

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  200097310A	(X2) MULTIPLE CONSTRUCTION  A. BUILDING  B. WING	(X3) DATE SURVEY COMPLETED  07/26/2022	
NAME OF PROVIDER OR SUPPLIER  HOME HEALTH CRUSADERS INC		STREET ADDRESS, CITY, STATE, ZIP CODE  3191 WILLOWCREEK ROAD, PORTAGE, IN, 46368		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS - REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
N0000	<p>Initial Comments</p> <p>This visit was for a State Re-licensure Survey of a Home Health provider.</p> <p>Survey Dates: 07/14, 15, 18, 19, 20, 21, 22, 25, and 26 (2022).</p> <p>Census: 35</p> <p>Facility #: IN009404</p> <p>Quality Review Completed on 8/11/22 by SFF</p>	N0000		2022-09-05
G0000	<p>INITIAL COMMENTS</p> <p>This was a fully extended Federal and State Home Health Agency (HHA) Recertification/Re-Licensure Survey completed by the Indiana Department of Health (IDOH). The administrator was notified the survey was fully extended on 7/21/2022 at 2:58 PM.</p> <p>An immediate jeopardy (IJ) was called on 7/25/2022. The administrator was notified on 7/25/2022 at 11:43 AM, regarding an IJ cited at the Condition of Participation 42 CFR §484.75:</p>	G0000		2022-09-05

	<p>Skilled Professional Services. It was determined prior to survey exit, that the IJ was abated, and the administrator was notified on 7/26/2022, at 3:15 PM.</p> <p>Survey Dates: 07/14, 15, 18, 19, 20, 21, 22, 25, and 26 (2022).</p> <p>Census: 35</p> <p>Facility #: IN009404</p> <p>Based on the Condition-level deficiencies during the 7/26/2022 survey, your HHA was subject to a partial or extended survey pursuant to section 1891(c)(2)(D) of the Social Security Act on 7/21/2022. Therefore, and pursuant to section 1891(a)(3)(D)(iii) of the Act, your agency is precluded from operating or being the site of a home health aide training, skills competency and/or competency evaluation program for a period of two years, beginning 7/26/2022 and continuing through 7/25/2024.</p>			
<p>E0000</p>	<p>Initial Comments</p> <p>An Emergency Preparedness survey was conducted by the Indiana Department of Health (IDOH) in accordance with 42 CFR §484.102 for a Home Health Provider.</p> <p>Survey Dates: 07/14, 15, 18, 19, 20, 21, 22, 25, and 26 (2022).</p> <p>Census: 35</p> <p>Facility #: IN009404</p> <p>At this Emergency Preparedness survey, Home</p>	<p>E0000</p>		<p>2022-09-05</p>

	<p>compliance with Conditions of Participation 42 CFR §484.102: Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, including staffing and the implementation of staffing during a pandemic.</p> <p>Quality Review Completed on 8/11/22 by SFF</p>			
<p>N0458</p>	<p>Home health agency administration/management</p> <p>410 IAC 17-12-1(f)</p> <p>Rule 12 Sec. 1(f) Personnel practices for employees shall be supported by written policies. All employees caring for patients in Indiana shall be subject to Indiana licensure, certification, or registration required to perform the respective service. Personnel records of employees who deliver home health services shall be kept current and shall include documentation of orientation to the job, including the following:</p> <ol style="list-style-type: none"> <li>(1) Receipt of job description.</li> <li>(2) Qualifications.</li> <li>(3) A copy of limited criminal history pursuant to IC 16-27-2.</li> <li>(4) A copy of current license, certification, or registration.</li> <li>(5) Annual performance evaluations.</li> </ol> <p>Based on record review and interview, the agency failed to ensure all employee personnel records included a lifetime national criminal history or an expanded criminal history search for 2 of 3 personnel records reviewed (registered nurse [RN]1, physical therapist [PT] 1).</p>	<p>N0458</p>	<p>HR record review of 100% of all active employees will be completed to ensure that lifetime national criminal history check or expanded criminal history search. Any deficient chart will have a national lifetime criminal history check or expanded history search completed. This is the responsibility of the Administrator and was completed on 8/10/22.</p> <p>Update to policy to include that a lifetime national criminal history check or expanded history check is completed on all new hires. This will be the responsibility of the Administrator and completed by 9/1/22.</p> <p>An audit of all new hires will be conducted within 30 days of hire to ensure that a lifetime national criminal history check or expanded history check is documented in the HR record. This will be completed x 6 months. This is the responsibility of the Administrator and will begin 9/1/22.</p>	<p>2022-09-01</p>

	<p>Findings include:</p> <ol style="list-style-type: none"> <li>1. An Indiana Code (IC) document with effective date 7/01/2016, titled "CRIMINAL HISTORY CHECKS STATE STATUTE IC-16-27-2" stated "... Ensure that the agency conducts a national criminal history or an expanded criminal history check on all employees ... The criminal history search must be a lifetime search not limited in years ...."</li> <li>2. An undated agency policy submitted on 7/15/2022, titled "Background Check", stated "... [agency] will apply for a copy of a limited criminal history record on employees providing direct patient care or access to patient records ...."</li> <li>3. Personnel records were reviewed on 7/15/2022 at 1:48 PM, with person 4 (office/human resource manager).</li> </ol> <p>RN 1's personnel record failed to include a lifetime national criminal history or an expanded criminal history search.</p> <p>PT 1's personnel record failed to include a lifetime national criminal history or an expanded criminal history search.</p> <ol style="list-style-type: none"> <li>4. During an interview on 7/15/2022 at 1:48 PM, person 4 indicated the agency obtained limited criminal history checks.</li> </ol>			
<p>N0460</p>	<p>Home health agency administration/management</p> <p>410 IAC 17-12-1(g)</p> <p>Rule 12 Sec. 1(g) As follows, personnel records</p>	<p>N0460</p>	<p>Administration management</p> <p>supervising nurse</p> <p>The supervising nurse lifetime national criminal history or expanded criminal history search will be completed and filed in the HR</p>	<p>2022-09-01</p>

of the supervising nurse, appointed under subsection (d) of this rule, shall:

- (1) Be kept current.
- (2) Include a copy of the following:
  - (A) Limited criminal history pursuant to IC 16-27-2.
  - (B) Nursing license.
  - (C) Annual performance evaluations.
  - (D) Documentation of orientation to the job.

Performance evaluations required by this subsection must be performed every nine (9) to fifteen (15) months of active employment.

Based on record review and interview, the agency failed to ensure the clinical supervisor's personnel record included a lifetime national criminal history or an expanded criminal history search.

Findings include:

An Indiana Code (IC) document with effective date 7/01/2016, titled "CRIMINAL HISTORY CHECKS STATE STATUTE IC-16-27-2" stated "... The agency shall submit current copies of criminal history for the ... nursing supervisor ... Ensure that the agency conducts a national criminal history or an expanded criminal history check on all employees ... The criminal history search must be a lifetime search not limited in years ...."

An undated agency policy submitted on 7/15/2022, titled "Background Check", stated "... [agency] will apply for a copy of a limited

chart by 8/10/22. This is the responsibility of the Administrator.

Update to policy to include that a lifetime national criminal history check or expanded history check is completed on all new hires.

This will be the responsibility of the Administrator and completed by 9/1/22.

	<p>providing direct patient care or access to patient records ...."</p> <p>Personnel records were reviewed on 7/15/2022 at 1:48 PM, with person 4 (office/human resource manager).</p> <p>The clinical supervisor's personnel record failed to include a lifetime national criminal history or an expanded criminal history search.</p>			
<p>G0536</p>	<p>A review of all current medications</p> <p>484.55(c)(5)</p> <p>A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.</p> <p>Based on observation, record review, and interview, the registered nurse (RN) failed to ensure the patient s medication profile included all medications the patient used, and/or indications, directions/precautions for use, for 4 of 8 clinical records reviewed (#1, 3, 4, 8).</p> <p>Findings include:</p> <p>1. An undated policy received on 7/22/2022, titled Skilled Nursing Services stated, ... The [RN] will ... Write the medication profile at the Start of Care [sic] update with any changes throughout the time of service ... Medication reconciliation is completed on each visit and updates to the medication record shall reflect any medication changes ....</p>	<p>G0536</p>	<p>Director of Nursing made home visits to all active patients to perform comprehensive assessments including medication record review which was completed on 7/29/22. This included the patient cited in the deficiency.</p> <p>Director of Nursing will educate clinicians on the need to complete medication record review on admission, recertification and discharge and whenever a medication change has occurred. All medications that the patient is currently taking should include name of medication, dosage , route and schedule and if needed location of where medication is to be applied. If the prescription bottle does not include all of these items then a verbal order should be obtained from the physician that includes all information.</p> <p>This will be completed by 8/15/22 and is responsibility of the DON. See document A Audit added to QAPI plan to conduct a clinical record review of 25% of the average daily census including both active or discharge</p>	<p>2022-09-01</p>

	<p>2. An undated policy received on 7/29/2022, titled Drugs and Biologicals stated, ... the clinician [RN] shall document all ... medications ... effectiveness of drug therapy ... side effects ... potential/actual ... adverse reactions ....</p> <p>3. A home visit was observed at Entity 9 (an assisted living facility [ALF]), with RN 1 and Patient #1 on 7/18/2022 at 10:00 AM. RN 1 failed to reconcile the patient s medications during the home visit, and exited the building with the surveyor.</p> <p>Review of a document received from Entity 9 on 7/18/2022 for date range 5/01/2022 7/31/2022, titled Medication Review Report indicated the patient s medications included colace (a stool softener) (start date 3/28/2022), and Levemir (long-acting insulin) (start date 2/25/2022) 19 Units (U) twice daily; and sliding scale insulin to be administered 4 times daily based on blood glucose (sugar) results, with 12 U to be given if blood sugar result was equal/greater to 401.</p> <p>Clinical record review for Patient #1 was completed on 7/26/2022, which included a document received on 7/15/2022, titled Medication Profile , for certification period 6/4/2022 8/02/2022. The document indicated the patient only used 16 U of Levemir twice daily; and failed to include the patient s medications included colace, or sliding scale insulin was to be administered 4 times daily based on blood glucose (sugar) results, with 12 U to be given if blood sugar result was equal/greater to 401.</p> <p>During an interview on 7/21/2022 at 11:15 AM, the clinical manager indicated Entity 9 and the agency s medication profiles should coincide, with the exception of things entity administered and the agency did not.</p> <p>4. A home visit was observed with the</p>		<p>records to begin 9/01/2022</p> <p>Monthly for documentation of complete medication record documentation</p> <p>After three consecutive months at 100% compliance obtained the audit will be reduce to quarterly audit of 25% of the average daily census of active or discharge records until 100% compliance is reached then audit can be reduced to every 6 months. If at any time the 100% compliance is not reached then audit will be increased back to monthly</p> <p>This is the responsibility of the DON with results reported to the Administrator.</p>	
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alternate clinical manager and Patient #3 on 7/18/2022 at 12:50 PM. During this time, the patient produced a plastic bag and indicated the bag contained all of her medications. Medications included potassium chloride (mineral supplement) 10 milliequivalents (mEq), ½ tablet daily (5 mEq), levothyroxine (brand name synthroid, a thyroid supplement) dose was 25 micrograms (mcg), and tylenol (acetaminophen, over-the-counter pain relief) 500 milligrams (mg), which the patient indicated she took 1-2 pills every 4 hours as needed.

Clinical record review for Patient #3 was completed on 7/26/2022. A document received on 7/15/2022, titled Medication Profile , for certification period 6/28/2022 8/26/2022, indicated the patient took 1 tablet (10 mEq) of potassium chloride, synthroid dose was 125 mcg, and tylenol dose was 325 mg, with 2 tablets taken every 4 hours as needed for pain.

During an interview on 7/19/2022 at 11:59 AM, the clinical manager indicated she expected the nurses to reconcile medications every 30 days, and medication orders should include indications and (anatomical) location for use.

5. A document received from Entity 5 (a wound clinic) on 7/25/2022, dated 7/12/2022 (for patient #4), titled "Physician Orders Details" included an entry dated 6/28/2022, which indicated the patient's primary care physician ordered oral antibiotics (to treat infection) the week of 6/19/2022, and the patient still had a few left to take (as of 6/28/2022).

Clinical record review for Patient #4 was completed on 7/26/2022 (start of care date 1/03/2022). A document received on 7/15/2022, titled Medication Profile , for certification period 7/2/2022 8/30/2022, included both current and discontinued medications from 1/03/2022 to the most recent entry dated 7/12/2022. The medication profile indicated to apply gentamicin

	<p>(antibiotic) topical ointment daily, but failed to identify the anatomical location to be applied; lidocaine topical patch (pain relief) to be applied every 24 hours, but failed to indicate the patch must be removed after 12 hours in any 24-hour period; and failed to include the antibiotic medication the patient was prescribed during the week of 6/19/2022.</p> <p>During an interview on 7/21/2022 at 12:46 PM, the clinical manager indicated the lidocaine patch order should include to remove patch after 12 hours.</p> <p>6. Clinical record review for Patient #8 was completed on 7/26/2022. A document titled Home Health Certification and Plan of Care indicated the patient s medications included a lidocaine topical patch to be applied daily to painful joints, and failed to identify which joints, maximum number of patches to apply (maximum of 3), or to remove after 12 hours in any 24-hour period.</p> <p>During an interview on 7/21/2022 at 3:14 PM, the clinical manager indicated the medication profile should include specific directions and precautions for the lidocaine patch.</p> <p>17-14-1(a)(1)(B)</p>			
<p>G0544</p>	<p>Update of the comprehensive assessment</p> <p>484.55(d)</p> <p>Standard: Update of the comprehensive assessment.</p>	<p>G0544</p>	<p>Director of Nursing made home visits to all active patients to perform comprehensive assessments including wound assessment which was completed on 7/25/22. This included the patient cited in the deficiency.</p> <p>Comprehensive Assessment</p> <p>Education was provided to all nursing staff on home health assessments, documentation and coordination of care based on best practice and Medicare Conditions of</p>	<p>2022-09-01</p>

<p>The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than-</p> <p>Based on observation, record review and interview, the registered nurse (RN) failed to update/revise the patient s comprehensive assessment for 3 of 3 records reviewed with patients who experienced a significant change in condition (#1, 3, 4).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. An undated policy received on 7/22/2022, titled Skilled Nursing Services stated, ... The [RN] will ... make necessary revisions/reassessments according to changing patient needs ....</li> <li>2. An undated policy received on 7/19/2022, titled Comprehensive Assessment stated, ... Additional comprehensive assessments will be completed for the following reasons ... for a significant change in the patient s condition ....</li> <li>3. Clinical record review for Patient #1 was completed on 7/26/2022, for certification period 6/04/2022 8/02/2022. A document dated and signed by RN 1 on 6/03/2022 titled ... Recertification (a comprehensive reassessment) indicated the patient had 1 venous stasis ulcer (an open wound caused by impaired blood flow) on each lower leg (2 total wounds).</li> </ol> <p>Review of subsequent skilled nursing visits dated 6/06, 6/08, 6/10, 6/13, 6/15, 6/17, 6/20, 6/22, 6/24, 6/27, 6/29, 7/01, 7/04, 7/06, 7/08, 7/11, 7/13, and 7/15 (2022) indicated the patient had only 2 venous stasis ulcers.</p> <p>A home visit was observed on 7/18/2022 at 10:00 AM with Patient #1 and RN 1. Upon</p>		<p>Participation on 7/26/22 by Diane Link RN, MHA consultant All nursing staff were in attendance. See Document B</p> <p>DON completed a visit with each active patient with wound to observe assessment and documentation This was completed on 07/25/22.</p> <p>100% review of all wound care patient's clinical documentation and wound photos submitted by staff will occur weekly x 8 weeks and if 100% compliance achieved will be decreased to 25% of active census monthly x 2 months then quarterly.</p> <p>If there is not 100% compliance then the frequency will be increased to weekly. This was initiated on 7/27/2022</p> <p>Audit added to QAPI plan to conduct a monthly clinical record review of 25% of average daily census including active or discharge records focused on completion of comprehensive assessment for changes in patient condition and documentation of follow up on identified changes beginning 9/01/22 . This is the responsibility of the DON</p>	
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patient's lower legs had large areas of very darkened skin (not within normal color for this patient), areas of white macerated tissue (indicative of excessive moisture/drainage), and multiple (greater than 4-6 on each leg) open, draining wounds on all aspects of the lower legs. The wounds and darkened skin comprised greater than half of each lower leg. RN 1 indicated the darkened skin was not present last skilled nursing visit (on 7/15/2022), and the multiple wounds "opened and closed". Observed two additional open areas on the top of the patient's right foot, which presented with absence of top layers of skin, pink wound beds, and each no greater than 1 cm (centimeter) in diameter.

A document dated and signed by RN 1 on 7/18/2022 titled Skilled Nurse Note stated, ... There is [sic] bilateral lower leg discoloration, approximately 5 cm [centimeters] below each knee and extending to base of ankles. This is a new finding as of today. There are also noted [sic], multiple ... venous stasis wounds to bilateral lower legs. Too many to enumerate. This is a new finding ....

During an interview on 7/20/2022 at 1:53 PM, Person 2 (the patient s nurse practitioner [NP]) indicated the multiple wounds and darkened skin on the patient was not a new finding (as of 7/18/2022 visit made by RN 1), there were multiple wounds, and she knew that for a fact .

During an interview on 7/22/2022 at 12:01 PM, the clinical manager indicated the patient s skin (on the lower legs) was a little darker than normal per her observation of the patient on the morning of 7/22/2022.

During an interview on 7/25/2022 at 11:43 AM, the clinical manager indicated the clinical record did not include documentation of the patient s significant change in condition from 6/03/2022 to 7/18/2022.

4. A home visit was observed with Patient #3 and the alternate clinical manager on 7/18/2022 at 12:50 PM. During this time, the patient indicated she had a stent placed (a tiny expandable metal mesh coil, inserted surgically into a newly opened area of the artery to help keep the artery from narrowing or closing again) to her left upper leg, in the middle of May, 2022, her left leg hurt, there was a bruise in her left groin (procedural insertion site of stent), and she developed a blood clot sometime after the procedure. Observed the left upper groin, which revealed a swollen (baseball size) area over the healed incision line. The patient also indicated the procedure was performed by Person 3 (a vascular physician).

During an interview on 7/20/2022 at 9:31 AM, Person 4 (office staff for Person 3, a vascular physician) indicated patient #3 had an angiogram with stent placement on 5/17/2022, a 2 week follow up visit on 6/1/2022, and was seen 6/15/2022 for complaint of a swollen left foot.

Documents were received 7/21/2022 from Person 3 s office. A document on Person 3 s letter head indicated the patient had a stent placed in her left femoral (thigh) artery on 5/17/2022. A document dated 6/01/2022, titled "SOAP Note [person 3's physician visit note]", indicated the patient was seen for a 2-week post-procedure follow up, had developed pain and swelling in the left groin with bruising, and swelling in the left foot. A document dated 6/15/2022, titled "SOAP Note", indicated the patient still had some residual pain and swelling in the left groin area, and a "swollen foot".

Clinical record review for Patient #3 was completed on 7/26/2022 for certification periods 4/29/2022 6/27/2022. The record evidenced the alternate clinical manager made routine skilled nursing visits on 5/19/2022, 5/26/2022, 6/02/2022, and 6/16/2022, but failed to evidence a comprehensive reassessment was performed for the patient s

<p>significant change in condition, which occurred on 5/17/2022.</p> <p>During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the agency did not have any clinical documents from person 4's office, the clinical record failed to indicate the alternate clinical manager assessed the patient's left groin incision during skilled nursing visits performed on 5/19/2022, 5/26/2022, 6/02/2022, 6/09/2022, or 6/16/2022.</p> <p>5. Clinical record review for Patient #4 was completed on 7/26/2022, for certification period 7/02/2022 8/30/2022. A document dated and signed by the alternate clinical manager on 6/20/2022 titled "Skilled Nurse Visit" indicated the patient reported a scrape to the left lower extremity, with a small scab and slight redness around area, the physician was made aware, and no new orders were received.</p> <p>A document dated and signed by the alternate clinical manager on 6/27/2022, titled "...Recertification" indicated the wound on the left lower extremity was an "abrasion" (scrape), which measured 2.1 cm (length) x 2.1 cm (width) x 2.1 cm (depth), and the surrounding tissue was red (worsened since last skilled nursing visit dated 6/20/2022).</p> <p>Documents requested and received 7/19/2022 titled "Skilled Nurse Visit", dated and signed by the alternate clinical manager on 7/04/2022 and 7/11/2022 failed to indicate the nurse assessed or measured the wound to the left lower extremity. The document dated 7/11/2022 indicated the patient was seen at a wound clinic, but failed to indicate when the patient was seen, or which wound clinic.</p> <p>During an interview on 7/21/2022 at 12:46 PM, the clinical manager indicated she was unaware the patient went to the wound clinic,</p>			
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	<p>and the agency did not have wound clinic notes.</p> <p>A document dated 6/28/2022, received from Entity 5 (a wound clinic) on 7/26/2022, titled "Physician Orders Details", indicated the patient had 2 wounds on the left lower leg, each with treatment orders. The patient's clinical record only indicated the presence of 1 wound.</p> <p>A document received from Entity 5 (a wound clinic) on 7/25/2022, dated 7/12/2022, titled "Physician Orders Details" indicated both left lower leg wounds originated on 5/28/2022 subsequent to trauma (patient hit her leg on a magazine rack), the patient's primary care physician ordered oral antibiotics (to treat infection) the week of 6/19/2022, and as of 7/12/2022, one of the wounds was healed. The remaining wound was worse, with a large amount (67-100%) necrotic (dead) tissue and slough (yellow/white material in the wound bed, consists of dead cells that accumulate in the wound drainage), and topical antibiotic ointment was ordered. The clinical record failed to indicate a comprehensive reassessment was performed due to the significant change in condition on or after 7/12/2022.</p> <p>17-14-1(a)(1)(B)</p>			
<p>G0560</p>	<p>Discharge Planning</p> <p>484.58</p> <p>Condition of Participation: Discharge planning.</p> <p>Based on record review and interview, the home health agency failed to develop and implement an effective discharge planning process based on current federal regulatory requirements (See tag G562); and failed to ensure it sent all necessary medical</p>	<p>G0560</p>	<p>Transfer and Discharge Policy will be updated to include providing patients that are transferred</p> <p>to SNF, IRF, LTCH or other home health agency will be provided with copies of the health</p> <p>compare quality measures for facilities /agencies that meet the patient needs and goals. This is</p> <p>the responsibility of the administrator and will be completed by 9/05/22.</p> <p>All clinical staff will be educated on discharge planning including the need to provide</p>	<p>2022-09-05</p>

	<p>information to the receiving facility or health care practitioner (See tag G564). This practice had the potential to affect all agency patients.</p> <p>Findings include:</p> <p>The cumulative effect of these systemic problems resulted in the home health agency being found not in compliance for the Condition of Participation: 42 CFR §484.58: Discharge Planning.</p>		<p>patients</p> <p>being transferred to a SNF, IRF, LTCH or Home Health Agency will be provided quality measures</p> <p>and data for facilities that meet the patient needs and goals. This information will be compiled</p> <p>from the health compare website and provided to the patient. This education is the responsibility of the DON and completed by 9/05/22</p> <p>Education will be provided to all clinicians that upon discharge or transfer from the agency a report must be sent to the receiving entity and/or health care provider following patient in the community. All sections on the EMR discharge /transfer summary must be completed. This education is the responsibility of the DON and will be completed by 9/05/22. Office manager will send out completed summaries with oversight by DON.</p> <p>An audit of 25% of all transfer or discharge records will be completed monthly to ensure that a</p> <p>completed transfer/discharge summary is sent to the receiving facility and/or health care</p> <p>provider in the community following the patient. This will be documented in the EMR. The</p> <p>audit will start on 9/01/22 Audit will be done monthly x 3 months and if 100% compliant then</p> <p>will be decreased to quarterly x 2 months. IF at any time the audit is less than 100% compliant</p> <p>the frequency will be increased to monthly This is the responsibility of the DON and reported</p> <p>to QAPI.</p>	
G0562	Discharge Planning	G0562	All clinical staff will be educated on discharge planning including the need to provide	2022-09-05

	<p>484.58(a)</p> <p>Standard: Discharge planning.</p> <p>An HHA must develop and implement an effective discharge planning process. For patients who are transferred to another HHA or who are discharged to a SNF, IRF or LTCH, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.</p> <p>Based on record review and interview, the home health agency failed to develop and implement an effective discharge planning process that went into effect 2/21/2020.</p> <p>Findings include:</p> <p>An undated agency policy received 7/19/2022, titled "Patient Discharge from Agency" failed to include a process/procedure on the agency's requirement to assist patients and their caregivers in selecting a post-acute care provider.</p> <p>During an interview on 7/21/2022 at 11:15 AM, the clinical manager indicated discharge plans were what they gave the patient for follow up, when to call 911, and other instructions.</p> <p>During an interview on 7/26/2022 at 3:27 PM, the administrator indicated she did not know there were new discharge/transfer regulations that went into effect 2/21/2020.</p>		<p>patients being transferred to a SNF, IRF, LTCH or Home Health Agency will be provided quality measures and data for facilities that meet the patient needs and goals. This education is the responsibility of the DON and completed by 9/05/22.</p> <p>Transfer and Discharge Policy will be updated by 8/31/22,</p> <p>to include providing patients that are transferred to SNF, IRF, LTCH or other home health agency will be provided with copies of the health compare quality measures for facilities /agencies that meet the patient needs and goals. All active patients will receive updated transfer/discharge policy. This is the responsibility of the administrator and will be completed by 9/5/22.</p> <p>An audit of 25% of transfer or discharges to SNF, IRF, LTCH or HHA will be completed monthly to ensure that the quality measures were provided to the patient and documented in the medical record. Once 100% compliance is achieved for 3 consecutive months then the audit will be decreased to quarterly x 2 quarters. If the audit is not 100% compliant then frequency will be increased back to monthly. This audit will start 9/01/22 and is the responsibility of the DON with reports to the QAPI.</p>	
G0564	Discharge or Transfer Summary Content	G0564	<p>Discharge Transfer Summary</p> <p>Education will be provided to all clinicians</p>	2022-09-01

	<p>484.58(b)(1)</p> <p>Standard: Discharge or transfer summary content.</p> <p>The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.</p> <p>Based on record review and interview, the home health agency failed to ensure it sent all necessary medical information to the receiving facility or health care practitioner, for 3 of 3 discharged records reviewed (#6, 7, 8).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. An undated agency policy received 7/19/2022, titled "Patient Discharge from Agency" stated "... A discharge summary shall be ... available to the physician upon request ...." The policy failed to indicate a discharge summary must be sent to the the receiving facility or health care practitioner.</li> <li>2. An undated agency policy received 7/19/2022, titled "Patient Transfer to an Inpatient Facility" stated, "... transfer summary will be completed ... sent to the admitting facility ... shall include ... destination ... Date and name of person receiving report ... Diagnosis related to the transfer ... Status of patient at time of transfer ...."</li> <li>3. Clinical record review for Patient #6 was completed on 7/26/2022. A document dated 1/30/2022, titled "Physician Order" stated "... Please discharge patient from home health services; patient will transfer to SNF after hospitalization ...."</li> </ol> <p>A document dated 2/09/2022, titled "Home Health Transfer Summary (Auto-Generated)"</p>		<p>that upon discharge or transfer from the agency a report must be sent to the receiving entity and/or health care provider following patient in the community. All sections on the EMR discharge /transfer summary must be completed. This education is the responsibility of the DON and will be completed by 8/15/22. See Document A</p> <p>An audit of 25% of all transfer or discharge records will be completed monthly to ensure that a completed transfer/discharge summary is sent to the receiving facility and/or health care provider in the community following the patient. This will be documented in the EMR. The audit will start on 9/01/22 Audit will be done monthly x 3 months and if 100% compliant then will be decreased to quarterly x 2 months. IF at any time the audit is less than 100% compliant the frequency will be increased to monthly This is the responsibility of the DON and reported to QAPI.</p>	
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included a section to complete with the name of the inpatient facility, date summary sent, and name of physician and date the summary was sent, all of which were blank; and failed to indicate the date the patient was transferred, or current status or diagnosis of patient upon transfer.

During an interview on 7/20/2022 at 11:49 AM, Person 14 (office staff of Person 13 [the patient's certifying physician]) indicated the home health agency did not send them a discharge or transfer summary.

During an interview on 7/21/2022 at 1:40 PM, the clinical manager indicated she did not have any paperwork about the patient's hospitalization, which would provide the patient's diagnosis and status related to the transfer.

4. Clinical record review for Patient #7 was completed on 7/26/2022. A document dated 6/08/2022, titled "Physician Order" stated "... Please hold home health services; patientt admitted to hospital ...."

A document dated 6/13/2022, titled SN [skilled nurse] Discharge Summary" indicated the patient was transferred to Entity 9 (an assisted living facility/skilled rehabilitation center), and Person 10 (the patient's certifying physician) was aware; and failed to indicate a discharge summary was sent to the physician, or the discharge summary included all required content.

During an interview on 7/21/2022 at 3:36 PM, the clinical manager indicated the agency had no hospital paperwork, which would provide the patient's diagnosis and status related to the transfer, and she didn't know why the patient went into the hospital.

5. Clinical record review for Patient #8 was

	<p>completed 7/26/2022. A document dated 6/01/2022, titled "Home Health Transfer Summary (Auto-Generated)", included a section to complete with the name of the inpatient facility, date summary sent, and name of physician and date the summary was sent, all of which were blank; and failed to indicate all required information.</p> <p>During an interview on 7/21/2022 at 3:14 PM, the clinical manager indicated she didn't know why the patient was hospitalized, she had no hospital paperwork, which would provide the patient's diagnosis and status related to the transfer, and the agency didn't contact hospitals for paperwork until after the patients were discharged.</p> <p>6. During an interview on 7/21/2022 at 11:15 AM, the clinical manager indicated discharge plans were what they gave the patient for follow up, when to call 911, and other instructions.</p> <p>7. During an interview on 7/26/2022 at 3:27 PM, the administrator indicated she did not know there were new discharge/transfer regulations that went into effect 2/21/2020.</p>			
<p>G0570</p>	<p>Care planning, coordination, quality of care</p> <p>484.60</p> <p>Condition of participation: Care planning, coordination of services, and quality of care.</p> <p>Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs</p>	<p>G0570</p>	<p>Care Planning, Coordination of Services</p> <p>Education was provided to all nursing staff on home health assessments, documentation and coordination of care based on best practice and Medicare Conditions of Participation on 7/26/22 by Diane Link RN, see document B</p> <p>MHA consultant All nursing staff were in attendance.</p> <p>Education will be provided to all clinical staff on developing individualized plans of care</p>	<p>2022-09-01</p>

<p>as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.</p> <p>Based on observation, record review, and interview, the registered nurse (RN) failed to ensure the patient received all services written on the plan of care, and/or the plan of care was individualized, and included patient-specific measurable outcomes and goals (See tag G572); failed to ensure the patient's plan of care included 1 or more of the following: all pertinent diagnoses, the patient's psychosocial status, supplies and/or equipment required, nutritional requirements, all treatments, safety measures to protect against injury, patient-specific education, information related to any advanced directives, or any additional items the agency chose to include, per its own policy (See tag G574); failed to administer treatments only as ordered by a physician or nurse practitioner (NP) (See tag G580); failed to inform the patient's relevant physician for patients who experienced a change condition (see tag G590); and failed to ensure the patient's revised plan of care included a summary of the patient's condition during the previous certification period, or information concerning the patient's progress toward the outcomes and goals (See tag G592). This practice had the potential to affect all agency patients.</p> <p>Findings include:</p> <p>The cumulative effect of these systemic problems resulted in the home health agency's inability to ensure the provision of quality health care in a safe environment for the Condition of Participation 42 CFR §484.60: Care Planning, Coordination of Services, and Quality of Care.</p>		<p>that include all required elements including patient specific measurable outcomes and goals, physician orders for all treatments provided, and coordination with physicians of changes in patient condition, recertification summary of care and all interventions are provided or documentation to reason not completed prior to discharge. This is the responsibility of the DON and will be completed on 8/15/22. See document A</p> <p>To begin 9/1/22, an audit of 25% of average daily census will</p> <p>be completed to ensure that the plan of care includes all required elements, the plan of care is individualized, orders for all treatments provided and coordination of care with physician for any changes in patient condition. This will be completed monthly x 3 months and if 100% compliance is maintained then will be decreased to quarterly x 2 quarters. If the audit would be less than 100% compliant then frequency will be increased to monthly. This is the responsibility of the DON and will be reported to the QAPI.</p>	
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<p>G0572</p>	<p>Plan of care</p> <p>484.60(a)(1)</p> <p>Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration. If a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician or allowed practitioner is consulted to approve additions or modifications to the original plan.</p> <p>Based on observation, record review, and interview, the registered nurse (RN) failed to ensure the patient received all services written on the plan of care, and/or the plan of care was individualized, and included patient-specific measurable outcomes and goals, for 5 of 5 active clinical records reviewed (#1, 2, 3, 4, 5).</p> <p>Findings include:</p> <p>1. An undated agency policy received on 7/19/2022 titled Plan of Care stated, ... services are furnished ... in accordance with a plan of care based on the patient s diagnosis and assessment of ... immediate and long-range needs ... based on current assessment by a Registered Nurse ... plan of care is individualized to each patient ... shall include ... Expected goals/outcomes ....</p> <p>2. A home visit was observed at Entity 9 (an assisted living facility [ALF]), with RN 1 and</p>	<p>G0572</p>	<p>Individualized POC</p> <p>Education will be provided to all clinicians on how to develop an individualized POC that is based on the comprehensive assessment and includes identification of any caregiver that will be providing interventions included on the plan of care. That the POC includes measurable goals and interventions and all interventions are completed or documentation on why not completed prior to discharge. Education will be provided on writing recertification visit frequency based on the patient needs and timing of the certification period. Education will be provided on have verbal orders for all intervention changes that may occur during the certification period and ensuring the plan of care at recertification includes all changes that are currently needed to meet the goals and outcomes of the patient. This will be responsibility of the DON and completed by 8/15/22. See document A.</p> <p>To begin 9/1/22, an audit of 25% of average daily census will be completed to ensure that the plan of care includes all required elements, the plan of care is individualized and based on the comprehensive assessment, orders for all treatments provided and at recertification the plan of care is updated to include all active interventions and goals. This will be</p>	<p>2022-09-01</p>

<p>this visit, RN 1 indicated the ALF staff administered the patient s medications, provided meals, provided all personal care (bathing, dressing), and transportation to appointments. The plan of care failed to be individualized to include what services the ALF provided.</p> <p>The clinical record review for Patient #1 was completed on 7/26/2022. A document dated 6/3/2022, titled ... Recertification (a comprehensive reassessment) indicated the patient had decreased cognition (trouble remembering, learning new things, concentrating, or making decisions that affects everyday life), experienced pain, at risk for skin breakdown, bowel and bladder incontinence, needed assist for personal care/hygiene, could not self-administer medications due to confusion, and had 2 venous stasis ulcers (wounds caused by fluid build-up in skin and tissue due to impaired blood flow).</p> <p>A review of the plan of care for the certification period of 6/04/2022 8/02/2022, indicated skilled nursing visits were ordered 3 times per week for 8 weeks, then once for 1 week; the patient had diabetes, congestive heart failure (a weakness of the heart that leads to a buildup of fluid in the lungs and surrounding body tissues), and diabetic nephropathy (the deterioration of kidney function most often caused by diabetes); medications included sliding scale insulin (administration of varying doses of insulin based on blood glucose level results; and diet was heart healthy, and 1800 calorie diabetic diet. The clinical record failed to evidence the patient received any nursing visits during the week of 6/04/2022; failed to be individualized to include interventions or measurable outcomes/goals to address diagnoses of congestive heart failure and diabetic nephropathy; how often the patient s blood sugar was checked, or who checked it; or how the RN ensured the patient adhered to a heart-healthy, 1800 calorie diabetic diet. The plan of care also failed to be individualized to include interventions or measurable outcomes/goals for pain, impaired cognition, risk for skin breakdown or prevention of</p>		<p>completed monthly x 3 months and if 100% compliance is maintained then will be decreased to quarterly x 2 quarters. If the audit would be less than 100% compliant then frequency will be increased to monthly. This is the responsibility of the DON and will be reported to the QAPI.</p>	
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new/worsening wounds, bowel and bladder incontinence, how the agency ensured the patient's personal care/hygiene needs were met, or how the agency ensured the patient took all medications as prescribed by the physician.

During an interview on 7/21/2022 at 11:15 AM, the clinical manager indicated no nursing visit was made during the first week due to the certification period began on a Saturday, the agency nurse would talk to the ALF nurse to ensure the patient adhered to an 1800 calorie diabetic diet, she knew the (agency) nurse talked to the ALF nurse, but he just didn't document it; the plan of care should indicate how often the patient's blood sugar was checked, and who checked it; the ALF administered medications, provided all personal care, toileting, meals, social activities, and transportation; she would expect to see interventions such as daily weights for diagnosis of congestive heart failure, she thought the ALF obtained weekly weights; and there were no patient-specific interventions/measurable outcomes or goals for the management of diabetes, diet, or congestive heart failure on the plan of care.

3. Clinical record review for Patient #2 was completed on 7/26/2022. A document dated 6/21/2022, titled ... Start of Care (a comprehensive assessment), indicated the patient had surgery to repair a broken femur bone and had a surgical incision; the patient experienced depression, needed assistance with personal care needs, and was a moderate nutritional risk with a score of 30 (moderate risk = score 26-55).

A review of the plan of care for the certification period of 6/21/2022 - 8/19/2022, failed to be individualized to include interventions or measurable outcomes/goals to address the surgical incision, depression, how the agency ensured personal care needs were met, or mitigation of nutritional risk.

A review of a skilled nursing visit note dated 7/14/2022, (the last skilled visit ordered on the plan of care) stated, ... [patient] Response to Care/Progress Toward Goals ... [patient] has 75% understanding of education taught ... The plan of care failed to include a measurable outcome/goal for the patient s understanding of the education taught.

During an interview on 7/21/2022 at 12:00 PM, the clinical manager indicated the RN did not provide all teaching interventions included in the plan of care, and the plan of care was not patient-specific to include how the patient s personal care needs were met.

4. Clinical record review for Patient #3 was completed on 7/26/2022. A review of the plan of care for the certification period 4/29/2022 6/27/2022, indicated skilled nursing visits were ordered once weekly for 8 weeks, diet included a heart-healthy, 2000-calorie diabetic diet; diagnoses included diabetes, hypertension (HTN) (high blood pressure), peripheral vascular disease (PVD) (a circulatory condition in which narrowed blood vessels reduce blood flow to the limbs), high cholesterol, and vitamin D deficiency; and indicated the patient had an old CVA (cerebral vascular accident/stroke) with hemiplegia (paralysis) to the left/dominant side. The plan of care failed to be individualized to include patient-specific interventions or measurable outcomes/goals for the patient s calorie-specific diet, the risk for stroke associated with HTN, PVD, or vitamin D deficiency; or risks associated with non-compliance with regular blood glucose monitoring.

The clinical record failed to evidence the patient received any nursing visits during the week of 4/29/2022.

A review of skilled nursing visit notes dated 5/05/2022, 5/12/2022, 5/19/2022, 5/26/2022, 6/02/2022, 6/09/2022, and 6/16/2022, stated ... Patient is non-compliant with checking blood

physician] already aware .... The plan of care failed to be updated to include patient-specific goals related to the patient's non-compliance with checking blood sugars.

During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the frequency of nursing visits wasn't met due to the certification period began at the end of the week (on a Friday), and no visit was made.

5. Clinical record review for Patient #4 was completed on 7/26/2022. A review of the plan of care for the certification period of 7/02/2022 8/30/2022, indicated skilled nursing was ordered once weekly for 9 weeks, the patient's primary diagnosis was moderate protein-calorie malnutrition (nutritional status in which reduced availability of nutrients leads to changes in body composition and function), other diagnoses included presence of a g-tube (a tube inserted into the stomach for administration of nutrition, fluids, and/or medications), an abrasion to the left lower leg, PVD, amyotrophic lateral sclerosis (ALS) (a progressive disease, characterized by a degeneration of motor nerve cells in the brain and spinal cord, which leads to loss of motor function), chronic obstructive pulmonary disease (COPD, lung disease), heart failure, dysphagia (difficulty swallowing), and diverticulosis (a condition in which small, bulging pouches develop in the digestive tract); diet included supplemental g-tube feedings and a mechanical soft diet (a diet that involves only foods that are physically soft, with the goal of reducing or eliminating the need to chew the food); and safety measures included aspiration precautions (measures to prevent materials such as food, fluid, saliva, or foreign objects from entering the lungs). The plan of care failed to be individualized to include patient-specific interventions or measurable outcomes/goals to address the patient's primary diagnosis of moderate protein-calorie malnutrition, or other diagnoses of PVD, ALS, COPD, heart failure, dysphagia, or diverticulosis; or risk of aspiration.

The clinical record failed to evidence the patient received a nursing visit during the week of 7/02/2022.

A physician order dated 6/28/2022 was received from Entity 5 (a wound clinic) on 7/26/2022, indicating the patient had 2 wounds on the left lower leg, each with treatment orders. The plan of care failed to include the patient had 2 wounds, or the patient was seen and received treatment orders from Entity 5.

A physician order dated 7/12/22 was received from Entity 5 (a wound clinic) on 7/25/2022, which indicated both left lower leg wounds originated on 5/28/2022 subsequent to trauma (the patient hit her leg on a magazine rack), the patient's primary care physician ordered oral antibiotics (to treat infection) the week of 6/19/2022, and as of 7/12/2022, one of the wounds was healed.

During an interview on 7/21/2022 at 12:46 PM, the clinical manager indicated the certification period began on a Saturday, so no skilled nursing visit was made during the first week of the certification period; and information for Entity 5 should be on the plan of care.

	<p>6. Clinical record review for Patient #5 was completed on 7/26/2022. A review of the plan of care for the certification period of 7/11/2022 - 9/08/2022, indicated the patient's primary diagnosis was COVID-19, and other diagnoses included pneumonia due to COVID-19, diabetes, HTN, and severe chronic (ongoing) kidney disease; and the ordered diet was heart healthy/1800 calorie diabetic. The plan of care failed to be individualized to include patient-specific interventions or measurable outcomes/goals to address the patient's primary diagnosis of COVID-19, or other diagnoses of diabetes, HTN, severe chronic kidney disease, or the patient-specific diet.</p> <p>During an interview on 7/21/2022 at 1:16 PM, the clinical manager indicated she had a separate order for the labs drawn on 7/11/2022, and the order was not on the plan of care; and the plan of care did not address patient-specific diagnoses or 1800-calorie diabetic diet.</p> <p>17-13-1(a)</p>			
G0574	<p>Plan of care must include the following</p> <p>484.60(a)(2)(i-xvi)</p> <p>The individualized plan of care must include the following:</p> <ul style="list-style-type: none"> <li>(i) All pertinent diagnoses;</li> <li>(ii) The patient's mental, psychosocial, and cognitive status;</li> <li>(iii) The types of services, supplies, and equipment required;</li> <li>(iv) The frequency and duration of visits to be made;</li> <li>(v) Prognosis;</li> </ul>	G0574	<p>POC requirements</p> <p>Education will be provided to all clinicians on the Medicare Conditions of Participation requirement for the elements on the plan of care based on the comprehensive assessment and includes all interventions required to meet the patient outcomes and goals. This will be the responsibility of the DON and completed on 8/15/22. See Document A.</p> <p>To begin 9/1/22, an audit of 25% of average daily census will</p> <p>be completed to ensure that the plan of care includes all required elements, the plan of</p>	2022-09-01

<p>(vi) Rehabilitation potential;</p> <p>(vii) Functional limitations;</p> <p>(viii) Activities permitted;</p> <p>(ix) Nutritional requirements;</p> <p>(x) All medications and treatments;</p> <p>(xi) Safety measures to protect against injury;</p> <p>(xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.</p> <p>(xiii) Patient and caregiver education and training to facilitate timely discharge;</p> <p>(xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;</p> <p>(xv) Information related to any advanced directives; and</p> <p>(xvi) Any additional items the HHA or physician or allowed practitioner may choose to include.</p> <p>Based on observation, record review, and interview, the registered nurse (RN) failed to ensure the patient s plan of care included 1 or more of the following: all pertinent diagnoses, the patient s psychosocial status, supplies, and/or equipment required, nutritional requirements, all treatments, safety measures to protect against injury, patient-specific education, information related to any advanced directives, or any additional items the agency chose to include, per its own policy, for 5 of 5 active records reviewed (#1, 2, 3, 4, 5).</p> <p>Findings include:</p> <p>1. An undated agency policy received on 7/19/2022 titled Plan of Care stated, ... The plan of care shall include ... Diagnoses/patient problems ... Surgical procedures ... Nutritional requirements/diet ... Treatments ... Safety measures to protect against injury ... duration of visits ... Any other appropriate patient-specific items ....</p>		<p>care is individualized and based on the comprehensive assessment, orders for all treatments provided and at recertification the plan of care is updated to include all active interventions and goals. This will be completed monthly x 3 months and if 100% compliance is maintained then will be decreased to quarterly x 2 quarters. If the audit would be less than 100% compliant then frequency will be increased to monthly. This is the responsibility of the DON and will be reported to the QAPI.</p>	
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2. An undated agency policy received on 7/22/2022 titled Advance Directives stated, ... If the advance directive does not identify the wish to withhold resuscitation and/or there is no physician order to do so, [agency] staff will initiate CPR [cardiopulmonary resuscitation] in event of Cardiopulmonary Arrest [absence of heart beat/voluntary breathing] and call 911 ....

3. A home visit was observed at Entity 9 (an assisted living facility [ALF]), with RN 1 and Patient #1 on 7/18/2022 at 10:00 AM. During this visit, observed the patient was edentulous (which makes chewing food difficult).

Review of a document received from Entity 9 on 7/18/2022 for date range 5/01/2022 7/31/2022, titled Medication Review Report included a section titled Dietary-Diet , which indicated the patient s diet was no concentrated sweets (NCS) (general diabetic diet which avoids sugar intake, without specific caloric limitation), and mechanical soft consistency (a diet that involves only foods that are physically soft, with the goal of reducing or eliminating the need to chew the food).

During an interview on 7/21/2022 at 11:15 AM, the clinical manager indicated the ALF provided the patient 24 hour supervision for safety, administered medications, provided and monitored meals/intake, and provided transportation; and in absence of advance directives (end of life treatment wishes), agency staff would consider the patient a full code and initiate CPR/call 911.

Clinical record review for Patient #1 was completed on 7/26/2022. A document dated 6/03/2022, for certification period 6/04/2022 8/02/2022, titled Home Health Certification and Plan of Care .... , indicated the patient s diet was an 1800 calorie restricted diabetic, heart healthy diet. The plan of care failed to include the patient s current diet as provided

by the ALF (NCS, mechanical soft) , safety measures included 24 hour supervision, and psychosocial needs included transportation via ALF for appointments. The plan of care also included a section titled Advanced [sic] Directives , which indicated the patient had no treatment preferences, but failed to indicate the patient was a full code .

4. A home visit was observed with Patient #2 and physical therapist (PT) 1 on 7/18/2022 at 3:00 PM. During this visit, the patient indicated she was getting into bed one night, and when she put her leg up onto the bed, she heard a very loud pop , a spontaneous fracture of her left femur (thigh bone), which required surgical intervention.

Clinical record review for Patient #2 was completed on 7/26/2022. A document dated 6/21/2022, titled ... Start of Care (a comprehensive assessment), indicated the patient had surgery to repair a broken femur bone, and had a surgical incision; and the patient experienced depression.

A document dated 6/21/2022, for certification period 6/21/2022 8/19/2022, titled Home Health Certification and Plan of Care .... , indicated the patient s diagnoses included osteoporosis (a condition in which bones become weak, brittle, and spontaneously break) and depression; and skilled nursing was ordered weekly for 4 weeks. The plan of care failed to include specific information about the patient s surgical procedure, patient-specific education related to osteoporosis or depression, or the patient was a full code .

During an interview on 7/21/2022 at 12:00 PM, the clinical manager indicated the plan of care did not include teaching for depression or osteoporosis, and did not include the patient s code status as a full code .

5. A home visit was observed with Patient #3

and the alternate clinical manager on 7/18/2022 at 12:50 PM. During this visit, the patient indicated she had a stroke in 2017, which left her with limited movement on her left side, and she had a stent placed in May 2022, in her left upper leg; and, she had a history of blood clots, she currently had a blood clot in her left leg, she had pain in her left groin and leg (from surgery), and pain in her left shoulder and left arm (from old stroke). Observed the patient s lower legs with tubi-grips (elastic tubular medical bandage, which comes in different sizes and levels of compression) applied from knees down to toes.

A document dated 6/23/2022, for certification period 6/28/2022 8/26/2022, titled Home Health Certification and Plan of Care ..., failed to include diagnoses of stroke with left sided impairment, pain to the left groin and leg, pain in the left shoulder and left arm, or history of, and current blood clot(s); indicated the patient had stent placement to the left upper leg, and developed a blood clot to the area , but failed to include when the surgical procedure occurred, when the blood clot developed, or the anatomical location of the blood clot; orders included skilled nursing to educate on non-pharmacological treatments of pain relief, but failed to specify the non-pharmacological treatments; failed to include other treatments included use of tubi-grips, with patient-specific size, or directions for use; failed to include patient-specific education for stroke or blood clots; and failed to include the patient s code status.

Documents dated 5/05/2022, 5/12/2022, 5/19/2022, 5/26/2022, 6/02/2022, 6/09/2022, and 6/16/2022, titled Skilled Nurse Visit , stated ... Patient is non-compliant with checking blood sugars; [person 10, the patient s certifying physician] already aware .... The plan of care failed to include the patient s psychosocial status of non-compliance with self-checking blood sugars, which could negatively affect patient s health outcome.

During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the agency did not have medical records for the patient's stent placement or subsequent complications, the plan of care should include patient-specific education, the plan of care did not include orders for the use of tubi-grips, but an order was received on 6/23/2022. When queried if orders from the previous certification period should be included on the current plan of care, the clinical manager indicated they should be.

6. Clinical record review for Patient #4 was completed on 7/26/2022. A document received from Entity 5 (a wound clinic) on 7/26/2022, dated 6/28/2022, titled "Physician Orders Details" indicated the patient had 2 wounds on the left lower leg, each with treatment orders.

A document dated 6/27/2022, for certification period 7/02/2022 - 8/30/2022, titled Home Health Certification and Plan of Care ..., indicated the patient's primary diagnosis was moderate protein-calorie malnutrition (nutritional status in which reduced availability of nutrients leads to changes in body composition and function), other diagnoses included presence of a g-tube (a tube inserted into the stomach for administration of nutrition, fluids, and/or medications), amyotrophic lateral sclerosis (ALS) (a progressive disease, characterized by a degeneration of motor nerve cells in the brain and spinal cord, which leads to loss of motor function), and an abrasion to the left lower leg. The plan of care failed to include a diagnosis for the second wound on the left lower leg, or treatment to the wound; equipment included g-tube supplies; wound care supplies; patient specific education related to the progression of ALS; or the patient's code status.

During an interview on 7/21/2022 at 12:46 PM, the clinical director indicated wound clinic orders, all treatments, and supplies/equipment should be on the plan of care,

	<p>5. Clinical record review for Patient #5 was completed on 7/26/2022. A document dated 7/11/2022 titled ... Start of Care indicated the patient experienced exhaustion, and was short of breath with exertion; and the RN obtained a blood sample for lab testing, ordered by person 11 (the patients certifying physician).</p> <p>A document dated 7/11/2022, for certification period 7/11/2022 9/08/2022, titled Home Health Certification and Plan of Care .... , indicated the patient s primary diagnosis was COVID-19, other diagnoses included hypertension (HTN) (high blood pressure), and severe chronic (ongoing) kidney disease. The plan of care failed to include orders for the RN to obtain a blood specimen, which labs were ordered, or patient-specific education for HTN, chronic kidney disease, COVID-19, or energy conservation due to exhaustion/shortness of breath; or the patient s code status.</p> <p>During an interview on 7/21/2022 at 1:16 PM, the clinical manager indicated she had a separate order for the labs drawn on 7/11/2022 (located in the patient s paper chart), and the order was not included on the plan of care; and the plan of care did not address patient-specific diagnoses.</p> <p>17-13-1(a)(1)(B) 17-13-1(a)(1)(C ) 17-13-1(a)(1)(D)(ii, viii, ix, x, xiii)</p>			
<p>G0580</p>	<p>Only as ordered by a physician</p> <p>484.60(b)(1)</p> <p>Drugs, services, and treatments are administered only as ordered by a physician or allowed practitioner.</p> <p>Based on observation, record review, and interview, the registered nurse failed to</p>	<p>G0580</p>	<p>Treatment orders</p> <p>Education will be provided to all staff on the need to have interventions on the plan of care for all treatment provided and if treatment changes are required then a verbal order is necessary. All verbal orders will become part of the plan of care and at</p>	<p>2022-09-01</p>

<p>administer treatments only as ordered by a physician or nurse practitioner (NP) for 2 of 3 clinical records reviewed with home visits (#1, 3).</p> <p>Findings include:</p> <p>1. An undated agency policy received on 7/19/2022, titled Plan of Care , stated, ... Physician orders are obtained prior to the initiation of care and with any changes in the plan of care ... plan of care must include services rendered by a registered nurse ... [to] include ... Treatments ... specific procedures to be performed ... Verbal orders will indicate updates to the plan of care during the episode. At the time of recertification all verbal orders will be included inthe recertificatrion plan of care ....</p> <p>2. An undated agency policy received on 7/22/2022, titled "Clinical Records", stated, "... The clinical records shall contain ... Physician orders including ... treatment ... orders ...."</p> <p>3. Clinical record review for Patient #1 was completed on 7/26/2022. A document received on 7/19/2022 at 1:17 PM, dated and signed by RN 1 on 7/15/2022 at 7:00 AM, titled Physician Order , stated ...Perform wound care to right and left lower leg wounds. Cleanse wounds with [normal saline (sterile salt water)] ... apply thin coat amount [sic] of ... Santyl [an ointment used to debride dead skin/tissue from wounds; care should be taken to apply only to wound bed(s), not to surrounding skin] ... to all wounds ....</p> <p>An additional document received on 7/19/2022 at 1:17 PM, dated and signed by RN 1 on 7/15/2022 at 7:00 AM, titled Physician Order , stated ... Discontinue BALSAM PERU &amp; CASTOR OIL [a topical to reduce odor, provide wound protection, and a moist wound environment] ....</p> <p>A document received on 7/19/2022 at 1:17</p>		<p>recertification the plan of care will include all active interventions. This will be responsibility of the DON and completed on 8/15/22. See document A.</p> <p>Education was provided to all nursing staff on home health assessments, documentation and coordination of care based on best practice and Medicare Conditions of Participation including wound care order requirements on 7/26/22 by Diane Link RN See document C.</p> <p>MHA consultant All nursing staff were in attendance.</p> <p>All nursing staff were assigned to complete online 30 hours CEU education on wound care by snfwoundcare.thinkific.com with completion by 8/10/22. See Document D.</p> <p>To begin 9/1/22, an audit of 25% of average daily census will be completed to ensure that the plan of care includes all required elements, the plan of care is individualized and based on the comprehensive assessment, orders for all treatments provided and at recertification the plan of care is updated to include all active interventions and goals. This will be completed monthly x 3 months and if 100% compliance is maintained then will be decreased to quarterly x 2 quarters. If the audit would be less than 100% compliant then frequency will be increased to monthly.</p>	
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	<p>PM, dated and signed by RN 1 on 7/15/2022, titled Skilled Nurse Visit indicated a visit was made on 7/15/2022 from 6:30 AM 7:15 AM. The document indicated RN 1 performed wound care to both lower legs, which included application of Balsam Peru &amp; Castor Oil ointment. RN 1 provided discontinued wound care, and failed to provide new wound care to include the use of Santyl, as ordered during this home visit.</p> <p>A home visit was observed on 7/18/2022 at 10:00 AM with Patient #1 and RN 1. RN 1 cleansed both lower legs with saline (sterile salt water), applied santyl ointment onto a gauze sponge, and applied the santyl in a generalized, rubbing/wiping motion all over the intact, darkened, macerated, and scabbed skin; and to the open wounds on each lower leg; then both legs were covered with non-adherent pads, ABD pads (a highly absorbent dressing that provides padding and protection for large wounds), wrapped with rolled gauze, secured with paper tape, and tubigrips (elastic, tubular support bandages) were applied over the dressings. Upon completion of wound care, the patient indicated her left leg hurt, to which RN 1 replied to the patient, and indicated the pain was due to the Santyl , and that meant it (Santyl) was doing its job .</p> <p>During an interview on 7/20/2022 at 1:53 PM, Person 2 (NP for Person 1, the patient s certifying physician) indicated the Santyl should not be applied in a generalized fashion over the entire lower extremities, it (Santyl) was used to remove flaky, dead skin and scabs, and she hoped he didn t do that.</p> <p>A document received 7/21/2022, dated and signed by RN 1 on 7/18/2022, titled Skilled Nurse Visit , stated, ... Treatment performed ... apply a small amount of Santyl Ointment to all wound beds .... RN 1 applied the ointment all over the lower extremities, not only to the wound beds.</p>		<p>This is the responsibility of the DON and will be reported to the QAPI.</p>	
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	<p>An additional home visit was observed with Patient #1, the clinical manager, RN 1, and Person 2, on 7/22/2022 at 9:00 AM. Observed person 2 use a cotton-tipped applicator to apply Santyl to the wound beds and scabbed areas, and indicated the Balsam Peru &amp; Castor Oil ointment should be applied to the surrounding dry skin.</p> <p>4. A home visit was observed with Patient #3 and the alternate clinical manager on 7/18/2022 at 12:50 PM. Observed the alternate clinical manager apply tubigrips (elastic tubular medical bandage, which comes in different sizes and levels of compression) to both lower legs, from the knees down to the toes.</p> <p>Clinical record review for Patient #3 was completed on 7/26/2022. A document dated and signed by the alternate clinical manager on 6/23/2022, titled Home Health Certification and Plan of Care .... , for certification period 6/28/2022 8/26/2022, failed to include a treatment order for the skilled nurse to apply tubigrips to the patient s lower legs.</p> <p>During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the tubigrip treatment order was not on the plan of care (for certification period 6/28/2022 8/26/2022), and indicated there was an order for the use of tubigrips dated 6/23/2022. When queried if orders from the previous certification should be included on the new plan of care as an active order, the clinical manager indicated they should.</p> <p>17-13-1(a)</p>			
<p>G0590</p>	<p>Promptly alert relevant physician of changes</p> <p>484.60(c)(1)</p>	<p>G0590</p>	<p>Physician notification</p> <p>Education was provided to all nursing staff on home health assessments, documentation</p>	<p>2022-09-01</p>

	<p>The HHA must promptly alert the relevant physician(s) or allowed practitioner(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.</p> <p>Based on observation, record review, and interview, the registered nurse failed to inform the patient's relevant physician for 1 of 2 home visits observed with patients who experienced <b>a change condition (#3)</b>.</p> <p><b>Findings include:</b></p> <p>An undated agency policy received on 7/19/2022, titled Plan of Care , stated, ... Changes in patient status ... are promptly reported to the physician ....</p> <p>An undated agency policy received on 7/22/2022, titled Skilled Nursing Services stated, ... Inform the physician and other appropriate medical personnel of changes in the patient s condition ....</p> <p>A home visit was observed with Patient #3 and the alternate clinical manager on 7/18/2022 at 12:50 PM. During this time, the patient indicated she had a stent placed (a tiny expandable metal mesh coil, inserted surgically into a newly opened area of the artery to help keep the artery from narrowing or closing again) to her left upper leg, in the middle of May, 2022, her left leg hurt, there was a bruise in her left groin (procedural insertion site of stent), and she developed a blood clot sometime after the procedure. The site was observed, which revealed a swollen (baseball size) area over the healed incision line. The patient also indicated the procedure was performed by Person 3 (a vascular physician). Also, during this visit, observed a "pin size" hard scab on the patient's left outer ankle over the boney area, and the surrounding skin was dark pink. The alternate clinical manager indicated the area "comes and goes".</p>		<p>and coordination of care based on best practice and Medicare Conditions of Participation including coordination of care with physician and clinicians on changes in patient status on 7/26/22 by Diane Link RN, MHA consultant All nursing staff were in attendance. See Document B.</p> <p>To begin on 9/1/22, An audit of 25% of average daily census will</p> <p>be completed to ensure that coordination of care between clinicians and physicians occurs for all changes in patient condition. This will be conducted monthly x 3 months and if 100% compliance is obtained then will be decreased to quarterly. This is the responsibility of the DON and will be reported to the QAPI.</p>	
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	<p>Clinical record review for Patient #3 was completed on 7/26/2022. A document dated and signed by the alternate clinical manager 7/18/2022 titled "Skilled Nurse Visit" stated "... Diabetic foot inspection ... with no problem identified ...." The document indicated Person 10 (the patient s certifying physician) was notified for pain to the patient s left arm, and bruising to the right leg status post traumatic injury from a dropped object hitting the leg; failed to indicate Person 10 was notified of the pain to the left groin, swelling to left groin, or area observed to the left outer ankle; failed to indicate Person 3 was notified pain to the left groin, or swelling to left groin.</p> <p>During an interview on 7/20/2022 at 9:31 AM, Person 4 (office staff for Person 3) indicated patient #3 had an angiogram with stent placement on 5/17/2022, a 2 week follow up visit on 6/1/2022, was seen 6/15/2022 for complaint of a swollen left foot, and the physician's office was unaware the patient had home health services.</p> <p>During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the agency did not have any clinical documents from Person 3's office, and the alternate clinical manager should report findings related to the surgery to Person 3.</p> <p>17-13-1(a)(2)</p>			
G0592	<p>Revised plan of care</p> <p>484.60(c)(2)</p> <p>A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals</p>	G0592	<p>Revision to POC</p> <p>Education was provided to all clinicians on the need to write a 60 day summary of care provided for prior certification period at the time of recertification. This summary will include documentation of progress towards goals including measurement of wounds,</p>	2022-09-01

<p>identified by the HHA and patient in the plan of care.</p> <p>Based on record review and interview, the registered nurse (RN) failed to follow agency policy to ensure the patient s revised plan of care included a summary of the patient s condition during the previous certification period, or information concerning the patient s progress toward the outcomes and goals, for 5 of 5 records reviewed when more than 1 certification period was provided (#1, 3, 4, 7, 8).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. An undated agency policy received on 7/19/2022, titled Plan of Care , stated, ... The plan of care shall be reviewed at least every 60 days ... review shall include ... Effectiveness according to patient outcomes and response to care ... The physician will be provided with a summary of the patient s condition during the previous plan of care, current condition ....</li> <li>2. Clinical record review for Patient #1 was completed on 7/26/2022, start of care date 2/04/2022, for certification period 6/04/2022 8/02/2022. A document dated 6/03/2022, titled Home Health Certification and Plan of Care (Recertification of Continuing Need for Care) , indicated skilled nursing was provided for patient assessments, wound treatment to 2 wounds, and skilled teaching. The plan of care failed to include a summary of the patient s condition during the previous certification period (such as wound measurements at the beginning and end of the certification period, vital sign ranges, or falls) or information concerning the patient s progress toward the outcomes and goals.</li> </ol> <p>During an interview on 7/21/2022 at 11:15 AM, the clinical manager indicated a lot of stuff was auto-populated on recertification plans of</p>		<p>pertinent changes in patient condition (such as surgeries or treatment changes) any medication changes and any community based care providers initiated since SOC. This education will be the responsibility of the DON and completed by 8/15/22. See Document A.</p> <p>To begin 9/1/22, an audit of 25% of recertifications include documentation of 60 day summary that includes a summary of care, progress towards goals and treatment/medication changes or community based care that have occurred during prior certification period. This audit will be done monthly x 3 months then reduced to quarterly if 100% compliance is achieved. This is the responsibility of the DON and will be reported to the QAPI.</p>	
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software also auto-populated an end of episode summary, and it was not part of the patient's plan of care.

3. Clinical record review for Patient #3 was completed on 7/26/2022, start of care date 12/30/2021, for certification period 6/28/2022 8/26/2022. A document dated 6/23/2022, titled Home Health Certification and Plan of Care (Recertification of Continuing Need for Care), indicated skilled nursing was provided for patient assessments, and skilled teaching; and the patient had a surgical procedure during the previous certification period. The plan of care failed to include a summary with the date the surgical procedure was performed, who performed the procedure, or any follow up visits attended by the patient; or information concerning the patient's progress toward the outcomes and goals.

During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the 60-day summary was not on the plan of care.

4. Clinical record review for Patient #4 was completed on 7/26/2022, start of care date 1/03/2022, for certification period 7/02/2022 7/25/2022. A document dated 6/20/2022, titled Skilled Nurse Visit, indicated the patient sustained a new abrasion to the left lower leg.

A document dated 6/20/2022, titled Infection Log stated ... Follow-Up Comments ... SN came to next visit on 6/27/2022 ... Wound to LLE [left lower extremity] has increased in size ....

A document received from Entity 5 (a wound clinic) on 7/25/2022, dated 7/12/2022, titled "Physician Orders Details" included an entry dated 6/28/2022, which indicated the patient's primary care physician ordered oral antibiotics (to treat infection) the week of 6/19/2022, and the patient still had a few left to take (as of 6/28/2022).

A document received from Entity 5 (a wound clinic) on 7/26/2022, dated 6/28/2022, titled "Physician Orders Details" indicated the patient had 2 wounds on the left lower leg, each with treatment orders.

A document received from Entity 5 (a wound clinic) on 7/25/2022, dated 7/12/2022, titled "Physician Orders Details" indicated both left lower leg wounds originated on 5/28/2022 subsequent to trauma (patient hit her leg on a magazine rack), the patient's primary care physician ordered oral antibiotics (to treat infection) the week of 6/19/2022, and as of 7/12/2022, one of the wounds was healed. The remaining wound was worse, with a large amount (67-100%) necrotic (dead) tissue and slough (yellow/white material in the wound bed, consists of dead cells that accumulate in the wound drainage), and topical antibiotic ointment was ordered.

A document dated 6/27/2022, titled Home Health Certification and Plan of Care (Recertification of Continuing Need for Care), indicated skilled nursing was provided for patient assessments, wound care to 1 wound on the left lower leg, and skilled teaching; and stated, ... Hard scrap [sic] on LLE; size of nickle [sic], redness around area .... The plan of care failed to include a summary with the date the injury occurred, the wound became infected and treated with antibiotics, a second wound was identified by the wound clinic, or the patient was seen at a wound clinic; or information concerning the patient s progress toward the outcomes and goals.

During an interview on 7/21/2022 at 12:46 PM, the clinical manager indicated she was unaware the patient went to the wound clinic, and the plan of care did not have a summary, the EMR auto generated a separate form.

5. Clinical record review for Patient #7 was

	<p>2/15/2022, for certification period 4/16/2022 6/14/2022. A document dated 4/12/2022, titled Home Health Certification and Plan of Care (Recertification of Continuing Need for Care) , indicated skilled nursing was provided for patient assessments, and skilled teaching. The plan of care failed to include a summary of care provided during the previous certification period, or information concerning the patient s progress toward the outcomes and goals.</p> <p>During an interview on 7/21/2022 at 3:36 PM, the clinical manager indicated the end of episode summary was not on the plan of care.</p> <p>6. Clinical record review for Patient #8 was completed on 7/26/2022, start of care date 3/18/2021, for certification period 5/12/2022 7/10/2022. A document dated 5/10/2022, titled Home Health Certification and Plan of Care (Recertification of Continuing Need for Care) , indicated skilled nursing was provided for patient assessments, wound care for 3 wounds, and skilled teaching. The plan of care failed to include a summary of care provided during the previous certification period, or information concerning the patient s progress toward the outcomes and goals.</p> <p>During an interview on 7/21/2022 at 3:14 PM, the clinical manager indicated the plan of care did not include a summary of the patient s condition from the previous certification period.</p>			
<p>G0687</p>	<p>COVID-19 Vaccination of Home Health Agency staff</p> <p>484.70 (d)-(d)(3)(i-x)</p> <p>§ 484.70 Condition of Participation: Infection Prevention and Control.</p> <p>(d) Standard: COVID-19 Vaccination of Home Health Agency staff. The home health agency</p>	<p>G0687</p>	<p>COVID 19</p> <p>The COVID -19 Vaccination policy was updated to include COVID 19 vaccination status, exemption for medical or religious means and measures the agency will put into place for those individuals that are exempt from the vaccination requirement. This is the</p>	<p>2022-09-05</p>

<p>(HHA) must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.</p> <p>(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following HHA staff, who provide any care, treatment, or other services for the HHA and/or its patients:</p> <ul style="list-style-type: none"> <li>(i) HHA employees;</li> <li>(ii) Licensed practitioners;</li> <li>(iii) Students, trainees, and volunteers; and</li> <li>(iv) Individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement.</li> </ul> <p>(2) The policies and procedures of this section do not apply to the following HHA staff:</p> <ul style="list-style-type: none"> <li>(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section; and</li> <li>(ii) Staff who provide support services for the HHA that are performed exclusively outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section.</li> </ul>		<p>responsibility of the Administrator and will be completed by 9/5/22</p> <p>Education will be provided to all staff on the new policy by 9/5/22 by the Administrator.</p>	
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(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the HHA and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an

vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the HHA has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the HHA's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

Based on record review and interview, the agency failed to ensure its **policies and procedures for COVID-19 Vaccination of Home Health Agency staff included all required elements.**

Findings include:

An agency policy updated 1/15/2022 failed to include a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who were not fully vaccinated for COVID-19; a process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC; a process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law; a process for tracking and securely documenting information provided by those staff who have requested, and for whom the HHA has granted, an exemption from the staff COVID-19 vaccination requirements; a process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications, and a statement by the authenticating practitioner recommending that the staff member be exempted from the HHA's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications; process for ensuring the tracking and secure documentation of the

	<p>vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; or contingency plans for staff who are not fully vaccinated for COVID-19.</p> <p>During an interview on 7/26/2022 at 3:26 PM, the administrator indicated the agency's COVID-19 policies did not include all currently required contents.</p>			
<p>G0700</p>	<p>Skilled professional services</p> <p>484.75</p> <p>Condition of participation: Skilled professional services.</p> <p>Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in §409.44 of this chapter, and physician or allowed practitioner and medical social work services as specified in §409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.</p> <p>Based on observation, record review, and interview, the registered nurse (RN) failed to assess the patient's wounds/incision(s), or ensured the patient's needs were addressed and met, which led to potential likelihood and/or actual serious harm, for 4 of 4 clinical records reviewed with patients who had wound(s)/incision(s) (#1, 3, 4, 8). This practice had the potential to affect all agency patients with wounds, or those at risk for wounds.</p> <p>Findings include:</p> <p>1. An undated policy received 7/22/2022 at</p>	<p>G0700</p>	<p><b>All patients with wounds will have picture of wound taken weekly via I-pad and uploaded to Axxess software at time of visit.</b></p> <p><b>Nicole Kennedy RN/DON informed all nursing clinicians on requirement for wound photography weekly starting week of 7/25/2022. This was implemented on 7/22/2022</b></p> <p><b>Completed by 7/27/22</b></p> <p><b>5/6 completed by 7/26/22</b></p> <p><b>1 to be completed by 7/27/22 per pt request</b></p> <p><b>All active patients will have comprehensive assessment completed by Director of Nursing to identify current patient status, identify if there are patient care needs</b></p>	<p>2022-07-26</p>

11:49 PM, titled "Director of Patient Services/Agency Supervisor", indicated the clinical manager (an RN) was responsible to ensure safe and adequate patient care was provided, and to monitor patient services to ensure professional standards of care were met.

2. An undated policy received 7/22/2022 at 11:29 AM, titled "Skilled Nursing Services", stated, "... Skilled nursing services ... To ensure that patients receive competent nursing care according to their individual needs ... provide services ... within the context of the patient's unique medical condition ... make necessary revisions/reassessments according to changing patient needs ... Skilled services include ... observation and assessment relate to the patient's problems ...."

3. Clinical record review for patient #8 was completed on 7/26/2022. A document dated and signed by RN 1 on 5/10/2022 titled "... Recertification" indicated the patient had 3 stasis ulcers (wounds caused by fluid buildup in the skin/tissues due to poor venous circulation), with 1 on the right heel (5.0 cm x 3.0 cm x 0.75 cm; minimum drainage, and no presence of necrotic tissue), 1 on the left outer ankle (1.0 cm x 1.0 cm x 0.25 cm; minimum drainage, and no presence of necrotic tissue), and 1 to the left heel (no measurements or description of the wound included).

Documents dated and signed by RN 1 on 5/17/2022 and 5/24/2022 titled "Skilled Nurse Visit" indicated all 3 wounds had no odor, minimal drainage, and no necrotic tissue was present.

A document dated and signed by RN 1 on 6/1/2022 titled "... Transfer" indicated the patient was hospitalized for an "unknown" reason.

Documents received from entity 7 (a hospital)

**not being addressed, address any patient care needs and update plan of care as needed. Patient care visits will be prioritized with wound care patients being highest priority then remainder of patients prioritized by risk of developing complications.**

**Nicole Kennedy RN/DON will review charts and create priority risk list on 7/25/22 and provide to Administrator and consultant.**

**Nicole Kennedy RN /DON will perform patient care assessment on every patient with wounds by end of day 7/27/22. Currently 6 active wound care patients. Remaining patient visits will be completed by 7/29/2022.**

**DON will discuss findings with Administrator at end of each visit day.**

**7/25/22 – completed patient risk levels as follows: 6 wound care patients, 10 high risk patients and 18 remaining patients.**

**Initiated visits on wound care patients on 7/25/22 with plan completion by 7/26/22. Then**

on 7/20/2022 indicated the patient presented to the ED (emergency department) on 5/29/2022, with complaint he did not feel well, decreased appetite, weakness, and fall. While in the ED, the patient developed a fever, and the right heel presented with necrosis of skin and deep tissue, extending down to the heel bone, gangrenous with gas in tissues (a bacterial infection which produces toxins that release gas and cause tissue death, a life-threatening condition), osteomyelitis (infection in bone), and sepsis (the body's response to widespread inflammation/infection, potentially life-threatening). The patient received intravenous (IV) antibiotics, surgical intervention, consult for partial amputation, and was discharged to entity 8 (a long-term acute care hospital [LTAC]) on 6/10/2022, for 6 weeks of IV antibiotic treatment for osteomyelitis of both feet.

During an interview on 7/21/2022 at 3:14 PM, the clinical manager indicated she didn't know why patient #8 was hospitalized, the agency's protocol included requesting hospital paperwork only after a patient was discharged from a facility, and the nurse's notes failed to indicate the patient had necrotic wounds, or signs of infection were present.

4. A home visit was observed on 7/18/2022 at 10:00 AM with patient #1 and RN 1. Upon removal of wound dressings, both of the patient's lower legs had large areas of very darkened skin (not within normal color for this patient), areas of white macerated tissue (indicative of excessive moisture/drainage), and multiple (greater than 4-6 on each leg) open, draining wounds on all aspects of the lower legs. The wounds and darkened skin comprised greater than half of each lower leg. RN 1 indicated the darkened skin was not present last skilled nursing visit (on 7/15/2022), and the multiple wounds "opened and closed". Two additional open areas were observed on the top of the patient's right foot, which presented with absence of top layers of skin, pink wound beds, and each no greater than 1 cm (centimeter) in diameter. The RN failed to measure, cleanse, or provide wound

**remaining high risk patients and current patient visits completed by 7/29/22**

**Comparison of patient assessment completed by DON with current chart documentation for each patient will be completed to identify any additional issues or staff education needs.**

**Nicole Kennedy RN is responsible for completion of chart review with results documented and provided to administrator by 7/29/22.**

**Completion by 7/29/22**

**Education will be provided to all nursing staff on home health comprehensive assessments, documentation and coordination of care based on best practice and Medicare Conditions of Participation. This will be provided by consultant Diane Link RN, MHA on 7/26/2022 at 9am via zoom conference. 9am-1pm via zoom conference.**

**Administrator is responsible for ensuring completion of education.**

care to the wounds on the top of the right foot.

An additional home visit was observed on 7/20/2022 at 9:00 AM with patient #1. Person 2 (Nurse practitioner [NP], colleague of person 1, the patient's certifying physician), RN 1, and the clinical manager were present. Person 2 indicated the darkened skin and multiple wounds on the patient's lower legs was ongoing for "months", and indicated venelex (an ointment to protect and deodorize wounds) should be used on the 2 wounds noted on the top of the patient's right foot, and to areas of intact, dry skin on the patient's lower extremities.

A document received 7/19/2022, dated 7/15/2022, titled "Skilled Nurse Visit", indicated the patient had 1 wound to the lower right leg, and 1 wound to the lower left leg. The document failed to indicate presence of any other wounds or lower extremity discoloration.

During an interview on 7/22/2022 at 12:01 PM, during review of the home visit with patient #1 conducted on 7/20/2022, the administrator queried the clinical manager about the patient's darkened skin, to which the clinical manager stated "... it was a little darker than normal".

5. A home visit was observed with patient #3 and the alternate clinical manager on 7/18/2022 at 12:50 PM. During this time, the patient indicated she had a stent placed (a tiny expandable metal mesh coil, inserted surgically into a newly opened area of the artery to help keep the artery from narrowing or closing again) to her left upper leg, in the middle of May, 2022, her left leg hurt, there was a bruise in her left groin (procedural insertion site of stent), and she developed a blood clot sometime after the procedure. The site was observed, which revealed a swollen (baseball size) area over the healed incision line. The patient also indicated the procedure was

**Completed by 7/26/22**

**Education will be provided to all nursing staff on basic wound assessment, wound care and documentation by Diane Link RN, MHA on 7/26/2022 at 9am via zoom conference.**

**Administrator is responsible for ensuring completion of education.**

**Completed 7/26/22**

**All nursing staff will be assigned to complete online 30 hours CEU education on wound care by snfwoundcare.thinkific.com Education must be started by 7/27/2022 and completed within 2 weeks.**

**Administrator is responsible for ensuring completion of education by nursing staff.**

**Completed by 8/10/22**

**100% review of all wound care patient's clinical documentation and wound photos submitted by staff will occur weekly.**

**DON is responsible for**

performed by person 3 (a vascular physician). Also, during this visit, observed a "pin size" hard scab on the patient's left outer ankle over the boney area, and the surrounding skin was dark pink. The alternate clinical manager indicated the area "comes and goes".

Clinical record review for patient #3 was completed on 7/26/2022. A document dated and signed by the alternate clinical manager 7/18/2022 titled "Skilled Nurse Visit" stated "... Diabetic foot inspection ... with no problem identified ...." The document failed to include documentation of the pain reported by the patient to her left groin, the swollen left groin incision, or presence of scab with dark pink surrounding skin on left outer ankle, all revealed during the 7/18/2022 home visit.

A document dated and signed by the alternate clinical manager on 6/23/2022, titled "... Recertification [a comprehensive assessment to recertify medicare home health services]" indicated the patient was diabetic, had peripheral vascular disease (impaired circulation of the lower extremities, which increases the chance of development of diabetic wounds) had stent placement to upper left leg, subsequently developed blood clot, swelling was present, and the patient was monitored closely by a physician. The document failed to indicate when the blood clot developed, the specific anatomical location of the blood clot, or which physician monitored it; or the RN assessed the pulse in the affected extremity, measured the diameter of the affected extremity, or provided patient education related to blood clots.

During an interview on 7/21/2022 at 12:30 PM, while reviewing patient #3's clinical record, the clinical manager indicated the agency did not have any clinical documents from person 4's office, the clinical record failed to indicate the alternate clinical manager assessed the patient's left groin incision during skilled nursing visits performed on 5/19/2022, 5/26/2022, 6/02/2022, 6/09/2022, 6/16/2022, or during the comprehensive reassessment

**and will document review completion and submit log to administrator weekly.**

**Ongoing (see below)**

**Director of Nursing will do joint visit with each nurse assigned a patient with wound (currently 6 patients) to observe assessment and documentation. If any issues are identified during supervisory visit they will be addressed at that time by DON and the nurse will be assigned additional education and additional supervisory visits weekly until 100% compliant.**

**DON will be responsible.**

**Completed by 8/5/22**

**All clinical staff that has deficient assessments or documentation identified during survey or during DON assessment visits will have one on one counseling**

**This is the responsibility of the DON.**

**Completed by 8/2/22**

**Clinical documentation review will be completed on 100% of**

visit conducted on 6/23/2022, and the alternate clinical manager should have provided patient education after the stent placement related to incision care, precautions, physical limitations, and potential complications.

During an interview on 7/20/2022 at 9:31 AM, person 4 (office staff for person 3) indicated patient #3 had an angiogram with stent placement on 5/17/2022, a 2 week follow up visit on 6/1/2022, was seen 6/15/2022 for complaint of a swollen left foot, and the physician's office was unaware the patient had home health services.

Review of a document received 7/21/2022 from person 4, dated 6/01/2022, titled "SOAP Note [person 3's physician visit note]", which indicated the patient was seen for a 2-week post-procedure follow up, had developed pain and swelling in the left groin with bruising, and swelling in the left foot.

Review of a document received 7/21/2022 from person 4, dated 6/15/2022, titled "SOAP Note", which indicated the patient still had some residual pain and swelling in the left groin area, and a "swollen foot".

6. Clinical record review for patient #4 was completed on 7/26/2022. A document dated and signed by the alternate clinical manager on 6/20/2022 titled "Skilled Nurse Visit" indicated the patient reported a scrape to the left lower extremity, with a small scab and slight redness around area, the physician was made aware, and no new orders were received.

A document dated and signed by the alternate clinical manager on 6/27/2022, titled "...Recertification" indicated the wound on the left lower extremity was an "abrasion" (scrape), which measured 2.1 cm (length) x 2.1 cm (width) x 2.1 cm (depth), and the surrounding tissue was red (worsened since last skilled

**all skilled nursing documentation visit including assessment and coordination of care with physician x 1 week through 8/10/22. If 100% compliance is reached, then will be decreased to 50% of visits x 1 week. If 100% compliance continues, then will be decreased to 25% clients monthly.**

**This will be completed by consultant and DON with reports sent weekly to Administrator. This will start with visits completed 7/25/22.**

**Ongoing**

	<p>nursing visit), and treatment orders were received.</p> <p>A document dated and signed by the alternate clinical manager on 6/27/2022 titled "Home Health Certification and Plan of Care" for certification period 7/02/2022 - 8/30/2022 indicated the patient had a wound on the left lower extremity, and treatment included the application of medihoney (a wound repair/antibacterial gel) daily by the skilled nurse and family.</p> <p>Documents requested and received 7/19/2022 titled "Skilled Nurse Visit", dated and signed by the alternate clinical manager on 7/04/2022 and 7/11/2022 failed to indicate the nurse assessed or measured the wound to the left lower extremity. The document dated 7/11/2022 indicated the patient was seen at a wound clinic, but failed to indicate when the patient was seen, or which wound clinic.</p> <p>A document received from entity 5 (a wound clinic) on 7/26/2022, dated 6/28/2022, titled "Physician Orders Details" indicated the patient had 2 wounds on the left lower leg, each with treatment orders. The patient's clinical record only indicated the presence of 1 wound.</p>			
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	<p>A document received from entity 5 (a wound clinic) on 7/25/2022, dated 7/12/2022, titled "Physician Orders Details" indicated both left lower leg wounds originated on 5/28/2022 subsequent to trauma (patient hit her leg on a magazine rack), the patient's primary care physician ordered oral antibiotics (to treat infection) the week of 6/19/2022, and as of 7/12/2022, one of the wounds was healed. The remaining wound was worse, with a large amount (67-100%) necrotic (dead) tissue and slough (yellow/white material in the wound bed, consists of dead cells that accumulate in the wound drainage), and topical antibiotic ointment was ordered. The clinical record failed to indicate presence of wound(s) until 6/20/2022.</p>			
<p>G0706</p>	<p>Interdisciplinary assessment of the patient</p> <p>484.75(b)(1)</p> <p>Ongoing interdisciplinary assessment of the patient;</p> <p>Based on record review and interview, the home health agency failed to ensure interdisciplinary assessment occurred for 1 of 1 clinical record reviewed for a patient who experienced a change in condition which required hospitalization (#6).</p> <p>Findings include:</p> <p>An undated agency policy received on 7/22/2022, titled "Clinical Records", stated, "... The clinical records shall contain ... Communications with the physician, other clinicians ...."</p> <p>Clinical record review for Patient #6 was completed on 7/26/2022, start of care date 1/17/2022, and discharge date 1/30/2022. A document dated 1/17/2022, titled Home Health Certification and Plan of Care , indicated the patient's primary diagnosis was Parkinson's disease (a progressive disease that</p>	<p>G0706</p>	<p>Education will be provided to all clinicians on the need to complete ongoing assessments, documentation of follow through on identified changes including communication with the interdisciplinary team and physician for changes in patient condition. Updated comprehensive assessments shall be completed for significant changes in condition. The DON is responsible for completion on 8/15/22. See document A.</p> <p>To begin 9/1/22, an Audit of 25% of average daily census of both active and discharge records will be completed</p> <p>to ensure that the documentation accurately reflects changes in patient condition and coordination/communication between Interdisciplinary members and physicians for changes.</p> <p>Any significant change in condition will have a comprehensive assessment. Documentation of follow up by RN/PT on any assessment changes reported. This audit will be done monthly x 3 months then reduced to quarterly when 100%compliance is achieved x 3 months. This is the responsibility of the DON and reported to</p>	<p>2022-09-01</p>

<p>affects the nervous system and the parts of the body controlled by the nerves), skilled nursing and physical therapy (PT) was ordered, the patient lived alone, and was recently released from the hospital after an exacerbation of Parkinson's disease which resulted in a fall, and the patient was on the floor for several hours after the fall.</p> <p>A document received on 7/22/2022 from entity 12 (a hospital), titled "Discharge Summary", indicated the patient was hospitalized 12/31/2021 - 1/14/2022, after a fall at home, was found to have dehydration and rhabdomyolysis (a breakdown of muscle tissue that releases a damaging protein into the blood), and subsequently underwent intensive rehabilitation.</p> <p>A document dated 1/17/2022, titled "... Start of Care" (initial comprehensive assessment) indicated the patient's risks included need for assistance with personal care, home safety risks (not further detailed), history of falls, and lived alone; and assessment findings included exhaustion, decline in physical function, and pain.</p> <p>A document dated 1/19/2022, titled "PT Evaluation", an assessment, did not indicate the patient wasn't feeling well.</p> <p>Documents dated 1/21/2022, 1/24/2022 and 1/26/2022, titled "Missed Visit", indicated physical therapy assistant (PTA) visits were missed due to the patient not feeling well, and PTA 2 notified PT (physical therapist) 1.</p> <p>A document dated 1/25/2022, titled "Skilled Nurse Visit", failed to indicate the nurse assessed the patient for ongoing complaint of "not feeling well". The clinical record failed to evidence interdisciplinary assessment occurred between the PTA, PT, and the skilled nurse.</p>		<p>QAPI.</p>	
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	<p>A document dated 1/30/2022, titled "... Transfer Discharge", indicated the patient was hospitalized for an exacerbation of Parkinson's disease.</p> <p>During an interview on 7/21/2022 at 1:40 PM, the clinical manager indicated she didn't see evidence of interdisciplinary communication/assessment between PT/PTA and the RN in the electronic medical record (EMR), and she didn't see that the nurse documented she was made aware the patient didn't feel well, or indicated the patient didn't feel well during the skilled nurse visit on 1/25/2022.</p> <p>17-12-2(g)</p>			
<p>G0714</p>	<p>Patient and caregiver education</p> <p>484.75(b)(5)</p> <p>Patient and caregiver education;</p> <p>Based on record review and interview, the home health agency failed to ensure the registered nurse (RN) provided the patient/caregiver with education based on the patient's current condition/needs per the plan of care, for 3 of 4 active records reviewed for patients who had more than 1 skilled nursing visit (#2, 3, 4).</p> <p>Findings include:</p>	<p>G0714</p>	<p>Education will be provided to all clinicians on the need to include education in the plan of care and provide education to the patient based on problems identified in the plan of care. Patient education must be completed prior to discharge of documentation of reason why education was not completed must be present. The DON is responsible for completing the education on 8/15/22. See Document A.</p> <p>To begin 9/1/22, an audit of 25% of average monthly census will be completed monthly x 3 months to ensure that the plan of care and clinician documentation includes patient education needed to meet patient outcomes and goals prior to discharge. Once 100% compliance is achieved then audit will be reduced to</p>	<p>2022-09-01</p>

<p>1. An undated agency policy received on 7/22/2022, titled "Skilled Nursing Services", stated, "...The Registered Nurse will ... Provide appropriate preventative and rehabilitative nursing procedures according to the Plan of Care and document on a progress note ... Skilled services include, but are not limited to ... Teaching and training activities related to the specified illness or injury ...."</p> <p>2. A home visit was observed with Patient #2 and physical therapist (PT) 1 on 7/18/2022 at 3:00 PM. During this visit, the patient indicated she was getting into bed one night, and when she put her leg up onto the bed, she heard a very loud pop , which was a spontaneous fracture of her left femur (thigh bone), and it required surgical intervention.</p> <p>The clinical record review for Patient #2 was completed on 7/26/2022. A document dated 6/21/2022, titled "... Start of Care", indicated the patient's areas of interest included how to manage symptoms; and indicated the patient had surgery to repair a broken femur bone and currently experienced depression.</p> <p>A review of the plan of care for the certification period of 6/21/2022 8/19/2022, indicated skilled nursing visits were ordered once weekly for 4 weeks, and interventions to teach disease process, diet (heart-healthy), hydration, prevention of pressure ulcer development, and infection control.</p> <p>Documents dated 6/30/2022, 7/07/2022, and 7/14/2022, titled "Skilled Nurse Visit" all failed to indicate skilled teaching was provided related to prevention of pressure ulcer development, dietary requirements, hydration, management of depression, infection control, and condition/needs related to recent spontaneous fracture due to osteoporosis.</p> <p>During an interview on 7/21/2022 at 12:00 PM,</p>		<p>quarterly. This is the responsibility of the DON and reported to QAPI.</p>	
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provide all the teaching interventions in the plan of care, including the recent spontaneous fracture due to osteoporosis, or management of depression.

3. A home visit was observed with Patient #3 and the alternate clinical manager on 7/18/2022 at 12:50 PM. During this time, the patient indicated she had a stent placed (a tiny expandable metal mesh coil, inserted surgically into a newly opened area of the artery to help keep the artery from narrowing or closing again) to her left upper leg, in the middle of May 2022, her left leg hurt, there was a bruise in her left groin (procedural insertion site of the stent), and she developed a blood clot sometime after the procedure. Observed the left upper groin, which revealed a swollen (baseball size) area over the healed incision line. The patient also indicated the procedure was performed by Person 3 (a vascular physician).

The clinical record review for Patient #3 was completed on 7/26/2022. A document titled "Home Health Certification and Plan of Care ..." for certification period 4/29/2022 - 6/27/2022 indicated skilled nursing orders included providing skilled teaching related to prevention of pressure ulcer development, dietary requirements and hydration, self-management of hypertensive status (high blood pressure [HTN]), why the patient is high risk for COVID-19 due to HTN and diabetes, infection control, environmental sanitation, stress/anxiety, developing a household plan and social distancing, blood sugar monitoring, hyper/hypoglycemia (high/low blood sugar) management, and long-term (diabetic) complications.

Documents dated 5/05/2022, 5/12/2022, 5/19/2022, 5/26/2022, 6/02/2022, 6/09/2022, and 6/16/2022, titled Skilled Nurse Visit , failed to evidence that the nurse provided education related to prevention of pressure ulcer development, dietary requirements and hydration, self-management of hypertensive status, why the patient is high risk for

COVID-19 due to HTN and diabetes, infection control, environmental sanitation, stress/anxiety, developing a household plan and social distancing, blood sugar monitoring, hyper/hypoglycemia management, and long-term (diabetic) complications.

A document dated 5/12/2022, titled "Skilled Nurse Visit" indicated the patient went to the emergency department (ED) on 5/08/2022 for extreme pain and swelling of the left leg and was diagnosed with a blocked artery, surgery to treat blockage was scheduled for 5/17/2022, and new medications were prescribed, which included Plavix (an anti-platelet), metoprolol (to lower blood pressure), omeprazole (to reduce stomach acid), potassium chloride (a mineral supplement), and simvastatin (to lower cholesterol levels in the blood); and stated, "... instructed on side effects ...." The document failed to evidence that education was provided based on current needs, which included uses or precautions associated with the newly prescribed medications, patient teaching related to blocked arteries, and prevention of new or worsening symptoms.

During an interview on 7/20/2022 at 9:31 AM, Person 4 (office staff for Person 3, a vascular physician) indicated patient #3 had an angiogram with stent placement on 5/17/2022, a 2-week follow-up visit on 6/1/2022, and was seen 6/15/2022 for the complaint of a swollen left foot.

Documents were received on 7/21/2022 from Person 3 s office. A document on Person 3 s letterhead indicated the patient had a stent placed in her left femoral (thigh) artery on 5/17/2022. A document dated 6/01/2022, titled "SOAP Note [person 3's physician visit note]", indicated the patient was seen for a 2-week post-procedure follow-up, and had developed pain and swelling in the left groin with bruising, and swelling in the left foot. A document dated 6/15/2022, titled "SOAP Note", indicated the patient still had some

area, and a "swollen foot".

The record evidenced the alternate clinical manager made routine skilled nursing visits on 5/19/2022, 5/26/2022, 6/02/2022, and 6/16/2022, and all notes failed to evidence that education was provided related to the patient's current needs, which included post-surgical incision care, physical limitations, or signs/symptoms to report to the agency nurse or surgical physician.

During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the nurse should have been teaching what s listed on the plan of care, and other risks identified and should have provided teaching for the patient's current needs related to post-surgical incision care, physical limitations, or signs/symptoms to report to the agency nurse or surgical physician.

4. Clinical record review for Patient #4 was completed on 7/26/2022. A document titled "Home Health Certification and Plan of Care ..." for certification period 7/02/2022 - 8/30/2022 indicated skilled nursing orders included to instruct on the disease process.

A document dated and signed by the alternate clinical manager on 6/20/2022 titled "Skilled Nurse Visit" indicated the patient reported a scrape to the left lower extremity, with a small scab and slight redness around the area, the physician was made aware, and no new orders were received. The document indicated teaching was provided for amlodipine (a drug to lower blood pressure) and failed to indicate teaching was provided for the care of the wound, signs/symptoms of wound deterioration, or signs/symptoms of infection to report to the agency nurse or physician.

A document dated and signed by the alternate clinical manager on 6/27/2022, titled "... Recertification" indicated the wound on the

left lower extremity was an "abrasion" (scrape), and the surrounding tissue was red (worsened since the last skilled nursing visit), and treatment orders were received. The document failed to evidence that education was provided for the care of the wound, signs/symptoms of wound deterioration, or signs/symptoms of infection to report to the agency nurse or physician.

A document received from Entity 5 (a wound clinic) on 7/26/2022, dated 6/28/2022, titled "Physician Orders Details" indicated the patient had 2 wounds on the left lower leg, each with treatment orders.

A document received from entity 5 (a wound clinic) on 7/25/2022, dated 7/12/2022, titled "Physician Orders Details" indicated both left lower leg wounds originated on 5/28/2022 subsequent to trauma (patient hit her leg on a magazine rack), the patient's primary care physician ordered oral antibiotics (to treat infection) the week of 6/19/2022.

Documents requested and received on 7/19/2022 titled "Skilled Nurse Visit", dated and signed by the alternate clinical manager on 7/04/2022, 7/11/2022, and 7/18/2022, all indicated the nurse provided teaching related to the medication amlodipine (a drug to lower blood pressure), and failed to evidence that the nurse provided education based on current condition/needs for care of the wound, signs/symptoms of wound deterioration, or signs/symptoms infection to report to the agency nurse or physician.

During an interview on 7/21/2022 at 12:46 PM, the clinical manager indicated skilled nurse notes dated 7/04/2022, 7/11/2022, and 7/18/2022 weren't QR'd (quality reviewed) yet, and the nurse would need to correct them. When queried if the notes were submitted, and considered completed by the nurse, the clinical manager stated, "Yes."

	17-14-1(a)(1)(H)			
G0716	<p>Preparing clinical notes</p> <p>484.75(b)(6)</p> <p>Preparing clinical notes;</p> <p>Based on record review and interview, the home health agency failed to ensure the registered nurse (RN) completed the clinical visit note on the day the service was provided, per agency policy, for 4 of 5 records reviewed (#1, 3, 4, 5).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. An undated agency policy received on 7/22/2022, titled "Skilled Nursing Services", stated, "...The Registered Nurse will ... Provide appropriate preventative and rehabilitative nursing procedures according to the Plan of Care and document on a progress note ...."</li> <li>2. An undated agency policy received on 7/22/2022, titled "Documentation of Patient Services", stated, "... Purpose ... To establish a standard for clinical documentation ... A separate note shall be completed for each visit ... Notes shall be ... completed on the day service is rendered ...."</li> <li>3. A home visit was conducted at Entity 9 (an assisted living facility [ALF]), with RN 1 and Patient #1 on 7/18/2022 at 10:00 AM, for observation of a skilled nursing visit.</li> </ol> <p>Clinical record review for Patient #1 was completed on 7/26/2022. During a review of</p>	G0716	<p>Preparing Clinical Notes</p> <p>Education was provided to all clinicians on the need to complete documentation within 24 hours of visit as required by revised policy. All SOC documentation must be completed within 48 hours of visit. This education will be provided by the DON and completed on 8/15/22. See Document A.</p> <p>Update to policy for clinical documentation will include requirement for all visit documentation to be completed within 24 hours of patient revisit or within 48 hours for start of care/recertification assessments. This is the responsibility of the administrator and will be completed by 9/5/2022.</p> <p>The Director of Nursing will run the past due visit report weekly starting week of 8/28/22 to identify any visit documentation not completed timely. Clinicians with outstanding notes will receive formal counseling by the DON. The administrator will be updated on any clinician not completing work within time frames by the DON.</p>	2022-09-05

7/20/2022 at 12:01 PM, a document dated 7/18/2022, titled "Skilled Nurse Note" was not completed or signed by RN 1.

During an interview on 7/21/2022 at 11:15 AM, the clinical manager indicated RN 1's visit note was not completed on 7/20/2022.

4. A home visit was conducted with the alternate clinical manager and Patient #3 on 7/18/2022 at 12:50 PM, for observation of a skilled nursing visit.

On 7/19/2022 at 11:55 PM, a printed copy of the complete medical record for certification periods 4/29/2022 - 6/27/2022, and 6/28/2022 - 8/26/2022 was requested to the administrator, and received at 1:17 PM from Person #4 (agency office manager). The documents did not include a skilled nursing visit dated 7/18/2022.

Clinical record review for Patient #3 was completed on 7/26/2022. During a review of the EMR on 7/20/2022 at 12:10 PM, a document dated 7/18/2022, titled "Skilled Nurse Note" was not completed or signed by the alternate clinical manager.

5. Clinical record review for Patient #4 was completed on 7/26/2022. During a review of the EMR on 7/20/2022 at 9:10 AM, a document dated 7/18/2022, titled "Skilled Nurse Note" was not completed or signed by the alternate clinical manager.

6. Clinical record review for Patient #5 was completed on 7/26/2022. During a review of the EMR on 7/20/2022 at 11:14 AM, a document dated 7/19/2022, titled "Skilled Nurse Note" was not completed or signed by RN 2.

	<p>7. During an interview on 7/21/2022 at 2:58 PM, the clinical manager indicated RN 2's skilled nursing visit note was not completed for a visit completed on 7/19/2022 with Patient #5, and the alternate clinical manager's skilled nursing visit note was not completed for a visit completed on 7/18/2022 with Patient #4.</p> <p>17-14-1(a)(1)(E)</p>			
<p>G0718</p>	<p>Communication with physicians</p> <p>484.75(b)(7)</p> <p>Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care;</p> <p>Based on record review and interview, the home health agency failed to ensure the registered nurse (RN) communicated with all physicians for 2 of 2 records reviewed with patients who had more than 1 physician involved in the patient's care (#3, 4).</p> <p><b>Findings include:</b></p> <p>1. An undated agency policy received on 7/22/2022, titled "Director of Patient Services [DPS]/Agency Supervisor", stated, "... The DPS shall have the following responsibilities: ...Maintain a liaison with physicians ... and other entities involved in patient care to ensure coordination of services ...."</p> <p>2. An undated agency policy received on 7/22/2022, titled "Clinical Records", stated, "... The clinical records shall contain ... Communications with the physician ... or other individuals or entities involved in the patient care ...."</p>	<p>G0718</p>	<p>Communication with Physician</p> <p>Education will be provided to all clinicians on the need to coordinate with DON on patients that have had hospital/emergency room/wound care clinics with changes. The DON will be responsible for obtaining any available documentation from the facilities and integrate it into the medical record. This will be responsibility of the DON and completed by 8/15/22. See document A</p> <p>To begin on 9/1/22, an audit of 25 % of active census will be conducted to ensure that documentation from facilities is obtained and made part of the clinical record if documentation is not available then a copy of the request for information will be part of the clinical record.</p> <p>This audit will be conducted monthly x 3 months and if 100% compliance is obtained then reduced to 25% quarterly x 2 quarters</p> <p>This is the responsibility of the DON with report to QAPI.</p>	<p>2022-09-01</p>

<p>3. A home visit was observed with Patient #3 and the alternate clinical manager on 7/18/2022 at 12:50 PM. During this time, the patient indicated she had a stent placed (a tiny expandable metal mesh coil, inserted surgically into a newly opened area of the artery to help keep the artery from narrowing or closing again) to her left upper leg, in the middle of May 2022, The patient also indicated the procedure was performed by Person 3 (a vascular physician).</p> <p>The clinical record review for Patient #3 was completed on 7/26/2022 for the certification period 4/29/2022 6/27/2022. A document dated 5/12/2022, titled "Skilled Nurse Visit" indicated the patient went to the emergency department (ED) on 5/08/2022 for extreme pain and swelling of the left leg and was diagnosed with a blocked artery, surgery to treat blockage was scheduled for 5/17/2022. The document failed to indicate the alternate clinical manager contacted the surgeon to obtain any pre-operative orders or instructions for the patient.</p> <p>During an interview on 7/20/2022 at 9:31 AM, Person 4 (office staff for Person 3, a vascular physician) indicated Patient #3 had an angiogram with stent placement on 5/17/2022, a 2-week follow-up visit on 6/1/2022, and was seen 6/15/2022 for a complaint of a swollen left foot, and was unaware the patient had home health services.</p> <p>During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the agency did not have any clinical documents from Person 3's office.</p> <p>A document dated and signed by the alternate clinical manager on 7/18/2022 titled "Skilled Nurse Visit" The document failed to indicate Person 3 was notified of pain in the left groin or swelling to the left groin, as revealed during the home visit conducted on 7/18/2022.</p>			
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	<p>During an interview on 7/21/2022 at 12:30 PM, the clinical manager indicated the agency did not have any clinical documents from Person 3's office, and the alternate clinical manager should report findings related to the surgery to Person 3.</p> <p>4. Clinical record review for Patient #4 was completed on 7/26/2022. A document received from Entity 5 (a wound clinic) on 7/26/2022, dated 6/28/2022, titled "Physician Orders Details" indicated the patient had 2 wounds on the left lower leg, each with treatment orders. The clinical record failed to indicate the alternate clinical manager communicated with entity 5's physician.</p> <p>During an interview on 7/21/2022 at 12:46 PM, the clinical manager indicated she was unaware the patient went to the wound clinic, and the agency had no wound clinic documents.</p> <p>17-14-1(a)(1)(G)</p>			
<p>G0940</p>	<p>Organization and administration of services</p> <p>484.105</p> <p>Condition of participation: Organization and administration of services.</p> <p>The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored</p>	<p>G0940</p>	<p>Organization and Administration of Services</p> <p>Education will be provided to the administrator and director of nursing on the requirements to ensure compliance with all rules and regulations including the Conditions of Participation and ways to monitor compliance. This education will be provided by Diane Link RN, MHA consultant by 9/5/2022.</p>	<p>2022-09-05</p>

	<p>and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.</p> <p>Based on observation, record review, and interview, the administrator failed to be responsible for all day-to-day operations of the home health agency (See tag G948); and the clinical manager failed to provide oversight of all patient care (See tag G958). This practice had the potential to affect all agency patients.</p> <p>Findings include:</p> <p>The cumulative effect of these systemic problems resulted in the home health agency's inability to ensure the provision of quality health care in a safe environment for the Condition of Participation 42 CFR §484.105: Organization and Administration of Services.</p>			
<p>G0948</p>	<p>Responsible for all day-to-day operations</p> <p>484.105(b)(1)(ii)</p> <p>(ii) Be responsible for all day-to-day operations of the HHA;</p> <p>Based on observation, record review, and interview, the administrator failed to be responsible for all day-to-day operations of the home health agency, which resulted in an identified immediate jeopardy (IJ), and citation of condition level deficiencies.</p> <p>Findings include:</p> <p>An undated agency policy received on 7/22/2022, titled "Administrator", stated "... The Administrator shall have the following responsibilities ... Ensure the agency meets all rules and regulations for licensure ... Have the authority for the management ... and overall operation of the agency ...."</p> <p>The administrator failed to ensure the</p>	<p>G0948</p>	<p>Administrator</p> <p>Education will be provided to the administration on requirements of the administrator, Conditions of Participation and other regulations required for oversight of the home health agency. Included will be ways to monitor for compliance. This will be provided by Diane Link RN, MHA consultant by 9/5/22.</p>	<p>2022-09-05</p>

	<p>day-to-day operations of the home health agency as evidenced by:</p> <p>The administrator failed to ensure each patient received an individualized written plan of care, which included any revisions or additions. Please see tag G570, Condition of Participation 42CFR §484.60: Care Planning, Coordination of Services, and Quality of Care, and the additional tags associated with this federal regulation.</p> <p>The administrator failed to ensure the RN assessed the patient's wounds/incision(s), or ensured the patient's needs were addressed and met, which led to potential likelihood and/or actual serious harm, with immediate jeopardy called on 7/25/2022. Please see tag G700, Condition of Participation 42CFR §484.75: Skilled Professional Services, and the additional tags associated with this federal regulation.</p> <p>The administrator failed to ensure its policies and procedures for COVID-19 Vaccination of Home Health Agency staff included all required elements (please see tag G687).</p> <p>The administrator failed to ensure the clinical manager provided oversight of all patient care services and personnel (please see tag G958).</p> <p>17-12-1(b)(3)</p> <p>17-12-1( c)(1)</p>			
G0958	<p>Clinical manager</p> <p>484.105(c)</p>	G0958	<p>Clinical Manager</p> <p>Education will be provided to the clinical manager on requirements of position and way to ensure oversight of patient care</p>	2022-09-05

Standard: Clinical manager.

One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following--

Based on observation, record review, and interview, the clinical manager failed to provide oversight of all the agency's clinical patient care, which resulted in an identified immediate jeopardy (IJ), and citation of condition level deficiencies.

Findings include:

1. An undated agency policy received 7/22/2022, titled "Director of Patient Services ... [Clinical Manager]", stated, "... to supervise ... Skilled Nursing ... services ... Direct ... the entire clinical program ... Ensure the actions of the agency facilitate the provision of safe and adequate patient care ... Monitor patient services to ensure that professional standards of care are being met ... Maintain quality [sic] standards through chart reviews, outcome evaluation ... Maintain a liaison with ... physicians ... entities involved with patient care ...."

The clinical manager failed to provide oversight of all the agency's clinical patient care, as evidenced by:

The clinical manager failed to ensure the registered nurse (RN) ensured the patient's medication profile included all medications the patient used, and/or indications, directions/precautions for use (see tag G536).

The clinical manager failed to ensure the RN updated/revised the patient's comprehensive assessment as often as needed (See tag G544).

including documentation, plans of care and requirements of the Conditions of Participation and other regulatory requirements. Included will be ways to monitor compliance, need for supervisory visits and coordination of care meetings. This education will be provided by Diane Link RN MHA consultant by 9/5/22.

The clinical manager failed to ensure each patient received an individualized written plan of care, which included any revisions or additions. Please see tag G570, Condition of Participation 42CFR §484.60: Care Planning, Coordination of Services, and Quality of Care, and the additional tags associated with this federal regulation.

The clinical manager failed to ensure the RN assessed the patient's wounds/incision(s), or ensured the patient's needs were addressed and met, which led to potential likelihood and/or actual serious harm, with immediate jeopardy called on 7/25/2022. Please see tag G700, Condition of Participation 42CFR §484.75: Skilled Professional Services, and the additional tags associated with this federal regulation.

17-12-1(d)

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 reverse for further 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.

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

TITLE

(X6) DATE