept between 36° to 46° Fahrenheit on 4/26/2017. The new log includes further detail of actions to be taken when a temperature is noted as out of range, which includes contacting maintenance and also the contracted pharmacy to determine whether the medications within the refrigerator were compromised and need to be removed from use.	5/12/2017 5/15/2017 4/13/2017 4/26/2017

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4 195	Continued From page 43 narcotics. The DON shared the policy for disposal of controlled drugs used on the nursing floors dated 12/12 is old, a new policy dated 5/16 is on line but has not been changed in the PharMerica policy binders used by the nursing staff. At 1:41 PM the same day interviewed Staff #108 regarding disposal of narcotics procedure. Staff #108 stated the narcotics are popped out of the blister pack and thrown into the sharps container, sometimes the pills are crushed. The liquid narcotics are poured onto a paper towel and discarded. Later that afternoon contacted the pharmacist consult (Staff #181) for the facility. When asked the recommendation and policy for disposal of controlled medications at the facility Staff #181 shared, the pharmacist does not have a role in narcotics disposal, once the medication leaves the pharmacy it belongs to the resident, nothing is returned to the pharmacy. Upon request from the facility pharmacy can advise the facility on discarding controlled medication. When informed about the practice of throwing away discontinued narcotics in the sharps containers or down the drain Staff #181 stated, "we don't look at that; we are more concerned with out of date drugs." A review of the pharmacy contract titled 'Hawaii Health Systems Corporation Agreement for Goods or Services Based Upon Competitive Sealed Proposals" states 2.12 Provide experienced, trained Geriatric Consultant Pharmacist to perform the following services: As per CMS requirements provide assistance with tracking, destroying; and reconciling unused controlled substances." Failure to provide pharmacy consultative services for discontinued controlled substances may potentially provide opportunity for misuse of controlled discontinued substances. 2) On 4/12/2017 at 10:40 AM reviewed the	4 195	HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to utilize the pharmacy for consultative services on all aspects of pharmaceutical services in the facility. WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: All nurse managers will audit compliance with the proper disposal of controlled substances and temperature adequacy of medication refrigerators through their respective logs - no less than twice weekly. Actions as necessary shall be taken to assure compliance – status reports will be made to the Director of Nursing for each instance of non-compliance. Audits on temperature management began 4/13/2017. Audits on controlled substance disposal began 5/15/2017. In collaboration with our contracted consultative pharmacy service, an alternate method of secure controlled substance disposal was identified. A procurement action has been taken and the order placed on 5/8/2017 for a liquid, patch, and solid controlled substance secured container system for each nursing unit. Once obtained, the revised policy and procedure will be finalized in conjunction with the contract pharmacy. The contracted pharmacy will begin reviewing controlled substance disposal logs for compliance with regulatory compliance 5/16/2017. The reviewed and revised Pharmacy p&p are available online and staff education as to their location has been ongoing – a reminder of their location being posted on the nursing unit computer monitors was sent 5/15/2017. A hard copy of this is also available in the Nursing Office.	4/13/2017 5/15/2017 5/8/2017 5/16/2017 5/15/2017

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4 195	Continued From page 44 temperature log on the 3rd floor of the facility. The log titled "MEDS Refrigerator/Freezer Temperature Log" was printed "REFRIGERATOR STANDARD: 33 degrees - 40 degrees FAHRENHEIT". The recorded refrigerator temperatures for April 2017 was found to be documented at 34 degrees on April 7 and April 8, and at 35 degrees on April 12, 2017. The refrigerator contained some of the following medications and amounts: Calcitonin Salmon Nasal Solution 1 box; Cathflor Activase a 2 mg vial; Biscodyl Suppository 13 packets; Acetaminophen Suppository 10 packets; Octreotide 50 mcg one box; Ativan vials, 4 bags with 5, 3, 5, and 5 vials per bag. The printed manufacturers label recommended temperature storage at 36 - 46 degrees for the Octreotide, Calcitonin Salmon Nasal Solution and Ativan. The temperature log was concurrently reviewed with Staff #116. Staff #116 provided a printed copy of the facility policy titled, "Refrigerator/Freezer Temperature control and Maintenance. The policy stated: "Refrigerator standard range if 33 degrees to 40 degrees Fahrenheit". On the same day at approximately 11:06 AM the temperature logs for the 4th and 2nd floors were reviewed. Observed that all the units were using the same standard log with the incorrect temperature range of 33 to 40 degrees Fahrenheit. The refrigerator on the second floor was observed to have the following medications and amounts: pneumococcal vaccine premeasured syringes one box; Calcitonin Salmon Nasal Spray 1 box; Influenza premeasured syringes 1 box; Tetanus 2 vials, and Ativan 3 vials. On 4/12/2017 at 1:49 PM pharmacy consultant (Staff #181) was interviewed by phone and asked about the effect	4 195	HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Nurse Managers will meet no less than monthly for the next 3 months to discuss audit results, compliance, and opportunities for further staff education to clarify compliance expectations. The aggregate results of compliance with controlled substance disposal, and maintenance of medication refrigerator temperatures will be compiled by our Quality RN and shared / discussed as a scheduled report at our Quality Assurance / Performance Improvement meeting.	5/23/2017

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4 195	Continued From page 45	4 195		

of the drug temperature being at 35 degrees when the manufacturers recommendation is at 36 degrees. Staff #181 stated, "one degree is not going to matter, even if the package says 36 degrees, it is OK". When asked if the manufacturer could be consulted for the medications found on the 2nd and 3rd floors stored below the manufacturers recommendation, Staff #181 stated a call would be made to the manufacturer but a response would not be available for a few days due to the time zones. Later that afternoon interviewed the DON regarding the discrepancy on the facility medication temperature log, the facility policy for refrigerated medications for storage range of 33 - 40 degrees versus the manufactures recommendation for refrigerated medications to be stored at 36 - 46 degrees. Also the concern for the efficacy of the medications stored out of temperature range. The DON shared the policy and logs were revised on 12/2016. Requested copies of the temperature logs for the past 4 months from January 2017 to April 2017 from all the nursing units for review.

On 4/13/2017 at 3:49 AM contacted the drug manufacturers Merck, for the pneumococcal vaccine; Phizer for the Ativan vials; and Sagent Pharmaceuticals for the Octreotide vial. Each manufacturer interviewed was asked about the efficacy of the drug when stored below the recommended 36 - 46 degrees. Ativan stored below 36 degrees had no information or recommendations of use. The Octreotide drug stability studies indicated the drug was stable up to 3 months under the accelerated conditions. Accelerated conditions are described as below 36 degrees. The pneumococcal vaccine efficacy was determined by the total number of hours kept below the manufacturers recommended

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4 195	Continued From page 46 temperature. On 4/13/2017 at 7:30 AM obtained from the DON the collection of medication refrigerator temperature logs from January 2017 to April 2017 for the entire facility, which had been requested from the DON on 4/12/2017. The following temp logs provided were missing: 4 North - missing April 2017 and January 2017; 3rd floor - missing March 2017. Review of the 2nd floor refrigerator log found that the pneumococcal vaccine had been stored below 36 degrees for 216 hours from Jan - April 2017. At 7:48 AM spoke to the Merck manufacturer consultant by phone regarding the 216 hours the pneumococcal vaccine was stored below 36 degrees. Per the manufacturers recommendation, given the number of hours kept below 36 degrees the recommendation was not to administer the vaccine to any patients and remove the vaccine from inventory. The manufactures advise was shared with Staff #108 and the DON. Review of the facility policy for "potency of medications" titled "Refrigerator/Freezer Temperature control and Maintenance" date effective 12/2016 found that the policy was not signed as approved and reviewed by a PharMerica consultant. Review of the contract agreement between HHSC and the Pharmacy Corporation of America states: 2.0 Contractor Requirements. The contractor shall provide "Long Term Care Pharmacy services" pursuant to the provisions specified below: 2.1 Provide the facility with a comprehensive range of professional pharmaceutical services related to the use, storage, distribution and administration of medicines." Inconsistency of nursing staff practice in the	4 195		

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4 195	Continued From page 47 proper disposal of controlled drugs; failure to update the PharMerica binder used on the floors by nursing staff on the disposal of controlled drugs; and failure to provide consultative pharmaceutical service for policy development and review in the area of medications stored in refrigerator/freezer has the potential for pharmaceutical errors.	4 195		
4 196	11-94.1-46(m) Pharmaceutical services (m) Drugs for external and internal use shall be kept separate and stored in locked, well-marked, separate cabinets. This Statute is not met as evidenced by: Based on observation, interviews, and policy review the facility failed to provide pharmaceutical services to meet the needs of each resident. Findings include: 1) On 4/10/2017 at 11:50 AM observed an IV bag hanging for Resident #44. The IV bag was not labeled with a resident's name or dated. At 12:00 PM interviewed Staff #116 regarding the unlabeled IV bag. Staff #116 agreed the bag hanging should be labeled. Staff #116 shared Resident #44 receives TPN nourishment through her PICC line and after the TPN is infused an IV bag is hung until the line is flushed. Staff #116 brought out an unopened IV bag to show that the pharmacy label is attached to the outside plastic wrap of the IV bag, when the bags are opened the pharmacy label is discarded. Unlabeled medications has the potential for medication errors.	4 196		

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4 196	Continued From page 48 2) On 4/12/2017 at 8:13 AM observed an unlocked treatment cart with one drawer pulled out resting in the hall outside of the dining hall. The opened drawer contained ointments. There was no staff seen near or around the opened cart. Shortly after observed Staff # 116 came out of the dining room. Staff #116 was asked about the unattended, unlocked treatment cart with the treatment drawer opened. Staff #116 stated she went to check a resident and had left the cart unlocked. Staff #116 agreed the cart should have been locked. Unlocked treatment carts has the potential for medication loss and misuse. 3) On 4/12/2017 at 10:40 AM interviewed Staff #116 regarding the procedure for discarding discontinued narcotics. Staff #116 stated that liquid narcotics are disposed into the drain and the controlled pills are discarded into the sharps container. The policy for disposal of discontinued narcotics was provided by Staff #116 and reviewed. The policy dated 12/12 stated: "1. The director of nursing and the consultant pharmacist will monitor for compliance with federal and state laws and regulations regarding the disposal of medications. The nursing care center should maintain approved containers to separate and securely store different types of pharmaceutical waste until it is scheduled for pick up. b. Authorized personnel who have access to medications should deposit pharmaceutical waste in the appropriately labeled container. Each container used to collect, separate and store each type of pharmaceutical waste will be labeled with the type of waste to be stored in the container. 2. Controlled Substances listed in Schedules II, III, IV and V remaining in the nursing care center after the order has been discontinued are retained in the nursing care center - until destroyed as outlined by state	4 196	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1)The administration of the TPN for R44 was modified on 4/10/2017 to be compliant with the expectation of appropriate labeling of the resident's name, date / time of infusion start and flow rate of volume over time as directed by the physician's order. 2) the treatment cart without a lock is no longer used in the hallway and is left in a room that is locked when unattended as of 4/13/2017. Staff were reminded 4/13/2017 regarding the requirement to maintain the storage of medications in a locked compartment at all times. 3) The policy and procedure for controlled substance disposal was modified with consultation with our contracted pharmacy service on 5/12/2017 to assure compliance. Staff education about this new process began on 5/15/2017, and 4) All medications with risk of compromise as determined by the manufacturer and our contracted consultative pharmacy service were disposed of on 4/13/2017. The medication refrigerator policy and log was corrected and signed with collaboration from our contracted consultative pharmacy to note the correct temperature range to be kept between 36° to 46° Fahrenheit on 4/26/2017. The new log includes further detail of actions to be taken when a temperature is noted as out of range, which includes contacting maintenance and also the contracted pharmacy to determine whether the medications within the refrigerator were compromised and need to be removed from use.	4/10/2017 4/13/2017 5/12/2017 5/15/2017 4/13/2017 4/26/2017

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4 196	Continued From page 49 regulation. a. Transfer to a container for release to a pharmaceutical waste contractor, was checked off on the policy. At 1:36 PM the same day interviewed the DON regarding nursing practice for disposal of discontinued resident narcotics. The DON shared the policy for disposal of controlled drugs used on the nursing floors dated 12/12 is old, a new policy dated 5/16 is on line but has not been changed in the PharMerica policy binders used by the nursing staff. At 1:41 PM the same day interviewed Staff #108 regarding disposal of narcotics procedure. Staff #108 stated the narcotics are popped out of the blister pack and thrown into the sharps container, sometimes the pills are crushed. The liquid narcotics are poured onto a paper towel and discarded. Later that afternoon contacted the pharmacist consult (Staff #181) for the facility. When asked the recommendation and policy for disposal of controlled medications at the facility Staff #181 shared, the pharmacist does not have a role in narcotics disposal, once the medication leaves the pharmacy it belongs to the resident, nothing is returned to the pharmacy. Upon request from the facility pharmacy can advise the facility on discarding controlled medication. When informed about the practice of throwing away discontinued narcotics in the sharps containers or down the drain Staff #181 stated, "we don't look at that; we are more concerned with out of date drugs." A review of the pharmacy contract titled 'Hawaii Health Systems Corporation Agreement for Goods or Services Based Upon Competitive Sealed Proposals" states 2.12 Provide experienced, trained Geriatric Consultant Pharmacist to perform the following services: As per CMS requirements provide assistance with tracking, destroying; and reconciling unused controlled substances." Failure to provide pharmacy consultative services	4 196	HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to ensure that quality pharmaceutical services are rendered to meet the needs of each resident. WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: 1) The nurse managers of units with residents receiving intravenous infusions will perform audits of no less than twice weekly to assess staff compliance with labeling requirements. 2) An alternate cart with a lock has was selected and is being ordered as a replacement. 3) In collaboration with our contracted consultative pharmacy service, an alternate method of secure controlled substance disposal was identified. A procurement action has been taken and the order placed on 5/8/2017 for a liquid, patch, and solid controlled substance secured container system for each nursing unit. Once obtained, the revised policy and procedure will be finalized in conjunction with the contract pharmacy. The nurse managers of units with residents receiving intravenous infusions will perform audits of no less than twice weekly to assess staff compliance with labeling requirements. All nurse managers will audit compliance with the 1) locking of treatment carts, 2) proper disposal of controlled substances, and 3) temperature adequacy of medication refrigerators through their respective logs - no less than twice weekly. Audits on cart locking and temperature management began 4/13/2017. Audits on controlled substance disposal began 5/15/2017. Actions as necessary shall be taken to assure compliance – status reports will be made to the Director of Nursing for each instance of non-compliance.	4/13/2017 5/15/2017 5/8/2017 4/13/2017 5/15/2017

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4 196	Continued From page 50 for discontinued controlled substances may potentially provide opportunity for misuse of controlled discontinued substances. 4) On 4/12/2017 at 10:40 AM reviewed the temperature log on the 3rd floor of the facility. The log titled "MEDS Refrigerator/Freezer Temperature Log" was printed "REFRIGERATOR STANDARD: 33 degrees - 40 degrees FAHRENHEIT". The recorded refrigerator temperatures for April 2017 was found to be documented at 34 degrees on April 7 and April 8, and at 35 degrees on April 12, 2017. The refrigerator contained some of the following medications and amounts: Calcitonin Salmon Nasal Solution 1 box; Cathflor Activase a 2 mg vial; Biscodyl Suppository 13 packets; Acetaminophen Suppository 10 packets; Octreotide 50 mcg one box; Ativan vials, 4 bags with 5, 3, 5, and 5 vials per bag. The printed manufacturers label recommended temperature storage at 36 - 46 degrees for the Octreotide, Calcitonin Salmon Nasal Solution and Ativan. The temperature log was concurrently reviewed with Staff #116. Staff #116 provided a printed copy of the facility policy titled, "Refrigerator/Freezer Temperature control and Maintenance. Purpose: To maintain proper temperatures for food safety and potency of medications". The policy stated: "Refrigerator standard range if 33 degrees to 40 degrees Fahrenheit". On the same day at approximately 11:06 AM the temperature logs for the 4th and 2nd floors were reviewed. Observed that all the units were using the same standard log with the incorrect temperature range of 33 to 40 degrees Fahrenheit. The refrigerator on the second floor was observed to have the following medications	4 196	HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Compliance with TPN labeling, treatment cart locking, controlled substance disposal, and maintenance of medication refrigerator temperatures will be reporting at the QA/PI meeting, along with actions taken to assure compliance.	5/23/2017

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4 196	Continued From page 51	4 196		

and amounts: Pneumococcal vaccine premeasured syringes one box; Calcitonin Salmon Nasal Spray 1 box; Influenza premeasured syringes 1 box; Tetanus 2 vials, and Ativan 3 vials. On 4/12/2017 at 1:49 PM pharmacy consultant (Staff #181) was interviewed by phone and asked about the effect of the drug temperature being at 35 degrees when the manufacturers recommendation is at 36 degrees. Staff #181 stated, "one degree is not going to matter, even if the package says 36 degrees, it is OK". When asked if the manufacturer could be consulted for the medications found on the 2nd and 3rd floors stored below the manufacturers recommendation, Staff #181 stated a call would be made to the manufacturer but a response would not be available for a few days due to the time zones. Later that afternoon interviewed the DON regarding the discrepancy on the facility medication temperature log, the facility policy for refrigerated medications for storage range of 33 - 40 degrees versus the manufactures recommendation for refrigerated medications to be stored at 36 - 46 degrees. Also the concern for the efficacy of the medications stored out of temperature range. The DON shared the policy and logs were revised on 12/2016. Requested copies of the temperature logs for the past 4 months from January 2017 to April 2017 from all the nursing units for review.

On 4/13/2017 at 3:49 AM contacted the drug manufactuers Merck, for the Pneumococcal vaccine; Phizer for the Ativan vials; and Sagent Pharmaceuticals for the Octreotide vial. Each manufacturer interviewed was asked about the efficacy of the drug when stored below the recommended 36 - 46 degrees. Ativan stored below 36 degrees had no information or

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4 196	Continued From page 52	4 196		

recommendations of use. The Octreotide drug stability studies indicated the drug was stable up to 3 months under the accelerated conditions. Accelerated conditions are described as below 36 degrees. The Pneumococcal vaccine efficacy was determined by the total number of hours kept below the manufacturers recommended temperature.

On 4/13/2017 at 7:30 AM obtained from the DON the collection of medication refrigerator temperature logs from January 2017 to April 2017 for the entire facility, which had been requested from the DON on 4/12/2017. The following temp logs provided were missing: 4 North - missing April 2017 and January 2017; 3rd floor - missing March 2017. Review of the 2nd floor refrigerator log found that the Pneumococcal vaccine had been stored below 36 degrees for 216 hours from Jan - April 2017. At 7:48 AM spoke to the Merck manufacturer consultant by phone regarding the 216 hours the Pneumococal vaccine was stored below 36 degrees. Per the manufacturers recommendation, given the number of hours kept below 36 degrees the recommendation was not to administer the vaccine to any patients and remove the vaccine from inventory. The manufactures advise was shared with Staff #108 and the DON.

Review of the facility policy for "potency of medications" titled "Refrigerator/Freezer Temperature control and Maintenance" date effective 12/2016 found that the policy was not signed as approved and reviewed by a PharMerica consultant. Review of the contract agreement between HHSC and the Pharmacy Corporation of America states: 2.0 Contractor Requirements. The contractor shall provide "Long Term Care Pharmacy services" pursuant to the

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4 196	Continued From page 53 provisions specified below: 2.1 Provide the facility with a comprehensive range of professional pharmaceutical services related to the use, storage, distribution and administration of medicines." Failure to properly label medication; failure to secure and lock treatment cart inventory; inconsistency of nursing staff practice in the proper disposal of controlled drugs; failure to update the pharmMerica binder used on the floors by nursing staff on the disposal of controlled drugs; and failure to provide consultative pharmaceutical service for policy development and review in the area of medications stored in refrigerator/freezer has the potential for pharmaceutical errors.	4 196		
4 197	11-94.1-46(n) Pharmaceutical services (n) Discontinued and outdated prescriptions and containers with worn, illegible, or missing labels shall be disposed of according to facility policy. This Statute is not met as evidenced by: Based on observations, interviews, and policy reviews the facility failed to utilize the pharmacy for consultation services on all aspects of the provision of pharmacy services in the facility and failed to provide pharmaceutical services to meet the needs of each resident Findings include: 1) On 4/12/2017 at 10:40 AM interviewed Staff #116 regarding the procedure for discarding discontinued narcotics. Staff #116 stated that	4 197		

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4 197	Continued From page 54 liquid narcotics are disposed into the drain and the controlled pills are discarded into the sharps container. The policy for disposal of discontinued narcotics was provided by Staff #116 and reviewed. The policy dated 12/12 stated: "1. The director of nursing and the consultant pharmacist will monitor for compliance with federal and state laws and regulations regarding the disposal of medications. The nursing care center should maintain approved containers to separate and securely store different types of pharmaceutical waste until it is scheduled for pick up. b. Authorized personnel who have access to medications should deposit pharmaceutical waste in the appropriately labeled container. Each container used to collect, separate and store each type of pharmaceutical waste will be labeled with the type of waste to be stored in the container. 2. Controlled Substances listed in Schedules II, III, IV and V remaining in the nursing care center after the order has been discontinued are retained in the nursing care center - until destroyed as outlined by state regulation. a. Transfer to a container for release to a pharmaceutical waste contractor, was checked off on the policy. At 1:36 PM the same day interviewed the DON regarding nursing practice for disposal of discontinued resident narcotics. The DON shared the policy for disposal of controlled drugs used on the nursing floors dated 12/12 is old, a new policy dated 5/16 is on line but has not been changed in the PharMerica policy binders used by the nursing staff. At 1:41 PM the same day interviewed Staff #108 regarding disposal of narcotics procedure. Staff #108 stated the narcotics are popped out of the blister pack and thrown into the sharps container, sometimes the pills are crushed. The liquid narcotics are poured onto a paper towel and discarded. Later that afternoon contacted	4 197	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1 & 5) The policy and procedure for controlled substance disposal was modified with consultation with our contracted pharmacy service on 5/12/2017 to assure compliance. Staff education about this new process began on 5/15/2017, 2&6) All medications with risk of compromise as determined by the manufacturer and our contracted consultative pharmacy service were disposed of on 4/13/2017. The medication refrigerator policy and log was corrected and signed with collaboration from our contracted consultative pharmacy to note the correct temperature range to be kept between 36° to 46° Fahrenheit on 4/26/2017. The new log includes further detail of actions to be taken when a temperature is noted as out of range, which includes contacting maintenance and also the contracted pharmacy to determine whether the medications within the refrigerator were compromised and need to be removed from use. 3) The administration of the TPN for R44 was modified on 4/13/17 to be compliant with the expectation of appropriate labeling of the resident's name, date / time of infusion start and flow rate of volume over time as directed by the physician's order. 4) the treatment cart without a lock is no longer used in the hallway and is left in a room that is locked when unattended as of 4/13/17. Staff were reminded 4/13/17 regarding the requirement to maintain the storage of medications in a locked compartment at all times.	5/12/2017 5/15/2017 4/13/2017 4/26/2017 4/13/2017 4/13/2017

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4 197	Continued From page 55 the pharmacist consult (Staff #181) for the facility. When asked the recommendation and policy for disposal of controlled medications at the facility Staff #181 shared, the pharmacist does not have a role in narcotics disposal, once the medication leaves the pharmacy it belongs to the resident, nothing is returned to the pharmacy. Upon request from the facility pharmacy can advise the facility on discarding controlled medication. When informed about the practice of throwing away discontinued narcotics in the sharps containers or down the drain Staff #181 stated, "we don't look at that; we are more concerned with out of date drugs." A review of the pharmacy contract titled 'Hawaii Health Systems Corporation Agreement for Goods or Services Based Upon Competitive Sealed Proposals" states 2.12 Provide experienced, trained Geriatric Consultant Pharmacist to perform the following services: As per CMS requirements provide assistance with tracking, destroying; and reconciling unused controlled substances." Failure to provide pharmacy consultative services for discontinued controlled substances may potentially provide opportunity for misuse of controlled discontinued substances. 2) On 4/12/2017 at 10:40 AM reviewed the temperature log on the 3rd floor of the facility. The log titled "MEDS Refrigerator/Freezer Temperature Log" was printed "REFRIGERATOR STANDARD: 33 degrees - 40 degrees FAHRENHEIT". The recorded refrigerator temperatures for April 2017 was found to be documented at 34 degrees on April 7 and April 8, and at 35 degrees on April 12, 2017. The refrigerator contained some of the following medications and amounts: Calcitonin Salmon Nasal Solution 1 box; Cathflor Activase a 2 mg vial; Biscodyl Suppository 13 packets;	4 197	HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of failing to utilize the pharmacy for consultative services on all aspects of pharmaceutical services in the facility. WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: 1&5) In collaboration with our contracted consultative pharmacy service, an alternate method of secure controlled substance disposal was identified. A procurement action has been taken and the order placed on 5/8/2017 for a liquid, patch, and solid controlled substance secured container system for each nursing unit. Once obtained, the revised policy and procedure will be finalized in conjunction with the contract pharmacy. 3) - nurse managers of units with residents receiving intravenous infusions will perform audits of no less than twice weekly to assess staff compliance with labeling requirements. 4) An alternate cart with a lock was selected and is being ordered as a replacement. 1,2,4,5,6) All nurse managers will audit compliance with the 1) locking of treatment carts, 2) proper disposal of controlled substances, and 3) temperature adequacy of medication refrigerators through their respective logs - no less than twice weekly. Audits on cart locking and temperature management began 4/13/2017. Audits on controlled substance disposal began 5/15/2017. Actions as necessary shall be taken to assure compliance – status reports will be made to the Director of Nursing for each instance of non-compliance.	5/8/52017 4/13/2017 5/15/2017 4/13/2017 5/15/2017

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4 197	Continued From page 56 Acetaminophen Suppository 10 packets; Octreotide 50 mcg one box; Ativan vials, 4 bags with 5, 3, 5, and 5 vials per bag. The printed manufacturers label recommended temperature storage at 36 - 46 degrees for the Octreotide, Calcitonin Salmon Nasal Solution and Ativan. The temperature log was concurrently reviewed with Staff #116. Staff #116 provided a printed copy of the facility policy titled, "Refrigerator/Freezer Temperature control and Maintenance. The policy stated: "Refrigerator standard range if 33 degrees to 40 degrees Fahrenheit". On the same day at approximately 11:06 AM the temperature logs for the 4th and 2nd floors were reviewed. Observed that all the units were using the same standard log with the incorrect temperature range of 33 to 40 degrees Fahrenheit. The refrigerator on the second floor was observed to have the following medications and amounts: pneumococcal vaccine premeasured syringes one box; Calcitonin Salmon Nasal Spray 1 box; Influenza premeasured syringes 1 box; Tetanus 2 vials, and Ativan 3 vials. On 4/12/2017 at 1:49 PM pharmacy consultant (Staff #181) was interviewed by phone and asked about the effect of the drug temperature being at 35 degrees when the manufacturers recommendation is at 36 degrees. Staff #181 stated, "one degree is not going to matter, even if the package says 36 degrees, it is OK". When asked if the manufacturer could be consulted for the medications found on the 2nd and 3rd floors stored below the manufacturers recommendation, Staff #181 stated a call would be made to the manufacturer but a response would not be available for a few days due to the time zones. Later that afternoon interviewed the DON	4 197	HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: Compliance with TPN labeling, treatment cart locking, controlled substance disposal, and maintenance of medication refrigerator temperatures will be reporting at the QA/PI meeting, along with actions taken to assure compliance.	5/23/2017

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4 197	Continued From page 57	4 197		

regarding the discrepancy on the facility medication temperature log, the facility policy for refrigerated medications for storage range of 33 - 40 degrees versus the manufactures recommendation for refrigerated medications to be stored at 36 - 46 degrees. Also the concern for the efficacy of the medications stored out of temperature range. The DON shared the policy and logs were revised on 12/2016. Requested copies of the temperature logs for the past 4 months from January 2017 to April 2017 from all the nursing units for review.

On 4/13/2017 at 3:49 AM contacted the drug manufacturers Merck, for the pneumococcal vaccine; Phizer for the Ativan vials; and Sagent Pharmaceuticals for the Octreotide vial. Each manufacturer interviewed was asked about the efficacy of the drug when stored below the recommended 36 - 46 degrees. Ativan stored below 36 degrees had no information or recommendations of use. The Octreotide drug stability studies indicated the drug was stable up to 3 months under the accelerated conditions. Accelerated conditions are described as below 36 degrees. The pneumococcal vaccine efficacy was determined by the total number of hours kept below the manufacturers recommended temperature.

On 4/13/2017 at 7:30 AM obtained from the DON the collection of medication refrigerator temperature logs from January 2017 to April 2017 for the entire facility, which had been requested from the DON on 4/12/2017. The following temp logs provided were missing: 4 North - missing April 2017 and January 2017; 3rd floor - missing March 2017. Review of the 2nd floor refrigerator log found that the pneumococcal vaccine had been stored below 36 degrees for 216 hours from

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4 197	Continued From page 58 Jan - April 2017. At 7:48 AM spoke to the Merck manufacturer consultant by phone regarding the 216 hours the pneumococcal vaccine was stored below 36 degrees. Per the manufacturers recommendation, given the number of hours kept below 36 degrees the recommendation was not to administer the vaccine to any patients and remove the vaccine from inventory. The manufactures advise was shared with Staff #108 and the DON. Review of the facility policy for "potency of medications" titled "Refrigerator/Freezer Temperature control and Maintenance" date effective 12/2016 found that the policy was not signed as approved and reviewed by a PharMerica consultant. Review of the contract agreement between HHSC and the Pharmacy Corporation of America states: 2.0 Contractor Requirements. The contractor shall provide "Long Term Care Pharmacy services" pursuant to the provisions specified below: 2.1 Provide the facility with a comprehensive range of professional pharmaceutical services related to the use, storage, distribution and administration of medicines." Inconsistency of nursing staff practice in the proper disposal of controlled drugs; failure to update the PharMerica binder used on the floors by nursing staff on the disposal of controlled drugs; and failure to provide consultative pharmaceutical service for policy development and review in the area of medications stored in refrigerator/freezer has the potential for pharmaceutical errors. 3) On 4/10/2017 at 11:50 AM observed an IV bag hanging for Resident #44. The IV bag was not labeled with a resident's name or dated. At	4 197		

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4 197	Continued From page 59 12:00 PM interviewed Staff #116 regarding the unlabeled IV bag. Staff #116 agreed the bag hanging should be labeled. Staff #116 shared Resident #44 receives TPN nourishment through her PICC line and after the TPN is infused an IV bag is hung until the line is flushed. Staff #116 brought out an unopened IV bag to show that the pharmacy label is attached to the outside plastic wrap of the IV bag, when the bags are opened the pharmacy label is discarded. Unlabeled medications has the potential for medication errors. 4) On 4/12/2017 at 8:13 AM observed an unlocked treatment cart with one drawer pulled out resting in the hall outside of the dining hall. The opened drawer contained ointments. There was no staff seen near or around the opened cart. Shortly after observed Staff # 116 came out of the dining room. Staff #116 was asked about the unattended, unlocked treatment cart with the treatment drawer opened. Staff #116 stated she went to check a resident and had left the cart unlocked. Staff #116 agreed the cart should have been locked. Unlocked treatment carts has the potential for medication loss and misuse. 5) On 4/12/2017 at 10:40 AM interviewed Staff #116 regarding the procedure for discarding discontinued narcotics. Staff #116 stated that liquid narcotics are disposed into the drain and the controlled pills are discarded into the sharps container. The policy for disposal of discontinued narcotics was provided by Staff #116 and reviewed. The policy dated 12/12 stated: "1. The director of nursing and the consultant pharmacist will monitor for compliance with federal and state laws and regulations regarding the disposal of medications. The nursing care center should maintain approved containers to	4 197		

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4 197	Continued From page 60 separate and securely store different types of pharmaceutical waste until it is scheduled for pick up. b. Authorized personnel who have access to medications should deposit pharmaceutical waste in the appropriately labeled container. Each container used to collect, separate and store each type of pharmaceutical waste will be labeled with the type of waste to be stored in the container. 2. Controlled Substances listed in Schedules II, III, IV and V remaining in the nursing care center after the order has been discontinued are retained in the nursing care center - until destroyed as outlined by state regulation. a. Transfer to a container for release to a pharmaceutical waste contractor, was checked off on the policy. At 1:36 PM the same day interviewed the DON regarding nursing practice for disposal of discontinued resident narcotics. The DON shared the policy for disposal of controlled drugs used on the nursing floors dated 12/12 is old, a new policy dated 5/16 is on line but has not been changed in the PharMerica policy binders used by the nursing staff. At 1:41 PM the same day interviewed Staff #108 regarding disposal of narcotics procedure. Staff #108 stated the narcotics are popped out of the blister pack and thrown into the sharps container, sometimes the pills are crushed. The liquid narcotics are poured onto a paper towel and discarded. Later that afternoon contacted the pharmacist consult (Staff #181) for the facility. When asked the recommendation and policy for disposal of controlled medications at the facility Staff #181 shared, the pharmacist does not have a role in narcotics disposal, once the medication leaves the pharmacy it belongs to the resident, nothing is returned to the pharmacy. Upon request from the facility pharmacy can advise the facility on discarding controlled medication. When informed about the practice of throwing	4 197		

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4 197	Continued From page 61	4 197		

away discontinued narcotics in the sharps containers or down the drain Staff #181 stated, "we don't look at that; we are more concerned with out of date drugs." A review of the pharmacy contract titled 'Hawaii Health Systems Corporation Agreement for Goods or Services Based Upon Competitive Sealed Proposals" states 2.12 Provide experienced, trained Geriatric Consultant Pharmacist to perform the following services: As per CMS requirements provide assistance with tracking, destroying; and reconciling unused controlled substances." Failure to provide pharmacy consultative services for discontinued controlled substances may potentially provide opportunity for misuse of controlled discontinued substances.

6) On 4/12/2017 at 10:40 AM reviewed the temperature log on the 3rd floor of the facility. The log titled "MEDS Refrigerator/Freezer Temperature Log" was printed "REFRIGERATOR STANDARD: 33 degrees - 40 degrees FAHRENHEIT".
The recorded refrigerator temperatures for April 2017 was found to be documented at 34 degrees on April 7 and April 8, and at 35 degrees on April 12, 2017. The refrigerator contained some of the following medications and amounts: Calcitonin Salmon Nasal Solution 1 box; Cathflor Activase a 2 mg vial; Biscodyl Suppository 13 packets; Acetaminophen Suppository 10 packets; Octreotide 50 mcg one box; Ativan vials, 4 bags with 5, 3, 5, and 5 vials per bag. The printed manufacturers label recommended temperature storage at 36 - 46 degrees for the Octreotide, Calcitonin Salmon Nasal Solution and Ativan. The temperature log was concurrently reviewed with Staff #116. Staff #116 provided a printed copy of the facility policy titled, "Refrigerator/Freezer Temperature control and

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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) COMPLETE DATE
4 197	Continued From page 62 Maintenance. Purpose: To maintain proper temperatures for food safety and potency of medications". The policy stated: "Refrigerator standard range if 33 degrees to 40 degrees Fahrenheit". On the same day at approximately 11:06 AM the temperature logs for the 4th and 2nd floors were reviewed. Observed that all the units were using the same standard log with the incorrect temperature range of 33 to 40 degrees Fahrenheit. The refrigerator on the second floor was observed to have the following medications and amounts: Pneumococcal vaccine premeasured syringes one box; Calcitonin Salmon Nasal Spray 1 box; Influenza premeasured syringes 1 box; Tetanus 2 vials, and Ativan 3 vials. On 4/12/2017 at 1:49 PM pharmacy consultant (Staff #181) was interviewed by phone and asked about the effect of the drug temperature being at 35 degrees when the manufacturers recommendation is at 36 degrees. Staff #181 stated, "one degree is not going to matter, even if the package says 36 degrees, it is OK". When asked if the manufacturer could be consulted for the medications found on the 2nd and 3rd floors stored below the manufacturers recommendation, Staff #181 stated a call would be made to the manufacturer but a response would not be available for a few days due to the time zones. Later that afternoon interviewed the DON regarding the discrepancy on the facility medication temperature log, the facility policy for refrigerated medications for storage range of 33 - 40 degrees versus the manufactures recommendation for refrigerated medications to be stored at 36 - 46 degrees. Also the concern for the efficacy of the medications stored out of temperature range. The DON shared the policy	4 197		

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4 197	Continued From page 63 and logs were revised on 12/2016. Requested copies of the temperature logs for the past 4 months from January 2017 to April 2017 from all the nursing units for review. On 4/13/2017 at 3:49 AM contacted the drug manufactuers Merck, for the Pneumococcal vaccine; Phizer for the Ativan vials; and Sagent Pharmaceuticals for the Octreotide vial. Each manufacturer interviewed was asked about the efficacy of the drug when stored below the recommended 36 - 46 degrees. Ativan stored below 36 degrees had no information or recommendations of use. The Octreotide drug stability studies indicated the drug was stable up to 3 months under the accelerated conditions. Accelerated conditions are described as below 36 degrees. The Pneumococcal vaccine efficacy was determined by the total number of hours kept below the manufacturers recommended temperature. On 4/13/2017 at 7:30 AM obtained from the DON the collection of medication refrigerator temperature logs from January 2017 to April 2017 for the entire facility, which had been requested from the DON on 4/12/2017. The following temp logs provided were missing: 4 North - missing April 2017 and January 2017; 3rd floor - missing March 2017. Review of the 2nd floor refrigerator log found that the Pneumococcal vaccine had been stored below 36 degrees for 216 hours from Jan - April 2017. At 7:48 AM spoke to the Merck manufacturer consultant by phone regarding the 216 hours the Pneumococal vaccine was stored below 36 degrees. Per the manufacturers recommendation, given the number of hours kept below 36 degrees the recommendation was not to administer the vaccine to any patients and remove the vaccine from inventory. The	4 197		

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4 197	Continued From page 64 manufactures advise was shared with Staff #108 and the DON. Review of the facility policy for "potency of medications" titled "Refrigerator/Freezer Temperature control and Maintenance" date effective 12/2016 found that the policy was not signed as approved and reviewed by a PharMerica consultant. Review of the contract agreement between HHSC and the Pharmacy Corporation of America states: 2.0 Contractor Requirements. The contractor shall provide "Long Term Care Pharmacy services" pursuant to the provisions specified below: 2.1 Provide the facility with a comprehensive range of professional pharmaceutical services related to the use, storage, distribution and administration of medicines." Failure to properly label medication; failure to secure and lock treatment cart inventory; inconsistency of nursing staff practice in the proper disposal of controlled drugs; failure to update the pharmMerica binder used on the floors by nursing staff on the disposal of controlled drugs; and failure to provide consultative pharmaceutical service for policy development and review in the area of medications stored in refrigerator/freezer has the potential for pharmaceutical errors.	4 197		
4 203	11-94.1-53(a) Infection control (a) There shall be appropriate policies and procedures written and implemented for the prevention and control of infectious diseases that shall be in compliance with all applicable laws of the State and rules of the department relating to infectious diseases and infectious	4 203		

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4 203	Continued From page 65 waste. This Statute is not met as evidenced by: Based on interview with staff member, the facility failed to establish and maintain an effective infection prevention and control program including the tracking and analyzing of outbreaks of infection. Findings include: 1) On 4/13/17 at 9:00 A.M. an interview was conducted with the Director of Nursing (DON) and Staff Member #122. The staff members were asked how they collect, trend and analyze their data related to infection control. Staff Member #122 reported the nurses will submit infection surveillance forms to report any concerns regarding infections as well as discuss infection issues in daily rounds. This information is collected for data and reviewed for trends. The staff member also reported the infection program also tracks the immunization process. The DON and Staff Member #122 confirmed the facility had an outbreak of Norovirus in February 2017. The Norovirus reportedly was isolated to the 4th floor; however, a resident on the 3rd floor also had Norovirus. Further queried whether the facility determined the source of the Norovirus outbreak. Staff Member #122 responded it's impossible to figure it out; however, the facility makes note if a cruise ship was in the port and possibly the Norovirus may have come from the children visiting from the school or a staff member being infected from their child. The data and trends collected by the facility were not specific enough to identify the origin of the Norovirus.	4 203	WHAT CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE: 1)The Quality / IC RN initiated a thorough tracking of all residents with infections and drug-resistant organisms on 5/1/2017. 2-3) Staff involved in the care of R44 were counseled with regard to expectations for compliance with facility policy "IV Site Care and Maintenance." The Nurse manager also reviewed the expectations with all licensed staff on 4/13/2017. For R#4 - The physician orders were clarified and signage updated with staff education on 4/11/2017. HOW THE FACILITY WILL IDENTIFY OTHER RESIDENTS HAVING THE POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION WILL BE TAKEN: All residents are at risk for the deficient practice of an ineffective infection prevention and control program, including the tracking and analyzing of outbreaks of infection.	5/1/2017 4/13/2017 4/11/2017

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4 203	Continued From page 66 A request was made to review their infection log/data. The facility provided data from January 2017 through April 6, 2017. The data included the resident's name, medical record number, room number, type of infection, culture, antibiotic and comment. The staff members were queried whether the infection control program determines whether infections were hospital or community acquired. The response was they did not think this is part of the policy to track whether infections are hospital or community acquired. Further discussion confirmed the facility does not perform root cause analysis of infections. 2) On 4/12/2016 at 8:40 AM observed Staff #180 prepare 2 prefilled syringes of normal saline and 2 prefilled syringes of heparin to do a PICC line flush for Resident #44. Staff #116 was present orientating Staff #180. Staff #180 opened the individual packaging of each syringe and placed all of the syringes on top of the resident's bed with no protective barrier between the bedding and the syringes. Staff #116 picked up all of the syringes on the bed and failing to wipe the table or use a protective barrier, placed the syringes on the resident's over bed table. Observed Staff #180 use each syringe to do the PICC line flush. After the procedure an interview was held with Staff #116 and Staff #180, regarding use of a protective barrier for the clean syringes. Staff #116 agreed a protective barrier should have been used for infection control practice. Failure to maintain a clean working environment when administering medications has the potential for development and transmission of infection. 3) On 4/12/2016 at 9:04 AM observed Staff #180 do a PICC line flush for Resident #44. Staff #116 was present orientating Staff #180. The PICC	4 203	WHAT MEASURES WILL BE PUT INTO PLACE OR WHAT SYSTEMIC CHANGES YOU WILL MAKE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT RECUR: In collaboration with other infection preventionists, the Director of Nursing, and Medical Director – the QA/IC RN initiated an infection prevention and control program throughout the facility. Instances of infection are identified and investigated using a root cause analysis methodology and trended to identify the source as facility or community acquired. The QA/IC RN is working with the nurse managers and staff to remain compliant with infection prevention and control practices. Additional education has been provided for staff caring for residents with intravenous lines to assure effective protective barriers and sterility techniques are maintained. All residents with positive cultures and / or isolation orders are evaluated to assess for adequate precautions are ordered and maintained by staff. This includes audits by both the nurse managers and QA/IC RN several times a week. We are presently scheduling our QA/IC RN to visit other nursing facilities and hospitals QA and IC practitioners to evaluate best practices for adoption. We have scheduled the week of 5/15/2017 as the first of several information-gathering meetings. HOW THE CORRECTIVE ACTION WILL BE MONITORED TO ENSURE THE DEFICIENT PRACTICE WILL NOT RECUR: The aggregate results will be compiled by our QA/IC RN and shared / discussed as a scheduled report at our Quality Assurance / Performance Improvement meeting.	5/15/2017 5/23/2017

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4 203	Continued From page 67 line had two ports. Staff #180 opened one line, did an alcohol wipe to the needleless hub, inserted the normal saline syringe tip into the hub, and pushed the normal saline flush through the PICC line. Staff #180 then disconnected the normal saline syringe and without doing an alcohol wipe to the hub connected a heparin syringe tip and pushed the heparin solution through the PICC line. Staff #180 then opened the second PICC line, wiped the PICC port with alcohol, connected the normal saline syringe and pushed the normal saline into the line. Staff #180 then disconnected the syringe and without doing an alcohol wipe connected a heparin syringe into the hub and pushed the heparin solution into the line. After the observation interviewed Staff #116 on the observation. Staff #116 was asked if an alcohol wipe should have been done prior to the heparin flush for each line. Staff #180 stated, "no need to do the wipe because the port is still clean". A concurrent review of the facility policy was done with Staff #180. The policy for IV Site Care and Maintenance. Procedure 4. states, "Scrub needleless injection cap prior to each entry with alcohol." Failure to do the recommended alcohol cleanse prior to each entry into the needleless IV port has the potential for development and transmission of infection. 4) On 04/10/2017 at 12:46 PM, during observation of the second floor nursing unit's lunch service, Staff #140 was observed sitting next to Resident #4 (R #4). Staff #140 was feeding the resident while she sat in bed. This resident had a contact isolation sign posted at the entrance to her room. The sign stated, "Stop Check with nurse before entering room...Wear Gloves for all contacts, Wear Yellow Gown within 3 feet, If splashing possible wear face shield..."	4 203		

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4 203	Continued From page 68	4 203		

The Nursing Home Administrator (NHA) was standing in the hallway with the surveyor and confirmed surveyor's observation that Staff #140 was not wearing any personal protective equipment (PPE), such as a disposable gown and gloves while assisting the resident to eat. The NHA asked the staff to stop feeding the resident and to wash her hands and come out of the room to wear the appropriate PPEs. Surveyor queried Staff #140 and asked why she was not wearing any PPEs. Staff #140 replied, "I think when you're feeding, not supposed to. All I hear is we use iso gowns, gloves, mask when we doing patient care." The NHA told Staff #140 that it includes feeding this resident, and asked the staff to wear the appropriate PPEs before returning to the resident's bedside.

On 04/10/2017 at 12:51 PM, the Staff #108 stated there was a new order from R #4's attending physician that said staff was "to gown only for peri-care," but acknowledged the signage did not reflect that. Staff #108 also said the attending physician wanted to ensure the family who visits daily during dinner would be able visit without wearing the PPEs as a quality of life matter for this 99 year old resident. The NHA pointed out this was inconsistent for the staff as to what they are supposed to be following for contact isolation, and if there was any breach because of not wearing the PPEs, then there was a potential risk for transmission to others, such as other residents, staff and her visitors.

On 04/11/2017 at 9:46 AM, chart review found the April 2017 Physician's Order Statement said the resident is on contact isolation from 8/15/16 for a diagnosis of [redacted]. On 04/12/2017 at 9:42 AM, the DON provided their policy and procedure, "Isolation Precautions, No.

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4 203	Continued From page 69 125-400-040." It stated, "V. A. Contact Precautions: These precautions are to be used to reduce the risk of transmission of resistant microorganisms by direct or indirect contact with a patient and/or patient's environment...CDC recommends continuing Contact Precautions routinely for ALL patients colonized or infected with MDROs. Gowns and gloves should be worn at a minimum. Masks are worn if splashes or projectile secretions are possible...HCWs (Health Care Workers) should always explain the necessity of PPEs and expanded precautions to the patient, patient's family and visitors." The facility failed to ensure staff followed the contact isolation precautions increasing the risk and potential for transmission of disease. The facility did not develop an infection prevention and control program which includes analysis of outbreaks of infection (root cause analysis) to formulate corrective action and plan for continued prevention.	4 203		