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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BLESSED HANDS HOME CARE AGENCY LLC	**4626 W WESTERN AVENUE** **SOUTH BEND, IN 46619**

(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
G 000	INITIAL COMMENTS This survey was for a Federal Home Health Recertification with complaints survey. The survey was fully extended on 2/19/19. Survey dates: 2/7/19 - 2/20/19 Complaint #: IN00271765: Complaint was substantiated. Federal deficiencies related to the complaint were cited. Complaint #: IN00254258: Complaint was substantiated. Federal deficiencies related to the complaint were cited. Complaint #: IN00249387: Complaint was substantiated. Federal deficiencies related to the complaint were cited. Complaint #: IN00246802: Complaint was substantiated. Federal deficiencies related to the complaint were cited. Complaint #: IN00246088: Complaint was substantiated. Federal deficiencies related to the complaint were cited. Complaint #: IN00240088: Complaint was substantiated. Federal deficiencies related to the complaint were cited. Complaint #: IN00220665: Complaint was substantiated. Federal deficiencies related to the complaint were cited. Facility ID: 013427 Provider #: 15K132	G 000		

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

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

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G 000	Continued From page 1 Medicaid #: 201270120 Census: 5 unduplicated skilled patients for past year 11 home health aide only patients in past year 6 personal service only patients in past year 16 Active patients 6 Discharged patients in past year Blessed Hands Home Care Agency is precluded from providing its own home health aide training and competency evaluation program for a period of 2 years beginning February 20, 2019 to February 20, 2021. The cumulative effect of this systemic problem resulted in the agency being out of compliance with the 484.50 Patient Rights, 484.60 Care planning, coordination of services, and quality of care, 484.65 Quality assessment and performance improvement; 484.70 Infection prevention and control; 484.80 Home health aide services; 484.105 Oranization and administration of services; and 484.110 Clinical records.	G 000		
G 372	Encoding and transmitting OASIS CFR(s): 484.45(a) Standard: An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary. This STANDARD is not met as evidenced by:	G 372		

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G 372	Continued From page 2	G 372		

Based on agency document review and Indiana State Department of Health (ISDH) document review, the agency failed to ensure OASIS data had been transmitted within 30 days of completing an assessment in 4 of 4 clinical records reviewed (#1, #2, #3, #4) of patients that received skilled services and required comprehensive assessments and had been on service over 60 days.

The findings include:

1. The agency document titled "Outcome and Assessment Information Set OASIS C-2 Guidance Manual Effective January 1, 2018, stated, "OASIS Data Encoding and Transmission: HHA's are required to encode and electronically submit OASIS data to CMS within 30 days of the date the assessment was completed."

2. ISDH documents evidenced Recertification assessments for clinical record #1 were completed 5/18/18, 7/20/18, and 9/17/18 and transmitted on 11/27/18.

Agency documents titled "CMS Submission Report OASIS Agency Final Validation Report" dated 11/28/18 evidenced Recertification assessments completed on 5/18/18, 7/20/18, and 9/17/18 were submitted on 11/27/18 to CMS.

3. ISDH documents evidenced Recertification assessment had been completed 5/11/18, 7/13/18, 9/11/18 for clinical record #2 and were transmitted on 11/28/18.

Agency documents titled "CMS Submission Report OASIS Agency Final Validation Report" dated 11/18/18 evidenced Recertification

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G 372	Continued From page 3 assessments completed on 5/11/18, 7/13/18, and 9/11/18 were submitted on 11/28/18. 4. ISDH documents evidenced Recertification assessments for clinical record #3 were completed 5/25/18, 7/26/18, and 9/25/18 and transmitted on 11/28/18. Agency documents titled "CMS Submission Report OASIS Agency Final Validation Report" dated 11/28/18 evidenced Recertification assessments completed on 5/25/18, 7/26/18, and 9/25/18 were submitted on 11/28/18 to CMS. 5. ISDH documents evidenced a start of care assessment for clinical record #4 dated 5/7/18 was submitted on 1128/18. Recertification assessments dated 7/6/18, 9/5/18, 10/31/18 were transmitted on 12/3/18. A discharge oasis dated 7/7/17 was submitted 11/28/18. Agency documents titled "CMS Submission Report OASIS Agency Final Validation Report" dated 12/3/18 evidenced a start of care dated 5/7/18 and Recertification assessment dated 9/5/18 transmitted on 12/3/18. Agency documents titled "CMS Submission Report OASIS Agency Final Validation Report" dated 11/28/18 evidenced a new record transaction dated 5/7/18 and transmitted on 11/28/18. Agency documents titled "CMS Submission Report OASIS Agency Final Validation Report" dated 11/28/18 evidenced a new record transaction dated 7/7/17 submitted on 11/28/18.	G 372		
G 406	Patient rights	G 406		

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G 406	Continued From page 4 CFR(s): 484.50 Condition of participation: Patient rights. The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights. This CONDITION is not met as evidenced by: Based on record review and interview, the agency failed to ensure the patients/ patient representatives received the home health agency administrator's name and contact information in order for the administrator to receive complaints (See G414); failed to ensure patient rights were adhered to by failing to accept and process complaints made by a patient (See G432); failed to ensure the patient was informed about changes to the care to be furnished (See G434); failed to ensure patient rights were adhered to and that a patient received consistent nursing care and treatment (See G436); failed to ensure they followed their policy and documentation of a patient/ patient representative being notified in advance of an impending discharge (See G462); failed to ensure they investigated a complaint made by the patient (See G 480); and failed to ensure they documented the existence and resolution of a complaint made by the patient (See G484). 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 484.50 Patient Rights.	G 406		
G 414	HHA administrator contact information	G 414		

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G 414	Continued From page 5 CFR(s): 484.50(a)(1)(ii) (ii) Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure the patients/ patient representatives received the home health agency administrator's name and contact information in order for the administrator to receive complaints for 7 of 7 active records reviewed (#1 - 4, #6, #9, #10). The findings include: The undated agency policy dated 2018 stated, "Patients will be advised at the time of admission and every Recertification about their rights and responsibilities regarding the receipt of home care services." A review of the undated Home Care Admission Packet failed to show the administrator's name or an alternate contact name. This was presented to the agency patients/ clients at admission. The above booklet contained the Patient Bill of Rights dated 2018 which stated, "To be advised of contact information for the agency's administrator [blank line and no name here] with phone number and address of agency listed. On 2/7/19 at 1:10 PM, the office manager indicated the above packet was given to the patients upon admission. A review of clinical record #1 with a start of care	G 414		

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G 414	Continued From page 6 on 2/2/16 failed to ensure the patient/ patient representative received the home health agency administrator's name in order to receive complaints. A review of clinical record #2 with a start of care on 11/16/17 failed to ensure the patient/ patient representative received the home health agency administrator's in order to receive complaints. A review of clinical record #3 with a start of care on 2/5/16 failed to ensure the patient/ patient representative received the home health agency administrator's name in order to receive complaints. A review of clinical record #4 with a start of care on 11/18/15 failed to ensure the patient/ patient representative received the home health agency administrator's name in order to receive complaints. A review of clinical record #6 with a start date of 8/10/17 failed to ensure the patient/ patient representative received the home health agency administrator's name in order to receive complaints. A review of clinical record #9 with a start of care date of 11/10/18 failed to ensure the patient/ patient representative received the home health agency's administrator's name in order to receive complaints. A review of clinical record #10 with a start of care date of 2/28/18 failed to ensure the patient/ patient representative received the home health agency's administrator's name in order to receive complaints.	G 414		

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During an interview on 2/7/19 at 11:20 AM, the office manager, and the owner indicated that there were no administrator or alternate administrator in place.

During an interview on 2/7/19 at 4:30 PM, the clinical supervisor indicated there was a lack of administrator and alternate administrator.

G 432 Make complaints to the HHA
CFR(s): 484.50(c)(3)

Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA;
This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to ensure patient rights were adhered to by failing to accept and process complaints made by a patient for 1 of 1 active records reviewed (#10) of a record found with a complaint.

The findings include:

The agency policy titled "Patient Rights and Responsibilities" dated 2018 stated, "Patient will be advised at the time of admission and at every Recertification about their rights and responsibilities regarding the receipt of home care services."

The agency policy titled "Patient Grievance Procedure" dated 2018 stated, "All grievances and concerns are to be dealt with by the administrator or his / her designee. When a

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G 432	Continued From page 8	G 432		

grievance is received, whether written or verbal, it is to be documented in the patient's clinical record by the administrator or his / her designee. It is also to be noted in a log kept by the administrator. 4. The resolution of the problem is also to be documented in the same manner. Each written grievance received is to be responded to in writing by the agency within 10 days."

The agency document titled "Patient Bill of Rights" dated 2018 stated, "The patient has the right ... to voice grievances regarding treatment or care that is [or fails to be furnished] ... by anyone who is furnishing services on behalf of the agency, or recommends changes in policy, staff, or service/ care without restraint, interference, coercion, discrimination or reprisal and to know that grievances will be resolved and the patient notified of the resolution within 30 days."

The agency document titled "Patient Grievance" dated 2018 stated, "Your complaints or problems are important to the agency. We will give full consideration to a problem or a complaint and make an effort to resolve the issue in an agreeable manner. We assure you that you will have the opportunity to voice grievances and recommend changes in services and/ or policies without discrimination, coercion, reprisal, or unreasonable interruption of services or in any manner from the agency ... You may also call to ask questions or lodge complaints about the agency with the Community Health Accreditation Program ... "

A review of clinical record #10 with a start of care on 11/16/17 failed to ensure the patient/ patient representative's complaint was investigated. This

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was further evidenced by the following:

A clinical record document titled "Supervisory Visit Report" dated 12/20/18 and signed by Employee H, RN, stated, "Patient voices concerns in regards to staffing. [Patient] states hours don't get made up, that [he/ she] is not notified if aides schedules are changed. [He/ she] states this is ongoing and there hasn't been much rectified. Nurse to report to office states [Employee R, Personal Service Attendant] is not reliable, and [he/ she] prefers to have other people." The report form was checked that the patient was not satisfied with the care.

A review of the complaint log on 2/14/18 failed to evidence a complaint made by patient #10 in regards to the complaint made on 12/20/18.

During an interview on 2/14/19 at 4:30 PM, the owner did not indicate agreement with the lack of a complaint investigation for the Supervisory Visit report dated 12/20/18.

During a phone interview on 2/15/19 at 9:40 AM, patient #10 indicated dissatisfaction with the care of Employee P, Home Health Aide. She indicated that Employee P did not drive and this caused problems with the staff running errands. The patient indicated Employee P did clean but no personal care was provided.

During an interview on 2/15/19 at approximately 4:30 PM, the owner indicated the office staff, Employee T, placed this complaint in the "wrong spot." This complaint was not placed in the complaint log.

During a phone interview on 2/18/19 at 9:30 AM,

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G 432	Continued From page 10 patient #10 indicated the office manager told her not to call anymore to complain about the lack of care received anymore. Patient #10 indicated staff would watch TV 50 % of the time when they were at her house.	G 432		
G 434	Participate in care CFR(s): 484.50(c)(4)(i,ii,iii,iv,v,vi,vii,viii) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to-- (i) Completion of all assessments; (ii) The care to be furnished, based on the comprehensive assessment; (iii) Establishing and revising the plan of care; (iv) The disciplines that will furnish the care; (v) The frequency of visits; (vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits; (vii) Any factors that could impact treatment effectiveness; and (viii) Any changes in the care to be furnished. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure patients were informed about changes to the care to be furnished for 2 of 4 active skilled clinical records reviewed (#1 and #4). The findings include: 1. The agency policy titled "2.28 Physician Notifications of Changes" dated 2018 stated, "When it is anticipated a visit cannot be made because of an unforeseen situation, the agency staff will immediately notify the office. a. The director of nursing or designee will contact the	G 434		

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G 434	Continued From page 11	G 434		

patient and notify them that an alternate direct care staff member will be conducting their visit in accordance with the plan of care or give the patient the option to reschedule the visit ... C. All documentation regarding the missed visit will be placed in the patient record."

2. The agency document titled "Patient Bill of Rights" dated 2018 stated, "The patient has the right to be fully informed in writing and knowledgeable of all rights and responsibilities before providing pre-planned care and to understand these rights can be exercised at any time 2. To receive appropriate care without discrimination in accordance with physician orders."

3. On 2/13/19 at 11 AM, the office manager indicated patient #1 had missed his/ her scheduled skilled nurse visit this morning due to the clinical manager's unexpected call off due to the weather. This patient had a planned skilled nurse visit every Monday, Wednesday, and Friday for a bowel program. (Note: The writer was able to make the visit to the office and area on this date).

A review of the clinical record #1 on 2/14/19 evidenced a plan of care for the certification period of 1/17/19 - 3/17/19. This plan of care evidenced the following: "SN Gastrointestinal interventions: Assess / Perform/ Instruct Pt / PCG [patient/ patient caregiver]: Bowel Program ... Bisacodyl [Dulcolax] 10 mg [milligram] Suppository Rectal Suppository M, W, F [Monday, Wednesday, Friday] start date 1/16/19." The patient had signed the patient rights at the start of care on 2/2/16.

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G 434	Continued From page 12 During a phone call interview on 2/13/19 at 2:28 PM, patient #1 indicated the skilled nurse visit was canceled this morning and having a pain level of 6 in the left abdominal area due to constipation and lack of the bowel program as scheduled. Patient #1 indicated another nurse would make a visit the next day for the bowel program. Patient #1 indicated the office staff did not understand how important it was for his/ her well being and comfort to have the bowel program as scheduled. Patient #1 indicated this missed visit with his/ her bowel program had happened before. Patient #1 indicated communication was lacking between the field staff and office staff. During a phone call interview on 2/15/19 at 12:35 PM, Employee H, RN, indicated being called to reschedule the bowel program for patient #1 about noon and that she was unable to complete the visit that day due to having another commitment. She was able to schedule this visit with the patient for 2/14/19. 4. A review of an aide supervisory visit report dated 1/3/19 and signed by Employee H, RN, stated, "Pt states aides follow POC (plan of care) when they come. [He/ she] stated there have been a few days [she/ he] has had no service." [He/ she] states staff is friendly and professional but [he/ she] wishes office would communicate changes."	G 434		
G 436	Receive all services in plan of care CFR(s): 484.50(c)(5) Receive all services outlined in the plan of care. This ELEMENT is not met as evidenced by: Based on record review and interview, the	G 436		

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G 436	Continued From page 13 agency failed to ensure patient rights were adhered to and that a patient received consistent nursing care and treatment for 1 of 4 active skilled records reviewed (#1). The findings include: The agency policy titled "2.28 Physician Notifications of Changes" dated 2018 stated, "When it is anticipated a visit cannot be made because of an unforeseen situation, the agency staff will immediately notify the office. a. The director of nursing or designee will contact the patient and notify them that an alternate direct care staff member will be conducting their visit in accordance with the plan of care or give the patient the option to reschedule the visit ... C. All documentation regarding the missed visit will be placed in the patient record." The agency document titled "Patient Bill of Rights" dated 2018 stated, "The patient has the right to be fully informed in writing and knowledgeable of all rights and responsibilities before providing pre-planned care and to understand these rights can be exercised at any time 2. To receive appropriate care without discrimination in accordance with physician orders." On 2/13/19 at 11 AM, the office manager indicated patient #1 had missed his/ her scheduled skilled nurse visit this morning due to the director of nursing's unexpected call off due to the weather. This patient had a planned skilled nurse visit every Monday, Wednesday, and Friday for a bowel program. (Note: The writer was able to make the visit to the office and area on this date).	G 436		

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G 436	Continued From page 14 During a phone call interview on 2/13/19 at 2:28 PM, patient #1 indicated the skilled nurse visit was canceled this morning and having a pain level of 6 in the left abdominal area due to the constipation and lack of the bowel program as scheduled. Patient #1 indicated another nurse would make a visit on 2/14/19 for the bowel program. Patient #1 indicated the office staff did not understand how important it was for his/ her well being and comfort to have the bowel program as scheduled. Patient #1 indicated missed visits with his/ her bowel program had happened before. Patient #1 indicated communication was lacking between the field staff and office staff. A review of the clinical record #1 on 2/14/19 evidenced a plan of care for the certification period of 1/17/19 - 3/17/19. This plan of care evidenced the following: "SN Gastrointestinal interventions: Assess / Perform/ Instruct Pt / PCG [patient / patient caregiver]: Bowel Program ... Bisacodyl [Dulcolax] 10 mg [milligram] Suppository Rectal Suppository M, W, F [Monday, Wednesday, Friday] start date 1/16/19." The patient had signed the patient rights at the start of care on 2/2/16. During a phone call interview on 2/15/19 at 12:35 PM, Employee H, RN, indicated being called to reschedule the bowel program for patient #1 about noon and that she was unable to complete the visit that day due to having another commitment. Employee H was able to schedule this visit with the patient for 2/14/19.	G 436		
G 462	Before discharge for cause HHA must: CFR(s): 484.50(d)(5)	G 462		

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The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (d)(5)(iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:
This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to ensure they followed their policy and documentation of a patient/ patient representative being notified in advance of an impending discharge for 1 of 1 discharged records of a skilled record reviewed (#5).

The findings included:

The agency policy titled "Discharge/ Transfer Policy dated 2018 stated, "At least 15 days before the discharge [final] visit the patient/ client will receive the discharge with instructions on the purpose of the form. The patient will be required to sign the notice of Medicare Noncoverage [NOMNC] ... "

A review of the closed record for clinical record #5 evidenced a start of care 7/25/18 and discharge on 10/25/18. This record evidenced that the patient was not given a discharge notice since what was used by the agency was not signed by the patient/ patient representative. The form used was called a Home Health Change of Care Notice and was not signed by the patient or patient representative. It was unknown when the patient received this notice.

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During an interview on 2/18/19 at 12:30 PM, the office manager indicated patient #5's discharge occurred because of the threatening calls from the patient's representative. A discharge notice was given.

G 480 Treatment or care G 480
CFR(s): 484.50(e)(1)(i)(A)

(i)(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately; and
This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to ensure they investigated a complaint made by the patient for 1 of 1 active records reviewed (#10) of a record found with a complaint.

The findings include:

The agency document titled "Patient Bill of Rights" dated 2018 stated, "The patient has the right ... to voice grievances regarding treatment or care that is [or fails to be furnished] ... by anyone who is furnishing services on behalf of the agency, or recommends changes in policy, staff, or service/ care without restraint, interference, coercion, discrimination or reprisal and to know that grievances will be resolved and the patient notified of the resolution within 30 days."

The agency document titled "Patient Grievance" dated 2018 stated, "Your complaints or problems are important to the agency. We will give full consideration to a problem or a complaint and make an effort to resolve the issue in an agreeable manner. We assure you that you will

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have the opportunity to voice grievances and recommend changes in services and/ or policies without discrimination, coercion, reprisal, or unreasonable interruption of services or in any manner from the agency ... You may also call to ask questions or lodge complaints about the agency with the Community Health Accreditation Program ... "

A review of clinical record #10 with a start of care on 11/16/17 failed to ensure the patient/ patient representative's complaint was investigated. This was further evidenced by the following:

A clinical record document titled "Supervisory Visit Report" dated 12/20/18 and signed by Employee H, RN, stated, "Patient voices concerns in regards to staffing. [Patient] states hours don't get made up, that [he/ she] is not notified if aides schedules are changed. [He/ she] states this is ongoing and there hasn't been much rectified. Nurse to report to office states [Employee R, Personal Service Attendant] is not reliable, and [he/ she] prefers to have other people." The report form was checked that the patient was not satisfied with the care.

A review of the complaint log on 2/14/18 failed to evidence a complaint made by patient #10 in regards to the complaint made on 12/20/18.

During an interview on 2/14/19 at 4:30 PM, the owner did not indicate agreement with the lack of a complaint investigation for the Supervisory Visit report dated 12/20/18.

During a phone interview on 2/15/19 at 9:40 AM, patient #10 indicated dissatisfaction with the care of Employee P, Home Health Aide. She indicated

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G 480	Continued From page 18 that Employee P did not drive and this caused problems with the staff running errands. The patient indicated Employee P did clean but no personal care was provided. During an interview on 2/15/19 at approximately 4:30 PM, the owner indicated the office staff, Employee T, placed this complaint in the "wrong spot." This complaint was not placed in the complaint log. During a phone interview on 2/18/19 at 9:30 AM, patient #10 indicated the office manager told her not to call anymore to complain about the lack of care received. Patient #10 indicated staff would watch TV 50 % of the time when they were at her house.	G 480		
G 484	Document complaint and resolution CFR(s): 484.50(e)(1)(ii) (ii) Document both the existence of the complaint and the resolution of the complaint; and This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure they documented the existence and resolution of a complaint made by the patient for 1 of 1 active records reviewed (#10) of a record found with a complaint. The findings include: The agency policy titled "Patient Grievance Procedure" dated 2018 stated, "All grievances and concerns are to be dealt with by the administrator or his / her designee. When a grievance is received, whether written or verbal, it is to be documented in the patient's clinical record by the administrator or his / her designee.	G 484		

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It is also to be noted in a log kept by the administrator. 4. The resolution of the problem is also to be documented in the same manner. Each written grievance received is to be responded to in writing by the agency within 10 days."

The agency document titled "Patient Bill of Rights" dated 2018 stated, "The patient has the right ... to voice grievances regarding treatment or care that is [or fails to be furnished] ... by anyone who is furnishing services on behalf of the agency, or recommends changes in policy, staff, or service/ care without restraint, interference, coercion, discrimination or reprisal and to know that grievances will be resolved and the patient notified of the resolution within 30 days."

The agency document titled "Patient Grievance" dated 2018 stated, "Your complaints or problems are important to the agency. We will give full consideration to a problem or a complaint and make an effort to resolve the issue in an agreeable manner. We assure you that you will have the opportunity to voice grievances and recommend changes in services and/ or policies without discrimination, coercion, reprisal, or unreasonable interruption of services or in any manner from the agency ... You may also call to ask questions or lodge complaints about the agency with the Community Health Accreditation Program ... "

A review of clinical record #10 with a start of care on 11/16/17 failed to ensure the patient/ patient representative's complaint was investigated. This was further evidenced by the following:

A clinical record document titled "Supervisory Visit

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G 484	Continued From page 20 Report" dated 12/20/18 and signed by Employee H, RN, stated, "Patient voices concerns in regards to staffing. [Patient] states hours don't get made up, that [he/ she] is not notified if aides schedules are changed. [He/ she] states this is ongoing and there hasn't been much rectified. Nurse to report to office states [Employee R, Personal Service Attendant] is not reliable, and [he/ she] prefers to have other people." The report form was checked that the patient was not satisfied with the care. A review of the complaint log on 2/14/18 failed to evidence a complaint made by patient #10 in regards to the complaint made on 12/20/18. During an interview on 2/14/19 at 4:30 PM, the owner did not indicate agreement with the lack of a complaint investigation for the Supervisory Visit report dated 12/20/18. During an interview on 2/15/19 at approximately 4:30 PM, the owner indicated the office staff, Employee T, placed this complaint in the "wrong spot." This complaint was not placed in the complaint log.	G 484		
G 536	A review of all current medications CFR(s): 484.55(c)(5) 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. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure all patient medications	G 536		

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were updated and correctly documented for 1 of 4 active skilled patients whose clinical records were reviewed (Patient #4).

The findings include:

The agency policy titled "2.54 Medication Profile" dated 2018 stated, "To ensure all patients/ clients have a current list of medications. Policy: 1. The comprehensive assessment includes a review of all medications the patient is currently using, both prescription and non - prescription ... the medication list is collectively maintained in the clinical record. The plan of care will demonstrate the patient/ client's current medication regimen, and additions and/ or modifications will be identified in clinical

On 2/13/18 at 1 PM, the office manager presented the most recent medication profile found in the clinical record #4, for the certification period of 11/4/18 - 1/2/19, completed by Employee H, Registered Nurse, evidenced the patient was to receive Insulin Glargine 100 unit/ ml (milliliter) 30 units subcutaneous route at bedtime for indication of diabetes. The date teaching performed was 5/8/18 on the insulin administration.

A review of a packet of information received from patient #4's incenter hemodialysis clinic dated 2/18/19 evidenced a home medication list that was last reviewed by an RN on 2/11/19. Included on the list, was Insulin Glargine inject 20 units at bedtime. The start date was 12/21/18, with an entered date of 1/21/19.

During an interview on 2/15/19 at 12:50 PM, Employee H, Registered Nurse, indicated the

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G 536	Continued From page 22 medication profile was not accurate and up - to - date.	G 536		
G 544	Update of the comprehensive assessment CFR(s): 484.55(d) Standard: Update of the comprehensive assessment. 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- This STANDARD is not met as evidenced by: Based on record review and interview, the agency failed to ensure the Registered Nurse consistently and accurately reassessed the patient's needs for 2 of 4 active skilled records reviewed (#2, #4). The findings include: 1. The agency policy titled "2.6 Service Policies Nursing Service" dated 2018 stated, "Nursing services are provided by Registered Nurses ... Professional Nurse: the RN gives direct care, teaches and supervises others in aspects of patient care, is responsible for assessing patient needs and for planning patient care ... In keeping with professional standards and depending upon each patient/ family need, all or a selection of the following nursing functions may be performed: a. Initial and ongoing assessments of the patient's needs, including Outcome and assessment information set [OASIS] assessments at appropriate time points ... Reassessment To ensure that the patient/ client's current problems and needs are continuously evaluated and the	G 544		

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care provided is adjusted accordingly, the patient's / client's status is reviewed periodically. The reassessment process is ongoing throughout the patient/ client's contact through the agency. Each patient/clients is reassessed to determine the patient/ client's response to care or services. Reassessment occurs ... every 60 days when the patient/ client is receiving skilled services."

2. A review of clinical record #2, start of care 11/16/17, failed to evidence the nurse completed the recertification reassessment for patient #2. This was further evidenced by the following:

The Recertification Follow up Assessment including OASIS Elements with Plan of Care / 485 Information, dated 11/10/18 and completed by Employee H, Registered Nurse, was reviewed and failed to show a complete assessment of the suprapubic catheter and urinary elimination. Under M 1610 on this assessment, the box was checked that the patient required a urinary catheter. Under this box, urinary elimination was not documented as well as blank boxes for the color of urine, clarity, odor, urinary catheter type, date last changed, and suprapubic. This was signed by Employee H on 11/12/18.

3. A review of Clinical Record #4, start of care 11/18/15, failed to evidence the nurse completed the recertification reassessment with patient #4. This was further evidenced by the following:

The Recertification / Follow up Assessment including OASIS elements and CMS 485 information, dated 1/3/19 and signed by Employee H, Registered Nurse, was reviewed and failed to evidence the nurse had not noted the AV fistula in the right arm and had taken a

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G 544	Continued From page 24 blood pressure in this right arm. The blood pressure was noted as 165/84 in the right arm. There was no documentation concerning the patient receiving hemodialysis 3 times a week at an in-center hemodialysis center. A review of a packet of information received from patient #4's in-center hemodialysis clinic dated 2/18/19, contained the following information about the patient's hemodialysis treatment and orders at a nearby in-center hemodialysis center. A review of the patient's current status at the in-center hemodialysis center stated, "Patient Transfer: Care Transitions report ... Current date 2/18/19 ... first date of dialysis 7/26/16 ... This patient receives chronic dialysis and a vascular hemodialysis access ... AV Fistula Standard / Above Elbow / Brachiocephalic - Right [Active] Please consider the following for admitting orders ... No BP [Blood Pressure], blood draws, or IVs in access arm; no blood draws or IV lines in hemodialysis catheter ... Dietary order 1.2 GM / KG [gram / kilogram] 1.2 GM / KG protein plus daily supplements, 2 GM potassium, no added salt, limit to 1 serving dairy per day, 1500 cc [cubic centimeters] fluid limit including supplements, no concentrated sweets if diabetes, high protein renal supplements 2 times a day ..." During an interview on 2/16/19 at 12:50 PM, Employee H, Registered Nurse, indicated record #4 was incomplete and the assessment failed to include information about the patient's right arm fistula and hemodialysis treatments.	G 544		
G 570	Care planning, coordination, quality of care CFR(s): 484.60	G 570		

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G 570	Continued From page 25 Condition of participation: Care planning, coordination of services, and quality of care. 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 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. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the agency failed to ensure the patient's medical and nursing needs were met in his or her place of residence for 3 of 12 clinical records reviewed with the potential to fail to provide safe and effective care to these patients (see G 570); failed to ensure skilled nursing provided bowel program per the plan of care, failed to ensure care was not provided absent of a physician ordered plan of care, and failed to ensure home health aide and skilled nursing provided visits per the plan of care(see G 572); failed to ensure the skilled nurse promptly notified the physician of changes in the patient's condition (see G 590); failed to ensure the plan of care was revised/ updated to include frequency and duration of skilled nurse and home health aide visits to be made, accurate medications, fluid restrictions, all	G 570		

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interventions, and all durable medical equipment (see G 592); failed to ensure they communicated new orders with the patient's primary care physician after a patient was discharged from the hospital (see G 602); failed to ensure skilled nursing and home health aides coordinated care amongst each other (see G 606); failed to ensure they coordinated care and services with the patient's dialysis center (see G 608); and failed to ensure the clinical manager's name and contact information was provided to 7 of 7 active patients (see G 622).

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 484.60 Care Planning, Coordination, Quality of Care.

In regards to G570, the findings include:

1. The agency policy titled "2.12 Referral and Acceptance of Patients" dated 2018 stated, "Acceptance of individuals who request home care services is based on a reasonable expectation that the individual's medical, nursing, and social needs will be met when home care staff members visit the applicant's place of residence."

2. On 2/13/19 at 11 AM, the office manager indicated patient #1 had missed his/ her scheduled skilled nurse visit this morning due to the director of nursing's unexpected call off due to the weather. This patient had a planned skilled nurse visit every Monday, Wednesday, and Friday for a bowel program. (Note: The writer was able to make the visit to the office and area on this

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date).

During a phone call interview on 2/13/19 at 2:28 PM, patient #1 indicated the skilled nurse visit was canceled this morning and having a pain level of 6 in the left abdominal area due to the constipation and lack of the bowel program as scheduled. Patient #1 indicated another nurse would make a visit on 2/14/19 for the bowel program. Patient #1 indicated the office staff did not understand how important it was for his/ her well being and comfort to have the bowel program as scheduled. Patient #1 indicated missed visits with his/ her bowel program had happened before. Patient #1 indicated communication was lacking between the field staff and office staff.

A review of the clinical record #1 on 2/14/19 evidenced a plan of care for the certification period of 1/17/19 - 3/17/19. This plan of care evidenced the following: "SN Gastrointestinal interventions: Assess / Perform/ Instruct Pt / PCG [patient / patient caregiver]: Bowel Program ... Bisacodyl [Dulcolax] 10 mg [milligram] Suppository Rectal Suppository M, W, F [Monday, Wednesday, Friday] start date 1/16/19." The patient had signed the patient rights at the start of care on 2/2/16.

During a phone call interview on 2/15/19 at 12:35 PM, Employee H, RN, indicated being called to reschedule the bowel program for patient #1 about noon and that she was unable to complete the visit that day due to having another commitment. Employee H was able to schedule this visit with the patient for 2/14/19.

3. A review of clinical record #4 on 2/14/19

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G 570	Continued From page 28 evidenced a hospitalization discharge document dated 2/18/18 - 3/2/18 from an emergency room document and discharge report summary evidenced the patient had long-acting insulin added to the medication regimen on 3/1/18. The discharge summary dated 3/2/18 evidenced the patient had a discharge diagnosis of " ... Type 2 Diabetes Mellitus with neurological and renal manifestations, uncontrolled; previously controlled by diet but now needing basal insulin and possibly adjustments as outpatient ... Discharged on Lantus [insulin glargine] 30 units subcutaneous nightly ... Blood Glucose Monitoring, adult Monitoring your blood glucose [also known as blood sugar] helps you to manage your diabetes. It also helps you and your health care provider monitor your diabetes and determine how well your treatment plan is working ... When should you test? Your health care provider will help you decide how often you should check your blood glucose. this may depend on the type of diabetes you have, your diabetes control, or the type of medicines you are taking. Be sure to write down all of your blood glucose readings so that this information can be reviewed with your health care provider. See below for examples of testing times that your health care provider may suggest ... Type 2 Diabetes It can vary with each person, but generally if you are on insulin, test 4 times a day ... How to monitor your blood glucose Supplies needed Blood glucose meter, test strips ..., a pricking needle [lancet], a device that holds the lancet, a journal or log book to write down your results ... It is a good idea to keep a daily record or log of your blood glucose readings ..." A review of a Plan of Care dated 11/4/18 - 1/2/19 failed to show the blood sugars would be checked	G 570		

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regularly or that the patient had a glucometer and other testing supplies available. The Recertification of Patient Eligibility showed the patient should have a diabetic foot examination at skilled nurse visits. There were no precautions about what arm to take blood pressures in or that the patient had a right upper arm fistula for in-center hemodialysis treatment three times a week. Insulin glargine 100 unit/ml (milliliter) subcutaneous 30 units at bedtime was listed under medications. Interventions included blood sugar is greater than 140 mg/dl (milligrams/ deciliter) or less than 60 mg/dl fasting random. Start 10/31/18. Under SN (Skilled Nurse) endocrine interventions, this document stated, "Assess/ perform/ instruct pt/ pcg (patient / patient caregiver) blood testing every [left blank] and importance of recording and compliance. effective date: 10/31/18." This care plan evidenced the home health aide was to visit 5 hours a day seven days a week.

A review of the home health aide visit notes for the certification period of 11/4/18 - 1/2/19 evidenced missed visits for daily scheduled home health aide visits. The aide was to visit 5 hours a day 7 days a week. Missing visits were found on 11/4/18, 11/10/18, 11/19/18, 11/23/18, 11/24/18, 11/25/18, 11/26/18, 11/28/18, 11/30/18, 12/1/18, 12/3/18, 12/5/18, 12/7/18, 12/8/18, 12/9/18, 12/12/18, 12/14/18, 12/15/18 12/19/18, 12/21/18, 12/22/18, and 12/27/18.

A review of an aide care plan dated 1/3/19 and signed by Employee H, Registered Nurse, evidenced the aide was to limit/ encourage fluids every visit (This was not specified). Blood pressures and other vital signs were to be completed per RN request. Diet was renal.

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A review of an aide supervisory visit report dated 1/3/19 and signed by Employee H stated, "Pt states aides follow POC (plan of care) when they come. [He/ she] stated there have been a few days [she/ he] has had no service." [He/ she] states staff is friendly and professional but [he/ she] wishes office would communicate changes."

A review of a Recertification and follow up assessment including OASIS elements and CMS 485 information dated 1/3/19 and completed by Employee H evidenced blood pressure was taken in the right arm and read 165/ 84. Under the endocrine and hematology section evidenced the patient had Type 2 Diabetes and required insulin. Blood sugar ranges were left blank as was who monitored blood sugars. Assessment findings under nutritional requirements showed intake adequate, hydration adequate. The form stated, "Patient/ caregiver education ... Glucometer use [checked yes]." Nursing interventions included diabetic observation, teach diabetic care. Under DME supplies, Diabetic supplies were left blank.

A review of a plan of care for the certification period of 1/3/19 - 3/3/19 evidenced the nurse was to visit 1 hour a week and the home health aide was to visit 5 hours a week, 7 days a week. Interventions include vital sign parameter notify the physician if blood glucose is greater than 140 mg/dl or less than 60 mg/dl fasting random start effective 1/4/19. Nutritional requirements evidenced a diabetic diet, diet as tolerated, and a renal diet. There was no mention of fluid restrictions. Under Gastrointestinal intervention: assess pt / pcg: diet/ hydration to promote proper management of the disease process. Under Endocrine interventions: Assess/ Instruct on

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G 570	Continued From page 31 diabetic diet, signs, and symptoms of hypo/ hyperglycemia and appropriate actions to take, on blood glucose testing every [left blank] and importance or recording and compliance, and skin and diabetic foot care. There was no evidence of where to take the patient's blood pressure safely. A review of a packet of information received from patient #4's in-center hemodialysis clinic received on 2/18/19 contained the following information about the patient's current orders: "AV Fistula Standard/ above elbow/ brachiocephalic - Right [active] Please consider the following for admitting orders ... No BP, blood draws, or IVs in access arm; no blood draws or IV lines in hemodialysis catheter ... dietary order [please consider the following diet order] 1.2 Gm/kg [gram/ kilogram] protein plus daily supplements, 2 GM Potassium, no added salt, limit to 1 serving dairy per day, 1500 cc [cubic centimeter] fluid limit including supplements, no concentrated sweets if diabetes ... Current outpatient nutrition orders ... fluid 1400 ml [milliliter] ... Start Date: 6/13/18 ... Current Medical info: Home Medication list 1/25/19 last RN Review date 2/11/19 Accucheck Aviva Plus Meter [Blood Glucose Meter] patient use daily start date 12/26/18 and entered date 1/21/19. Accucheck Aviva plus test strip [blood sugar diagnostic] Patient notes ... 3 times a day ... start date 12/26/18 entered date 1/21/19 ... Accucheck soft click lancets ... Test 3 times a day start date 12/26/18 entered dated 1/21/19 ... Touji - solo star ... Insulin glargine ... inject 20 units at bedtime ... " A review of a skilled nursing visit notes dated 1/17/19, 1/24/19, 1/31/19, 2/8/19 completed by Employee H evidenced a blood pressure	G 570		

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G 570	Continued From page 32 completed in the right arm. A review of aide visit records evidenced the home health aides encouraged fluids on 11/6/18, 11/7/18, 11/12/18, 11/13/18, 11/14/18, 11/15/18, 11/16/18, 11/17/18, 11/18/18, 11/20/18, 11/22/18, 11/27/18, 11/29/18, 12/2/18, 12/4/18, 12/6/18, 12/10/18, 12/11/18, 12/13/18, 12/16/18, 12/17/18, 12/18/18, 12/20/18, 12/24/18, 12/25/18, 12/31/18, 1/2/19, 1/3/19, 1/4/19, 1/5/19, 1/6/19, 1/7/19, 1/8/19, 1/10/19, 1/15/19, 1/19/19, 1/20/19, 1/22/19, 1/24/19, 1/26/19 and 1/29/19. During an interview on 2/13/19 at 11:15 AM, the owner failed to agree that missing visits had occurred with clinical record #4. During an interview on 2/14/19 at 12:20 PM, Employee J, Personal Service Attendant, indicated she worked as a home health aide. Employee J indicated patient #4 did not drink water but only pop so they would encourage water instead of sugary drinks. During an interview on 2/14/19 at 2:20 PM, the owner indicated patient #4's care was always covered even though there were missed visits. The owner indicated concern about the blood pressures documented in the right arm. During an interview on 2/15/19 at 12:50 PM, Employee H, RN, indicated the patient had a shunt on the right arm for dialysis. Employee H indicated the patient was not on insulin when they started care and indicated the medication profile, including the insulin order, was currently not accurate. Employee H indicated the glucometer checks should be daily and there should be specific orders and equipment for daily blood sugar checks. Employee H did not indicate	G 570		

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knowledge of specific fluid restrictions for this patient.

During an interview on 2/15/19 at 4:15 PM, the owner indicated staff nurses did not carry glucometers but the patients were to have their own glucometers in the home.

During an interview on 2/15/19 at 5 PM, the owner indicated patient #4 did not have a glucometer in the home, the patient did not check their blood sugars at home, and that the dialysis facility may check the patient's blood sugars.

During a phone call on 2/20/19 at 3:35 PM, Employee H indicated patient #4 did not have a glucometer.

5. During an office observation on 2/15/19 at 10:30 AM, the office manager was heard speaking to patient #9's family on the phone in which the office manager indicated the patient had fallen recently.

During an interview on 2/15/19 at 11:10 AM, the office manager indicated patient #9 had bumped his/ her head with a recent fall at home, the patient had no concerns with this fall, and the physician had not been notified.

During an interview on 2/15/19 at 1:00 PM, Employee H, Registered Nurse, indicated patient #9 was not one of her cases.

During an interview on 2/15/19 at 1:06 PM, the office manager indicated activating a fall report. The office manager instructed Employee H to visit patient #9 since a fall had occurred and had been reported by the patient's representative.

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G 570	Continued From page 34 During a phone call on 2/19/19 at 11:55 AM, the patient's representative for patient #9 was called. The patient representative indicated the patient had fallen and bumped his/ her head, a bruise on the head disappeared quickly, and the patient was fine. The patient's representative indicated Emergency Medical Personnel had come to the house and transport to the emergency room was declined. During an interview on 2/20/19 at 3:35 PM, Employee H indicated she did not go see the patient for he/ she was told by the owner of the agency to not visit patient #9 after the fall.	G 570		
G 572	Plan of care CFR(s): 484.60(a)(1) 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 refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. This STANDARD is not met as evidenced by: Based on record review and interview, the agency failed to ensure skilled nursing provided bowel program per the plan of care for 1 of 1 (#1) patient record review of a patient with a bowel program, failed to ensure care was not provided absent of a physician-ordered plan of care for 4 of 12 records reviewed, and failed to ensure home	G 572		

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health aide and skilled nursing provided visits per the plan of care for 6 of 12 clinical records reviewed (#1, #2, #3, #4, #7, #9).

The findings include:

1. The agency policy titled "2.3 Services Provided," dated 2018 stated, "Registered Nurses / Licensed Practical Nurses: 1. Registered Nurses [RNs] provide quality nursing care by the visit or the shift. The highly trained professionals follow the physician's orders, monitor, and instruct the patient regarding their care."

2. The agency policy titled "2.36 Coordination of Services," dated 2018 stated, "All personnel involved in the patient's care are responsible for coordinating care effectively to support the objectives outlined in the patient's plan of care ... "

3. A review of clinical record #1 failed to show that the patient's bowel program and a skilled nurse visit scheduled for every Monday, Wednesday, Friday occurred on Wednesday, 2/13/19.

On 2/13/19 at 11 AM, the office manager indicated patient #1 had missed his/ her scheduled skilled nurse visit this morning due to the director of nursing's unexpected call off due to the weather. This patient had a planned skilled nurse visit every Monday, Wednesday, and Friday for a bowel program. (Note: The writer was able to make the visit to the office and area on this date).

A review of the clinical record #1 on 2/7/19 and 2/14/19 evidenced a plan of care for the

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certification period of 1/17/19 - 3/17/19. This plan of care evidenced the following: "SN Gastrointestinal interventions: Assess / Perform/ Instruct Pt / PCG [patient / patient caregiver]: Bowel Program ... Bisacodyl [Dulcolax] 10 mg [milligram] Suppository Rectal Suppository M, W, F [Monday, Wednesday, Friday] start date 1/16/19."

During a phone call interview on 2/13/19 at 2:28 PM, patient #1 indicated the skilled nurse visit was canceled this morning and having a pain level of 6 in the left abdominal area due to constipation and lack of the bowel program as scheduled. Patient #1 indicated another nurse would make a visit on 2/14/19 for the bowel program. Patient #1 indicated the office staff did not understand how important it was for his/ her well being and comfort to have the bowel program as scheduled. Patient #1 indicated a missed visit with his/ her bowel program had happened before. Patient #1 indicated communication was lacking between the field staff and office staff.

4. A review of an audit trail document on 2/15/19 for patient #2 evidenced the plan of care for the certification period of 1/10/19 - 3/10/19 was created and saved on 2/7/19. The plan of care was not completed in a timely manner and care took place without the plan of care being completed and sent to the physician for approval. This was further evidenced by the following:

A document titled "Plan of Care" dated 2/7/19 for the certification period of 1/10/19 - 3/10/19 evidenced the home health aide was to visit 7 times a week for 9 weeks and the RN one time a month for 9 weeks.

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G 572	Continued From page 37 A review of the record on 2/14/19 and 2/20/19 evidenced the aide visited on 1/10/19, 1/11/9, 1/12/19, 1/13/19, 1/14/19, 1/15/19, 1/16/19, 1/18/19, 1/19/19, 1/24/19, 1/25/19, 1/27/19, 1/29/19, 1/31/19, 2/2/19, 2/3/19, 2/4/19, 2/5/19, 2/6/19, 2/7/19, 2/8/19, 2/9/19, 2/10/19, 2/11/19, 2/12/19. The skilled nurse only visited on 2/6/19. 5. A review of record #3 on 2/8/19 and 2/15/19 evidenced the plan of care for the certification period of 1/24/19 - 3/24/19 was created and saved on 2/7/19 and faxed to the physician on 2/7/19. The plan of care was not completed in a timely manner and care took place without the plan of care being completed and sent to the physician for approval. This was further evidenced by the following: A document titled "Plan of care" dated 2/7/19 for the certification period of 1/24/19 - 3/4/19 failed to evidence any frequency and duration for skilled nursing or home health aides services. However, the plan of care evidenced skilled nurse interventions which included neurological, respiratory, gastrointestinal, genitourinary, musculoskeletal, integumentary, pain interventions to assess the patient's neurological status. The home health aide interventions were not mentioned. A review of a document titled "Aide Care Plan" dated 1/22/19 evidenced the aide was to visit 8 hours a day 7 days a week and the skilled nurse 1 hour one week. A review of the record evidenced skilled nurse visits were completed on 1/29/19, 2/5/19, and 2/12/19 and aide visits were completed on	G 572		

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1/24/19, 1/25/19, 1/26/19, 1/27/19, 1/28/19, 1/29/19, 1/30/19, 1/31/19, 2/1/19, 2/2/19, 2/3/19, 2/4/19, 2/5/19, 2/6/19, 2/7/19, 2/8/19, 2/9/19, 2/10/19, 2/11/19, and 2/13/19.

6. A review of record # 4 evidenced a plan of care for the certification period of 11/4/18 - 1/2/19, with orders for home health aide services 5 hours a day, seven days a week. A review of the home health aide visit notes, the aide failed to visit the patient on 11/10/18, 11/19/18, 11/23/18, 11/24/18, 11/25/18, 11/26/18, 11/28/18, 11/30/18, 12/1/18, 12/3/18, 12/5/18, 12/7/18, 12/8/18, 12/9/18, 12/12/18, 12/14/18, 12/15/18, 12/19/18, 12/21/18, and 12/22/18.

A review of an audit trail document dated 2/7/19 evidenced the plan of care for the certification period of 1/3/19 - 3/3/19 was not created, saved, or faxed to the physician until 2/7/19. After the agency provided the late plan of care for the certification period of 1/3/19 - 3/3/19, the document evidenced the home health aide was to visit the patient 5 hours a day, seven days a week, and the skilled nurse was to visit once a week for 9 weeks.

A review of the home health aide visit notes evidenced aide visits on 1/3/19, 1/4/19, 1/5/19, 1/6/19, 1/7/19, 1/8/19, 1/10/19, 1/11/19, 1/12/19, 1/13/19, 1/14/19, 1/15/19, 1/16/19, 1/20/19, 1/21/19, 1/22/19, 1/23/19, 1/24/19, 1/25/19, 1/26/19, 1/27/19, 1/28/19, 1/31/19, 2/1/19, 2/2/19, and 2/10/19.

A review of the skilled nursing visit notes evidenced skilled nurse visits on 1/17/19, 1/24/19, 1/31/19, and 2/8/19.

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During an interview on 2/14/19 at 2:20 PM, the owner indicated there was a huge turnover with patient #4's staff and that despite missing visit notes, patient #4's care was always covered.

7. A review of record #5 on 2/13/19 failed to evidence a physician signature on the plan of care for the certification period of 9/23/18 - 11/21/18. Services were provided absent of a physician's signature and absent of the frequency and duration of the skilled nurse visits and home health aide visits on this plan of care. This was evidenced by the following:

A review of visit notes evidenced aide visits on 9/23/18, 9/27/18, 9/28/18, 0/1/18, 10/2/18, 10/3/18, 10/4/18, 10/5/18, 10/8/19, 10/9/18, 10/10/18, 10/11/18, 10/18/18, 10/19/18, 10/22/18, and 10/25/18.

During an interview on 2/18/19 at 12:45 PM, the office manager indicated the physician signed plan of care was not present in the record.

8. A review of record #7 on 2/19/19 evidenced a plan of care for the certification period of 12/9/16 - 2/6/17, with orders for home health aide visits as scheduled for 7.5 hours a day seven days a week. The clinical record failed to evidence visits on 12/16/16, 12/17/16, 12/28/16, 1/11/17, and 1/14/17.

9. A review of record #9 on 2/15/19 evidenced a plan of care for the certification period of 1/9/19 - 3/9/19, with orders for home health aide visits to be seven days a week for 9 weeks. This plan of care did not evidence how many visits a day or how many hours a day would occur.

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G 572	Continued From page 40 A review of the undated aide care plan evidenced the patient was to be visited 6 hours daily. This was signed by Employee H, RN. A review of the record showed visits occurred more than once a day. Employee KK, HHA, visited the patient on 1/9/19 - 1/11/19 for 5 hours, 1/9/19 - 1/11/19 for 1 hour, 1/16/19 - 1/19/19 for 1 hour a day, 5 hours a day from 1/15/19 - 1/18/19, 1/19/19 for 3 hours, 1/20/19 for 1 hours, 1/23/19 for 1 hours, 1/24/19 for 1 hours, 1/25/19 for 1 hours, 1/26/19 for 1 hours, 1/27/19 for 1 hours, 2/1/19 for 1 hour, 2/2/19 for 1 hour, for 2/4/19 for 7 hours, 2/6/18 for 7 hours, 2/7/19 for 4.5 hours, 2/8/19 for 2.5 hours, 2/9/19 for 3 hours, 2/10/19 for 3 hours, on 2/14/19 and 2/15/19 for 7 hours, on 2/16/19 for 3 hours. During an interview on 2/15/19 at 11:15 AM, the office manager indicated the recently created plans of care for patient #2, #3, and #4 were not completed in a timely manner.	G 572		
G 590	Promptly alert relevant physician of changes CFR(s): 484.60(c)(1) The HHA must promptly alert the relevant physician(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. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency and the skilled nurse failed to ensure the physician was notified of a patient's fall with possible injury in 1 of 7 active clinical records reviewed (#9) The findings include:	G 590		

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G 590	Continued From page 41 The agency policy titled "2.6 Service Policies Nursing Service" dated 2018 stated, "Nursing service is provided by Registered Nurses [RNs] or Licensed Practical Nurses [LPNs] ... Professional Nursing [RN] functions: In keeping with professional standards and depending upon each patient / family need, all or a selection of the following nursing functions may be performed ... informing the physician and other staff of changes in the patient's condition / needs." During a office observation on 2/15/19 at 10:30 AM, the office manager was heard speaking to patient #9's family on phone and indicated the patient had fallen recently. During an interview on 2/15/19 at 11:10 AM, the office manager indicated patient #9 had bumped his / her head with a recent fall at home, patient had no concerns with this fall, and the physician had not been notified. During an interview on 2/15/19 at 1:06 PM, the office manager indicated activating a fall report. The office manager instructed Employee H, RN, to visit patient #9 since a fall had occurred and been reported by the patient's representative. The fall report was requested but not received. A review of the record #9 failed to show any documentation about the patient #9's recent fall or that the physician had been notified of the incident.	G 590		
G 592	Revised plan of care CFR(s): 484.60(c)(2) A revised plan of care must reflect current	G 592		

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information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.
This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to ensure the plan of care was revised/ updated to include frequency and duration of skilled nurse and home health aide visits to be made in 4 of 7 active clinical records (#1, #3, #4, #9) and 1 of 5 closed records (#5), accurate medications, fluid restrictions, all interventions, and all durable medical equipment for 1 of 1 (#4) in a sample of 12.

The finding include:

1. The agency policy titled "Physician's Plan of Treatment" dated 2018 stated, "A physician prepares a plan of treatment and it is made available to the agency ... A physician's plan of treatment must be signed by the physician and in the chart within 30 days after admission to the agency and must include ... the frequency and duration of visits to be made."

2. A review of clinical record #1's (start of care 2/2/16) plan of care for the certification period of 1/17/19 - 3/17/19 failed to evidence frequency and duration for skilled nurse and home health aide visits on this plan of care document.

During an interview on 2/7/19 at 3 PM, the clinical supervisor indicated the plan of care lacked the frequency and duration of visits needed.

3. A review of clinical record #3's (start of care

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2/5/16) plan of care for the certification period of 1/24/19 - 3/24/19 failed to evidenced a frequency and duration for skilled nurse and home health aide visits on this plan of care document.

During an interview on 2/8/19 at 3:55 PM, the clinical supervisor indicated the plan of care lacked the frequency and duration needed.

4. A review of clinical record #4 (start of care 11/18/15) plan of care for the certification period of 1/3/19 - 3/3/19 failed to evidence the physician orders individualized for this patient's blood sugar testing needs, precautions on taking blood pressures in right arm, and fluid restrictions. This was further evidenced by the following;

A review of clinical record #4 on 2/14/19 evidenced a hospitalization discharge document dated 2/18/18 - 3/2/18 from an emergency room document and discharge report summary evidenced the patient had long acting insulin added to the medication regimen on 3/1/18. The discharge summary dated 3/2/18 evidenced the patient had a discharge diagnosis of Type 2 Diabetes Mellitus with neurological and renal manifestations, uncontrolled; previously controlled by diet but now needing basal insulin and possibly adjustments as outpatient ... Discharged on lantus [insulin glargine] 30 units subcutaneous nightly ... Blood Glucose Monitoring, adult Monitoring your blood glucose [also known as blood sugar] helps you to manage your diabetes. It also helps you and your health care provider monitor your diabetes and determine how well your treatment plan is working ... When should you test? Your health care provider will help you decide how often you should check your blood glucose. this may

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depend on the type of diabetes you have, your diabetes control, or the type of medicines you are taking. Be sure to write down all of your blood glucose readings so that this information can be reviewed with your health care provider. See below for examples of testing times that your health care provider may suggest ... Type 2 Diabetes It can vary with each person, but generally if you are on insulin, test 4 times a day ... How to monitor your blood glucose Supplies needed Blood glucose meter, test strips ..., a pricking needle [lancet], a device that holds the lancet, a journal or log book to write down your results ... It is a good idea to keep a daily record or log of your blood glucose readings ..."

A review of a plan of care for the certification period of 1/3/19 - 3/3/19 evidenced the nurse was to visit 1 hour a week and the home health aide was to visit 5 hours a week, 7 days a week. Interventions include vital sign parameter notify physician if blood glucose is greater than 140 mg/dl or less than 60 mg/dl fasting random start effective 1/4/19. Nutritional requirements evidenced a diabetic diet, diet as tolerated, and a renal diet. There was no mention of fluid restrictions. Under Endocrine interventions: Assess/ Instruct on diabetic diet, signs and symptoms of hypo/ hyperglycemia and appropriate actions to take, on blood glucose testing every [left blank] and importance or recording and compliance, and skin and diabetic foot care. There was no evidence on this document where to take the patient's blood pressure safely.

A review of a packet of information received from patient #4's in-center hemodialysis clinic received on 2/18/19 contained the following information

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G 592	Continued From page 45 about the patient's current orders: "AV Fistula Standard/ above elbow/ brachiocephalic - Right [active] Please consider the following for admitting orders ... No BP, blood draws, or IVs in access arm; no blood draws or IV lines in hemodialysis catheter ... dietary order [please consider the following diet order] 1.2 Gm/kg [gram/ kilogram] protein plus daily supplements, 2 GM Potassium, no added salt, limit to 1 serving dairy per day, 1500 cc [cubic centimeter] fluid limit including supplements, no concentrated sweets if diabetes ... Current outpatient nutrition orders ... fluid 1400 ml [milliliter] ... Start Date: 6/13/18 ... Current Medical info: Home Medication list 1/25/19 last RN Review date 2/11/19 Accucheck Aviva Plus Meter [Blood Glucose Meter] patient use daily start date 12/26/18 and entered date 1/21/19. Accucheck Aviva plus test strip [blood sugar diagnostic] Patient notes ... 3 times a day ... start date 12/26/18 entered date 1/21/19 ... Accucheck soft click lancets ... Test 3 times a day start date 12/26/18 entered dated 1/21/19 ... Touji - solo star ... Insulin glargine ... inject 20 units at bedtime .... " During an interview on 2/15/19 at 12:50 PM, Employee H, RN, indicated the patient has a shunt on the right arm for dialysis. Employee H indicated that glucometer checks should be daily and there should be specific orders and equipment for daily blood sugar checks. She did not indicate knowledge of specific fluid restrictions for this patient. During an interview on 2/15/19 at 4:15 PM, the owner indicated staff nurses did not carry glucometers but the patients were to have their own glucometers in the home.	G 592		

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G 592	Continued From page 46 During an interview on 2/15/19 at 5 PM, the owner indicated patient #4 does not have a glucometer in the home and patient does not check blood sugars at home. Dialysis facility may check the patient's blood sugars. 5. A review of record #5 on 2/13/19 evidenced a plan of care for the certification period of 9/23/18 - 11/21/18. The plan of care failed to evidence the frequency and duration of the skilled nurse visits and home health aide visits on this plan of care. 6. A review of record #9 on 2/15/19 evidenced a plan of care for the certification period of 1/9/19 - 3/9/19 evidenced the frequency and duration of the home health aide visits was to be seven days a week for 9 weeks. This plan of care did not evidence how many visits a day or how many hours a day would occur. A review of the undated aide care plan evidenced the patient was to be visited 6 hours daily. This was signed by Employee H, RN.	G 592		
G 602	Communication with all physicians CFR(s): 484.60(d)(1) Assure communication with all physicians involved in the plan of care. This ELEMENT is not met as evidenced by: Based on record review and interview, the home health agency failed to ensure they communicated new orders with the patient's primary care physician after a patient was discharged from the hospital in 1 of 1 record reviewed (#4) of a patient discharged from the hospital.	G 602		

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The findings include:

The agency policy titled "2.36 Coordination of Services" dated 2018 stated, "1. To Coordinate services in order to provide comprehensive home care and assure continuity of care. 2. All personnel involved in the patient's care are responsible for coordinating care effectively to support the objectives outlined in the patient's plan of care ... the agency coordinates care by a. Ensuring communication with all physicians involved in the plan of care. b. Integrating orders from all physicians involved in the plan of care to ensure the coordination of all services and interventions provided to the patient c. Integrating services, whether services are provided directly or under arrangement, to ensure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines. d. Coordinating care delivery to meet the patient's needs, and involve the patient ... in the coordination of care activities ...."

A review of clinical record #4 evidenced a hospitalization discharge document dated 2/18/18 - 3/2/18 from an emergency room document and discharge report summary evidenced the patient had long acting insulin added to the medication regimen on 3/1/18. The discharge summary dated 3/2/18 evidenced the patient had a discharge diagnosis of Type 2 Diabetes Mellitus with neurological and renal manifestations, uncontrolled; previously controlled by diet but now needing basal insulin and possibly adjustments as outpatient ... Discharged on lantus [insulin glargine] 30 units subcutaneous nightly ... Blood

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G 602	Continued From page 48 Glucose Monitoring, adult Monitoring your blood glucose [also known as blood sugar] helps you to manage your diabetes. It also helps you and your health care provider monitor your diabetes and determine how well your treatment plan is working ... When should you test? Your health care provider will help you decide how often you should check your blood glucose. This may depend on the type of diabetes you have, your diabetes control, or the type of medicines you are taking. Be sure to write down all of your blood glucose readings so that this information can be reviewed with your health care provider. See below for examples of testing times that your health care provider may suggest ... Type 2 Diabetes It can vary with each person, but generally if you are on insulin, test 4 times a day ... How to monitor your blood glucose Supplies needed Blood glucose meter, test strips ..., a pricking needle [lancet], a device that holds the lancet, a journal or log book to write down your results ... It is a good idea to keep a daily record or log of your blood glucose readings ...." The clinical record failed to evidence that the patient's primary physician was notfied of the new discharge orders. During an interview on 2/15/19 at 5 PM, the owner indicated patient #4 did not have a glucometer in the home and patient did not check blood sugars at home. Dialysis facility may check the patient's blood sugars. The clinical record failed to evidence that the physician was notified of the patients lack of glucometer.	G 602		
G 606	Integrate all services CFR(s): 484.60(d)(3) Integrate services, whether services are provided	G 606		

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directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.
This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to ensure skilled nursing and home health aides coordinated care amongst each other in 1 of 12 records reviewed. (#5)

Findings include:

The agency policy titled "2.36 Coordination of Services" dated 2018 stated, "1. To Coordinate services in order to provide comprehensive home care and assure continuity of care. 2. All personnel involved in the patient's care are responsible for coordinating care effectively to support the objectives outlined in the patient's plan of care ... the agency coordinates care by a. Ensuring communication with all physicians involved in the plan of care. b. Integrating orders from all physicians involved in the plan of care to ensure the coordination of all services and interventions provided to the patient. c. Integrating services, whether services are provided directly or under arrangement, to ensure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines. d. Coordinating care delivery to meet the patient's needs, and involve the patient ... in the coordination of care activities ..."

A review of clinical record #5, start of care 7/17/18 and discharge 10/25/18, with a diagnosis of quadriplegia, failed to evidence coordination of

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G 606	Continued From page 50 care between the nurses and home health aides caring for patient #5. A data entry note dated 8/17/18 and written by the office manager evidenced the following statement: "HHA texted office manager to notify supervising RN [Employee D] of blood pressure reading as requested. I took the message and went to [Employee D's] desk to inform her of the b/p [blood pressure] reading sent in by CHHA. [Employee D] asked for the phone number of the aide, and d /t [due to] issues of the past with aides/ clients making harassment claims, I instructed her to call the patient 's phone to speak to aide since aide was on duty. At this time, [Employee D] became visibly upset and stated that I was interfering with coordination of care. I informed her due to previous allegations [that are documented] I found it to be in the best interest that aides call the office to speak to her, or call from the patient's phone. Due to the agency not having an RN administrator at this time, all aides have been instructed to call the office and the office will reach the nurse for further instruction. When [Employee D] became aware of this, she stated that she would document in her notes that I was interfering with coordination of care and that she was not able to have the aides personal phone numbers." A review of an aide visit record dated 8/17/19 signed by Employee K, HHA, evidenced the patient had blood pressure 178 over 85 at 12:10 PM. BP 141 / 116 at 12 PM, 124/78 at 12:40 PM With a note that all reported to the office. A review of a skilled nurse visit note dated 8/17/18 and signed by Employee D, RN, evidenced this nurse visited the physician with the	G 606		

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G 606	Continued From page 51 patient at 2 PM. The note also stated, "This RN requested CHHA phone number to update on condition, pain monitoring, need VS [vital signs]. Office manager refused to give this RN Aides number stated call pt's number, RN did so, no answer. RN was informed it was company policy to have aides call the office to report any changes, falls, etc regarding their pts. This RN stated, "RN and aide need to coordinate care as they are part of the interdisciplinary team." During an interview on 2/13/19 at 12:05 PM, the office manager indicated Employee D, past administrator and patient representative for patient #5 made it hard for the agency to provide services to this patient. Employee D indicated many aides quit over the situation with Employee D. The office manager indicated there was tension because of the request by the patient for the aides to walk the large dog and many aides were afraid of the dog. There was a lot of "He says / she says" stories and talking behind people's backs that made for an uncomfortable situation. The office manager stated, "I wrote a complaint against [past Employee D] and she didn't agree that we directed the aides." The office manager indicated the aides were to call the office with concerns and Employee D indicated this was interfering with the coordination of care between the aides and nursing staff. The office manager stated, "I wrote her up for this and she refused to sign this write up."	G 606		
G 608	Coordinate care delivery CFR(s): 484.60(d)(4) Coordinate care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the	G 608		

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G 608	Continued From page 52 coordination of care activities. This ELEMENT is not met as evidenced by: Based on record review and interview, the home health agency failed to ensure they coordinated care and services with the patient's dialysis center in 1 of 1 record reviewed (#4) of a patient receiving dialysis in a sample of 12. The findings include: The agency policy titled "2.36 Coordination of Services" dated 2018 stated, "1. To Coordinate services in order to provide comprehensive home care and assure continuity of care. 2. All personnel involved in the patient's care are responsible for coordinating care effectively to support the objectives outlined in the patient's plan of care ... the agency coordinates care by a. Ensuring communication with all physicians involved in the plan of care. b. Integrating orders from all physicians involved in the plan of care to ensure the coordination of all services and interventions provided to the patient c. Integrating services, whether services are provided directly or under arrangement, to ensure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines. d. Coordinating care delivery to meet the patient's needs, and involve the patient ... in the coordination of care activities ..." A review of a packet of information received from patient #4's in-center hemodialysis clinic received on 2/18/19 contained the following information about the patient's current orders: "AV Fistula Standard/ above elbow/ brachiocephalic - Right [active] Please consider the following for	G 608		

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admitting orders ... No BP, blood draws, or IVs in access arm; no blood draws or IV lines in hemodialysis catheter ... dietary order [please consider the following diet order] 1.2 Gm/kg [gram/ kilogram] protein plus daily supplements, 2 GM Potassium, no added salt, limit to 1 serving dairy per day, 1500 cc [cubic centimeter] fluid limit including supplements, no concentrated sweets if diabetes ... Current outpatient nutrition orders ... fluid 1400 ml [milliliter] ... Start Date: 6/13/18 ... Current Medical info: Home Medication list 1/25/19 last RN Review date 2/11/19 Accucheck Aviva Plus Meter [Blood Glucose Meter] patient use daily start date 12/26/18 and entered date 1/21/19. Accucheck Aviva plus test strip [blood sugar diagnostic] Patient notes ... 3 times a day ... start date 12/26/18 entered date 1/21/19 ... Accucheck soft click lancets ... Test 3 times a day start date 12/26/18 entered dated 1/21/19 ... Touji - solo star ... Insulin glargine ... inject 20 units at bedtime .... "

During an interview on 2/15/19 at 9:15 AM, Person C, the facility administrator of patient #4's dialysis clinic, indicated very little coordination of care occurred with the home health agency.

During an interview on 2/15/19 at 5 PM, the owner indicated patient #4 does not have a glucometer in the home and patient does not check blood sugars at home. Dialysis facility may check the patient's blood sugars.

The home health agency failed to evidence coordination of care between the agency and the patient's in center hemodialysis clinic where patient #4 received dialysis treatments three times a week due to End Stage Renal Disease.

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G 622	Name/contact information of clinical manager CFR(s): 484.60(e)(5) Name and contact information of the HHA clinical manager. This ELEMENT is not met as evidenced by: Based on record review and interview, the home health agency failed to ensure the clinical manager's name and contact information was provided to 7 of 7 active patients (# 1 - #4, #6, #9, #10). The findings included: 1. A review of the purple colored admission folder with the agency name and contact information on the cover on 2/7/19 failed to evidence the clinical manager's name and contact information. On 2/7/19 at 1:10 PM, the office manager indicated the staff and patients were instructed to call the office staff with any concerns and these concerns were passed on to the nurses if necessary. 2. A review of clinical record #1 evidenced patient #1 received the admission folder at the start of care. 3. A review of clinical record #2 evidenced patient #2 received the admission folder at the start of care. 4. A review of clinical record #3 evidenced patient #3 received the admission folder at the start of care. 5. A review of clinical record #4 evidenced patient #4 received the admission folder at the	G 622		

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G 622	Continued From page 55 start of care. During an interview on 2/11/19 at 2:30 PM, patient #4 indicated his / her contact was the office manager and the owner. 6. A review of clinical record #6 evidenced patient #6 received the admission folder at the start of care. 7. A review of clinical record #7 evidenced patient #7 received the admission folder at the start of care. 8. A review of clinical record #10 evidenced patient #10 received the admission folder at the start of care. During an interview on 2/15/19 at 1:40 PM, patient #10 indicated would call office staff if needed. Patient #10 did not know who clinical manager was or the contact information for the clinical manager.	G 622		
G 640	Quality assessment/performance improvement CFR(s): 484.65 Condition of participation: Quality assessment and performance improvement (QAPI). The HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of	G 640		

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emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.
This CONDITION is not met as evidenced by:
Based on record review and interview, the agency failed to develop, implement, evaluate and maintain an effective, ongoing, data-driven QAPI program for 1 of 1 agency (see G 640); failed to be able to show measurable improvement in quality indicators, measure, analyze, and track quality indicators, including adverse patient events (G 642); failed to utilize quality indicator data, including measures derived from OASIS any other relevant data as well as identify opportunities for improvement (G 644); and failed to take actions aimed at performance improvement and measure its success (G 656).

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: 484: 65 Condition: Quality Assessment / Performance Improvement.

The findings included:

A review of the policy "Performance Improvement Program [QAPI] dated 12/6/17 stated, "To evaluate all areas of concern and implement plans to resolve the issues ... Special Instructions 1. The development of a performance improvement plan will be guided by the mission, vision, and strategic goals of the organization. Additional activities for performance improvement

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will be prioritized by the agency's management team ... data will be collected to allow the agency to monitor its performance. Data will be collected, measured, and analyzed ..."

A review of the agency document titled "Title of Position" Quality Improvement Manager" dated 2018 stated, "Title of Immediate Supervisor: Director of Nurses ... Duties: Assist in the development, implementation, and evaluation of the Continuous Quality Improvement ... Program and activities that support the Agency's objectives in delivering quality patient care services .... "

A review of the agency policy titled "1.19 Agency Supervision" dated 2018 stated, "Administrator's Duties shall be to ... direct and monitor organizational and performance improvement activities."

A review of the agency documents and interviews on 2/7/19 failed to show a quality assurance program was in effect and had plans, measurable data, and other evidence of a functioning, ongoing, effective quality assurance program.

On 2/7/19 at 2 PM, the office manager indicated the quality assurance meetings and program were lacking at this time.

At the entrance conference on 2/7/19 at 11:00 a.m., the quality assurance program was requested. At 4:20 PM, the quality assurance program was requested again and the office manager presented the documents. The office manager indicated documents provided was the program minutes in its entirety.

The agency document titled "Professional

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G 640	Continued From page 58 Advisory Committee of Blessed Hands Home Care Agency LLC for Profit Home Health Agency" stated, "On 12/4/18 at 10:30 AM, the Board of Directors of Blessed Hands ... called for a Professional Advisory Committee Meeting. the following directors were present at the meeting: [the owner, President; Employee V, Vice President; Employee A, office coordinator; Employee B, clinical manager; Employee H, RN; Employee T, Data entry clerk]. Agency evaluation In reviewing the agency's overall success, the office coordinator [employee A] had brought up many points. First, the agency has a census of 16 patients with 11 being HHA patients and of those 11 4 are skilled. It is in the best interest that the company not take on any more clients at this time r/t the disorganization that will be presented in this meeting. After review of 10 % of the current records, it is noted that paperwork is missing, recerts are done late and some are incomplete but have been processed. [Employee B] the clinical manager works another job, thus making it impossible for her to function at the max capacity of her role. It has also been noted that there have been no client satisfaction surveys quarterly to measure patient satisfaction. The RN's in the field are bringing back concerns/ complaints from the clients, whom are not calling the office. There have been no review of the agency budget and no meetings for leadership to outline key agency objectives. The director of finance [the owner] has not found time to distribute a budget for the company. At this time, the company functions without an administrator in place, and patient care is becoming a concern, especially with the number of complaints being raised by clients. Staff retention is at a low staff that have been here believe they should receive raises. Raises aren't feasible with the number of	G 640		

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clients that are current. It is also noted clinical reviews of active charts are not being done quarterly. There is a plan of correction being implemented for all of this issues that myself and the clinical team has found. Agency appointments: The agency does not have a qualified candidate to apply for the administrator / alternate administrator or alternate clinical manager role. The agency has yet to find and appoint a medical director."

A review of an undated document with no title evidenced the following: "The team has addressed and developed clinical expectations in the area of OASIS, and OASIS submissions. It was the understanding of the agency that the electronic medical record system was exporting and submitting the OASIS data. Upon recent discovery, we have found that it isn't the case. The agency has written a plan of correction and going forward for OASIS sets will be submitted at least 1 X monthly. The sets should occur no less that every 60 days for patients. It has been brought to the attention of the professional advisory staff that, training in regard to OASIS C is necessary for the staff nurses. Clinical record review/ outcome based quality management: Quarterly review: 10 records selected, open and closed, all disciplines, variety of diagnostic categories and rehospitalizations, focus on indicators of quality and utilization, Clinical staff representing the scope of services provided in the reviews, General findings demonstrated that care was appropriate, adequate, and effective in meeting client needs, specific areas for improvement are addressed individually with staff members, and with in-services. Education is also carried out via text messages and mailbox in-services. The quarterly review also included

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G 640	Continued From page 60 OBQM reports that list potential adverse events, low frequency, negative and untoward events which potentially reflect a serious health issue or decline in health status for an individual client. This year we continue to process improvement work in the areas of in-depth documentation, ensuring each professional is educations clients related to their diagnosis, and client falls. In-depth documentation: the agency has educated the professional staff entering client homes to make sure they are documenting client home conditions ... Patient Education ... Emergency Preparedness ... Employee Tardiness / Absenteeism ... Drug testing ... HIPAA ... Discharges ... Goals: Improve QAPI process, Improve employee Tracking and absenteeism, increased level of education related to diagnosis, drug testing randomly, less breaches of HIPAA, improve and sustain continuity of nursing visits, fully integrate process measures and best practices, updated budget, minimize on client complaints, leadership meetings, in-service meetings, improved documentation time, Emergency Preparedness training for aides." The minutes were transcribed by Employee T, office staff.	G 640		
G 680	Infection prevention and control CFR(s): 484.70 Condition of Participation: Infection prevention and control. The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases. This CONDITION is not met as evidenced by: Based on record review and interview, the home health agency failed to have an active infection	G 680		

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G 680	Continued From page 61 control program for 1 of 1 agency (see G 680); failed to maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infections and communicable diseases and incorporated the information into the agencies QAPI (quality assurance and performance improvement) program for 1 of 1 agency. 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: 484.70 Condition of participation: Infection prevention and control. Findings include: On 2/7/19 at 2:10 PM, Employee B, the clinical supervisor, indicated no involvement with the infection control program and no knowledge about where the infection control program was at this agency. There had been no infections since Employee B started with the agency in August 2018. There was no documentation of a program or activities since March 2018. A review of the infection control log on 2/19/19 evidenced the entries for infection activities for February and March 2018. There was no other documentation in the log for later in 2018.	G 680		
G 706	Interdisciplinary assessment of the patient CFR(s): 484.75(b)(1) Ongoing interdisciplinary assessment of the patient; This ELEMENT is not met as evidenced by: Based on observation, record review, and	G 706		

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interview, the agency failed to ensure that a skilled nurse went out to assess a patient who had fallen and bumped their head for 1 of 1 conversation overheard of a patient who had fallen. (#9)

Findings include:

The agency policy titled "2.6 Service Policies Nursing Service" dated 2018 stated, "Nursing service is provided by Registered Nurses [RNs] or Licensed Practical Nurses [LPNs] ... Professional Nursing [RN] functions: In keeping with professional standards and depending upon each patient / family need, all or a selection of the following nursing functions may be performed ... informing the physician and other staff of changes in the patient's condition / needs."

During a office observation on 2/15/19 at 10:30 AM, the office manager was heard speaking to patient #9's family on phone and indicated patient had a fall recently.

During an interview on 2/15/19 at 11:10 AM, the office manager indicated patient #9 had bumped his / her head with a recent fall at home and the patient had no concerns with this fall.

During an interview on 2/15/19 at 1:06 PM, the office manager indicated activating a fall report. The office manager instructed Employee H, RN, to visit patient #9 since a fall had occurred and been reported by the patient's representative. The fall report was requested but not received.

A review of the record #9 failed to show any documentation about the patient #9's recent fall.

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G 706	Continued From page 63 During a phone call on 2/19/19 at 11:55 AM, the patient representative for patient #9 was called. The patient's representative indicated the patient had fallen and bumped his / her head, a bruise on the head disappeared quickly, and the patient was fine. The patient's representative indicated the Emergency Medical Personnel had come to the house, and transport to the emergency room was declined. During an interview on 2/20/19 at 3:35 PM, Employee H indicated being told by the owner of the agency not to visit patient #9 after the fall.	G 706		
G 750	Home health aide services CFR(s): 484.80 Condition of participation: Home health aide services. All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. This CONDITION is not met as evidenced by: Based on home visit observation, record review and interview, the agency failed to ensure all home health aides completed a competency evaluation program and / or were currently listed in good standing on the state nurse aide registry or home health aide registry for 4 of 15 records reviewed of staff who worked as home health aides for the agency (see G 752), failed to ensure home health aide visits were furnished as ordered on the home health aide plan of care for 1 of 3 active patients who were observed at a home health aide observation (see G 798) and failed to ensure a home health aides only completed tasks allowed under state law during home visits for 2 of 3 home visits observed with a home health	G 750		

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G 750	Continued From page 64 aide and 2 of 7 active clinical records reviewed with home health aide services (see G 800). 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 484.80 Home Health Aide Services.	G 750		
G 754	A qualified HH aide successfully completed: CFR(s): 484.80(a)(1)(i-iv) A qualified home health aide is a person who has successfully completed: (i) A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or (ii) A competency evaluation program that meets the requirements of paragraph (c) of this section; or (iii) A nurse aide training and competency evaluation program approved by the state as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the state nurse aide registry; or (iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure all home health aides completed a competency evaluation program and/ or were currently listed in good standing on the state nurse aide registry or home health aide registry for 4 of 15 records reviewed (#J, L, N, S) of staff who worked as home health aides for the agency. The findings included:	G 754		

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1. A review of the policy titled "2.52 Home Health Aide Service" dated 2018 stated, "Duties of a Home Health Aide The nurse or therapist is demonstrated or observe the skills involved before they are performed by an HHA if the HHA does not have documented training or experience in performing the tasks prescribed in the plan of care."

2. A review of the policy titled "Screening and Hiring" dated 2108 stated, "Licensed and Nonlicensed Personnel will they demonstrate they are qualified for the position they are applying for ... all individuals must meet the minimum qualified in accordance with applicable laws and regulations and agency job description."

3. A review of the policy titled "Employee Qualifications" dated 2018 stated, "Home Health Aides 1. Must have completed an aide training program of at least 75 hours which conforms to state and Federal requirements."

4. A review of Employee J's file, with unknown hire date and first patient contact date, failed to evidence the home health aide was listed in good standing on the state nurse aide registry or home health aide registry. A competency checklist had been completed on 11/3/16 for this employee.

During an interview on 2/14/19 at 2:20 PM, the owner indicated Employee J wrote her qualifications as a Home health aide when she was not.

5. A review of Employee L's File, with a hire date of 5/12/16 and first patient contact date of 5/23/16, evidenced this home health aide did not

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G 754	Continued From page 66 become registered as a home health aide until 3/7/17. The file evidenced a personal care skills checklist dated 5/17/16 and a companion/ homemaker competency checklist dated 5/18/16. The home health aide competency test was dated 5/12/16 with a score of 87%. 6. A review of Employee N's file, HHA, with unknown hire date and first patient contact date failed to evidence the home health aide was listed in good standing on the state nurse aide registry or home health registry. The personnel file included a home health aide/ job description signed by the employee on 2/3/17. There was no competency checklist in the record. During an interview on 2/19/19 at 1:30 PM, the office manager indicated the employee worked as a personal care attendant and not a home health aide. 7. A review of Employee S's file, HHA, with a hire date of 12/28/16 and first patient contact 3/5/17 failed to evidence this employee had been placed on the aide registry. During an interview on 2/18/19 at 4:15 PM, the owner of the agency indicated this staff member was not on the aide registry as a home health aide or CNA.	G 754		
G 798	Home health aide assignments and duties CFR(s): 484.80(g)(1) Standard: Home health aide assignments and duties. Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care	G 798		

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instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).
This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the agency failed to ensure home health aide visits were furnished as ordered on the aide care plan and failed to ensure the aide care plan was made available to the employee for 1 of 3 active patients who were observed at a home health aide observation (#10).

The findings included:

The agency policy titled "2.52 Home Health Aide Service" dated 2018 stated, "Definition of Home Health Aide Service ... a. A home health aide provides services that are: i. ordered by the physician ii. included in the plan of care ... specific service standards: a. Assignment of home health aide duties."

Review of the clinical record of patient #10 on 2/14/19, evidenced a start of care date of 11/1/16, and contained a plan of care for the certification period of 12/25/18 - 2/22/19, with an order for home health aide (HHA), visits five times a week for 9 weeks. Interventions for the home health aide's care were not listed on this plan of care.

Review of an aide care plan dated 12/28/18 and signed by Employee H, RN, evidenced tasks that were be completed by the home health aide such as assisted bath or chair bath, personal care, assist with dressing, hair care, shampoo, check pressure areas, nail care file on Thursdays, clean dentures, assist with elimination, assist with

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ambulation, and positioning every 2 hours.

During a home visit observation on 2/15/19 at 1:40 PM, Employee P, HHA was observed to only clean the patient's home and failed to complete any personal care tasks. During this time, Employee P was asked why she did complete the tasks as listed on the aide care plan. Employee P indicated she did not have an aide care plan available.

During an interview on 2/15/19 at 1:40 PM, patient #10 indicated his/she would take a shower independently and did all of his/ her personal care, and his/her nail care.

During an interview on 2/18/19 at 11 AM, the clinical manager indicated the aide care plan needed tweaking.

G 800 — Services provided by HH aide
CFR(s): 484.80(g)(2)

A home health aide provides services that are:
(i) Ordered by the physician;
(ii) Included in the plan of care;
(iii) Permitted to be performed under state law; and
(iv) Consistent with the home health aide training.
This ELEMENT is not met as evidenced by:
Based on observation, record review and interview, the home health agency failed to ensure a home health aides only completed tasks allowed under state law during home visits for 2 of 3 home visits observed (patient #2) with a home health aide (Employee C, HHA) and 2 of 7 active clinical records reviewed with home health aide services (#2 and #4).

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The findings include:

1. The agency policy titled "2.55 Administration of Medication" dated 2018 stated, "Medication may be administered by RNs and LPNs in accordance with their skill, training, applicable state regulations, and established agency policies and procedures.

2. The agency document titled "2.52 Home Health Aide Service" dated 2018 stated, "A home health aide provides services that are i. Ordered by the physician ii. included in the plan of care iii. permitted to be performed under state law, and iv. consistent with the home health aide training."

3. The agency policy titled "2.11 Delegation of Tasks to Unlicensed Personnel" dated 2018 stated, "The RN shall provide the supervision of all nursing tasks delegated to unlicensed persons in accordance with the following conditions. The degree of supervision required shall be determined by the RN after an evaluation of appropriate factors ... Tasks which may not be delegated ... non - sterile procedures such as dressings ... f. administration of medications."

4. A review of clinical record #2 occurred on 2/14/19 and 2/20/19 evidenced an aide care plan dated 1/3/19 with a procedure to inspect/ reinforce dressing.

During a home visit observation on 2/11/19 at 9:30 AM, Employee C, HHA was observed to give patient #2 a bed bath. Employee C was observed to take a dressing off the suprapubic catheter site and then wash around the catheter site with warm soapy water. When the bath was complete, Employee C was observed to cut dressing with

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scissors by placing a notch into the gauze and then applying a dressing onto the site with a 4 X 4 dressing and taping this dressing into place.

During an interview on 2/20/19 at 2:25 PM, the owner indicated knowledge that the dressing change had occurred.

5. A review of an aide care plan dated 1/3/19 evidenced the aide was to apply numbing cream every Monday, Wednesday, and Friday to dialysis site.

A review of a patient case conference note dated 1/3/19 and signed by Employee H, RN, stated, "Patient receives (aide services) 5 hours a day every day. MWF [Monday, Wednesday, Friday] aides assist pt [patient] in getting ready for dialysis by giving med cues, fixing breakfast, tidying living areas of client, applying numbing cream to dialysis site."

A review of aide visit records dated 1/4/19, 1/9/19, 1/7/19, 1/11/19, 1/12/19, 1/14/19, 1/16/19, 1/18/19, 1/21/19, 1/23/19, 1/25/19, 1/30/19, 2/4/19, 2/6/19, 2/7/19, 2/10/19, 2/13/19 evidenced the numbing cream had been applied.

During an interview on 2/11/19 at 2:30 PM, patient #4 indicated needing the numbing cream applied approximately a half hour before leaving for dialysis treatments and the home health aide would complete this task when necessary.

During an observation on 2/11/19 at 3:15 PM, it was observed the numbing cream was Lidocaine 2.5 % and Prilocaine 2.5 % ointment.

During an interview on 2/11/19 at 3:15 PM,

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G 800	Continued From page 71 Employee C, HHA, indicated the patient needed assistance with the administration of the numbing cream due to visual problems and the inability to apply the cream. The patient's arm was washed, the cream applied and then plastic wrap applied before the patient attended hemodialysis treatments three times a week. During a phone interview on 2/15/19 at 11:50 AM, Person D, a nurse at patient #4's dialysis clinic, indicated the patient was prescribed the lidocaine cream.	G 800		
G 940	Organization and administration of services CFR(s): 484.105 Condition of participation: Organization and administration of services. 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 and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the Governing Body failed to ensure the agency was providing optimal care to achieve the goals and outcomes identified in the patients careplans, assure that administrative and supervisory functions are not delegated to an unauthorized agent of the agency, failed to	G 940		

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ensure that the agency had an alternate Clinical Manager to assume the responsibilities when the Clinical Manager was not available, and failed to ensure orgazinational structure were accurate for 1 of 1 agency (see G 940); failed to ensure the Governing Body assumed full legal responsibility for the agency's overall management and operations, fiscal operations, review of the budget, and its quality assessment and performance program until an administrator and/ or alternate could be put into place (G 942); Governing body failed to ensure they had an Administrator appointed to be responsible for all day to day operations of the agency (G 948); failed to ensure a clinical manager was available during all operating hours (see G 950); failed to ensure all home health aides completed a competency evaluation program and / or were currently listed in good standing on the state nurse aide registry or home health aide registry (see G 952); failed to ensure that an alternate administrator was designated and authorized in writy to asseme the same responsibilities and obligations as the administrator (G 954); the Clinical Manager failed to provide oversight of all patient care services and personnel (G 958); failed to ensure the clinical supervisor made patient and personnel assignments (see G 960); and failed to ensure clinical supervisor coordinated referrals (see G 964).

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: 484.105 Condition: Organization and Administration of Services.

In regards to G 940, the findings include:

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G 940	Continued From page 73 1. The agency policy titled "1.19 Agency Supervision" dated 2018 stated, "The Governing Body was approved the appointment of a clinical manager, who may also be the administrator. This person shall be available at all times during working hours. 2. Administrator's duties: The administrator is authorized to organize and director the agency's ongoing functions. The administrator shall be to: a. Assume responsibility of the day to day operations of the agency. b. Designate, in conjunction with the Governing Body and in writing, a qualified person to assume the same responsibilities and obligations as the administrator. This individual may be the clinical supervisor. c. Remains available, or has a qualified alternate available, during all operating hours. d. ensure that the clinical manager is available during all operating hours. e. Organize and direct the agency's operations to assure the availability and provision of care and services f. Implement governing body directives and organizational policies g. understand and ensure compliance with applicable laws and regulations h. Maintain liaison among the governing body, the QAPI committee, staff and the community, i. ensures that the agency employs qualified personnel, including assuring the development of personnel qualifications and policies ... k. direct and monitor organizational performance improvement activities ... ensure the accuracy of public information materials ... implement an effective budget and accounting system and manage operations in accordance with established fiscal parameters r. Submit to the governing body periodic reports of agency activity including financial statements ... oversee the agency's performance improvement program ... the	G 940		

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administrator shall authorize the hiring of administrative, clinical, and clerical positions as needed depending on the volume of services provided by the agency."

2. During observation from 2/7/19 - 2/20/19, it was observed that no administrator or alternate administrator was available to organize and direct the agency. The agency operated Wednesday - Friday 10 -5 PM.

A letter from the ISDH / Acute Care Program Director dated 4/18/18 evidenced the Employee A, office manager, had resigned from the administrator position effective 4/11/18 and Employee E, alternate administrator / clinical supervisor had resigned 2/1/18. The agency had been asked to submit documentation about the advertisement of the open positions in this letter and how soon the agency had planned to have the positions filled.

On 2/7/19 at 10:48 AM, Employee A, office manager, indicated there was no administrator or alternate administrator currently at the agency. Employee A indicated the clinical supervisor, Employee B, had a full time job elsewhere and was not at the agency during this time but could be available. There was no alternate clinical supervisor on staff at the current time.

On 2/8/19 at 11:10 AM, the owner indicated that herself and the office manager were responsible for the daily operations of the agency and the clinical manager is available by phone. The owner indicated not being able to afford a full time administrator who would work a 40 hour work week.

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On 2/8/19 at 1:49 PM, the office manager indicated April - May 2018 was a tense time with no administrative staff in place. There was a nurse (Employee I, RN) working at the agency.

A document titled "Blessed Hands Home Care Agency" presented 2/8/19 and prepared by Employee A, office manager, was written at writer's request to show all of the administrator / clinical services positions and dates of inception since the agency start on November 13, 2014. March 2017 evidenced the administrator and director of nursing was Employee D, RN, and the alternate administrator and alternate director of nursing were Employee B, RN. March 2017 evidenced the administrator and director of nursing was Employee D, RN, and the alternate administrator and alternate director of nursing were Employee B, RN. August 2017 evidenced the alternate administrator was Employee F, RN and Employee E, Clinical Manager. November 2017 showed the administrator was Employee A, office manager, and director of nursing and alternate administrator was Employee E, RN. April 2018 showed the administrator / alternate administrator vacant since April 2018. April - July 2018, there was no clinical supervisor or alternate clinical supervisor in the agency. August 2018 evidenced the clinical manager was Employee B, RN. There was no alternate director of nursing.

A letter written by the owner of the agency dated 7/1/18 evidenced the agency was recruiting for open management positions including facebook, zip recruiter, and indeed. This letter evidenced the agency lacked an administrator, alternate administrator, clinical manager, and alternate clinical manager.

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During an interview on 2/19/19 at 11:35 AM, the writer presented the owner with a copy of the office manager's discontinuation as administrator from the ISDH which had been sent to the agency. The owner did not indicate knowledge of this letter and was surprised about this letter's existence.

3. A review of a resume for the office manager who applied for the administrator position for the agency. This resume was presented on 2/19/19. This resume was not accurate since the office manager did not have a Bachelor's in Health Care Administration. The resume evidenced the degree in health care administration had been completed in January 2019.

During an interview on 2/20/19 at 11:10 AM, the office manager indicated not finishing her degree yet. She indicated having a class to finish.

During an interview on 2/20/19 at 3:30 PM, the owner indicated the office manager had not finished her degree yet and the resume was not accurate.

4. A review of the organizational chart on 2/719 evidenced auxiliary services were listed on the organizational chart. These auxiliary services included physical therapist, occupational therapist, speech therapist, and medical social worker.

During the entrance conference on 2/7/19 at 11:00 a.m., the office manager and owner indicated the agency only offered skilled nursing and home health aide related services.

During an interview on 2/719 at 1:20 PM, the

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G 940	Continued From page 77 office manager indicated this was the agency's organizational chart. The agency did not have therapies or social worker services.	G 940		
G 942	Governing body CFR(s): 484.105(a) Standard: Governing body. A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its quality assessment and performance improvement program. This STANDARD is not met as evidenced by: Based on record review and interview, the agency failed to ensure the governing body exercised full legal responsibility for the agency's overall management and operations, fiscal operations, review of the budget, and its quality assessment and performance program for 1 of 1 agency. The findings include: The agency policy titled "Agency Organizational Guidelines" dated 2018 stated, "Introduction: It shall be the policy of the agency to strive to render home health care services according to the highest medical and ethical standards. The board of directors, also known as the governing body, assumes full legal authority, responsibility, and accountability for the operation of the agency, including the agency's management and fiscal affairs. The Governing Body adopts and reviews the agency's bylaws and articles of incorporation ... services shall be available 7 days per week 24	G 942		

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hours per day.

A review of the agency from 2/7/19 - 2/20/19 failed to evidence the governing body had a qualified administrator or alternate administrator in place, a budget was in place, review of agency by-laws had occurred, accountability of the agency for its organizational structure was upheld, the clinical manager or alternate clinical manager was available during all operating hours, and a quality assurance program was functioning and active.

The agency document titled "Professional Advisory Committee of Blessed Hands Home Care Agency LLC for Profit Home Health Agency" stated, "On 12/4/18 at 10:30 AM, the Board of Directors of Blessed Hands ... called for a Professional Advisory Committee Meeting. the following directors were present at the meeting: [the owner, President; Employee V, Vice President; Employee A, office coordinator; Employee B, clinical manager; Employee H, RN; Employee T, Data entry clerk]. Agency evaluation In reviewing the agency's overall success, the office coordinator [employee A] had brought up many points. First, the agency has a census of 16 patients with 11 being HHA patients and of those 11 4 are skilled. It is in the best interest that the company not take on any more clients at this time r/t the disorganization that will be presented in this meeting. After a review of 10 % of the current records, it is noted that paperwork is missing, recerts are done late and some are incomplete but have been processed. [Employee B] the clinical manager works another job, thus making it impossible for her to function at the max capacity of her role. It has also been noted that there have been no client satisfaction

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surveys quarterly to measure patient satisfaction. The RN's in the field are bringing back concerns/ complaints from the clients, whom are not calling the office. There have been no review of the agency budget and no meetings for leadership to outline key agency objectives. The director of finance [the owner] has not found time to distribute a budget for the company. At this time, the company functions without an administrator in place, and patient care is becoming a concern, especially with the number of complaints being raised by clients. Staff retention is at a low staff that have been here believe they should receive raises. Raises aren't feasible with the number of clients that are current. It is also noted clinical reviews of active charts are not being done quarterly. There is a plan of correction being implemented for all of these issues that myself and the clinical team has found. Agency appointments: The agency does not have a qualified candidate to apply for the administrator / alternate administrator or alternate clinical manager role. The agency has yet to find and appoint a medical director."

A document with no title addressed the development of the clinical expectations in the Area of OASIS and OASIS submissions and the reason that the lack of exporting and submitting data had occurred. This has been corrected and will be done monthly. This document went on to explain what would be done to improve the agency including improving the quality improvement process, improve employee tracking and absenteeism, increased level of education related to diagnosis, drug testing randomly, less breaches of HIPAA, improve and sustain continuity of nursing visits, updated budget, minimize on client complaints. This was

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transcribed by Employee T, the data entry clerk. There was no date. There was no data or active programs in place.

A review of the department's documents on 2/7/19 evidenced the administrator, Employee A, had resigned 4/11/18 and the alternate administrator / clinical supervisor (past Employee B) had resigned effective 2/1/18. A review of other documents evidenced a lack of administrator since 4/11/18, lack of alternate administrator since 2/1/18, a lack of alternate clinical supervisor since November 2017.

A document titled "Blessed Hands Home Care Agency administration timeline" prepared by Employee A, office manager on 2/8/19 evidenced the following:

November 13, 2014: Employee OO, RN, administrator, and director of nursing
Employee PP, alternate administrator and alternate director of nursing.

March 5, 2015: Employee E, administrator, and director of nursing
Employee PP, alternate administrator and alternate director of nursing

March 2016: Employee PP, administrator, director of nursing
Employee PP, alternate administrator
No alternate director of nursing

March 2017: Employee D, administrator, and director of nursing
Employee B, alternate administrator and alternate director of nursing

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August 2017: Employee FF, alternate administrator
Employee B, alternate director of nursing
Employee E, clinical manager
(continue with Employee D as administrator)

November 2017: Employee A, administrator
Employee E, alternate administrator, and director of nursing
No alternate director of nursing

April 2018: Administrator / alternate administrator: Open

August 2018: Employee B, RN clinical manager.

The agency document titled "Indeed" and presented 2/19/19 evidenced advertisements for the following positions: HHA, RN administrator, Payroll Clerk / Human Resources, Registered Nurse. The dates on these May 3rd, 2018. LPN was dated June 29, 2018.

A review of a resume for the office manager who applied for the administrator position for the agency. This resume was presented on 2/19/19. This resume was not accurate since the office manager did not have a Bachelor's in Health Care Administration. The resume evidenced the degree in health care administration had been completed in January 2019.

During an interview on 2/7/19 at 1:25 PM, the office manager indicated the quality assurance program was overseen by the owner. There was no budget committee in place. There were no

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disaster services currently.

During an interview on 2/7/19 at 1:55 PM, the owner indicated the agency had yet to find qualified staff for the administrator, alternate administrator, and alternate clinical supervisor. The budget was not in place and had not been reviewed and that the quality assurance program was lacking.

During an interview on 2/20/19 at 11:10 AM, the office manager indicated not finishing her degree yet. She indicated having a class to finish.

During an interview on 2/20/19 at 3:30 PM, the owner indicated the office manager had not finished her degree yet and the resume was not accurate.

G 950 Ensure clinical manager is available
CFR(s): 484.105(b)(1)(iii)

(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;
This ELEMENT is not met as evidenced by:
Based on observation, record review and interview, the agency failed to ensure a clinical manager was available during all operating hours for 1 of 1 agency.

The findings include:

The agency policy titled "1.19 Agency Supervision" dated 2018 stated, "The Governing Body was approved the appointment of a clinical manager, who may also be the administrator. This person shall be available at all times during working hours. 2. Administrator's duties: The

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administrator is authorized to organize and direct the agency's ongoing functions. The administrator shall be to: a. Assume responsibility of the day to day operations of the agency. b. Designate, in conjunction with the Governing Body and in writing, a qualified person to assume the same responsibilities and obligations as the administrator. This individual may be the clinical supervisor. c. Remains available, or has a qualified alternate available, during all operating hours. d. ensure that the clinical manager is available during all operating hours."

On 2/7/19 at 10:48 AM, Employee A, office manager indicated the clinical supervisor, Employee B, had a full-time job and was not here at this time but could be available. There is no alternate clinical supervisor on staff at the current time. There was no clinical supervisor at the agency at this time.

A review of personnel file B's file on 2/8/19 evidenced an acceptance letter dated 8/1/18 for part-time of RN. The letter did not evidence that this employee would be the clinical supervisor. The letter stated, "Dear [clinical supervisor] Welcome to Blessed Hands Home Care Agency. I am pleased to confirm your acceptance of our offer for the part-time ... position of RN; reporting to [Employee D, a past employee]. Your starting salary will be at the rate of ... per hour ... We are delighted you are joining us and your role as a Home Health Aide [not accurate job description] ... is critical in fulfilling the mission of the agency .. During your first few weeks, you will meet many co-workers, supervisors, managers and human resource staff. We are all here to support you. These individuals are available to serve as a

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resource, so please let them know what you need to accomplish your new responsibilities. You may contact [office manager] for scheduling and call offs and [office manager] for employment verifications and any human resource things you may need ... Sincerely, [office manager signature, chief operations manager]. This was signed by the clinical supervisor also. Handwritten on this document was 25 hours/ week.

On 2/13/19 at 11:25 AM, Employee A indicated the clinical supervisor would not be available due to the weather.

Per office telephone call on 2/13/19 at 11:44 AM, Employee A indicated leaving a message with the clinical supervisor to return call and this call was not returned until 1:15 PM.

During a face time phone call on 2/13/19 at 1:15 PM, the clinical manager called. She explained she could not get out of her apartment building due to the weather and would not be in the office.

During an interview on 2/14/19 at 11:50 AM, the clinical supervisor was not available by phone or in the office. This was discussed with the office manager at this time.

During an interview on 2/14/19 at 2:01 PM, the clinical supervisor was not available by phone or in the office. This information was discussed with the office manager at this time.

During an interview on 2/14/19 at 2:20 PM, the owner/ governing body indicated the clinical supervisor was a nervous winter driver and was not available today.

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G 950	Continued From page 85 On 2/14/19 at 3:21 PM, it was observed that the owner, Employee C, received a text from the clinical manager. This text stated that the clinical manager was not available, the clinical manager just had a physical, severe UTI, chills, dehydration, and an elevated temperature of 101.5 degrees, and was on her way home. During an interview on 2/15/19 at 10:35 AM, the office manager, Employee A, indicated the clinical supervisor would not be in today. She works Fridays at her other job. During an interview on 2/18/19 at 10:25 AM, the clinical supervisor, Employee B, indicated working part-time at this agency 7 -12 hours a week including caring for patient #1 and #3. She indicated the office manager would make the personnel assignments and coordinates referrals. During an interview on 2/18/19 at 12 noon, the clinical supervisor, Employee B, indicated being very tired, ill, would be leaving the agency at this time, and would not be available.	G 950		
G 952	Ensure that HHA employs qualified personnel CFR(s): 484.105(b)(1)(iv) (iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure all home health aides completed a competency evaluation program and/ or were currently listed in good standing on the state nurse aide registry or home health aide registry for 4 of 15 records reviewed (#J, L, N, S) of staff who worked as home health aides for the	G 952		

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G 952	Continued From page 86 agency. The findings included: 1. A review of the policy titled "2.52 Home Health Aide Service" dated 2018 stated, "Duties of a Home Health Aide. The nurse or therapist demonstrate or observe the skills involved before they are performed by an HHA if the HHA does not have documented training or experience in performing the tasks prescribed in the plan of care." 2. A review of the policy titled "Screening and Hiring" dated 2108 stated, "Licensed and Nonlicensed Personnel will they demonstrate they are qualified for the position they are applying for ... all individuals must meet the minimum qualified in accordance with applicable laws and regulations and agency job description." 3. A review of the policy titled "Employee Qualifications" dated 2018 stated, "Home Health Aides 1. Must have completed an aide training program of at least 75 hours which conforms to state and Federal requirements." 4. A review of Employee J's file, with unknown hire date and first patient contact date, failed to evidence the home health aide was listed in good standing on the state nurse aide registry or home health aide registry. The personnel file included a personal care worker/ homemaker job description signed by Employee J on 9/28/16. A competency checklist had been completed on 11/3/16 for this employee. During an interview on 2/14/19 at 2:20 PM, the owner indicated Employee J wrote her	G 952		

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G 952	Continued From page 87 qualifications as Home health aide which she is not. 5. A review of Employee L's File, with a hire date of 5/12/16 and first patient contact date of 5/23/16, evidenced this home health aide did not become registered as a home health aide until 3/7/17. The file evidenced a personal care skills checklist dated 5/17/16 and a companion/ homemaker competency checklist dated 5/18/16. The home health aide competency test was dated 5/12/16 with a score of 87%. 6. A review of Employee N's file, HHA, with unknown hire date and first patient contact date failed to evidence the home health aide was listed in good standing on the state nurse aide registry or home health registry. The personnel file included a home health aide/ job description signed by the employee on 2/3/17. There was no competency checklist in the record. During an interview on 2/19/19 at 1:30 PM, the office manager indicated the employee worked as a personal care attendant and not a home health aide. 7. A review of Employee S's file, HHA, with a hire date of 12/28/16 and first patient contact 3/5/17 failed to evidence this employee had been placed on the aide registry. During an interview on 2/18/19 at 4:15 PM, the owner of the agency indicated this staff member was not on the aide registry as a home health aide or CNA.	G 952		
G 960	Make patient and personnel assignments, CFR(s): 484.105(c)(1)	G 960		

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Making patient and personnel assignments,
This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency's clinical supervisor failed to make patient and personnel assignments for 1 of 1 agency.

The findings include:

The agency policy titled "1.19 Agency Supervision" dated 2018 stated, "The Administrator may act as the clinical manager if he/ she is qualified, or may appoint another qualified individual who has authority and responsibility to supervise clinical service but not limited to the major functions listed below ... implement planned programs and services, ensuring quality care standards."

During an interview on 2/18/19 at 10:25 AM, the clinical supervisor, Employee B, indicated working part-time at this agency 7 -12 hours a week including caring for patient #1 and #3. Employee B indicated that the office manager would make the personnel assignments.

During an interview on 2/20/19 at 11:40 AM, the office manager indicated she and the owner made the personnel assignments for the patients around the 25th of each month.

On 2/8/19 at 11:10 AM, the owner indicated that she and the office manager were responsible for the daily operations of the agency. The owner indicated not being able to afford a full-time administrator who would work a 40 hour work week.

On 2/8/19 at 1:49 PM, the office manager

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G 960	Continued From page 89 indicated April - May 2018 was a tense time with no administrative staff in place.	G 960		
G 964	Coordinate referrals; CFR(s): 484.105(c)(3) Coordinating referrals, This ELEMENT is not met as evidenced by: Based on record review and interview, the agency's clinical manager failed to coordinate referrals for 1 of 1 agency. The findings include: The agency policy titled "1.19 Agency Supervision" dated 2018 stated, "The Administrator may act as the clinical manager if he/ she is qualified, or may appoint another qualified individual who has authority and responsibility to supervise clinical service but not limited to the major functions listed below ... implement planned programs and services, ensuring quality care standards." During an interview on 2/18/19 at 10:25 AM, the clinical supervisor, Employee B, indicated working part-time at this agency 7 -12 hours a week including caring for patient #1 and #3. Employee B indicated that the office manager would coordinates referrals.	G 964		
G1008	Clinical records CFR(s): 484.110 Condition of participation: Clinical records. The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to	G1008		

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G1008	Continued From page 90 current clinical record documentation standards of practice, and be available to the physician(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the agency failed to ensure they followed their agency policy and that the clinical records contained accurate information for 2 of 12 records reviewed (see G 1008); failed to ensure clinical records contained plans of care (see G 1012); and failed to ensure a physician signed and dated a plan of care within a timely manner. (see G 1024). 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: 484.110 Condition: Clinical Records. Regarding G 1008, the findings include: 1. The agency policy titled "2.43 Clinical Record Contents" dated 2018 stated, "The agency maintains a confidential clinical record for each patient / client admitted to care ... The identifying data includes ... signed, timed and dated admission and clinical notes that are written the day the service is rendered and incorporated at least weekly ... All required documentation must be completed and in the patient / client record within 14 days of service delivery. 2. A review of record #4 evidenced duplicate aide visits on the same days and times. Employee O had not visited the patient. This is further	G1008		

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	15K132	A. BUILDING ______ B. WING ______	02/20/2019

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G1008	Continued From page 91	G1008		

evidenced by the following:

A review of record #4 evidenced an aide weekly visit record showing Employee O, HHA had visited patient #4 on 4/16/18, 4/17/18, 4/18/18, 4/19/18, 4/20/18 from 11 AM - 4 PM and completed tasks including shower, complete bath, personal care, assist with dressing, skin care, foot care, and check pressure areas and other tasks. Another aide visit record evidenced Employee J, HHA had visited patient #4 on 4/18/18, 4/19/18, 4/20/18, 4/21/18 from 11 AM - 4 PM and completed bed bath, bath assist in a chair, assist with dressing, skin care, medication reminders, and light housekeeping. These records showed the aides visited at the same time and did the same tasks.

On 2/11/19 at 2:28 PM, patient #4 indicated only one aide is here at a time unless they are changing shifts.

On 2/14/19 at 12:20 PM, Employee J indicated always working by herself and without other employees present. She indicated not knowing Employee O.

On 2/14/19 at 2 PM, the owner explained the difference between home health aide records and personal service records and indicated the agency did not duplicate services.

A review of a plan of care for the certification period of 1/3/19 - 3/3/19 evidenced a signature from the physician on 2/3/19. A date on the top of this document showed the completion date of 2/7/19.

During an interview on 2/15/19 at 11:50 AM, the

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G1008	Continued From page 92 office manager indicated the signature on last plan of care with patient #4 was an error. This was superimposed on paper and was a mistake. 3. A review of clinical record #10 evidenced visits made with Employee O on 11/12/18, 11/13/18, 11/14/18, 11/15/18, and 11/16/18. During a phone interview on 2/15/19 at 9:40 AM, patient #10 indicated he/ she never had a male aide come into the home, including Employee O.	G1008		
G1012	Required items in clinical record CFR(s): 484.110(a)(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician orders; This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure clinical records contained plans of care for 1 of 12 records reviewed. (#6) Findings include: 1. The agency policy titled "1.23 Electronic Records" dated 2018 stated, "All legal requirements for maintaining, protecting, and storing paper medical records must be followed for electronic records ... the medical record must meet all statutory, regulatory and professional requirements for clinical purposes as well as business purposes. The electronic medical record, to be a legal record, must conform to the same requirements as medical records in general and for business records on computers more specifically .... "	G1012		

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G1012	Continued From page 93	G1012		

2. The agency policy titled "Clinical Record Maintenance" dated 2018 stated, "The agency shall maintain clinical records for all patients which contain the physician's plan of treatment [if required], clinical and progress notes, and other pertinent information. Entries to patient record documentation are made only y authorized staff and in accordance with organizational policy and procedure ..."

3. A review of an audit trail document for patient #2 on 2/15/19 evidenced the plan of care for the certification period of 1/10/19 - 3/10/19 was created and saved on 2/7/19. The plan of care was not completed in a timely manner and care took place without the plan of care being completed and sent to and approved by the physician.

4. A review of record #3 on 2/8/19 and 2/15/19 evidenced the plan of care for the certification period of 1/24/19 - 3/24/19 was created and saved on 2/7/19 and faxed to the physician on 2/7/19. The plan of care was not completed in a timely manner and care took place without the plan of care being completed and sent to the physician for approval.

5. A review of an audit trail document for patient # 4 evidenced the plan of care for the certification period of 1/3/19 - 3/3/19 was not created, saved, or faxed to the physician until 2/7/19. Care had taken place during this time.

6. During an interview on 2/15/19 at 11:15 AM, the office manager indicated the recently created plans of care for patient #2, #3, and #4 were not completed in a timely manner.

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G1024	Continued From page 94	G1024		
G1024	Authentication CFR(s): 484.110(b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry. This STANDARD is not met as evidenced by: Based on record review and interview, the agency failed to ensure a physician signed a plan of care within a timely manner for 1 of 12 records reviewed. (#5) Findings include: The agency policy titled "2.43 Clinical Record Contents" dated 2018 stated, "Physician orders ... A verbal or written physician order is obtained prior to starting care ... These orders are to be renewed as necessary and a minimum of every 2 months for patients / clients receiving skilled care .... " A review of record #5 on 2/13/19 failed to evidenced a physician's signature on the plan of care for the certification period of 9/23/18 - 11/21/18. During an interview on 2/18/19 at 12:45 PM, the office manager indicated the physician signed plan of care was not present in the record.	G1024		