

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15K003	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 10/19/2012
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NAME OF PROVIDER OR SUPPLIER ALERE WOMEN'S AND CHILDREN'S HEALTH LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 6525 E 82ND ST STE 101 INDIANAPOLIS, IN 46250
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G0000	<p>This visit was for a home health federal recertification survey. This was a partial extended survey.</p> <p>Survey dates: 10/1612 - 10/19/12</p> <p>Facility # 005951</p> <p>Medicaid# 100025130A</p> <p>Survey Team:</p> <p>Dawn Snider, RN, PHNS-Team Leader Eric Moran, RN, PHNS-Team member, orientation</p> <p>Census Service Type:</p> <p>Skilled Patients: 671 Home Health Aide Only Patients: 0 Personal Service Only Patients: 0 Total: 671</p> <p>Sample:</p> <p>RR w HV: 4 RR w/o HV: 8</p> <p>Total RR: 12</p> <p>Quality Review: Joyce Elder, MSN, BSN,</p>	G0000	Opening comments accepted. No deficiency noted on N0000. Deficiencies addressed below on following tags.	
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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

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RN	October 25, 2012				

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G0121	<p>484.12(c) COMPLIANCE W/ ACCEPTED PROFESSIONAL STD The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA. Based on procedure and policy review, observation, and interview, the agency failed to ensure employees provided services in accordance with the policy for "Sterile IV(intravenous) Dressing Change for Midline Catheters" in 1 of 1 changing a dressing of a PICC (peripherally inserted central catheter) line observed where a patient was receiving IV therapy creating the potential for transfer of organisms among the patient and the potential to affect all patients of the agency. (#9)</p> <p>Findings include:</p> <ol style="list-style-type: none"> The procedure dated 2/1/2012 and titled "P1-Sterile IV Dressing Change for Midline Catheters" states, "13. clean the site with chlorhexidine prep using a back and forth scrubbing motion for 30 seconds. Allow to air dry thoroughly before proceeding. 14. Clean the catheter with alcohol and allow to air dry." The policy dated 12/24/2009 and titled "Infection Prevention Practices" states, "A. Standard precautions are to be 	G0121	G121 The Agency Administrator/ Alternate Administrator will review policy on sterile PICC dsq change with nursing staff and require that all staff caring for patient's with PICC lines complete the required CEU course on Alere learning systems by 11/15/2012 Agency Administrator/Alternate Administrator will co-travel with nursing staff ,when patient population permits, caring for PICC line patients Quarterly x2 visits. Any nurse found out of compliance with policy will be required to complete a skills day session on PICC dsq changes in the Indianapolis office.Administrator/Alternate Administrator are responsible monitoring and ensuring compliance and that all staff are properly trained to provide sterile PICC dsq change as well as taking appropriate actions to correct deficiency to ensure it will not reoccur.	11/15/2012			

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	<p>followed for ALL patients. ... 3. Patients and caregivers administering infusion therapy or parenteral medications (injections) are instructed in proper hand washing and aseptic techniques as needed. ... G. Aseptic and sterile procedures. 1. Sterile technique appropriate to the service being provided is practiced by nurses. 2. Patients and caregivers will be instructed on proper storage and handling of sterile supplies, medical devices, and equipment, and the safe care of an infusion site (e.g., site change, IV tubing change, medication administration, etc.)"</p> <p>3. During the home visit on 10/18/12 at 4:45 PM, employee E was observed to follow the procedure for a PICC line dressing change on patient #9. After removal of the PICC line dressing, upon initiation of sterile technique, Employee E measured the circumference of the patient's arm at the insertion site with a tape measure contained in the sterile dressing tray. She cleansed the insertion site and surrounding skin area with the chlorhexidine prep, cleansed the IV tubing and connections and again cleansed the surrounding area of the insertion site using the same chlorhexidine prep (creating the potential for contamination). She measured the area of tubing from the insertion site to the hub</p>			

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	<p>of the connection tubing with the same tape measure used to measure the arm circumference (creating the potential for contamination).</p> <p>4. On 10/19/12 at 12:30 PM the administrator indicated Employee E was a very experienced registered nurse regarding PICC line care, but indicated employee E's care did result in the potential for contamination.</p>			
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G0159	<p>484.18(a) PLAN OF CARE The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.</p> <p>Based on clinical record review and policy review, the agency failed to ensure the medical plan of care was signed by the physician within 30 days of the start of care as required by agency policy on 1 of 12 clinical records reviewed (#10) with the potential to affect all the patients of the agency.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #10, start of care 7/21/12, included a plan of care for the certification period 7/21/12 to 9/18/12. The plan of care failed to evidence a physician's signature. The plan of care was stamped "second request 10/16/12" with "please date and sign" along with a fax cover page to the physician. 2. The policy date 11/20/09 titled "Physician Orders" states, "D. Orders must be signed by the physician and 	G0159	G159 Agency Administrator/Alternate Administrator will review with agency staff the required interval for MD signature on Physician Plan of Treatment(PPOT).The PPOT will be faxed weekly x 2 wks then the office will be called daily after day 14 until orders are returned with signature within appropriate time frame.The Agency Administrator/ALternate Administrator will monitor all charts a minimun of bi-weekly to ensure timely return of physician orders. Agency Administrator/Alternate Administrator are responsible for monitoring compliance with regulations and ensuring gorrective action takes place to ensure that deficiency does not recur.	11/15/2012			

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	returned to the center in accordance with state regulations, but not exceed 30 days from the date the order was written. (Fax signatures are, as permitted by state regulations, considered to be the same as original signatures.) ... J. Signed physician orders returned to Alere, must be reviewed by the nurse, signed and dated, and placed in the patient's medical record within 30 days of the date the order was written or in accordance with state regulations."			

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G0332	<p>484.55(a)(1) INITIAL ASSESSMENT VISIT The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.</p> <p>Based on clinical record review, policy review, and interview, the agency failed to ensure the registered nurse made an initial assessment visit within forty-eight hours of a physician referral or on the physician-ordered start of care date (SOC) for 2 of 12 (#1 and 7) clinical records reviewed and agency policy was in compliance with federal requirements with the potential to affect all the agency's new admissions.</p> <p>Findings include:</p> <p>1. Clinical record #1, start of care 7/12/12, evidenced a referral intake form dated 5/30/12. The physician signed order dated 6/11/12 states, "Admit to Alere for weekly 17P [17 Alpha-hydroxyprogesterone Caproate] injections per Alere protocol to begin after insurance approval and upon patients [sic] acceptance to service." The physician ordered start of care date is unclear. The consent for treatment, initial assessment visit, and comprehensive assessment was completed on 7/12/12.</p>	G0332	<p>G332 Agency Administrator/Alternate Administrator have created a referral timeline checklist identifying Referral status, insurance approval, date RN assigned and date Patient request Start of care (SOC). Verbal orders will be written for all referrals identifying that MD has agreed that SOC will occur per Alere protocol , after insurance approval, and upon patient's acceptance of service. If for any reason SOC falls outside of the Alere protocol/guidelines (17P to be started wk 16 or as otherwise ordered by MD) , MD is to be notified and documentation is to occur. RN staff is to be educated on the conditions for participation and necessity in documenting all communication with patient and MD office regarding SOC variances. Agency Administrator/ Alternate Administrator will complete chart audits monthly on 10% of all charts for appropriate documentation to measure compliance and ensure that deficiency is corrected. Agency Administrator/Alternate Administrator are responsible for monitoring corrective actions and ensuring compliance.</p>	11/15/2012

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	<p>2. Clinical record #7 evidenced a referral intake form dated 6/12/12. The physician signed order dated 7/17/12 states,"Admit to Alere for weekly 17P injections per Alere protocol to begin after insurance approval and upon patients [sic] acceptance to service." The physician ordered start of care date is unclear. The consent for treatment, initial assessment visit, and comprehensive assessment was completed on 8/1/12.</p> <p>A. On 8/21/12, the physician ordered the patient discharged from services.</p> <p>B. On 8/29/12, the physician ordered to resume 17P injections. When the injections were to resume was not identified. The consent for treatment, initial assessment visit, and comprehensive assessment was completed on 9/5/12.</p> <p>3. The policy last review date January 2009 titled "Patient Admission Criteria states, "H. When applicable, an initial patient assessment will be performed by a nurse within 3 days of referral or discharge from a referring facility." This is not what is required by this regulation.</p> <p>4. The policy dated 5/10/10 titled "Skilled Nursing Visit" states, "A. Admission assessments are performed by a registered</p>			

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	<p>nurse within 72 hours of the: 1. Time of the referral; 2. Patient's return home or hospital start of care, as applicable; or 3. Physician-ordered start of care date." This is not what is required by this regulation.</p> <p>5. On 10/18/12 at 11:30 AM, the administrator indicated the start of care date was the first date of the certification period because the physician signs the plan of care which contains the certification period dates. (However, this is signed after the start of care has already occurred.) Protocol orders allow for patient acceptance to service.</p>			

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G0339	<p>484.55(d)(1) UPDATE OF THE COMPREHENSIVE ASSESSMENT The comprehensive assessment must be updated and revised (including the administration of the OASIS) the last 5 days of every 60 days beginning with the start of care date, unless there is a beneficiary elected transfer; or significant change in condition resulting in a new case mix assessment; or discharge and return to the same HHA during the 60 day episode.</p> <p>Based on clinical record review, the agency failed to ensure the registered nurse updated the comprehensive reassessment during the last five days of the certification period and before completing a new plan of care in 1 of 12 (#5) clinical records reviewed of patients receiving skilled nursing services for at least 60 days with the potential to affect all the patients of the agency receiving services longer than 60 days.</p> <p>Findings include:</p> <p>Clinical record # 5, start of care 7/5/12, failed to evidence a recertification comprehensive assessment was completed during the last five days of the certification period before creating the plan of care beginning 9/3/12. The clinical record revealed a recertification assessment was completed on 9/5/12.</p>	G0339	<p>G339 Agency Administrator/Alternate Administrator will re-educate staff on the 60 day recertification and the requirement that the reassessment visit must be updated and revised in the last 5 days of the 60 day certification period. Agency administrator/Alternate Administrator will audit 10% of all charts quarterly for evidence that a comprehensive assessment was completed within the proper time frame. Agency Administrator/Alternate Administrator will be responsible for monitoring compliance with regulations and ensuring that this deficiency is corrected and will not reoccur.</p>	11/15/2012	

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N0000	<p>This visit was for a home health state relicensure survey.</p> <p>Survey dates: 10/16/12 - 10/19/12</p> <p>Facility # 005951</p> <p>Medicaid# 100025130A</p> <p>Survey Team:</p> <p>Dawn Snider, RN, PHNS-Team Leader Eric Moran, RN, PHNS-Team member, orientation</p> <p>Census Service Type:</p> <p>Skilled Patients: 671 Home Health Aide Only Patients: 0 Personal Service Only Patients: 0 Total: 671</p> <p>Sample:</p> <p>RR w HV: 4 RR w/o HV: 8</p> <p>Total RR: 12</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN</p>	N0000	Opening comments accepted. No deficiency noted on N0000. Deficiencies addressed below on following tags.		

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N0470	<p>410 IAC 17-12-1(m) Home health agency administration/management Rule 12 Sec. 1(m) Policies and procedures shall be written and implemented for the control of communicable disease in compliance with applicable federal and state laws.</p> <p>Based on procedure and policy review, observation, and interview, the agency failed to ensure employees provided services in accordance with the policy for "Sterile IV(intravenous) Dressing Change for Midline Catheters" in 1 of 1 changing a dressing of a PICC (peripherally inserted central catheter) line observed where a patient was receiving IV therapy creating the potential for transfer of organisms among the patient and the potential to affect all patients of the agency. (#9)</p> <p>Findings include:</p> <p>1. The procedure dated 2/1/2012 and titled "P1-Sterile IV Dressing Change for Midline Catheters" states, "13. clean the site with chlorhexidine prep using a back and forth scrubbing motion for 30 seconds. Allow to air dry thoroughly before proceeding. 14. Clean the catheter with alcohol and allow to air dry."</p> <p>2. The policy dated 12/24/2009 and titled</p>	N0470	N0470 The Agency Administrator/ Alternate Administrator will review policy on sterile PICC dsq change with nursing staff and require that all staff caring for patient's with PICC lines complete the required CEU course on Alere learning systems by 11/15/2012Agency Administrator/Alternate Administrator will co-travel with nursing staff ,when patient population permits, caring for PICC line patients Quarterly x2 visits. Any nurse found out of compliance with policy will be required to complete a skills day session on PICC dsq changes in the Indianapolis office.Administrator/Alternate Administrator are responsible monitoring and ensuring compliance and that all staff are properly trained to provide sterile PICC dsq change as well as taking appropriate actions to correct deficiency to ensure it will not reoccur.	11/15/2012	

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	<p>"Infection Prevention Practices" states, "A. Standard precautions are to be followed for ALL patients. ... 3. Patients and caregivers administering infusion therapy or parenteral medications (injections) are instructed in proper hand washing and aseptic techniques as needed. ... G. Aseptic and sterile procedures. 1. Sterile technique appropriate to the service being provided is practiced by nurses. 2. Patients and caregivers will be instructed on proper storage and handling of sterile supplies, medical devices, and equipment, and the safe care of an infusion site (e.g., site change, IV tubing change, medication administration, etc.)"</p> <p>3. During the home visit on 10/18/12 at 4:45 PM, employee E was observed to follow the procedure for a PICC line dressing change on patient #9. After removal of the PICC line dressing, upon initiation of sterile technique, Employee E measured the circumference of the patient's arm at the insertion site with a tape measure contained in the sterile dressing tray. She cleansed the insertion site and surrounding skin area with the chlorhexidine prep, cleansed the IV tubing and connections and again cleansed the surrounding area of the insertion site using the same chlorhexidine prep (creating the potential</p>						

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	<p>for contamination). She measured the area of tubing from the insertion site to the hub of the connection tubing with the same tape measure used to measure the arm circumference (creating the potential for contamination).</p> <p>4. On 10/19/12 at 12:30 PM the administrator indicated Employee E was a very experienced registered nurse regarding PICC line care, but indicated employee E's care did result in the potential for contamination.</p>			

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N0524	<p>410 IAC 17-13-1(a)(1) Patient Care Rule 13 Sec. 1(a)(1) As follows, the medical plan of care shall:</p> <ul style="list-style-type: none"> (A) Be developed in consultation with the home health agency staff. (B) Include all services to be provided if a skilled service is being provided. (B) Cover all pertinent diagnoses. (C) Include the following: <ul style="list-style-type: none"> (i) Mental status. (ii) Types of services and equipment required. (iii) Frequency and duration of visits. (iv) Prognosis. (v) Rehabilitation potential. (vi) Functional limitations. (vii) Activities permitted. (viii) Nutritional requirements. (ix) Medications and treatments. (x) Any safety measures to protect against injury. (xi) Instructions for timely discharge or referral. (xii) Therapy modalities specifying length of treatment. (xiii) Any other appropriate items. <p>Based on clinical record review and policy review, the agency failed to ensure the medical plan of care was signed by the physician within 30 days of the start of care on 1 of 12 clinical records reviewed (#10) with the potential to affect all the patients of the agency.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Clinical record #10, start of care 7/21/12, included a plan of care for the 	N0524	N 0524Agency Administrator/Alternate Administrator will review with agency staff the required interval for MD signature on Physician Plan of Treatment(PPOT).The PPOT will be faxed weekly x 2 wks then the office will be called daily after day 14 until orders are returned with signature within appropriate time frame.The Agency Administrator/ALternate Administrator will monitor all charts a minimun of bi-weekly to ensure timely return of physician	11/15/2012
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	<p>certification period 7/21/12 to 9/18/12.</p> <p>The plan of care failed to evidence a physician's signature. The plan of care was stamped "second request 10/16/12" with "please date and sign" along with a fax cover page to the physician.</p> <p>2. The policy date 11/20/09 titled "Physician Orders" states, "D. Orders must be signed by the physician and returned to the center in accordance with state regulations, but not exceed 30 days from the date the order was written. (Fax signatures are, as permitted by state regulations, considered to be the same as original signatures.) ... J. Signed physician orders returned to Alere, must be reviewed by the nurse, signed and dated, and placed in the patient's medical record within 30 days of the date the order was written or in accordance with state regulations."</p>		<p>orders. Agency Administrator/Alternate Administrator are responsible for monitoring compliance with regulations and ensuring corrective action takes place to ensure that deficiency does not recur.</p>	

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N0541	<p>410 IAC 17-14-1(a)(1)(B) Scope of Services Rule 14 Sec. 1(a) (1)(B) Except where services are limited to therapy only, for purposes of practice in the home health setting, the registered nurse shall do the following: (B) Regularly reevaluate the patient's nursing needs.</p> <p>Based on clinical record review, the agency failed to ensure the registered nurse reevaluated the patient's needs before completing a new plan of care in 1 of 12 (#5) clinical records reviewed of patients receiving skilled nursing services for at least 60 days with the potential to affect all the patients of the agency receiving services longer than 60 days.</p> <p>Findings include:</p> <p>Clinical record # 5, start of care 7/5/12, failed to evidence the registered nurse reevaluated the patient's needs before creating the new plan of care. The new plan of care was created beginning 9/3/12, but the reassessment was not completed until 9/5/12.</p>	N0541	<p>N0541Agency Administrator/Alternate Administrator will re-educate staff on the 60 day recertification and the requirement that the reassessment visit must be updated and revised in the last 5 days of the 60 day certification period. Agency administrator/Alternate Administrator will audit 10% of all charts quarterly for evidence that a comprehensive assessment was completed within the proper time frame. Agency Administrator/Alternate Administrator will be responsible for monitoring compliance with regulations and ensuring that this deficiency is corrected and will not reoccur.</p>	11/15/2012	