STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 000}	INITIAL COMMENTS	{G 000}		

This was a federal and state post condition re-visit from a survey originally completed on 8/27/20.

An immediate jeopardy (IJ) was called on 12/18/2020. The administrator was notified on 12/18/20 at 5:09 PM regarding an IJ at 42 CFR 484.55 Comprehensive assessment, and 42 CFR 484.60 Care Planning, coordination, quality of care. The IJ was not abated upon exit on 1/12/2021 due to all patients' records had not been reviewed nor all patient reassessment had occurred since the IJ was called. The agency, by their own admission, indicated on an IJ removal plan submitted 1/08/21, that all record reviews and sending coordination forms to involved agencies would not be completed until 1/22/2021.

Survey Dates: December 15, 16, 17, 18, 28, 29, 30 (2020); and January 4, 5, 6, 7, 11, 12, (2021)

Facility Number: IN005372

Provider Number: 157211

Active Census: 143

During this survey, 2 of 2 Conditions remained unabated: 42 CFR 484.60 Care planning, coordination, quality of care, and 42 CFR 484.105 Organization and administration of services; and 2 new conditions were cited: 42 CFR 484.50 Patient Rights, and 42 CFR 484.55 Comprehensive assessment of patients; 6 standards were corrected; 17 standards were re-cited; and 22 new standards were cited.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/24/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 000}	Continued From page 1 Based on the Condition-level deficiencies during the January 12, 2021 survey, Home Nursing Services was subject to a post-condition revisit survey pursuant to section 1891(c)(2)(D) of the Social Security Act on August 20, 2020. Therefore, and pursuant to section 1891(a)(3)(D)(iii) of the Act, Home Nursing Services is precluded from operating or being the site of a home health aide training and/or competency evaluation programs for the two years beginning January 12,2021 and continuing through January 12, 2023 for being found out of compliance with the Conditions of Participation 42 CFR 484.50 Patient Rights; 42 CFR 484.55 Comprehensive assessment of patients; 42 CFR 484.60 Care Planning, coordination, quality of care; and 42 CFR 484.105 Organization and administration of services. Quality review completed on 2/5/20 by Area 2	{G 000}		
G 406	Patient rights 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 all agency patients with known wounds were free from neglect (See Tag G 430). The cumulative effect of these systemic problems resulted in the agency's inability to ensure all patients' rights were maintained as required by	G 406		

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	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 406	Continued From page 2 the Condition of Participation 484.50 Patient Rights.	G 406		
G 430	Be free from abuse CFR(s): 484.50(c)(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property; This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to assume any responsibility for patients with known wounds and neglected the needs of the patients, including, but not limited to: not assessing the patients appropriately or identifying and completing the interventions needed; not providing coordination of care to other entities who also provided care to patients with wounds; and failed to assume any responsibility to notify the physician of significant changes in condition which led to new or worsening wounds, urinary tract infection, hospitalization, amputation, and/or death for 3 of 7 patients' records reviewed with wounds (#1, 7, and 9). Findings include: 1. Review of an undated agency policy titled "Home Care Client Rights and Responsibilities" stated "... You [client/patient] have the right to: ... be free from ... neglect ...." Review of a reference document N Engl J Med 1995 Feb 16; 332(7):437-43 titled "Abuse and Neglect of Elderly Persons" stated "[patient neglect, defined as] the failure of a designated caregiver to meet the needs of a dependent."	G 430		

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G 430	Continued From page 3	G 430		

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021.

Review of a document received on 12/28/2020 titled "SN [skilled nurse] SOC [start of care] OASIS and Comprehensive Assessment" dated 12/10/2019 evidenced the patient had no wounds, and was alert and oriented to person, place, and time, without confusion or disruptive behaviors.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 10/3/2020 (for certification period 10/5/2020-12/3/2020) evidenced the patient was fully oriented and able to make own decisions, normal behavior, and had a wound on his right groin area. The document stated "... Right groin ... Irtritation [sic] from brief rubbing on the area ... scabbed over area ... measurements: 1x2 ... MD to evaluate wound ... Wound care orders already in place: No ... Orders need to be obtained: Yes ... Overall, the level of function has been: Slowly deteriorating ... Does the physician-ordered plan of care include the following ... Interventions to prevent pressure ulcer (wound) ... [box checked] Yes ... now has home attendant from entity B [personal care services] ... and they are responsible for these services ... heavy smoker ... observed foul smelling wound to the groin. Area appears dark red in color with puss [sic]-like drainage present. Advised POA [power of attorney- family member] to keep all follow-up appointments with the wound clinic due to possible infection to the area ... complete depandence [sic] on nece [sic] for all care ... Any immediate concerns or issues to be resolved before next visit: No ... Next visit [skilled nurse] planned to occur: 11/3/2020 [one month later] ...."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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G 430	Continued From page 4	G 430		

The document also evidenced a Braden scale was completed, with a score of 16 (patients with a total score of 16 or less are considered to be at risk for developing pressure ulcers; 15 or 16 = low risk, 13 or 14 = moderate risk, and 12 or less = high risk.) The assessment evidenced (but not limited to) the patient's skin was occasionally moist, requiring a linen change approximately once a day (score of 3), and evidenced the patient moved in bed and chair independently and could maintain good positioning in bed or chair (score 3). However, the assessment also evidenced the patient was incontinent of stool more often than once daily, which would require linen changes more than once daily (score 2 - skin is often, but not always moist), and he was a bilateral amputee and unable to sit unsupported, major physical limitations, was dependent for all personal care, and was unable to transfer self from bed to chair (score 1 - requires moderate to maximum assistance in moving). The adjusted score would have been 13 (moderate risk). The document also evidenced the plan of care included interventions to prevent pressure ulcers, but were not evidenced on the plan of care. The document failed to evidence wound diagnoses, failed to evidence the physician was contacted to report wound assessment findings (with possible infection), and wound treatment orders, failed to evidence entity B was contacted for care coordination regarding the wound and possible incorrect application of brief (too tight causing pressure/friction), and failed to evidence the niece (primary caregiver) was educated on signs or symptoms of infection (redness, heat, pain, foul odor, pus-like drainage, fever), wound care/treatment, or correct application of briefs, and failed to evidence a timely skilled nursing follow up visit was scheduled to re-assess the

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HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 430	Continued From page 5	G 430		

wound, ensure treatment orders were received, and the family member was competent in performing the treatment(s). No other wounds were identified during this assessment.

The clinical record contained a plan of care for the certification period of 12/4/2020 - 2/1/2021 which indicated orders for skilled nursing once per month for indwelling catheter change and system assessment with vital signs.

Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/3/2020 stated "... Client has a pressure ulcer on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs. These are both being treated by the [entity C- wound clinic]. At time of assessment, the wounds were covered and not able to be assessed ...." The document failed to evidence wound diagnoses, and failed to evidence care coordination with entity C or the physician for new home care orders, which included but not limited to wound care orders.

During an interview on 12/16/2020 at 2:16 PM, when asked if their clinic records evidenced communication or care coordination with Home Nursing Services, a staff member at entity C stated, "I don't see any communication with home care ... not sure we even knew he had home health care."

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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G 430	Continued From page 6	G 430		

(full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

During an interview on 12/17/2020 at 3:44 PM, the comprehensive assessment for patient #1 dated 12/3/2020 was completed today (12/17/2020), and the plan of care was completed today (12/17/2020) and sent to the physician. Both were reviewed and approved by employee M (registered nurse) It was verified by the clinical director and the administrator that employee L (registered nurse) initiated the comprehensive assessment on 12/3/2020 but didn't complete it, and she did not assess the wounds. When asked, the clinical director agreed the certifying physician would not be able to provide/approve orders to meet the patient's needs without complete and accurate assessment findings. During this time, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No."

During an interview on 12/18/2020 at 1:00 PM,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 430	Continued From page 7	G 430		

when asked who finished the comprehensive assessment dated 12/3/2020, the director of nursing stated "[employee N- registered nurse]." When asked if she was the nurse that initiated the comprehensive assessment on 12/3/2020, the director of nursing stated "No." When asked why employee L didn't complete the assessment, the director of nursing stated "We discovered she was behind, we wanted to get it done, so we sent it to [employee N]." She also indicated employee N saw the patient on 12/15/2020, and that visit represented completion of the comprehensive assessment dated 12/3/2020. When asked if the patient's electronic clinical record evidenced education for mitigation of pressure ulcers/wounds, the clinical director stated "No, but I can get the [paper portion] chart." Employee M retrieved it. When asked if the chart evidenced education for mitigation of pressure ulcers/wounds, employee M stated "No, looks like he goes to the wound clinic and they just advise him to keep his appointments."

During an interview on 12/18/2020 at 3:20 PM, when asked which nurse did which portions of the comprehensive assessment dated 12/3/2020, the administrator stated "I can only tell [employee L] visited [the patient] on the 3rd, started writing [on the assessment on] 11th, [employee N] saw the patient on the 15th, and employee M reviewed and approved the assessment document on the 17th ... [employee M] signed the plan of care." The administrator also indicated he didn't know who did the wound assessments, or when the wounds were last assessed by staff.

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "...

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 430	Continued From page 8	G 430		

A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today [12/22/2020] to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... His catheter bag [bag connected urine drain tube] was stuffed an opening [sic] in the side of his wheelchair. The urine in the tube was pale yellow with sediment present ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She indicated they might have. Also asked about adding protein to the diet, niece indicated she did not remember for sure, maybe." The document failed to evidence wound diagnoses, failed to evidence the nurse and patient's niece scheduled a follow up visit to assess the wounds, failed to evidence the nurse followed up with the physician regarding orders for supplemental vitamins or additional protein diet, failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, and failed to evidence education was provided to the caregiver on proper placement of the urine drainage bag below the bladder to avoid urine back up into the bladder, which would increase risk of urinary tract infection.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 9	G 430		

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated patient #1 expired in the hospital on 12/27/2020.

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head." When asked why there was no follow up visit scheduled to assess the patient's wounds after 12/22/2020, she stated "... planned on going back after the holidays." When asked if it was appropriate to wait so long to assess wounds (as part of the comprehensive assessment), she stated "Yes ...." When asked if she spoke with the certifying physician after she saw the patient on 12/22/2020, she stated "No ma'am." When asked if she should speak with the certifying physician after completing a comprehensive assessment, she stated "If I find something that's different or out of the ordinary." When asked if it was out of the ordinary for the patient to resist/refuse assessment of vital signs and not interact with the nurse during the assessment on 12/22/2020, she indicated it was not out of the ordinary. However, all other clinical notes evidenced the patient was cooperative during skilled nursing visits. When asked if measurements from wound clinic documentation counted as part of her comprehensive assessment, she stated "No, but I

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 10	G 430		

was going to go back after the holiday." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted.

Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...."

Review of a document titled "Care Coordination Note" dated 12/28/2020 stated "... [nurse] made a visit on Tuesday [12/22/2020] ... The client was resistive of being touched and could not hear the conversation ... The client continued to be tired and not wanting to get out of bed on Wednesday [12/23/2020] ... niece called EMS to take the client to the hospital due to him not acting right ...."

Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020 ...."

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021, which evidenced a document

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 430	Continued From page 11	G 430		

titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 10/30/2020 stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... 1 ... Stage 3 ... 1 ... Stage 1 ... 1 ... Location ... left foot (all toes) ... right foot ... all toes ... left upper coccyx ... HNS [name of agency] is not responsible for wound care ... Chronic UTI ... Yes ... Supra pubic [sic] catheter which is changed every two weeks ... Bedfast, unable to transfer and is unable to turn and position self ... unable to be up in a chair ..." The document failed to identify stage of each wound, assessment or measurements, or evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, or infection control teaching related to the urinary catheter. The document evidenced the patient had diagnoses (but not limited to) of history of stroke with left sided paralysis, indwelling urinary catheter, oxygen use for chronic lung disease, incontinent of bowel. The record failed to include diagnosis for wound on coccyx or other area(s).

Review of a document dated 11/11/2020 titled "Skilled Nurse Visit Note" stated "... Urinating through penis and around [catheter] ... [after catheter change] ... Draining freely dark yellow, cloudy urine ...." The document failed to evidence wounds were assessed, failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, or infection control teaching related to the urinary catheter, including (but not limited to signs and symptoms of clogged tubing or infection.

Review of a wound clinic document dated 11/24/2020 (obtained by the wound clinic, not from clinical record) titled "Wound Treatment #1

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 12	G 430		

(Order 262060966)" stated "... Wash wound(s) with mild soap and water, then pat dry. Place Medihoney [wound bed ointment] and cover with ABD [surgical absorbent gauze pad]. Change dressing daily ... Home Healthcare to visit for wound care 2-3 [times] weekly and PRN [as needed] wound care/dressing changes ... left lower extremity ... right lower extremity ...." The agency record failed to evidence it provided skilled nursing visits 2-3 times weekly.

Review of a document dated 12/8/2020 titled "Skilled Nurse Visit Note" stated "...Location: left heel ... wound type: pressure ... date originally reported: 6/26/2020 ... Comments: wound remains to the left heel ... Location: BLE [bilateral lower extremities]; 4th toes and left heel ... Wound type: unknown ... Date originally reported: 12/8/2020 ... Purulence [thick and milky discharge from a wound, often indicates an infection and needs treatment as soon as possible] drainage and scant blood around suprapubic stoma/foley [insertion site on abdomen for direct access to bladder with urinary drainage tube] ...." The document failed to evidence wounds were assessed/measured or treated by the nurse, the physician was notified of new open area(s) and signs of infection at urinary insertion site and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown or signs and symptoms of infection.

Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... [blank] ... Stage 3 ... [blank] ... Unstageable [full thickness skin and tissue loss in which the extent

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 13	G 430		

of the damage within the ulcer cannot be determined due to scabbing or dead fibrous tissue; once removed to expose wound, a stage 3 or 4 would be revealed] ... Stage 1 ... 0 ... Does this patient have a stasis ulcer [ulcer caused by impaired circulation]? ... Yes ... Current number of Stasis Ulcers that are observable ... 3 ... status of most problematic ... Not Healing ... Location ... left second toe ... left third toe ... right second toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... Integument [skin] Impression: ... unstable ... in need of skilled intermittent care ... Will continue to monitor during regular visits, but not be a focus of care ... Will require a lot of attention ... Current possible UTI symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The document also evidenced the patient was a high risk for skin breakdown. The document failed to evidence the wounds were treated by the nurse, or education was provided to the caregiver to mitigate worsening or new skin breakdown.

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician added Juven (nutritional supplement) twice daily to assist

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 14	G 430		

wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was a high risk for skin breakdown, stated "... Does this patient have a stasis ulcer? ... Yes ... Current number of Stasis Ulcers that are observable ... 4 ... status of most problematic ... Not Healing ... Location ... right big toe ... right second toe ... left second toe ... left third toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... wife cleanses, applies medihoney dresses every other day and will see wound clinic 1/14/20 [sic] ...." The document failed to evidence contact precautions for VRE, skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote wound healing, frequent turning schedule, or padding of bony prominences, or wound care was performed by the nurse. The document evidenced the certifying physician was contacted for orders, but the clinical record failed to evidence orders dated 1/5/2021.

Review of a document dated 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, applying an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received. Additionally, during the exit interview on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 15	G 430		

1/12/2021 at 2:50 PM, the clinical director indicated she did not know the name of the ointment the spouse applied to the wound(s).

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), the administrator, and the alternate administrator stated "... 1-10-2021, 12:20pm. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her home remedy for his back is working ... She does not need me to stop by today to help her ...." The document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified the wife was applying a home remedy to his wound(s). Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), employee D (medical records coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 16	G 430		

agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound with wounds, and a new wound that developed post-hospitalization, and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted.

4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document titled "SN Re-Cert [recertification] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 11/1/2020 "... right second toe amputation ... Non-removable dressing present. Wound managed by orthopedics ... Report any abnormal findings to VA [veterans affairs] MD ... skilled nurse ... physical assessment ... and notify MD of any abnormal findings ... had his right second toe amputated ... His 3rd right toe is black and shriveled ...." The document also evidenced the patient had diagnoses (but not limited to) atherosclerotic

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 17	G 430		

heart disease (hardening of the arteries causing impaired circulation), and diabetes with diabetic neuropathy (diabetes with damage to nerves in your legs and feet, causing pain and numbness in your legs and feet). The document failed to evidence the physician was notified of the change in condition of the wound.
Review of a document dated 11/2/2020 titled "Skilled Nurse Visit Note" stated "... Right second toe amputation site not healing. 3rd toe black and very painful ...." The document failed to evidence the nurse measured the wounds, performed wound care, or notified the physician for the change in the patient's integumentary or pain status.

Review of a document dated and signed by employee M 11/16/2020 titled "Skilled Nurse Visit Note" stated, "... "posterior foot blackening about an 1 1/2 inch on ball of right foot, 3rd toe black and shriveled, outer edge of 5th toe; see diagram" The clinical record failed to evidence a diagram of the wound, or failed to evidence the physician was notified of the declining wound status.

During an interview on 1/6/2021 at 3:56 PM, when asked if the doctor should have been notified of the change in wound status on 11/16/2020, the alternate clinical director stated, "He should be, I don't know if she did call." When asked if this failure to contact the physician could have potentially led to a negative outcome for the patient, she stated "Yes."

Review of a document dated and signed by employee M on 11/30/2020 titled "Skilled Nurse Visit Note" stated "...: "No fever, No cough, No complaints, Right foot, big toe starting to blacken,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 18	G 430		

middle toe black and shriveled. Per wife, US [ultrasound] showed multiple blockages and patient may lose foot d/t [due to] occlusions ...." The document failed to evidence the physician was notified of the declining wound status.

Review of a document dated and signed by employee M on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE [right lower extremity] Femoral Endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain. Pain 10/10. Taking Norco for pain. 2 weeks of meds set-up. 100% medication compliant. The document failed to evidence the physician was notified of the declining wound status or severe pain.

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence the agency coordinated with the hospital to provide patient's current status or request hospital records.

Review of a document titled "Skilled Nurse Visit Note" dated 12/28/2020 stated "... returned from hospital S/P [after] Right femoral endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] and Right partial amputation of foot. Right groin incision C/D/I [clean, dry, and intact] no redness, no draining, no swelling. OTA [open to air]. Right foot dressing

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 19	G 430		

C/D/I with orders not to remove same until f/u [follow up] with Podiatry 1/4/21. Plavix [medication to prevent formation of blood clots and to keep blood vessels open after surgical procedures, and may cause easy bleeding/bruising] ... added to medication regimine [sic] ... Client is NWB [non-weight bearing] R foot ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document dated 12/28/2021 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which previously had not been identified), and the nurse failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the nurse instructed on non-weight bearing status to the right foot, which could potentially have a negative outcome on the surgical healing process, failed to evidence the nurse assessed the left second toe pain, and failed to evidence the physician was notified.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 20 Review of a document dated 12/28/2021 titled "SN ROC OASIS and Comprehensive Assessment" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without devices in his home ... Has had no ... hospitalizations ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and resumption of care orders. Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/28/2021 (additional document for same nurse visit same day) stated "... Pain Assessment: ... right foot. Severity (0-10), 6 ... Cardiovascular Assessment: ... blood thinners ... Plavix ... Integumentary [skin] Assessment: No issues noted ... incisions ... open to air ... right foot ... surgical dressing in place ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection, nutritional requirements for wound healing, or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and recertification care orders.	G 430		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 430	Continued From page 21 Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 1/1/2021 - 3/1/2021 stated "... [skilled nursing orders] ... one visit ... every 2 weeks ... medication tray set-up, to monitor compliance ... physical assessment, and report any abnormal findings to MD ...." The document failed to evidence skilled nursing interventions such as wound care/treatments, patient/family education for wound care/treatment, interventions to mitigate new or worsening skin breakdown, appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, or signs and symptoms of infection, nutritional requirements for wound healing or other indications that should be reported to the agency and/or physician. Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2021), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education.	G 430		
{G 454}	HHA can no longer meet the patient's needs CFR(s): 484.50(d)(1) The transfer or discharge is necessary for the patient's welfare because the HHA and the physician who is responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. The HHA must arrange a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's	{G 454}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 454}	Continued From page 22	{G 454}		

capabilities;
This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to immediately contact the receiving entity (hospital), or send a transfer summary, to facilitate a safe transfer of all patients when the agency could no longer meet the patients' needs for 3 of 3 records reviewed with hospital transfers (#1, 7, 9), and 1 of 1 patients (without clinical record review) identified during an interview who was previously hospitalized, and subsequently sent back to the emergency room (#11).

Findings include:

1. Review of an undated copyrighted Briggs Healthcare policy C-840 titled "Transfer Policy" stated "... A client may be transferred ... identified need that cannot be met by Home Nursing Services ... A transfer summary shall be completed by the registered nurse ... form shall be sent to the new provider or facility ... a copy shall be retained for the client's chart ... discussed with the physician and orders obtained approving the client's transfer ...."

2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021. The record evidenced the patient's health status declined, the agency no longer met the patient's needs, and per the agency's own policy, the record failed to evidence the physician was contacted with a summary of the reason for transfer, and a physician's verbal order was received for the patient's transfer/discharge.

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 454}	Continued From page 23	{G 454}		

Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ...."

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated the patient was admitted to the hospital on 12/23/2020, and expired in the hospital on 12/27/2020.

Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...."

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 454}	Continued From page 24	{G 454}		

who the patient's certifying physician was, she stated "I do not know off the top of my head." The alternate director also stated "... sent an order to discharge to [person M, patient's certifying physician] this morning ...." During this time, when asked if the agency contacted hospitals for care coordination, the clinical director stated she was "... unaware of a policy for getting hospital information ... we usually don't, because they usually come home with papers ...." When asked how would the hospital know the patient received home care, the clinical director stated "Through the client or the client's family."

During the daily conference with the agency, the alternate administrator indicated the agency probably kept (patient#1) on service too long.

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021. The record failed to evidence a transfer summary was sent to the receiving facility, or the certifying physician was notified.

4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document dated and signed by employee M (registered nurse) on 12/14/2020

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 454}	Continued From page 25	{G 454}		

titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE [right lower extremity] Femoral Endarterectomy on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain ...."

During an interview on 1/12/2021 at 1:10 PM, employee M stated "I didn't contact the physician [on 12/14/2020] because he already had an appointment scheduled [for 12/18/2020] and the [physician] was already aware."

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence a transfer summary was sent to the hospital or certifying physician.

5. During an interview on 1/6/2021 2:45 PM the alternate indicated she received report this morning/today (1/6/2021) from employee M's (registered nurse), and indicated patient (#11-no clinical record review) went to the emergency room (ER) today. She also indicated an agency aide reported it to employee M, the patient had fempop bypass (Femoral popliteal bypass surgery which requires a stay in the hospital) about two weeks ago, and he was still having pain. The clinical director and alternate clinical director indicated they did not know if the aide saw the patient today, did not know when the patient was last seen by a nurse, didn't know if the agency had hospital paperwork regarding the hospitalization for bypass surgery, and the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 454}	Continued From page 26 agency was previously unaware the patient was hospitalized. When asked if the hospital was contacted today and a summary was sent, the alternate clinical director stated "No. She said they were just sending him." When asked if the physician was contacted, she stated "I don't know. She was out in the field. ....", and indicated it was employee M's job to coordinate with the physician.	{G 454}		
G 510	Comprehensive Assessment of Patients CFR(s): 484.55 Condition of participation: Comprehensive assessment of patients. Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. This CONDITION is not met as evidenced by: An immediate jeopardy (IJ) related to comprehensive assessment and re-assessment of patients was identified on 12/18/2020. The administrator was notified on 12/18/20 at 5:09 PM. The immediate jeopardy remained unremoved after exit on 1/12/21. The cumulative effect of these systemic problems resulted in the home health agency's inability to ensure the provision of quality health care in a safe environment for the Condition of Participation 42 CFR 484.55 Comprehensive Assessment of Patients. Based on record review and interview, agency failed to ensure the registered nurse (RN)	G 510		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 510	Continued From page 27	G 510		

completed comprehensive assessment/re-assessment accurately to describe the patient's status, to measure or describe wounds; failed to include current health of wound status and functional limitations due to wounds; failed to include interventions regarding the patient's wounds; failed to evidence progress towards measurable outcomes by describing/measuring wounds in the assessment; failed to evidence medical, and nursing needs were met by including all pertinent diagnoses and identifying the patient's needs in a comprehensive assessment/re-assessment that led to new or worsening wounds, urinary tract infection, hospitalization, amputation, and/or death. Additionally, the registered nurse failed to ensure all comprehensive assessments included patients' current health status (See Tag G 528); included progress towards goals (See Tag G 530, the patients' medical needs (See Tag G 534), a review of all medications (See Tag G 536), primary caregiver willingness, availability, and schedule (See Tag G 538), completed updated comprehensive re-assessment for worsening in health status (See Tag G 544), and completed updated comprehensive re-assessment during the last five days of the certification period (See Tag G 546). This practice affected all agency patients.

Findings include:

1. Review of an undated agency policy C-155 titled "Comprehensive Client Assessment" stated "... A thorough, well-organized, comprehensive and accurate assessment, consistent with the client's immediate needs will be completed ... no later than five (5) calendar days after start of care ... To determine the appropriate care, treatment

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 28	G 510		

and services to meet initial needs and his/her changing needs ...."

Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised as often as the client's condition warrants due to a major decline or improvement in health status ... To identify decline or improvement ... are reassessed when significant changes occur in their condition ... [or] diagnosis ...."

Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Skilled Nursing Services" stated "... Skilled nursing services will be provided ... In determining whether a service requires the skills of a Nurse, the inherent complexity of the service, condition of the client ... Regularly reevaluates the client needs ... Provides services requiring specialized nursing skill and initiates appropriate preventive and rehabilitative nursing procedures ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021.

Review of a document received on 12/28/2020 titled "SN [skilled nurse] SOC [start of care] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 12/10/2019 evidenced the patient had no wounds, and was alert and oriented to person, place, and time, without confusion or disruptive behaviors.

Review of a document titled "SN Re-Cert [Recertification/Re-Assessment] OASIS and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 29	G 510		

Comprehensive Assessment" dated 10/3/2020 (for certification period 10/5/2020-12/3/2020) evidenced the patient was fully oriented and able to make own decisions, normal behavior, and had a wound on his right groin area. The document stated "... Right groin ... Irtritation [sic] from brief rubbing on the area ... scabbed over area ... measurements: 1x2 ... MD to evaluate wound ... Wound care orders already in place: No ... Orders need to be obtained: Yes ... Overall, the level of function has been: Slowly deteriorating ... Does the physician-ordered plan of care include the following ... Interventions to prevent pressure ulcer (wound) ... [box checked] Yes ... now has home attendant from entity B [personal care services] ... and they are responsible for these services ... heavy smoker ... observed foul smelling wound to the groin. Area appears dark red in color with puss [sic]-like drainage present. Advised POA [power of attorney- family member] to keep all follow-up appointments with the wound clinic due to possible infection to the area ... complete depandence [sic] on nece [sic] for all care ... Any immediate concerns or issues to be resolved before next visit: No ... Next visit [skilled nurse] planned to occur: 11/3/2020 [one month later] ...." The document also evidenced a Braden scale was completed, with a score of 16 (patients with a total score of 16 or less are considered to be at risk for developing pressure ulcers; 15 or 16 = low risk, 13 or 14 = moderate risk, and 12 or less = high risk.) The assessment evidenced (but not limited to) the patient's skin was occasionally moist, requiring a linen change approximately once a day (score of 3), and evidenced the patient moved in bed and chair independently and could maintain good positioning in bed or chair (score 3). However, the assessment also evidenced the patient was incontinent of stool

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 30	G 510		

more often than once daily, which would require linen changes more than once daily (score 2 - skin is often, but not always moist), and he was a bilateral amputee and unable to sit unsupported, major physical limitations, was dependent for all personal care, and was unable to transfer self from bed to chair (score 1 - requires moderate to maximum assistance in moving). The adjusted score would have been 13 (moderate risk). The document also evidenced the plan of care included interventions to prevent pressure ulcers but were not evidenced on the plan of care. The document failed to evidence wound diagnoses, failed to evidence the physician was contacted to report wound assessment findings (with possible infection), and wound treatment orders, failed to evidence entity B was contacted for care coordination regarding the wound and possible incorrect application of brief (too tight causing pressure/friction), and failed to evidence the niece (primary caregiver) was educated on signs or symptoms of infection (redness, heat, pain, foul odor, pus-like drainage, fever), wound care/treatment, or correct application of briefs, and failed to evidence a timely skilled nursing follow up visit was scheduled to re-assess the wound, ensure treatment orders were received, and the family member was competent in performing the treatment(s). No other wounds were identified during this assessment.

The clinical record contained a plan of care for the certification period of 12/4/2020 - 2/1/2021 which indicated orders for skilled nursing once per month for indwelling catheter change and system assessment with vital signs.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 31	G 510		

12/3/2020 stated "... Client has a pressure ulcer on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs. These are both being treated by the [entity C-wound clinic]. At time of assessment, the wounds were covered and not able to be assessed ...." The document failed to evidence wound diagnoses and failed to evidence care coordination with entity C or the physician for new home care orders, which included but not limited to wound care orders.

During an interview on 12/16/2020 at 2:16 PM, when asked if their clinic records evidenced communication or care coordination with Home Nursing Services, a staff member at entity C stated, "I don't see any communication with home care ... not sure we even knew he had home health care."

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 32	G 510		

document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

During an interview on 12/17/2020 at 3:44 PM, the comprehensive assessment for patient #1 dated 12/3/2020 was completed today (12/17/2020), and the plan of care was completed today (12/17/2020) and sent to the physician. Both were reviewed and approved by employee M (registered nurse) It was verified by the clinical director and the administrator that employee L (registered nurse) initiated the comprehensive assessment on 12/3/2020 but didn't complete it, and she did not assess the wounds. When asked, the clinical director agreed the certifying physician would not be able to provide/approve orders to meet the patient's needs without complete and accurate assessment findings. During this time, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No."

During an interview on 12/18/2020 at 1:00 PM, when asked who finished the comprehensive assessment dated 12/3/2020, the director of nursing stated "[employee N- registered nurse]." When asked if she was the nurse that initiated the comprehensive assessment on 12/3/2020, the director of nursing stated "No." When asked why employee L didn't complete the assessment, the director of nursing stated, "We discovered she was behind, we wanted to get it done, so we sent it to [employee N]." She also indicated employee N saw the patient on 12/15/2020, and that visit represented completion of the comprehensive assessment dated 12/3/2020.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 33	G 510		

When asked if the patient's electronic clinical record evidenced education for mitigation of pressure ulcers/wounds, the clinical director stated "No, but I can get the [paper portion] chart." Employee M retrieved it. When asked if the chart evidenced education for mitigation of pressure ulcers/wounds, employee M stated "No, looks like he goes to the wound clinic and they just advise him to keep his appointments."

During an interview on 12/18/2020 at 3:20 PM, when asked which nurse did which portions of the comprehensive assessment dated 12/3/2020, the administrator stated "I can only tell [employee L] visited [the patient] on the 3rd, started writing [on the assessment on] 11th, [employee N] saw the patient on the 15th, and employee M reviewed and approved the assessment document on the 17th ... [employee M] signed the plan of care." The administrator also indicated he didn't know who did the wound assessments, or when the wounds were last assessed by staff. When asked if there had been any discipline for employee L, the administrator stated, "I don't know."

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today [12/22/2020] to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 34	G 510		

appointment [with agency nurse] can be set up to see wounds at a further date ... His catheter bag [bag connected urine drain tube] was stuffed an opening [sic] in the side of his wheelchair. The urine in the tube was pale yellow with sediment present ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She indicated they might have. Also asked about adding protein to the diet, niece indicated she did not remember for sure, maybe." The document failed to evidence wound diagnoses, failed to evidence the nurse and patient's niece scheduled a follow up visit to assess the wounds, failed to evidence the nurse followed up with the physician regarding orders for supplemental vitamins or additional protein diet, failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, and failed to evidence education was provided to the caregiver on proper placement of the urine drainage bag below the bladder to avoid urine back up into the bladder, which would increase risk of urinary tract infection.

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated patient #1 expired in the hospital on 12/27/2020.

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 35	G 510		

wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head." When asked why there was no follow up visit scheduled to assess the patient's wounds after 12/22/2020, she stated "... planned on going back after the holidays." When asked if it was appropriate to wait so long to assess wounds (as part of the comprehensive assessment), she stated "Yes ...." When asked if she spoke with the certifying physician after she saw the patient on 12/22/2020, she stated "No ma'am." When asked if she should speak with the certifying physician after completing a comprehensive assessment, she stated "If I find something that's different or out of the ordinary." When asked if it was out of the ordinary for the patient to resist/refuse assessment of vital signs and not interact with the nurse during the assessment on 12/22/2020, she indicated it was not out of the ordinary. However, all other clinical notes evidenced the patient was cooperative during skilled nursing visits. When asked if measurements from wound clinic documentation counted as part of her comprehensive assessment, she stated "No, but I was going to go back after the holiday." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted.

Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 36 12-27-2020 ...." Review of a document titled "Care Coordination Note" dated 12/28/2020 stated "... [nurse] made a visit on Tuesday [12/22/2020] ... The client was resistive of being touched and could not hear the conversation ... The client continued to be tired and not wanting to get out of bed on Wednesday [12/23/2020] ... niece called EMS to take the client to the hospital due to him not acting right ...." Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020 ...." 3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 10/30/2020 stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... 1 ... Stage 3 ... 1 ... Stage 1 ... 1 ... Location ... left foot (all toes) ... right foot ... all toes ... left upper coccyx ... HNS [name of agency] is not responsible for wound care ... Chronic UTI ... Yes ... Supra pubic [sic] catheter which is changed every two weeks ... Bedfast, unable to transfer and is unable to turn and position self ... unable to be up in a chair ..." The document failed to identify stage of each	G 510		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 37	G 510		

wound, assessment or measurements, or evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, or infection control teaching related to the urinary catheter. The document evidenced the patient had diagnoses (but not limited to) of history of stroke with left sided paralysis, indwelling urinary catheter, oxygen use for chronic lung disease, incontinent of bowel. The record failed to include diagnosis for wound on coccyx or other area(s).

Review of a document dated 11/11/2020 titled "Skilled Nurse Visit Note" stated "... Urinating through penis and around [catheter] ... [after catheter change] ... Draining freely dark yellow, cloudy urine ...." The document failed to evidence wounds were assessed, failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, or infection control teaching related to the urinary catheter, including (but not limited to signs and symptoms of clogged tubing or infection).

Review of a wound clinic document dated 11/24/2020 (obtained by the wound clinic, not from clinical record) titled "Wound Treatment #1 (Order 262060966)" stated "... Wash wound(s) with mild soap and water, then pat dry. Place Medihoney [wound bed ointment] and cover with ABD [surgical absorbent gauze pad]. Change dressing daily ... Home Healthcare to visit for wound care 2-3 [times] weekly and PRN [as needed] wound care/dressing changes ... left lower extremity ... right lower extremity ...." The agency record failed to evidence it provided skilled nursing visits 2-3 times weekly.

Review of a document dated 12/8/2020 titled "Skilled Nurse Visit Note" stated "...Location: left

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 38	G 510		

heel ... wound type: pressure ... date originally reported: 6/26/2020 ... Comments: wound remains to the left heel ... Location: BLE [bilateral lower extremities]; 4th toes and left heel ... Wound type: unknown ... Date originally reported: 12/8/2020 ... Purulence [thick and milky discharge from a wound, often indicates an infection and needs treatment as soon as possible] drainage and scant blood around suprapubic stoma/foley [insertion site on abdomen for direct access to bladder with urinary drainage tube] ...." The document failed to evidence wounds were assessed/measured or treated by the nurse, the physician was notified of new open area(s) and signs of infection at urinary insertion site and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown or signs and symptoms of infection.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... [blank] ... Stage 3 ... [blank] ... Unstageable [full thickness skin and tissue loss in which the extent of the damage within the ulcer cannot be determined due to scabbing or dead fibrous tissue; once removed to expose wound, a stage 3 or 4 would be revealed] ... Stage 1 ... 0 ... Does this patient have a stasis ulcer [ulcer caused by impaired circulation]? ... Yes ... Current number of Stasis Ulcers that are observable ... 3 ... status of most problematic ... Not Healing ... Location ... left second toe ... left third toe ... right second toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... Integument [skin] Impression: ... unstable ... in need of skilled intermittent care ... Will continue to monitor during regular visits, but

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 39	G 510		

not be a focus of care ... Will require a lot of attention ... Current possible UTI symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The document also evidenced the patient was a high risk for skin breakdown. The document failed to evidence the wounds were treated by the nurse, or education was provided to the caregiver to mitigate worsening or new skin breakdown.

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

Review of a document titled "SN ROC [resumption of care] OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was a high risk for skin breakdown, stated "... Does this patient have a stasis ulcer? ... Yes ... Current number of Stasis Ulcers that are

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 40	G 510		

observable ... 4 ... status of most problematic ... Not Healing ... Location ... right big toe ... right second toe ... left second toe ... left third toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... wife cleanses, applies medihoney dresses every other day and will see wound clinic 1/14/20 [sic] ...." The document failed to evidence contact precautions for VRE, skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote wound healing, frequent turning schedule, or padding of bony prominences, or wound care was performed by the nurse. The document evidenced the certifying physician was contacted for orders, but the clinical record failed to evidence orders dated 1/5/2021.

Review of a document dated 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, applying an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received. Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated she did not know the name of the ointment the spouse applied to the wound(s).

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M, the administrator, and the alternate administrator stated "... 1-10-2021, 12:20pm. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her home remedy for his back is working ... She does not need me to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 41	G 510		

stop by today to help her ...." The document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified the wife was applying a home remedy to his wound(s). Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C, employee M, employee D (medical records coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound with wounds, and a new wound that developed post-hospitalization, and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 510	Continued From page 42	G 510		

During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted.

4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/1/2020 "... right second toe amputation ... Non-removable dressing present. Wound managed by orthopedics ... Report any abnormal findings to VA [veterans affairs] MD ... skilled nurse ... physical assessment ... and notify MD of any abnormal findings ... had his right second toe amputated ... His 3rd right toe is black and shriveled ...." The document also evidenced the patient had diagnoses (but not limited to) atherosclerotic heart disease (hardening of the arteries causing impaired circulation), and diabetes with diabetic neuropathy (diabetes with damage to nerves in your legs and feet, causing pain and numbness in your legs and feet). The document failed to evidence the physician was notified of the change in condition of the wound.

Review of a document dated 11/2/2020 titled "Skilled Nurse Visit Note" stated "... Right second toe amputation site not healing. 3rd toe black and very painful ...." The document failed to evidence the nurse measured the wounds, performed wound care, or notified the physician for the change in the patient's integumentary or pain

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 510	Continued From page 43	G 510		

status.

Review of a document dated and signed by employee M on 11/16/2020 titled "Skilled Nurse Visit Note" stated "... "posterior foot blackening about an 1 1/2 inch on ball of right foot, 3rd toe black and shriveled, outer edge of 5th toe; see diagram" The clinical record failed to evidence a diagram of the wound, or failed to evidence the physician was notified of the declining wound status.

During an interview on 1/6/2021 at 3:56 PM, when asked if the doctor should have been notified of the change in wound status on 11/16/2020, the alternate clinical director stated, "He should be, I don't know if she did call." When asked if this failure to contact the physician could have potentially led to a negative outcome for the patient, she stated "Yes."

Review of a document dated and signed by employee M on 11/30/2020 titled "Skilled Nurse Visit Note" stated "...: "No fever, No cough, No complaints, Right foot, big toe starting to blacken, middle toe black and shriveled. Per wife, US [ultrasound] showed multiple blockages and patient may lose foot d/t [due to] occlusions ...." The document failed to evidence the physician was notified of the declining wound status.

Review of a document dated and signed by employee M on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE [right lower extremity] Femoral Endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 44	G 510		

with foot. Foot is starting to get wet and drain. Pain 10/10. Taking Norco for pain. 2 weeks of meds set-up. 100% medication compliant. The document failed to evidence the physician was notified of the declining wound status or severe pain.

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence the agency coordinated with the hospital to provide patient's current status or request hospital records.

Review of a document titled "Skilled Nurse Visit Note" dated 12/28/2020 stated "... returned from hospital S/P [after] Right femoral endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] and Right partial amputation of foot. Right groin incision C/D/I [clean, dry, and intact] no redness, no draining, no swelling. OTA [open to air]. Right foot dressing C/D/I with orders not to remove same until f/u [follow up] with Podiatry 1/4/21. Plavix [medication to prevent formation of blood clots and to keep blood vessels open after surgical procedures and may cause easy bleeding/bruising] ... added to medication regimine [sic] ... Client is NWB [non-weight bearing] R foot ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 45	G 510		

should be reported to the agency and/or physician and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document dated 12/28/2020 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which previously had not been identified), and the nurse failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the nurse instructed on non-weight bearing status to the right foot, which could potentially have a negative outcome on the surgical healing process, failed to evidence the nurse assessed the left second toe pain, and failed to evidence the physician was notified.

Review of a document dated 12/28/2020 titled "SN ROC OASIS and Comprehensive Assessment" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without devices in his home ... Has had no ... hospitalizations ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 510	Continued From page 46	G 510		

should be reported to the agency and/or physician and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/28/2020 (additional document for same nurse visit same day) stated "... Pain Assessment: ... right foot. Severity (0-10), 6 ... Cardiovascular Assessment: ... blood thinners ... Plavix ... Integumentary [skin] Assessment: No issues noted ... incisions ... open to air ... right foot ... surgical dressing in place ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection, nutritional requirements for wound healing, or other indications that should be reported to the agency and/or physician and failed to evidence the physician was notified for report and recertification care orders.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 1/1/2021 - 3/1/2021 stated "... [skilled nursing orders] ... one visit ... every 2 weeks ... medication tray set-up, to monitor compliance ... physical assessment, and report any abnormal findings to MD ...." The document failed to evidence skilled nursing interventions such as wound care/treatments, patient/family education for wound care/treatment, interventions to mitigate new or worsening skin breakdown, appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 47	G 510		

precautions, or signs and symptoms of infection, nutritional requirements for wound healing or other indications that should be reported to the agency and/or physician.

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2020), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.
During an interview on 1/6/2021 at 3:56 PM, the clinical director and alternate clinical director confirmed the skilled nursing frequency remained every two weeks since hospital discharge. When asked if waiting two weeks to see this patient could lead to a potentially negative outcome, they both stated "Yes."

During an interview on 1/12/2021 at 1:50 PM, regarding the skilled nursing visit on 11/16/2020, employee M indicated she did not contact the physician, he was already aware, it (the wound/blackening of toe/foot) started as just the tip, and it was an ongoing process; regarding the skilled nursing visit on 12/14/2020, she stated "I did not call the physician ...."

During the entrance conference on 12/15/2020 at 11:00 AM, when asked how the agency determined when there has been a major decline or improvement in the patient's health status, the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 510	Continued From page 48 clinical director stated, "Through nursing assessment." During an interview on 12/18/2020 at 1:00 PM, when asked the purpose of the comprehensive assessment, the clinical director stated, "To develop the plan of care." When asked if it was her expectation for staff to look at entire head to toe for comprehensive assessment, the clinical director stated, "Yes."	G 510		
{G 528}	Health, psychosocial, functional, cognition CFR(s): 484.55(c)(1) The patient's current health, psychosocial, functional, and cognitive status; This ELEMENT is not met as evidenced by: Based on record review and interview, the home health agency failed to ensure all comprehensive assessments and/or comprehensive re-assessments were completed or included (but not limited to) the patients' current complete health status for 10 of 10 records reviewed (#1, 2, 3, 4, 5, 6, 7, 8, 9, 10). Findings include: 1. Review of an undated agency policy C-145 titled "Comprehensive Client Assessment" stated "... A thorough, well-organized, comprehensive and accurate assessment, consistent with the client's immediate needs will be completed for all clients ... To determine the appropriate care, treatment and services to meet initial needs and his/her changing needs ... To collect data about the client's health history, (physical, functional and psychological) and their needs as appropriate ... To identify clients medical, nursing ... needs ... In addition to general health status/system	{G 528}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 49	{G 528}		

assessment ... the comprehensive assessment ... will include ... Integumentary [skin] status ... Neuro/emotional/behavioral status ... Clinical measurements ... Client populations with specialized needs (i.e. mental health, pediatric) will be assessed by professionals with appropriate skills and in accordance with specific policies developed for those services ...."

Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised as often as the client's condition warrants due to a major decline or improvement in health status ... To identify decline or improvement ... are reassessed when significant changes occur in their condition ... [or] diagnosis ...."

Review of an undated agency policy C-200 copyright Briggs Healthcare titled "Skilled Nursing Services" stated "... Skilled nursing services will be provided ... In determining whether a service requires the skills of a Nurse, the inherent complexity of the service, condition of the client ... Regularly reevaluates the client needs ... Provides services requiring specialized nursing skill and initiates appropriate preventive and rehabilitative nursing procedures ...."

Review of agency policy dated 6/2000 titled "Home Nursing Services Job Description: Registered Nurse" stated "... Becomes familiar with the diagnostic services available for home health care and follows the directions of the Clinical Director in utilizing these services to meet the needs of the client ... Documents fully and accurately to record a complete, total picture of

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 50	{G 528}		

the client's status and progress, and gives a complete synopsis of the care provided by the skilled registered nurse ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "SN [skilled nurse] Re-Cert [recertification] OASIS [Outcome and Assessment Information Set] and Comprehensive Assessment" dated 12/3/2020 stated "... Client has a pressure ulcer on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs ... At time of assessment, the wounds were covered and not able to be assessed ...." The document failed to evidence wound diagnoses were listed and failed to evidence the nurse assessed the wounds.

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of an additional document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

During an interview on 12/18/2020 at 3:20 PM, the administrator indicated he didn't know who when the wounds were last assessed by nursing staff.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 51	{G 528}		

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 and signed by the alternate clinical director titled "Follow Up Assessment (FUA) Non-Recert OASIS" failed to evidence wound diagnoses, failed to evidence the nurse assessed the wounds, and failed to evidence the nurse assessed the patient's current cognitive/psychological status.

During an interview on 12/28/2020 at 11:26 AM, when asked if measurements from wound clinic documentation counted as part of her comprehensive assessment on 12/22/2020, she stated "No, but I was going to go back after the holiday [to assess the wounds]." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted.

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement) and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 52	{G 528}		

1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

5. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/9/2020 for certification period 12/11/2020 - 2/8/2021 stated "... 1 stage 4 wound on 5th metatarsal head [ball of the foot, and is the location under the foot where you push off when walking or running] and 1 stage 2 on R [right] heel and 1 stage 2 on lower right back area ... can feel pressure when working on lower back wound ...." The document failed to evidence the lower back was assessed by the registered nurse, or the wound on the lower back was resolved.

During a home visit on 12/17/2020, the patient's lower back was not assessed by employee K (licensed practical nurse.)

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 53	{G 528}		

6. The clinical record of patient #5 was reviewed on 1/12/21, start of care date of 11/3/21. The record contained a plan of care for certification period 11/3/21-1/1/21, which indicated diagnoses of (but not limited to) congenital absence, atresia, and stenosis of small intestine (narrowing or obstruction of the small intestine). The record failed to evidence a comprehensive assessment or re-assessment was completed.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/3/2020 failed to evidence the registered nurse assessed the patient in sections subtitled: Skilled Observation, Neuromuscular, Cardiopulmonary, Skin/Wounds, Gastrointestinal, Genitourinary, Medication, and IV (intravenous). The sections evidenced no documentation (they were blank).

7. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/21-2/1/21 which failed to evidence presence of a comprehensive assessment or comprehensive re-assessment and failed to evidence a history and physical from patient referral/admission, to present date of review (1/12/2021).

During an interview on 12/28/20 at 3:20 PM, while reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days).

8. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 54 again on 1/11/2021. Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) evidenced the patient had diagnosis of (but not limited to) seizures/convulsions, had current depression and took daily medications for treatment, had chronic severe pain, managed by pain management clinic, had pain "all the time", the patient was "overweight", he currently had 3 unstageable (deep tissue injury with dead skin/scab covering wound bed) pressure ulcers, 3 stasis ulcers (wounds due to poor circulation), which were not healing ("left second toe, left third toe, right second toe, left foot (all toes), right foot (all toes)", and a wound on the left upper coccyx (tailbone). The document failed to evidence assessment seizures, depression, or pain, such as (but not limited to) pain level, onset, duration, or description, failed to evidence assessment of height/weight, failed to include depression and wound diagnoses in current diagnoses list, failed to evidence assessments for all 6 wounds identified, and failed to evidence the medication the patient took for depression. The document evidenced the patient exhibited signs and symptoms of UTI (urinary tract infection), and a urine specimen was taken to entity N (laboratory). However, the document also indicated the patient had recently been hospitalized for sepsis (systemic infection) related to UTI, but the patient was not hospitalized until 1/2/2021. Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI and was discharged 1/5/2021. The document also	{G 528}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 55	{G 528}		

evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was 67" tall, weighed 200 pounds (patient's body mass index 31.3, which indicated obesity, by having body mass index of 30 or greater), had chronic severe pain, had no pressure ulcers, had 4 unhealing stasis ulcers ("left second toe, left third toe, right second toe, left foot (all toes), right foot (all toes)", had a surgical wound which was not healing, a wound on the left upper coccyx. The document failed to evidence patient was assessed for depression, (box checked "No"), failed to include depression on current diagnosis list, failed to evidence all wounds documented were assessed, failed to evidence addition of nutritional supplement to diet, and failed to evidence contact precautions due to VRE of the urine.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 56	{G 528}		

didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound with wounds, and a new wound that developed post-hospitalization, and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted.

9. The clinical record review for patient #8 was completed on 1/11/2021. Review of a document titled "RN Re-Certification Assessment" dated 11/20/2020 evidenced the patient received HHA (home health aide) services 2 hours per day, five days per week, and the patient had a diabetic foot ulcer [open wound commonly located on the bottom of the foot] on the outside of his right foot. The document failed to evidence the wound was assessed or listed diabetic ulcer in patient diagnoses.

10. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document dated 12/28/2020 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 57	{G 528}		

previously had not been identified), and the nurse failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the patient's current non-weight bearing status to the right foot, which could potentially have a negative outcome on the surgical healing process and failed to evidence the nurse assessed the left second toe pain.

Review of a document titled "RN Re-Certification Assessment [comprehensive re-assessment]" dated 12/28/2020 (additional document for same nurse visit same day) stated "... Pain Assessment: ... right foot. Severity (0-10), 6 ... right foot ... surgical dressing in place ... Integumentary Assessment ... No issues noted ...." The document evidenced the patient had a post-surgical incision to his right groin, and was non-weight bearing to the right foot, but failed to evidence complete assessment including measurements of the right groin incision. The assessed pain level of 6 was inconsistent with the pain level assessed as 5 on another document titled Pain Location Assessment", same day, same nurse.

Review of a document dated 12/28/2020 titled "Nursing Resumption of Care [comprehensive re-assessment]" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 58	{G 528}		

devices in his home ... Has had no ... hospitalizations ...." The document failed to evidence the patient's current post-surgical status of non-weight bearing right lower foot and other physical restrictions, and assessment including measurements of the right groin incision.

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2020), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.

11. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/13/2020 for certification period 11/14/2020 - 1/12/2021 stated "... Integument Assessment ... Wound Tracking ... Location ... Abdomen ... Action Taken Today ... Not Specified ... Integument Impression: Overall, this system is: abnormal/dysfunctional, and has steadily been declining. The system appears: ... in need of skilled intermittent care. Will require a lot of attention, will be a focus of care during regular visits ...." Additionally, the assessment evidenced pain in the patient's back, stomach, and abdominal wound, which was "Progressively worsening over time", the wound was being managed by the wound clinic, and the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 528}	Continued From page 59 patient took "narcotics" (controlled substance pain medication) for the wound pain. The document failed to evidence any assessment of the wound, assessment of pain such as (but not limited to) pain level, onset, duration, or description, assessment of last bowel movement, and the medication profile failed to evidence the narcotic the patient took for pain. 12. During the entrance conference on 12/15/2020 at 11:00 AM, when asked how the agency determined when there has been a major decline or improvement in the patient's health status, the clinical director stated, "Through nursing assessment." During an interview on 12/18/2020 at 1:00 PM, when asked the purpose of the comprehensive assessment, the clinical director stated, "To develop the plan of care." When asked if it was her expectation for staff to assess head to toe for comprehensive assessment, she stated "Yes."	{G 528}		
{G 530}	Strengths, goals, and care preferences CFR(s): 484.55(c)(2) The patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA; This ELEMENT is not met as evidenced by: Based on record review and interview, the home health agency failed to ensure all comprehensive assessments and/or comprehensive re-assessments evidenced patient specific goals and measurable outcomes identified by the agency for 10 of 10 records reviewed (#1, 2, 3, 4,	{G 530}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 530}	Continued From page 60 5, 6, 7, 8, 9, 10). Findings include: 1. Review of an undated agency policy C-155 submitted for review on 1/6/2021 titled "Comprehensive Client Assessment" stated "... Special attention will be paid to client-centered goal setting, clarifying the client's personal goals and his/her expectations of the home care services ...." Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Purpose ... To identify progress toward goals and effectiveness of interventions ... Clients are reassessed to determine their response to care ... Special attention will be paid to client-centered goal setting, clarifying the client's personal goals and his/her expectations of the home care services ...." 2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "SN [skilled nurse] Re-Cert [recertification] OASIS [Outcome and Assessment Information Set] and Comprehensive Assessment" dated 12/3/2020 failed to evidence the patient's personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services . Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 and signed by the alternate clinical director titled "Follow Up Assessment (FUA) Non-Recert OASIS" failed to	{G 530}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 530}	Continued From page 61	{G 530}		

evidence the patient's personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services.

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement) and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 530}	Continued From page 62	{G 530}		

re-assessments were performed by a registered nurse.

5. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/9/2020 for certification period 12/11/2020 - 2/8/2021 failed to evidence the patient's personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services.

6. The clinical record of patient #5 was reviewed on 1/12/21 and indicated a start of care date of 3/14/19. The record contained a plan of care for the certification period of 11/3/21-1/1/21 that indicated diagnoses of, but not limited to, congenital absence (absent during development), atresia (narrowing), and stenosis (obstruction) of small intestine. The document titled "Skilled Nurse Visit Note" dated 11/3/20 contained no information (blank) in the sections labeled; Skilled Observation, Neuromuscular, Cardiopulmonary, Skin/Wounds, Gastrointestinal, Genitourinary, Medication, and IV sections. The comprehensive assessment failed to evidence the patient strengths, goals, and care preferences.

7. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/21-2/1/21 that indicated diagnoses of, but not limited to, achalasia of cardia (nerve damage in the esophagus causing it to become paralyzed and dilated). The clinical record failed to evidence a comprehensive assessment that evidenced the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 530}	Continued From page 63 patient strengths, goals, and care preferences. During an interview on 12/28/20 at 3:20 PM, while reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days). 8. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021. Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) failed to evidence the patient's personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services. Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 failed to evidence the patient's personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services. 9. The clinical record review for patient #8 was completed on 1/11/2021. Review of a document titled "RN Re-Certification Assessment [comprehensive re-assessment]" dated 11/20/2020 evidenced the patient received HHA (home health aide) services 2 hours per day, five days per week, and the patient had a diabetic foot ulcer [open wound commonly located on the bottom of the foot] on the outside of his right foot. The document failed to evidence the patient's	{G 530}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 530}	Continued From page 64	{G 530}		

personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services.

10. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document titled "RN Re-Certification Assessment " dated 12/28/2020 failed to evidence the patient's personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services.

Review of a document dated 12/28/2020 titled "Nursing Resumption of Care [comprehensive re-assessment]" (additional document for same nurse visit same day) failed to evidence the patient's personal goals, progress to those goals, measurable or the patient's expectations of the home care services.

11. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/13/2020 for certification period 11/14/2020 - 1/12/2021 failed to evidence the patient's personal goals, progress to those goals, measurable outcomes, or (per agency policy) the patient's expectations of the home care services.

12. During the entrance conference on 12/15/2020 at 11:00 AM, when asked how the agency determined when there has been a major decline or improvement in the patient's health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 530}	Continued From page 65 status, the clinical director stated, "Through nursing assessment." During an interview on 12/18/2020 at 1:00 PM, when asked the purpose of the comprehensive assessment, the clinical director stated, "To develop the plan of care." When asked if it was her expectation for staff to assess head to toe for comprehensive assessment, she stated "Yes."	{G 530}		
{G 534}	Patient's needs CFR(s): 484.55(c)(4) The patient's medical, nursing, rehabilitative, social, and discharge planning needs; This ELEMENT is not met as evidenced by: Based on record review, the home health agency failed to ensure all comprehensive assessments/ re-assessments included individualized patient discharge planning needs for 10 of 10 records reviewed (#1, 2, 3, 4, 5, 6, 7, 8, 9, 10). Findings include: 1. Review of an undated agency policy copyright Briggs Healthcare (included in the patient admission packet) titled "Client Discharge Process" stated "... The transfer process is based on the client's needs ... Planning for discharge is provided as part of the ongoing assessment ... The client/family will participate ...." 2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "SN [skilled nurse] Re-Cert [recertification] OASIS [Outcome and Assessment Information Set] and Comprehensive Assessment" dated 12/3/2020 stated "... Discharge Planning: Patient will be	{G 534}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 534}	Continued From page 66	{G 534}		

discharged when: their care is no longer medically necessary or reasonable, If the client becomes permanently institutionalized ... Discharge Planning: Likely Status: The likely discharge planning status is that: patient will remain in current living situation with ongoing assistance provided by: Federal Government, State Government, Local or Community, Private Duty by Our [Home Nursing Services] or Another Agency, Family/Friend Caregiver(s). patient [sic] will likely remain with long term care needs. no [sic] realistic discharge in foreseeable future. Discharge is only likely at client/family request, loss of payer source, institutionalization, or death. Care is custodial and discharge is unlikely." The document failed to evidence an ongoing patient specific discharge plan.

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 and signed by the alternate clinical director titled "Follow Up Assessment (FUA) Non-Recert OASIS" failed to evidence any discharge plans.

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement) and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 534}	Continued From page 67	{G 534}		

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

5. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/9/2020 for certification period 12/11/2020 - 2/8/2021 stated "...Discharge Planning: Patient will be discharged when: their care is no longer skilled, their care is no longer medically necessary or reasonable ... Discharge Planning: Likely Status: The likely discharge planning status is that: patient will remain in current living situation with ongoing assistance provided by: State Government. patient [sic] will remain under close care of the physician. Level of assistance anticipated that will be needed upon discharge, N/A [not applicable]." The document failed to evidence an ongoing patient specific

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 534}	Continued From page 68	{G 534}		

discharge plan.

During a home visit on 12/17/2020, the patient's lower back was not assessed by employee K (licensed practical nurse.)

6. The clinical record of patient #5 was reviewed on 1/12/21, start of care date of 11/3/21. The record contained a plan of care for certification period 11/3/21-1/1/21, which indicated diagnoses of (but not limited to) congenital absence, atresia, and stenosis of small intestine (narrowing or obstruction of the small intestine). The record failed to evidence a comprehensive assessment or re-assessment was completed.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/3/2020 failed to evidence the registered nurse assessed the patient in sections subtitled: Skilled Observation, Neuromuscular, Cardiopulmonary, Skin/Wounds, Gastrointestinal, Genitourinary, Medication, and IV (intravenous). The sections evidenced no documentation (they were blank).

7. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/21-2/1/21 which failed to evidence a comprehensive assessmennt or comprehensive re-assessment was completed.

During an interview on 12/28/20 at 3:20 PM, while reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days).

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 534}	Continued From page 69	{G 534}		

8. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Discharge Planning: Likely Status: The likely discharge planning status is that: patient will remain in current living situation with ongoing assistance provided by: State Government. no [sic] realistic discharge in foreseeable future." The document failed to evidence an ongoing patient specific discharge plan.

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 failed to evidence any discharge planning.

9. The clinical record review for patient #8 was completed on 1/11/2021, start of care 11/15/2010, for certification period 11/22/2020 - 1/20/2021.

Review of a document titled "RN Re-Certification Assessment [comprehensive re-assessment]" dated 11/20/2020 stated "... Discharge Planning: Likely Status: The likely discharge planning status is that: patient will remain in current living situation with ongoing assistance provided by: Federal Government, State Government, Local or Community, Private Duty by Our [Home Nursing Services] or Another Agency, Facility, Waiver home through [entity O, a group home], Family/Friend Caregiver(s). patient [sic] will likely remain with long term care needs. no [sic] realistic discharge in foreseeable future. Discharge is only likely at client/family/group

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 534}	Continued From page 70	{G 534}		

home request, loss of payer source, institutionalization, or death. Care is considered to be custodial, therefore, there are no plans for discharge." The document failed to evidence an ongoing patient specific discharge plan.

10. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document titled "RN Re-Certification Assessment " dated 12/28/2020 stated "... Discharge Planning: Likely Status: The likely discharge planning status is that: patient will remain in current living situation with ongoing assistance provided by: Federal Government. patient [sic] will remain under close care of the physician. patient [sic] will likely remain with long term care needs. no [sic] realistic discharge in foreseeable future. Discharge in the event of loss of payer source, client/VA request, permanent institutionalization, client death. Level of assistance anticipated that will be needed upon discharge, N/A." The document failed to evidence an ongoing patient specific discharge plan.

Review of a document dated 12/28/2020 titled "Nursing Resumption of Care" (additional document for same nurse visit same day) stated "... Discharge Planning: Likely Status: Patient will remain in current living situation with ongoing assistance provided by: Federal Government. Patient will remain under close care of the physician. Patient will likely remain with long term care needs. No realistic discharge in foreseeable future. loss [sic] of payer source, moves away from geographical area, client/family request, permanent institutionalization, death ...." The

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 534}	Continued From page 71 document failed to evidence an ongoing patient specific discharge plan. 11. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/13/2020 for certification period 11/14/2020 - 1/12/2021 stated "... Discharge Planning: Likely Status: The likely discharge planning status is that: patient will remain in current living situation with ongoing assistance provided by: Federal Government, State Government, Local or Community, Private Duty by Our or Another Agency. no [sic] realistic discharge in foreseeable future. Discharge is only likely at client/family request, loss of payer source, institutionalization, or death. Care is considered custodial; therefore, there are no plans for discharge." The document failed to evidence an ongoing patient specific discharge plan. 12. During the exit conference on 1/12/2021 at 2:50 PM, the administrator was notified of this concern and had nothing further to submit for review.	{G 534}		
{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	{G 536}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 72	{G 536}		

registered nurse (RN) failed to ensure the comprehensive assessment contained a complete review of medications, and the medication list was maintained for 10 of 10 records reviewed (#1, 2, 3, 4, 5, 6, 7, 8, 9, 10).

Findings include:

1. Review of an undated agency policy C-145 submitted for review on 12/18/2020 titled "Comprehensive Client Assessment" stated "... A thorough, well organized, comprehensive and accurate assessment, consistent with the client's immediate needs will be completed for all clients ... The Comprehensive Assessment will include a review of all medications the client is using (prescription and non-prescription). This assessment will identify the potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy ... In addition to general health status/system assessment, the Home Nursing Services comprehensive assessment tool ... will include: ... Medications ... reconciliation and follow up ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "SN [skilled nurse] Re-Cert [recertification] OASIS [Outcome and Assessment Information Set] and Comprehensive Assessment" dated 12/3/2020 evidenced skilled nursing monthly for indwelling catheter change and physical assessment, report any abnormal findings to MD, and indicated medications, but not limited to, albuterol, carvedilol (coreg), acetaminophen, albuterol-ipratropium bromide, and stated "...

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 73	{G 536}		

Medications ... reconciliation performed? Yes ... Were issues noted during reconciliation? Yes ... Notes: [10/27/2020] added Ozempic to client's med profile list ... 60-Day Summary ... Client was prescribed Ozempic by his PCP [physician M -certifying physician] on 10/27/2020 but the client refuses to take this medication ...." The document failed to evidence indications for the use of PRN (as needed) medications, failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy, which identified a major medication interaction, and failed to evidence the physician was notified for issues identified in the DRR.

On 1/12/2021 all medications from the agency comprehensive assessment were checked on Drugs.com for interactions. The interactions showed a major interaction with albuterol and carvedilol, as well as multiple moderate interactions, and a therapeutic duplication. The Drugs.com Major interaction definition stated "Highly clinically significant. Avoid combinations; the risk of the interaction outweighs the benefit."

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 74	{G 536}		

to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse, and failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy.

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse, and failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy.

5. The clinical record review of patient #4, start of care date 8/19/2019, was completed on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 75	{G 536}		

1/12/2021, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/9/2020 for certification period 12/11/2020 - 2/8/2021 evidenced the patient received, but not limited to, skilled nursing visits 3 times weekly for wound care and physical assessment, and alert MD for any abnormal findings. Medications listed included fluoxetine 40 mg (milligrams) daily, lisinopril 10 mg daily, and vesicare 5 mg daily. The record failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy.

During a home visit with the patient on 12/30/2020 at 9:45 AM, the patient indicated he took vesicare 5 mg daily, myrbetriq 50 mg daily, prozac 50 mg daily, and denied any other medications were taken.

6. The clinical record of patient #5 was reviewed on 1/12/21, start of care date of 11/3/21. The record contained a plan of care for certification period 11/3/21-1/1/21, which indicated diagnoses of (but not limited to) congenital absence, atresia, and stenosis of small intestine (narrowing or obstruction of the small intestine). The record failed to evidence a comprehensive assessment or re-assessment was completed.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/3/2020 failed to evidence the registered nurse assessed the patient in sections subtitled: Skilled Observation, Neuromuscular, Cardiopulmonary, Skin/Wounds, Gastrointestinal, Genitourinary,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 76	{G 536}		

Medication, and IV (intravenous). The sections evidenced no documentation (they were blank).

7. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/21-2/1/21 which failed to evidence a comprehensive assessment or comprehensive re-assessment was completed.

During an interview on 12/28/20 at 3:20 PM, while reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days).

8. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient received, but not limited to, skilled nursing every other week to complete a full head to toe assessment,vital signs, and change the patient's suprapubic catheter (a tube inserted into an opening in the lower abdomen directly into the bladder to drain urine), and home health aide (HHA) services for personal care "up to 60 hours". Medications listed on the medication list included, but not limited to, citalopram, oxycodone, lyrica, trazadone, insulin (Tresiba), insulin (Novolog Flexpen), potassium chloride, oxybutynin, and topiramate. The document evidenced the patient's wife was going to be picking up a medication (levofloxican) from the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 77	{G 536}		

pharmacy for the patient to begin taking, which was not listed on the comprehensive assessment medication list. The record failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy, which evidenced, but not limited to, 7 major medication interactions, and failed to evidence the physician was notified for issues identified in the DRR.

On 1/12/2021 all medications from the agency comprehensive assessment were checked on Drugs.com for interactions. The interactions showed major interactions with levofloxican and citalopram, oxycodone and pregabalin, trazadone and citalopram, levofloxican and insulin (Tresiba), levofloxican and insulin (Novolog Flexpen), oxybutynin and potassium chloride, oxybutynin and topiramate, as well as 37 moderate interactions, and 4 therapeutic duplications. The Drugs.com Major interaction definition stated "Highly clinically significant. Avoid combinations; the risk of the interaction outweighs the benefit."

9. The clinical record review for patient #8 was completed on 1/11/2021. Review of a document titled "RN Re-Certification Assessment [comprehensive re-assessment]" dated 11/20/2020 evidenced the patient received HHA (home health aide) services 2 hours per day, five days per week, and RN to supervise patient to ensure needs and goals were met. Medications listed included, but were not limited to, ibuprofen, aspirin, niacin, and atorvastatin. The record failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 78	{G 536}		

and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy, which evidenced, but not limited to, 2 major medication interactions, and failed to evidence the physician was notified for issues identified in the DRR.

On 1/12/2021 all medications from the agency comprehensive assessment were checked on Drugs.com for interactions. The interactions showed major interactions with ibuprofen and aspirin, niacin and atorvastatin, 65 moderate interactions, and 13 therapeutic duplications. The Drugs.com Major interaction definition stated "Highly clinically significant. Avoid combinations; the risk of the interaction outweighs the benefit."

10. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021. Review of a document dated 12/28/2020 titled "Nursing Resumption of Care [comprehensive re-assessment]" evidenced the patient received skilled nursing services every 2 weeks to fill and organize medication delivery system as scheduled and when medications were changed. Medicacations on the medication list included, but not limited to, omeprazole, and clopidogrel (Plavix). The record failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy, which evidenced, but not limited to, 1 major medication interaction, and failed to evidence the physician was notified for issues identified in the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 79	{G 536}		

DRR.

On 1/12/2021 all medications from the agency comprehensive assessment were checked on Drugs.com for interactions. The interactions showed, but not limited to, a major interaction with omeprazole and clopidogrel (Plavix). The Drugs.com Major interaction definition stated "Highly clinically significant. Avoid combinations; the risk of the interaction outweighs the benefit."

11. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/13/2020 for certification period 11/14/2020 - 1/12/2021 which evidenced skilled nursing services every other week to include, but not limited to, set up medications in medication boxes, perform a system assessment, and notify doctor of changes in condition, and medications on medication list included, but not limited to, aspirin and eliquis. The record failed to evidence a drug regimen review (DRR) was completed to identify potential adverse effects and drug reactions, including ineffective therapy, significant side effects, significant drug interactions, duplicate drug therapy and non-compliance with therapy, which evidenced, but not limited to, 1 major medication interaction, and failed to evidence the physician was notified for issues identified in the DRR.

On 1/12/2021 all medications from the agency comprehensive assessment were checked on Drugs.com for interactions. The interactions showed, but not limited to, a major interaction with aspirin and eliquis. The Drugs.com Major interaction definition stated "Highly clinically

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 80	{G 536}		

significant. Avoid combinations; the risk of the interaction outweighs the benefit."

12. During the entrance conference on 12/15/2020 at 11:00 AM, the clinical director indicated a drug regimen review was completed upon admission, and then every 60 days. During this time, employee M indicated the drug regimen review consisted of the medications, dose, frequency, side effects, diagnosis with each medication, interactions, and verification with the physician.

During an interview on 1/6/2021 at 3:56 PM, when asked how a drug regimen review was completed, the clinical director indicated they followed the list on the back of the medication profile form. When asked how the registered nurse would know if there was an interaction, she stated "... ask client or primary caregiver." During this time, the alternate clinical director indicated the agency software did not have a built in drug interactions checker, and also referred to the back of the medication profile form. Also during this time, a document with revision date 6/2019 (Med-Pass) titled "(Addendum to Comprehensive Assessment) Medication Profile" was submitted for review. The last 8 pages of the document evidenced medication class and side effects, but failed to evidence other requirements for a DRR.

During an interview on 1/11/2021 at 4:00 PM, employee O (registered nurse, case manager) indicated she was not entirely sure what was included in a DRR, and stated "... I could make some guesses ...."

During an interview on 1/12/2021 11:54 AM, employee K (licensed practical nurse) indicated

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 536}	Continued From page 81 she did not know how often a DRR was completed, she thought either the registered nurse case manager or the clinical manager completed them, and when asked what the DRR consisted of, she stated "I don 't know, because I don't do those." During an interview on 1/12/21 12:48 PM, when asked how she completed her DRR, employee M stated "... I look them up. Sometimes I know some of them ...."	{G 536}		
{G 538}	Primary caregiver(s), if any CFR(s): 484.55(c)(6)(i,ii) The patient's primary caregiver(s), if any, and other available supports, including their: (i) Willingness and ability to provide care, and (ii) Availability and schedules; This ELEMENT is not met as evidenced by: Based on record review and interview, the home health agency failed to ensure the comprehensive assessment included the presence of the patient's primary caregiver, the caregiver's willingness, and ability to provide care, and the caregiver's availability and schedules for 6 of 10 records reviewed (#2, 3, 4, 5, 6, 10). Findings include: 1. Review of an undated agency policy C-145 titled "Comprehensive Client Assessment" stated "... A thorough, well organized, comprehensive and accurate assessment, consistent with the client's immediate needs will be completed for all clients ... In addition to general health status/system assessment, the Home Nursing Services comprehensive assessment tool ... will include: ... Living arrangement ... Supportive	{G 538}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 538}	Continued From page 82	{G 538}		

assistance ..."

Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated " ... The initial and ongoing assessments include consideration of the following: ... Involvement of family friends [sic], and other individuals or organizations ... Appropriateness of the level of care provided by the family or support system to safely meet the client needs ... Ability/willingness of the client/family to assume responsibility for healthcare needs ... Client needs and the availability and adequacy of family and support systems will be considered in the care planning process ...."

2. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse that evidenced the presence of the patient's primary caregiver, the caregiver's willingness and ability to provide care, and the caregiver's availability and schedules.

3. The clinical record review of patient #3, start of care date 1/21/2003, was completed on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 538}	Continued From page 83	{G 538}		

1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse that evidenced the presence of the patient's primary caregiver, the caregiver's willingness and ability to provide care, and the caregiver's availability and schedules

4.. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/9/2020 for certification period 12/11/2020 - 2/8/2021 evidenced the patient received, but not limited to, skilled nursing visits 3 times weekly for wound care and physical assessment, had attendant care from entity K (personal services agency), was paralyzed from the waist down, and confined to a wheelchair. The record failed to evidence the patient's primary caregiver, the caregiver's willingness and ability to provide care, and the caregiver's availability and schedules.

5. The clinical record of patient #5 was reviewed

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 538}	Continued From page 84	{G 538}		

on 1/12/21, start of care date of 11/3/21. The record contained a plan of care for certification period 11/3/21-1/1/21, which indicated diagnoses of (but not limited to) congenital absence, atresia, and stenosis of small intestine (narrowing or obstruction of the small intestine). The record failed to evidence a comprehensive assessment or re-assessment was completed.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/3/2020 failed to evidence the registered nurse assessed the patient in sections subtitled: Skilled Observation, Neuromuscular, Cardiopulmonary, Skin/Wounds, Gastrointestinal, Genitourinary, Medication, and IV (intravenous). The sections evidenced no documentation (they were blank).

6. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/21-2/1/21 which failed to evidence a comprehensive assessment or comprehensive re-assessment was completed.

During an interview on 12/28/20 at 3:20 PM, while reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days).

11. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/13/2020 for certification period 11/14/2020 - 1/12/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 538}	Continued From page 85 which evidenced skilled nursing services every other week to include, but not limited to, set up medications in medication boxes, perform a system assessment, and notify doctor of changes in condition. The document failed to evidence patient's primary caregiver, or the caregiver's availability and schedules.	{G 538}		
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 registered nurse failed to ensure the comprehensive assessment was updated and revised as frequently as the patient's condition warranted due to a major decline or improvement in the patient's health status for 7 of 10 records reviewed (#1, 2, 3, 7, 8, 9, 10). Findings include: 1. Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised as often as the client's condition warrants due to a major decline or improvement in health status ... To identify decline or improvement ... are reassessed when significant changes occur in their condition	G 544		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 86 ... [or] diagnosis ...." Review of agency policy dated 6/2000 titled "Home Nursing Services Job Description: Registered Nurse" stated "... Becomes familiar with the diagnostic services available for home health care and follows the directions of the Clinical Director in utilizing these services to meet the needs of the client ... Documents fully and accurately to record a complete, total picture of the client's status and progress, and gives a complete synopsis of the care provided by the skilled registered nurse ...." 2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021. Review of a document received on 12/28/2020 titled "SN [skilled nurse] SOC [start of care] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 12/10/2019 evidenced the patient had no wounds, and was alert and oriented to person, place, and time, without confusion or disruptive behaviors. Review of a document titled "SN Re-Cert [Recertification/Re-Assessment] OASIS and Comprehensive Assessment" dated 10/3/2020 (for certification period 10/5/2020-12/3/2020) evidenced the patient was fully oriented and able to make own decisions, normal behavior, and had a wound on his right groin area. The document stated "... Right groin ... Irtritation [sic] from brief rubbing on the area ... scabbed over area ... measurements: 1x2 ... MD to evaluate wound ... Wound care orders already in place: No ... Orders need to be obtained: Yes ... Overall, the level of function has been: Slowly deteriorating ...	G 544		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 87	G 544		

Does the physician-ordered plan of care include the following ... Interventions to prevent pressure ulcer (wound) ... [box checked] Yes ... now has home attendant from entity B [personal care services] ... and they are responsible for these services ... heavy smoker ... observed foul smelling wound to the groin. Area appears dark red in color with puss [sic]-like drainage present. Advised POA [power of attorney- family member] to keep all follow-up appointments with the wound clinic due to possible infection to the area ... complete depandence [sic] on nece [sic] for all care ... Any immediate concerns or issues to be resolved before next visit: No ... Next visit [skilled nurse] planned to occur: 11/3/2020 [one month later] ...." The document also evidenced a Braden scale was completed, with a score of 16 (patients with a total score of 16 or less are considered to be at risk for developing pressure ulcers; 15 or 16 = low risk, 13 or 14 = moderate risk, and 12 or less = high risk.) The assessment evidenced (but not limited to) the patient's skin was occasionally moist, requiring a linen change approximately once a day (score of 3), and evidenced the patient moved in bed and chair independently and could maintain good positioning in bed or chair (score 3). However, the assessment also evidenced the patient was incontinent of stool more often than once daily, which would require linen changes more than once daily (score 2 - skin is often, but not always moist), and he was a bilateral amputee and unable to sit unsupported, major physical limitations, was dependent for all personal care, and was unable to transfer self from bed to chair (score 1 - requires moderate to maximum assistance in moving). The adjusted score would have been 13 (moderate risk). The document also evidenced the plan of care included interventions to prevent pressure ulcers,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 88	G 544		

but were not evidenced on the plan of care. The document failed to evidence wound diagnoses, failed to evidence the physician was contacted to report wound assessment findings (with possible infection), and wound treatment orders, failed to evidence entity B was contacted for care coordination regarding the wound and possible incorrect application of brief (too tight causing pressure/friction), and failed to evidence the niece (primary caregiver) was educated on signs or symptoms of infection (redness, heat, pain, foul odor, pus-like drainage, fever), wound care/treatment, or correct application of briefs, and failed to evidence a timely skilled nursing follow up visit was scheduled to re-assess the wound, ensure treatment orders were received, and the family member was competent in performing the treatment(s). No other wounds were identified during this assessment.

The clinical record contained a plan of care for the certification period of 12/4/2020 - 2/1/2021 which indicated orders for skilled nursing once per month for indwelling catheter change and system assessment with vital signs.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/3/2020 stated "... Client has a pressure ulcer on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs. These are both being treated by the [entity C-wound clinic]. At time of assessment, the wounds were covered and not able to be assessed ...." The document failed to evidence the nurse completed the updated comprehensive assessment by failing to assess the wounds.

During an interview on 12/16/2020 at 2:16 PM,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 89	G 544		

when asked if their clinic records evidenced communication or care coordination with Home Nursing Services, a staff member at entity C stated "I don't see any communication with home care ... not sure we even knew he had home health care."

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

During an interview on 12/17/2020 at 3:44 PM, the comprehensive assessment for patient #1 dated 12/3/2020 was completed today (12/17/2020), and the plan of care was completed today (12/17/2020) and sent to the physician. Both were reviewed and approved by employee M (registered nurse) It was verified by the clinical

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 90	G 544		

director and the administrator that employee L (registered nurse) initiated the comprehensive assessment on 12/3/2020 but didn't complete it, and she did not assess the wounds. When asked, the clinical director agreed the certifying physician would not be able to provide/approve orders to meet the patient's needs without complete and accurate assessment findings. During this time, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No."

During an interview on 12/18/2020 at 1:00 PM, when asked who finished the comprehensive assessment dated 12/3/2020, the director of nursing stated "[employee N- registered nurse]." When asked if she was the nurse that initiated the comprehensive assessment on 12/3/2020, the director of nursing stated "No." When asked why employee L didn't complete the assessment, the director of nursing stated "We discovered she was behind, we wanted to get it done, so we sent it to [employee N]." She also indicated employee N saw the patient on 12/15/2020, and that visit represented completion of the comprehensive assessment dated 12/3/2020. When asked if the patient's electronic clinical record evidenced education for mitigation of pressure ulcers/wounds, the clinical director stated "No, but I can get the [paper portion] chart." Employee M retrieved it. When asked if the chart evidenced education for mitigation of pressure ulcers/wounds, employee M stated "No, looks like he goes to the wound clinic and they just advise him to keep his appointments."

During an interview on 12/18/2020 at 3:20 PM, when asked which nurse did which portions of the comprehensive assessment dated 12/3/2020, the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 91	G 544		

administrator stated "I can only tell [employee L] visited [the patient] on the 3rd, started writing [on the assessment on] 11th, [employee N] saw the patient on the 15th, and employee M reviewed and approved the assessment document on the 17th ... [employee M] signed the plan of care." The administrator also indicated he didn't know who did the wound assessments, or when the wounds were last assessed by staff. When asked if there had been any discipline for employee L, the administrator stated, "I don't know."

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today [12/22/2020] to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... His catheter bag [bag connected urine drain tube] was stuffed an opening [sic] in the side of his wheelchair. The urine in the tube was pale yellow with sediment present ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She indicated they might have. Also

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 92	G 544		

asked about adding protein to the diet, niece indicated she did not remember for sure, maybe." The document failed to evidence wound diagnoses, failed to evidence the nurse and patient's niece scheduled a follow up visit to assess the wounds.

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated patient #1 expired in the hospital on 12/27/2020.

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head." When asked why there was no follow up visit scheduled to assess the patient's wounds after 12/22/2020, she stated "... planned on going back after the holidays." When asked if it was appropriate to wait so long to assess wounds (as part of the comprehensive assessment), she stated "Yes ...." When asked if she spoke with the certifying physician after she saw the patient on 12/22/2020, she stated "No ma'am." When asked if she should speak with the certifying physician after completing a comprehensive assessment, she stated "If I find something that's different or out of the ordinary." When asked if it was out of the ordinary for the patient to resist/refuse assessment of vital signs and not interact with the nurse during the assessment on 12/22/2020, she

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 93	G 544		

indicated it was not out of the ordinary. However, all other clinical notes evidenced the patient was cooperative during skilled nursing visits. When asked if measurements from wound clinic documentation counted as part of her comprehensive assessment, she stated "No, but I was going to go back after the holiday." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted.

Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...."

Review of a document titled "Care Coordination Note" dated 12/28/2020 stated "... [nurse] made a visit on Tuesday [12/22/2020] ... The client was resistive of being touched and could not hear the conversation ... The client continued to be tired and not wanting to get out of bed on Wednesday [12/23/2020] ... niece called EMS to take the client to the hospital due to him not acting right ...."

Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 94	G 544		

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

5. The clinical record of patient #5 was reviewed

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 95	G 544		

on 1/12/21, start of care date of 11/3/21. The record contained a plan of care for certification period 11/3/21-1/1/21, which indicated diagnoses of (but not limited to) congenital absence, atresia, and stenosis of small intestine (narrowing or obstruction of the small intestine). The record failed to evidence a comprehensive assessment or re-assessment was completed.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/3/2020 failed to evidence the registered nurse assessed the patient in sections subtitled: Skilled Observation, Neuromuscular, Cardiopulmonary, Skin/Wounds, Gastrointestinal, Genitourinary, Medication, and IV (intravenous). The sections evidenced no documentation (they were blank).

6. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/21-2/1/21 which failed to evidence a comprehensive assessment or comprehensive re-assessment was completed.

During an interview on 12/28/20 at 3:20 PM, while reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days).

7. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.

Review of a document titled "SN ROC OASIS and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 96	G 544		

Comprehensive Assessment" dated 1/5/2021 (after the IJ was called) evidenced the patient received, but not limited to, skilled nursing every other week to complete a full head to toe assessment,vital signs, and change the patient's suprapubic catheter (a tube inserted into an opening in the lower abdomen directly into the bladder to drain urine), and home health aide (HHA) services for personal care "up to 60 hours". The document evidenced a wound to the left upper coccyx, but failed to evidence it was assessed by the nurse.

Review of a document dated 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, applying an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received. Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated she did not know the name of the ointment the spouse applied to the wound(s).

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), the administrator, and the alternate administrator stated "... 1-10-2021, 12:20pm. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her home remedy for his back is working ... She does not need me to stop by today to help her ...." The document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified the wife was applying a home remedy to his wound(s). Additionally, during the exit interview

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 97	G 544		

on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), employee D (medical records coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound with wounds, and a new wound that developed post-hospitalization, and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 98	G 544		

she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted.

8. The clinical record review for patient #8 was completed on 1/11/2021. Review of a document titled "RN Re-Certification Assessment [comprehensive re-assessment]" dated 11/20/2020 evidenced the patient received HHA (home health aide) services 2 hours per day, five days per week, and RN to supervise patient to ensure needs and goals were met, and the patient had a diabetic foot ulcer [open wound commonly located on the bottom of the foot] on the outside of his right foot. The document failed to evidence the wound was assessed, or listed diabetic ulcer in patient diagnoses.

9. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document dated 12/28/2020 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which previously had not been identified), and the nurse failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the patient's current non-weight bearing status to the right foot, which could potentially

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 99	G 544		

have a negative outcome on the surgical healing process, and failed to evidence the nurse assessed the left second toe pain.

Review of a document titled "RN Re-Certification Assessment [comprehensive re-assessment]" dated 12/28/2020 (additional document for same nurse visit same day) stated "... Pain Assessment: ... right foot. Severity (0-10), 6 ... right foot ... surgical dressing in place ... Integumentary Assessment ... No issues noted ...." The document evidenced the patient had a post-surgical incision to his right groin, and was non-weight bearing to the right foot, but failed to evidence complete assessment including measurements of the right groin incision. The assessed pain level of 6 was inconsistent with the pain level assessed as 5 on another document titled Pain Location Assessment", same day, same nurse.

Review of a document dated 12/28/2020 titled "Nursing Resumption of Care [comprehensive re-assessment]" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without devices in his home ... Has had no ... hospitalizations ...." The document failed to evidence the patient's current post-surgical status of non-weight bearing right lower foot and other physical restrictions, and assessment including measurements of the right groin incision.

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2020), which indicated (but not limited to)

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 100	G 544		

the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.

10. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 11/13/2020 for certification period 11/14/2020 - 1/12/2021 stated "... Integument Assessment ... Wound Tracking ... Location ... Abdomen ... Action Taken Today ... Not Specified ... Integument Impression: Overall, this system is: abnormal/dysfunctional, and, has steadily been declining. The system appears: ... in need of skilled intermittent care. Will require a lot of attention, will be a focus of care during regular visits ...." Additionally, the assessment evidenced pain in the patient's back, stomach, and abdominal wound, which was "Progressively worsening over time", the wound was being managed by the wound clinic, and the patient took "narcotics" (controlled substance pain medication) for the wound pain. The document failed to evidence any assessment of the wound, assessment of pain such as (but not limited to) pain level, onset, duration, or description, assessment of last bowel movement, and the medication profile failed to evidence the narcotic the patient took for pain.

11. During the entrance conference on 12/15/2020 at 11:00 AM, when asked how the agency determined when there has been a major decline or improvement in the patient's health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 544	Continued From page 101 status, the clinical director stated, "Through nursing assessment." During an interview on 12/18/2020 at 1:00 PM, when asked the purpose of the comprehensive assessment, the clinical director stated, "To develop the plan of care." When asked if it was her expectation for staff to assess head to toe for comprehensive assessment, she stated "Yes."	G 544		
G 546	Last 5 days of every 60 days unless: CFR(s): 484.55(d)(1)(i,ii,iii) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a- (i) Beneficiary elected transfer; (ii) Significant change in condition; or (iii) Discharge and return to the same HHA during the 60-day episode. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure all patients' comprehensive re-assessments were completed and/or updated the last five days of every certifications period for 6 of 10 records reviewed (#1, 2, 3, 4, 5, 6) and for 28 additional agency patients (without record review) with re-assessments due between 12/1/2020 and 12/18/2020. Findings include: 1. Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised as often as the client's condition warrants due to a major decline or improvement in health status ... To	G 546		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 546	Continued From page 102	G 546		

identify decline or improvement ... are reassessed when significant changes occur in their condition ... [or] diagnosis ... at least every fifty-six to sixty (56-60) days ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "SN [skilled nurse] Re-Cert [recertification] OASIS [Outcome and Assessment Information Set] and Comprehensive Assessment" dated 12/3/2020 evidenced skilled nursing monthly for (but not limited to) indwelling catheter change and physical assessment, and report any abnormal findings to MD.

During an interview on 12/18/2020 at 1:00 p.m., the clinical manager indicated employee L (indicate title) didn't complete the comprehensive assessment document (for patient #1) due to the comprehensive assessment being behind and the agency wanted it done so it was sent to employee N (indicate title) for completion. The clinical manager indicated employee N was not the nurse that had initiated the comprehensive assessment but had seen the patient on 12/15/20 and this represented the completion of the comprehensive assessment which was initially conducted on 12/03/2020 (12 days after the initial comprehensive assessment). The clinical manager then indicated there were multiple incomplete assessments unfinished by employee L which were being completed / "fixed" by other clinicians who had not conducted the visits / assessments. At 1:38 p.m., a document was received from the clinical manager which evidenced 33 patients from 12/01/2020 - 12/18/2020 had incomplete assessments with no updated plan of care.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 546	Continued From page 103	G 546		

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

5. The clinical record review of patient #4, start of

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 546	Continued From page 104	G 546		

care date 8/19/2019, was completed on 1/12/2021, which evidenced a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/9/2020 for certification period 12/11/2020 - 2/8/2021 evidenced the patient received, but not limited to, skilled nursing visits 3 times weekly for wound care and physical assessment, and alert MD for any abnormal findings. This assessment was originally assigned to employee L, but was subsequently completed by employee M, with unknown actual completion date. This assessment was on the list of incomplete assessments submitted by the agency.

6. The clinical record of patient #5 was reviewed on 1/12/21 and indicated a start of care date of 11/3/21. The record contained a plan of care for the certification period of 11/3/20-1/1/21 that indicated diagnoses of, but not limited to, congenital absence, atresia, and stenosis of small intestine (narrowing or obstruction of the small intestine). The record failed to evidence a complete recertification comprehensive assessment.

7. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/20-2/1/21 that indicated diagnoses of, but not limited to, achalasia of cardia (nerve damage in the esophagus causing it to become paralyzed and dilated). The record lacked a history and physical upon referral/admission, or any time during dates of care for the client. The record failed to evidence a recertification comprehensive assessment.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 546	Continued From page 105 During an interview on 12/28/20 at 3:20 PM, Employee E (Administrator) agreed that no comprehensive assessment on patient #6 had been done for the past 3 certification periods. #2 had been done for the past 3 certification periods.	G 546		
G 550	At discharge CFR(s): 484.55(d)(3) At discharge. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure an updated comprehensive assessment was completed upon discharge for all agency patients. 1. Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised ... Within forty-eight (48) hours of (or knowledge of) discharge or transfer ...." Review of an undated agency policy copyright Briggs Healthcare titled "Client Discharge Process" stated "... A discharge Summary shall be developed that is documented in writing and includes all written//verbal instruction regarding the client's ongoing care needs and available resources provided to the client and family ...." 2. During the exit conference on 1/12/2021 at 2:50 PM, when asked if a comprehensive assessments were performed when patients were going to be discharged from the agency, the clinical director stated "No."	G 550		
{G 564}	Discharge or Transfer Summary Content CFR(s): 484.58(b)(1)	{G 564}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 564}	Continued From page 106 Standard: Discharge or transfer summary content. The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care. This STANDARD is not met as evidenced by: Based on record review and interview, the agency failed to ensure a completed transfer summary all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care for 3 of 3 records reviewed with patient transfers to an inpatient facility (#1, 7, 9), and 1 of 1 patients (without clinical record review) identified during an interview who was previously hospitalized, and subsequently sent back to the emergency room (#11). Findings include: 1. Review of an undated copyrighted Briggs Healthcare policy C-840 titled "Transfer Policy" stated "... A client may be transferred ... identified need that cannot be met by Home Nursing Services ... A transfer summary shall be completed by the registered nurse ... form shall be sent to the new provider or facility ... a copy shall be retained for the client's chart ... discussed with the physician and orders obtained approving the client's transfer ...."	{G 564}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 564}	Continued From page 107	{G 564}		

2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021. During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated the patient expired in the hospital on 12/27/2020.

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head."

Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020 ...."

Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...." The record failed to evidence a transfer summary, or that a transfer summary

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 564}	Continued From page 108	{G 564}		

was sent to the physician. Upon exit, nothing further was submitted.

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021. Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current possible UTI (urinary tract infection) symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The record also evidenced a document titled "Transfer to Inpatient Facility (Not Discharged) OASIS [outcome and assessment information set]" was completed and dated 1/2/2021, but failed to evidence a transfer summary, or that a transfer summary was sent to the physician or receiving facility.

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021.

Review of a document dated 1/5/2021 titled "Physician Order" stated "... Please place client on HOLD [sic] as of 1/2/2021 due to being inpatient at ... to treat UTI ...."

3. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 -

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 564}	Continued From page 109	{G 564}		

12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document dated and signed by employee M (registered nurse) on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE [right lower extremity] Femoral Endarterectomy on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain ...."

During an interview on 1/12/2021 at 1:10 PM, employee M stated "I didn't contact the physician [on 12/14/2020] because he already had an appointment scheduled [for 12/18/2020] and the [physician] was already aware."

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence a transfer summary was sent to the hospital or certifying physician.

5. During an interview on 1/6/2021 2:45 PM the alternate clinical director indicated she received report this morning/today (1/6/2021) from employee M's (registered nurse), and indicated patient (#11-no clinical record review) went to the emergency room (ER) today. She also indicated an agency aide reported it to employee M, the patient had fempop bypass (Femoral popliteal bypass surgery which requires a stay in the hospital) about two weeks ago, and he was still having pain. The clinical director and alternate

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 564}	Continued From page 110 clinical director indicated they did not know if the aide saw the patient today, did not know when the patient was last seen by a nurse, didn't know if the agency had hospital paperwork regarding the hospitalization for bypass surgery, and the agency was previously unaware the patient was hospitalized. When asked if the hospital was contacted today and a summary was sent, the alternate clinical director stated "No. She said they were just sending him." When asked if the physician was contacted, she stated "I don't know. She was out in the field. ....", and indicated it was employee M's job to coordinate with the physician.	{G 564}		
{G 570}	Care planning, coordination, quality of care CFR(s): 484.60 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:	{G 570}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 111	{G 570}		

An immediate jeopardy (IJ) related to comprehensive assessment and re-assessment of patients was identified on 12/18/2020. The administrator was notified on 12/18/20 at 5:09 PM. The immediate jeopardy remained unremoved after exit on 1/12/21.

The cumulative effect of these systemic problems resulted in the home health agency's inability to ensure the provision of quality health care for the Condition of Participation 42 CFR 484.60 Care planning, coordination, and quality of care.

Based on record review and interview, the home health agency failed to ensure the needs of the patients were met for 3 of 7 patients' records reviewed with wounds (#1, 7, and 9); failed to ensure all patients' plans of care included (but not limited to) all pertinent diagnoses; failed to evidence the frequency and duration of visits to be made; failed to evidence rehabilitation potential; failed to evidence all medications and treatments; failed to evidence a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors; failed to evidence patient and caregiver education and training to facilitate timely discharge; failed to evidence patient-specific interventions and education; and measurable outcomes and goals identified by the agency and the patient (See Tag G574); failed to evidence treatments were administered only as ordered by a physician (See Tag G580); failed to evidence physicians' verbal orders were accurately dated and timed (See Tag G584); failed to evidence the plans of care were reviewed as frequently as the patient's condition or needs required, but no less frequently than once every 60 days (See Tag

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 112	{G 570}		

G588); failed to evidence the physician was promptly notified of any changes in the patient's condition or needs that suggested the plan of care should be altered (See Tag G590); failed to evidence the revised plan of care reflected current information from the patient's updated comprehensive assessment (See Tag G592); failed to evidence integrated orders from all physicians involved in the plan of care to ensure the coordination of all services and interventions provided to the patient (See Tag G604); failed to evidence coordinated care with other agencies involved with the patients' care (See Tag G608); and failed to evidence patients/caregivers received ongoing education and training provided by the agency regarding the care and services identified in the plans of care (See Tag G610). This practice had the potential to affect all agency patients.

In regard to G570, findings include:

1. Review of an undated copyrighted Briggs Healthcare policy C-580 titled "Plan of Care" stated "... Home Nursing Services staff to develop a plan of care individualized to meet [patient] specific identified needs ...."

2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021. The agency failed to ensure the needs of the patient were met by failing to measure wounds, contact physician for changes in wound status, potential dehydration, signs and symptoms of infection, or education to the patient/caregiver to mitigate worsening or new skin breakdown as evidenced by:

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 10/5/2020 - 12/3/2020

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 113	{G 570}		

stated "... SN [skilled nurse] monthly for full assessment with vital signs and ... foley catheter change ... Coordination of Care: SN will report changes in condition to MD, Client has Home attendant services from [entity B] and they are responsible for these services [personal care and hygiene] ... friendly and pleasant during visit ... catheter ... draining thick, dark, gold-colored urine ... Foul smelling wound to the groin remains ... Advised POA [power of attorney] to have MD [physician] assess wound at appointment next week ...."

Review of a document titled "Wound Location Assessment" dated 11/5/2020 stated "... Location: left [sic] groin ... Wound type: unknown ... Date originally reported: 2/3/2020 ... Comments: Small open area to the right groin area ... Client is being treated at the wound clinic for this wound ... Location: left buttocks ... Wound type: Pressure ... Date originally reported: 4/3/2020 ... Small reddened area on the buttocks...."

Review of a document titled "Skilled Nurse Visit Note" dated 12/3/2020 stated "... Skin/Wounds ... Turgor: [box checked] Poor ... [box checked] See Wound Location Assessment ... encouraged to increase fluids ... Hydration adequate [box checked] No ...."

Review of a document titled "Wound Location Assessment" dated 12/3/2020 stated "... Location: left [sic] groin ... Wound type: unknown ... Date originally reported: 2/3/2020 ... Comments: Small open area to the right groin area ... Treatments to the area continue with [entity C- a wound clinic] ... Location: left buttocks ... Wound type: Pressure ... Date originally reported: 4/3/2020 ... Small reddened area on the buttocks ... Treatments to the area continue by family at home following wound clinic orders ...."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 114	{G 570}		

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/3/2020 stated "... Client has a pressure ulcer on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs. These are both being treated by the [entity C]. At time of assessment, the wounds were covered and not able to be assessed ...."

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).
During an interview on 12/17/2020 at 3:44 PM, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 115	{G 570}		

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She stated they might have. Also asked about adding protein to the diet, niece stated she does not remember for sure, maybe ...." The document failed to evidence the nurse and patient's niece scheduled a follow up visit to assess the wounds, failed to evidence the nurse followed up with the physician regarding orders for supplemental vitamins or additional protein diet, and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown.

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated patient #1 expired in the hospital on 12/27/2020.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 116 During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head." When asked why there was no follow up visit scheduled to assess the patient's wounds after 12/22/2020, she stated "... planned on going back after the holidays." When asked if it was appropriate to wait so long to assess wounds (as part of the comprehensive assessment), she stated "Yes ...." When asked if she spoke with the certifying physician after she saw the patient on 12/22/2020, she stated "No ma'am." When asked if she should speak with the certifying physician after completing a comprehensive assessment, she stated "If I find something that's different or out of the ordinary." When asked if measurements from wound clinic documentation counted as part of her comprehensive assessment, she stated "No, but I was going to go back after the holiday." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted. Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...."	{G 570}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 117	{G 570}		

Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020 ...."

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/1/2020 - 12/30/2020 stated "... [skilled nursing orders] System assessment with each skilled nursing visit ... report any abnormal findings to [physician] ... open area on coccyx that is being treated by the wound clinic ...."

Review of a wound clinic document dated 11/24/2020 (obtained by the wound clinic, not from clinical record) titled "Wound Treatment #1 (Order 262060966)" stated "... Wash wound(s) with mild soap and water, then pat dry. Place Medihoney [wound bed ointment] and cover with ABD [surgical absorbent gauze pad]. Change dressing daily ... Home Healthcare to visit for wound care 2-3 [times] weekly and PRN [as needed] wound care/dressing changes ... left lower extremity ... right lower extremity ...." The agency record failed to evidence it provided skilled nursing visits 2-3 times weekly.

Review of a document dated 11/27/2020, 12/8/20,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 570}	Continued From page 118	{G 570}		

and 12/23/2020 titled "Skilled Nurse Visit Note" failed to evidence wounds were assessed or treated by nurse and failed to evidence education was provided to the caregiver to mitigate worsening, signs and symptoms of infection, dehydration, urinary tract infections or new skin breakdown.
Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... [blank] ... Stage 3 ... [blank] ... Unstageable [full thickness skin and tissue loss in which the extent of the damage within the ulcer cannot be determined due to scabbing or dead fibrous tissue; once removed to expose wound, a stage 3 or 4 would be revealed] ... Stage 1 ... 0 ... Does this patient have a stasis ulcer [ulcer caused by impaired circulation]? ... Yes ... Current number of Stasis Ulcers that are observable ... 3 ... status of most problematic ... Not Healing ... Location ... left second toe ... left third toe ... right second toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... Integument [skin] Impression: ... unstable ... in need of skilled intermittent care ... Will continue to monitor during regular visits, but not be a focus of care ... Will require a lot of attention ... Current possible UTI symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The document also evidenced the patient was a high risk for skin breakdown. The document failed to evidence the wounds were treated by the nurse, or education was provided to the caregiver to mitigate worsening or new skin breakdown.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order"

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 119	{G 570}		

for certification period 12/31/2020 - 2/28/2021 stated "... [skilled nursing orders] 1 visit every other week x 9 weeks ... System assessment with each skilled nursing visit ... full head to toe assessment ... change suprapubic catheter ... RHHA up to 60hr ... catheter care ... Teach/train in proper positioning to reduce pressure on pressure prone areas ... Assess wound for infection and healing ...."

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.
Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was a high risk for skin breakdown, stated "... Does this patient have a stasis ulcer? ... Yes ... Current number of Stasis Ulcers that are observable ... 4 ... status of most problematic ... Not Healing ... Location ... right big

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 120	{G 570}		

toe ... right second toe ... left second toe ... left third toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... wife cleanses, applies medihoney dresses every other day and will see wound clinic 1/14/20 [sic] ...." The document failed to evidence contact precautions for VRE, skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote wound healing, frequent turning schedule, or padding of bony prominences, or wound care was performed by the nurse. The document evidenced the certifying physician was contacted for orders, but the clinical record failed to evidence orders dated 1/5/2021.
Review of a document dated 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, applying an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received. Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated she did not know the name of the ointment the spouse applied to the wound(s).

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), the administrator, and the alternate administrator stated "... 1-10-2021, 12:20pm. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her home remedy for his back is working ... She does not need me to stop by today to help her ...." The document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

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HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 570}	Continued From page 121	{G 570}		

the wife was applying a home remedy to his wound(s). Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), employee D (medical records coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.
4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 570}	Continued From page 122	{G 570}		

Review of a document titled "SN Re-Cert [recertification] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 11/1/2020 "... right second toe amputation ... Non-removable dressing present. Wound managed by orthopedics ... Report any abnormal findings to VA [veterans affairs] MD ... skilled nurse ... physical assessment ... and notify MD of any abnormal findings ... had his right second toe amputated ... His 3rd right toe is black and shriveled ...."

Review of a document dated 11/2/2020 titled "Skilled Nurse Visit Note" stated "... Right second toe amputation site not healing. 3rd toe black and very painful ...."

Review of a document dated and signed by employee M 11/16/2020 titled "Skilled Nurse Visit Note" stated "... "posterior foot blackening about an 1 1/2 inch on ball of right foot, 3rd toe black and shriveled, outer edge of 5th toe; see diagram"

During an interview on 1/6/2021 at 3:56 PM, when asked if the doctor should have been notified of the change in wound status on 11/16/2020, the alternate director of nursing stated, "He should be, I don't know if she did call." When asked if this failure to contact the physician could have potentially led to a negative outcome for the patient, she stated "Yes".

Review of a document dated and signed by employee M on 11/30/2020 titled "Skilled Nurse Visit Note" stated "...: "No fever, No cough, No complaints, Right foot, big toe starting to blacken, middle to black and shriveled. Per wife, US

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

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HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 570}	Continued From page 123	{G 570}		

[ultrasound] showed multiple blockages and patient may lose foot d/t [due to] occlusions ...."

Review of a document dated and signed by employee M on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE Femoral Endarterectomy on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain. Pain 10/10. Taking Norco for pain. 2 weeks of meds set-up. 100% medication compliant ...."

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home."

Review of a document titled "Skilled Nurse Visit Note" dated 12/28/2020 stated "... returned from hospital S/P [after] Right femoral endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] and Right partial amputation of foot. Right groin incision C/D/I [clean, dry, and intact] no redness, no draining, no swelling. OTA [open to air]. Right foot dressing C/D/I with orders not to remove same until f/u [follow up] with Podiatry 1/4/21. Plavix [medication to prevent formation of blood clots and to keep blood vessels open after surgical procedures, and may cause easy bleeding/bruising] ... added to medication regimine [sic] ... Client is NWB [non-weight bearing] R foot ...."

During an interview on 1/5/2021 at 1:29 PM person F (staff at entity E) indicated the patient

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 570}	Continued From page 124 was seen 1/4/2021 for surgical follow up. When asked if she received any communication/coordination from the agency, she stated "On 12/29 [2020] we got a call from [employee M] to request PT/OT [physical and occupational therapy] order. That's the only thing I see ...." During an interview on 1/6/2021 at 3:56 PM, the clinical director and alternate clinical director confirmed the skilled nursing frequency remained every two weeks since hospital discharge. When asked if waiting two weeks to see this patient could lead to a potentially negative outcome, they both stated "Yes." During an interview on 1/12/2021 at 1:50 PM, regarding the skilled nursing visit on 11/16/2020, employee M indicated she did not contact the physician, he was already aware, it (the wound/blackening of toe/foot) started as just the tip, and it was an ongoing process; regarding the skilled nursing visit on 12/14/2020, she stated "I did not call the physician ...."	{G 570}		
{G 574}	Plan of care must include the following CFR(s): 484.60(a)(2)(i-xvi) The individualized plan of care must include the following: (i) All pertinent diagnoses; (ii) The patient's mental, psychosocial, and cognitive status; (iii) The types of services, supplies, and equipment required; (iv) The frequency and duration of visits to be made; (v) Prognosis; (vi) Rehabilitation potential;	{G 574}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 125 (vii) Functional limitations; (viii) Activities permitted; (ix) Nutritional requirements; (x) All medications and treatments; (xi) Safety measures to protect against injury; (xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors. (xiii) Patient and caregiver education and training to facilitate timely discharge; (xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient; (xv) Information related to any advanced directives; and (xvi) Any additional items the HHA or physician may choose to include. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure all patients' plans of care included (but not limited to) all pertinent diagnoses; failed to evidence the frequency and duration of visits to be made; failed to evidence rehabilitation potential; failed to evidence all medications and treatments; failed to evidence a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors; failed to evidence patient and caregiver education and training to facilitate timely discharge; failed to evidence patient-specific interventions and education; and measurable outcomes and goals identified by the agency and the patient for 10 of 10 records reviewed (#1, 2, 3, 4, 5, 6, 7, 8, 9, 10). Findings include:	{G 574}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 126	{G 574}		

1. Review of an undated copyrighted Briggs Healthcare policy C-580 titled "Plan of Care" stated "... Home Nursing Services staff to develop a plan of care individualized to meet [patient] specific identified needs ... to include ... specific procedures ... medications, treatments, and procedures ... other appropriate items ... professional staff shall promptly alert the physician to any changes that suggest a need to alter the Plan of Care ...."

Review of an undated copyrighted Briggs Healthcare policy C-100 titled "Services Provided" stated "... Services will be coordinated by the Registered Nurse managing the care. This will include implementing, revising, and updating the Plan of Care; physician conferencing ... conferencing with health team members to plan and evaluate client [patient] care ...."

Review of an undated copyrighted Briggs Healthcare policy C-360 titled "Coordination of Client Services" stated "... to ensure appropriate, quality care is being provided to clients ... to establish effective interchange, reporting and coordination of client care does occur ... Coordination with other agencies and institutions ... alert physician to changes in client condition ...."

Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Skilled Nursing Services" stated "... Skilled nursing services will be provided ... In determining whether a service requires the skills of a Nurse, the inherent complexity of the service, condition of the client ... Regularly reevaluates the client needs ... Initiates the Plan of Care and necessary revisions and updates to the plan of care ... Provides services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 127	{G 574}		

requiring specialized nursing skill and initiates appropriate preventive and rehabilitative nursing procedures ... Informs the physician and other personnel of changes in the client condition and needs ... Counsels the client and family/caregivers in meeting their needs ... Prepares clinical and progress notes ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a plan of care (POC) for certification period 12/4/2020 - 2/1/2021, with primary diagnosis Diabetes with diabetic peripheral angiopathy (blood vessel disease caused by high blood sugar levels), and other pertinent diagnoses chronic obstructive pulmonary disease, essential (primary) hypertension, hyperlipidemia (high cholesterol), peripheral vascular disease (impaired circulation), depression, neuromuscular dysfunction of bladder, urinary incontinence, anemia, chronic atrial fibrillation, nicotine dependence (cigarettes), history of falling, encounter for fitting and adjustment of urinary device, acquired absence of right leg below knee, and acquired absence of left leg below knee. The POC failed to evidence diagnoses of stage 3 pressure ulcer to right groin, or stage 4 pressure ulcer to left stump, the frequency and duration of visits to be made, rehabilitation potential, wound treatments; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, patient and caregiver education and training to facilitate timely discharge, patient-specific interventions and education, and measurable outcomes and goals identified by the agency and the patient.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 128	{G 574}		

The POC also evidenced a section titled "Professional Service Orders" which stated "RN [registered nurse] Orders: ... periodic planned and unplanned supervisory visits ... 1x/month for indwelling catheter change ...." The section titled "Goals" failed to evidence patient identified measurable goals. The section titled "Rehabilitation Potential" stated "The potential for rehab is N/A [not applicable] ...."

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

During an interview on 12/17/2020 at 3:44 PM, when asked, the clinical director agreed the certifying physician would not be able to provide/approve orders (plan of care) to meet the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 129	{G 574}		

patient's needs without complete and accurate assessment findings.

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021 with primary diagnosis unspecified injury at C6 (6th cervical vertebrae) level of spinal cord, and other pertinent diagnoses of unspecified injury at C7 (7th cervical vertebrae) level of spinal cord, laceration (cut) without foreign body of left buttock, presence of urogenital implants, autonomic dysreflexia, hyperlipidemia, muscle spasm, iron deficiency, constipation, essential (primary) hypertension, and unspecified cataract. The POC failed to evidence diagnoses of stage 4 pressure injury to left buttock, rehabilitation potential, wound treatments or catheter care; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, patient and caregiver education and training to facilitate timely discharge, patient-specific interventions and education, and measurable outcomes and goals identified by the agency and the patient.

The POC also evidenced a section titled "60 Day Summary" which evidenced the patient had a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock, the agency performed wound care as needed, and the patient had a suprapubic catheter (a tube inserted into a hole in the lower abdomen into the bladder to drain urine). The section titled "Goals" failed to evidence patient identified measurable goals. The section titled "Rehabilitation Potential"

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 130	{G 574}		

stated "The potential for rehab is N/A [not applicable] ...."

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 12/17/2020 - 2/14/2021 with primary diagnosis of cerebral palsy, and other pertinent diagnoses of profound intellectual disabilities, hearing loss, asthma, chronic obstructive pulmonary disease, attention and concentration deficit, sleep apnea, gastro-esophageal reflux disease without esophagitis, restlessness and agitation, impulse disorder, attention-deficit hyperactivity disorder, predominantly hyperactive type, seizures, constipation, other specified nonpsychotic mental disorders, seasonal allergies, gastrostomy (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.) status, and tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) status. The POC failed to evidence rehabilitation potential, patient specific g tube or tracheostomy care/treatment orders, trach size; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, caregiver education and training to facilitate timely discharge, patient/family-specific interventions and education, and measurable outcomes and goals identified by the agency and the family/caregiver.

The POC evidenced the patient received skilled

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 131	{G 574}		

nursing services (but not limited to) for tracheostomy care, g-tube, administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The section titled "Goals" failed to evidence patient/family identified measurable goals. The section titled "Rehabilitation Potential" stated "The potential for rehab is N/A [not applicable] ...."

5. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 12/17/2020 - 2/14/2021 with primary diagnosis of paraplegia, and other pertinent diagnoses of essential (primary) hypertension, anxiety disorder, fusion of spine-lumbar region, and incontinence without sensory awareness. The POC failed to evidence duration of skilled nursing visits, rehabilitation potential, a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, caregiver education and training to facilitate timely discharge, patient/family-specific interventions and education, and measurable outcomes and goals identified by the patient.

The POC evidenced the patient received skilled nursing services (but not limited to) 3 times per week for wound care. The section titled "Goals" failed to evidence patient/family identified measurable goals. The section titled "Rehabilitation Potential" stated "(No information available)."

6. The clinical record of patient #5 was reviewed on 1/12/21 and indicated a start of care date of

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 132	{G 574}		

11/3/21. The record contained a plan of care for the certification period of 11/3/20-1/1/21, which failed to identify rehabilitation potential and patient-specific interventions.

7. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/20-2/1/21, which failed to identify rehabilitation potential and patient-specific interventions.

During an interview on 12/28/20 at 3:20 PM, while reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days).

8. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 12/31/2020 - 2/28/2021 with primary diagnosis cerebrovascular disease, and other pertinent diagnoses of paralytic syndrome, unspecified, unspecified convulsions, urinary calculus, panlobular emphysema, essential (primary) hypertension, chronic pain syndrome, pain in unspecified hip, diabetes with neuropathy, gout, pure hypercholesterolemia, insomnia, neuromuscular dysfunction of bladder, other sequelae of cerebral infarction (stroke), unspecified acquired deformity of unspecified limb, peripheral vascular disease, migraine without aura, not intractable, without status migrainosus, gastro-esophageal reflux disease without esophagitis, mixed irritable bowel

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 133	{G 574}		

syndrome, and chronic systolic (congestive) heart failure. The POC failed to evidence diagnoses of wounds, duration of home health aide visits, rehabilitation potential, skilled nursing wound care/treatment orders; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, caregiver education and training to facilitate timely discharge, patient/family-specific interventions and education, and measurable outcomes and goals identified by the patient.

The POC evidenced the patient received skilled nursing every other week to complete a full head to toe assessment, vital signs, and change the patient's suprapubic catheter (a tube inserted into an opening in the lower abdomen directly into the bladder to drain urine), and home health aide (HHA) services for personal care "up to 60 hours". The section titled "Goals" failed to evidence patient/family identified measurable goals. The section titled "Rehabilitation Potential" stated "(No information available)." The section "60 Day Summary" evidenced the patient had wounds both feet, 2nd toes, and left 3rd toe.

9. The clinical record review for patient #8, start of care date 11/15/2010, completed on 1/11/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/22/2020 - 1/20/2021 with primary diagnosis diabetes without complications, and other pertinent diagnoses moderate intellectual disabilities, schizophrenia, unspecified, chronic obstructive pulmonary disease, hyperlipidemia, essential (primary) hypertension, diabetes with diabetic neuropathy, obstructive sleep apnea, malignant neoplasm (cancer) of unspecified

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 134	{G 574}		

kidney, except renal pelvis, functional urinary incontinence, obesity, tobacco use, hyperglycemia, constipation, diarrhea, and gastro-esophageal reflux disease without esophagitis. The POC failed to evidence diagnoses of the wound, frequency and duration of RN visits, rehabilitation potential, skilled nursing wound care/treatment orders; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, patient/caregiver education and training to facilitate timely discharge, patient/family-specific interventions and education, and measurable outcomes and goals identified by the patient.

The POC evidenced the patient received HHA (home health aide) services 2 hours per day, five days per week, and RN to supervise patient to ensure needs and goals were met. The section titled "Goals" failed to evidence patient/family identified measurable goals. The section titled "Rehabilitation Potential" stated "The potential for rehab is N/A [not applicable] ...." The section titled "60 Day Summary" evidenced the patient had a diabetic foot ulcer.

10. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/2/2020 - 12/31/2020 with primary diagnosis atherosclerotic heart disease of native coronary artery without angina pectoris, and other pertinent diagnoses of mixed hyperlipidemia, essential (primary) hypertension, chronic

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 135	{G 574}		

obstructive pulmonary disease, diabetes with diabetic neuropathy, gout, gastro-esophageal reflux disease without esophagitis, chronic atrial fibrillation, progressive systemic sclerosis, vitamin D deficiency, and iron deficiency anemia. The POC failed to evidence diagnoses of the wounds, rehabilitation potential, skilled nursing wound care/treatment orders; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, patient/caregiver education and training to facilitate timely discharge, patient/family-specific interventions and education, and measurable outcomes and goals identified by the patient.

The POC evidenced the patient received skilled nursing services once every 2 weeks for (but not limited to) medication tray set up. The section titled "Goals" failed to evidence patient/family identified measurable goals. The section titled "Rehabilitation Potential" stated "The potential for rehab is N/A [not applicable] ...." The section titled "60 Day Summary" evidenced the patient had a non-removable post-surgical dressing on his right foot secondary to right 2nd toe amputation, and his 3rd right toe was black and shriveled.

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2021), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 136	{G 574}		

Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.

Review of an additional document titled "Home Health Certification/Recertification Plan of Care Order" for dates 1/1/2021 - 3/1/2021 with primary diagnosis atherosclerotic heart disease of native coronary artery without angina pectoris, and other pertinent diagnoses of mixed hyperlipidemia, essential (primary) hypertension, chronic obstructive pulmonary disease, diabetes with diabetic neuropathy, gout, gastro-esophageal reflux disease without esophagitis, chronic atrial fibrillation, progressive systemic sclerosis, vitamin D deficiency, and iron deficiency anemia, and stated "... [skilled nursing orders] ... one visit ... every 2 weeks ... medication tray set-up, to monitor compliance ... physical assessment, and report any abnormal findings to MD ...."

The POC failed to evidence diagnoses of the wounds, rehabilitation potential, skilled nursing interventions such as wound care/treatments, patient/family education for wound care/treatment, interventions to mitigate new or worsening skin breakdown, appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, nutritional requirements for wound healing, or signs and symptoms of infection or other indications that should be reported to the agency and/or physician; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, patient/caregiver education and training to facilitate timely discharge,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 137	{G 574}		

patient/family-specific interventions and education, and measurable outcomes and goals identified by the patient.

11. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/14/2020 - 1/12/2021 with primary diagnosis other amnesia, and other pertinent diagnoses of hypertensive heart and chronic kidney disease with heart failure and stage 1-4 unspecified chronic kidney disease, diabetes without complications, chronic obstructive pulmonary disease, essential (primary) hypertension, unspecified open wound abdominal wall- unspecified with/without penetration into the peritoneal cavity, other injury of unspecified body region, initial encounter, cellulitis of trunk, unspecified, depression, pure hypercholesterolemia, constipation, radiculopathy, old myocardial infarction, personal history of peptic ulcer disease, gastro-esophageal reflux disease without esophagitis, and cervicalgia. The POC failed to evidence rehabilitation potential, skilled nursing wound care/treatment orders; a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions for pain, wound care/management, a description of the patient's risk for emergency department visits and hospital re-admission, and all necessary skilled nursing interventions to address the underlying risk factors, patient/caregiver education and training to facilitate timely discharge, patient/family-specific interventions and education, and measurable outcomes and goals

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 574}	Continued From page 138 identified by the patient. The POC evidenced the patient received skilled nursing services once every other week to (but not limited to) medication tray set up. The section titled "Goals" failed to evidence patient/family identified measurable goals. The section titled "Rehabilitation Potential" stated "The potential for rehab is N/A [not applicable] ...." The section titled "60 Day Summary" evidenced the patient had an open wound on her abdomen that was non-healing and getting worse, pain requiring narcotic medication use, and she had a history of medication non-compliance. 12. During an interview on 1/11/2021 at 4:00 PM, when asked if a nurse was assessing/treating a patient for multiple diagnoses, would she expect to see those diagnoses on the POC, employee O (registered nurse) stated "Yes." During an interview on 1/12/2021 at 11:54 AM, when asked if a nurse was assessing/treating a patient for multiple diagnoses, would she expect to see those diagnoses on the POC, employee K (licensed practical nurse) stated "Yes." During an interview on 1/12/2021 at 12:48 PM, when asked if a nurse was assessing/treating a patient for multiple diagnoses, would she expect to see those diagnoses on the POC, employee M (registered nurse) stated "Yea."	{G 574}		
{G 580}	Only as ordered by a physician CFR(s): 484.60(b)(1) Drugs, services, and treatments are administered only as ordered by a physician. This ELEMENT is not met as evidenced by:	{G 580}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 580}	Continued From page 139	{G 580}		

Based on record review and interview, the agency failed to ensure services and treatments were administered only as ordered by a physician for 3 of 10 records reviewed (#2, 3, 5), and administered only as ordered by a physician for 1 of 3 incident reports reviewed with home health aide involvement on or after 11/3/2020 which affected patient (#14).

Findings include:

1. Review of an undated copyrighted Briggs Healthcare policy C-635 titled "Physician Orders," stated "... All medications, treatments, and services provided to clients must be ordered by a physician, physician assistance, nurse practitioner, or clinical nurse specialist ...."

Review of an undated copyrighted Briggs Healthcare policy C-580 titled "Plan of Care" stated "... Home Nursing Services staff to develop a plan of care individualized to meet [patient] specific identified needs ... to include ... specific procedures ... medications, treatments, and procedures ... other appropriate items ... professional staff shall promptly alert the physician to any changes that suggest a need to alter the Plan of Care ...."

Review of an undated copyrighted Briggs Healthcare policy C-100 titled "Services Provided" stated "... Services will be coordinated by the Registered Nurse managing the care. This will include implementing, revising, and updating the Plan of Care; physician conferencing ... conferencing with health team members to plan and evaluate client [patient] care ...."

Review of an undated copyright Briggs

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 580}	Continued From page 140	{G 580}		

Healthcare policy C-340 titled "Home Health Aide Supervision," stated "Home Nursing Services shall provide Home Health Aide services ... when personal care services are indicated and ordered by the physician ...."

Review of an internet reference document https://cnazone.com/Tests/Materials/C031materials.pdf titled "Therapeutic Use of Heat and Cold" stated "... These are best used by a health care professional as they require special equipment and training in order to use them correctly and safely ... Only apply heat or cold if you are directed to do so by your supervisor or if these therapies have been ordered by a physician ...."

2. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021 with primary diagnosis unspecified injury at C6 (6th cervical vertebrae) level of spinal cord, and other pertinent diagnoses of unspecified injury at C7 (7th cervical vertebrae) level of spinal cord, laceration (cut) without foreign body of left buttock, presence of urogenital implants, autonomic dysreflexia, hyperlipidemia, muscle spasm, iron deficiency, constipation, essential (primary) hypertension, and unspecified cataract. The section titled "Professional Service Orders" stated "... SN [skilled nurse] 1 visit every other day ... to provide a bowel program ...." The section titled "60 Day Summary" evidenced entity R (a home health agency) provided wound care to a stage 4 pressure injury to left buttock, but HNS (Home Nursing Services) provided wound care as needed for soiling. The POC failed to evidence diagnoses of stage 4 pressure injury to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 580}	Continued From page 141	{G 580}		

left buttock, and failed to evidence orders for wound care.

3. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 12/17/2020 - 2/14/2021 with primary diagnosis of cerebral palsy, and other pertinent diagnoses of profound intellectual disabilities, hearing loss, asthma, chronic obstructive pulmonary disease, attention and concentration deficit, sleep apnea, gastro-esophageal reflux disease without esophagitis, restlessness and agitation, impulse disorder, attention-deficit hyperactivity disorder, predominantly hyperactive type, seizures, constipation, other specified nonpsychotic mental disorders, seasonal allergies, gastrostomy (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.) status, and tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) status. The POC evidenced the patient received skilled nursing services (but not limited to) for tracheostomy care, g-tube, administer medications via g-tube, breathing treatments via nebulizer machine, and personal care, but failed to evidence the specific treatment orders for tracheostomy and g-tube care.

4. The clinical record of patient #5, start of care 3/14/2019, was reviewed on 1/12/21, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/3/2020 - 1/1/2021 which evidenced orders for skilled nursing monthly for to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 580}	Continued From page 142	{G 580}		

"change central line dressing and cap; blood lab draw of CBC w diff [complete blood count with differential], CMP [sic comprehensive metabolic panel], trig. [sic triglycerides], magnesium, phosphurus [sic] every week and teach caregiver on TPN [total parenteral nutrition], and g tube [gastrostomy -tube inserted through the belly that brings nutrition directly to the stomach] maintenance. Call physician with any concerns or changes. Weekly weights to be called into pharmacy ..."

Review of a documents titled "Skilled Nurse Visit Note" dated 11/17/2020, 11/24/2020, 12/1/2020, and 12/8/2020 stated; "... dressing change not completed due to parent changing the day before. Parent has demonstrated proper skill and knowledge to change dressing ...."

During an interview with employee D on 1/11/21 at 3:30 pm, when asked if is appropriate for a guardian to be doing central line dressing changes without proved education, employee L (director of nursing) stated, "With proved education, yes." When asked if there was a policy on caregivers providing treatments, employee L and D, stated, "no."

5. Review of an agency document dated 11/3/2020 titled "Home Nursing Services Incident Report" for patient #14 stated "... Date of incident 11/3/2020 ... Witness of Incident [employee R, HHA] ... Description of Incident ... Client dropped laundry basket on her toe. Toe is bruised ... HHA applied ice ...." The home health aide failed to follow the plan of care (applied ice to the patient's toe, there was no order to apply ice, and this was outside of the scope of practice for a home health aide).

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 580}	Continued From page 143 6. During an interview on 1/11/2021 at 4:00 PM, when asked if a nurse provided skilled care to a patient, would she expect to see orders for care/treatment on the POC, employee O (registered nurse) stated "Yes." During an interview on 1/12/2021 at 11:54 AM, when asked if a nurse provided skilled care to a patient, would she expect to see orders for care/treatment on the POC, employee K (licensed practical nurse) stated "Yes." During an interview on 1/12/2021 at 12:48 PM, when asked if a nurse provided skilled care to a patient, would she expect to see orders for care/treatment on the POC, employee M (registered nurse) stated "Yes."	{G 580}		
G 584	Verbal orders CFR(s): 484.60(b)(3)(4) (3) Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies. (4) When services are provided on the basis of a physician's verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies.	G 584		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 584	Continued From page 144	G 584		

This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to ensure the registered nurse signed, dated and timed the all physician verbal orders received for 3 of 10 records reviewed (#1, 7, 9)

Findings include:

1. Review of an undated copyrighted Briggs Healthcare policy C-635 titled "Physician Orders" stated "... All medications, treatments and services provided to clients must be ordered by a physician ... The order must include the date, time, specific order, be signed with the full name and title of the person receiving the order ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 certification period 12/4/2020 - 2/1/2021, evidenced a document titled "Physician Order" dated 12/3/2020 which failed to evidence the time the order was received, and evidenced a document titled "Physician Order" dated 12/28/2020, for physician M (the patient's certifying physician), which stated "... Please discharge this client from Home Nursing Services due to Death in the hospital ...." The document failed to evidence the name, signature, or title of the registered nurse who received the order.

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 584	Continued From page 145	G 584		

physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head."

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021, evidenced a document titled "Physician Order" dated 12/30/2020 failed to evidence the time the order was received, a document titled "Physician Order" dated 1/5/2021 (effective 1/2/2021) failed to evidence the name, signature, or title of the registered nurse who received the order, or the time the order was received, and a document titled "Physician Order" dated 1/6/2021 (effective 1/5/2021) failed to evidence the name, signature, or title of the registered nurse who received the order, or the time the order was received.

4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021. Review of a document titled "Physician Order" dated 12/28/2020 failed to evidence the name, signature, or title of the registered nurse who received the order, or the time the order was received, a document titled "Physician Order" dated 12/18/2020 failed to evidence the name, signature, or title of the registered nurse who received the order, or the time the order was received, and a document titled "Physician Order" dated 1/11/2021 failed to evidence the name or title of the registered nurse who received the order, or the time the order was received.

5. During an interview on 12/28/2020 at 11:26 AM, when asked if she spoke with a patient's

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 584	Continued From page 146 certifying physician after completing a comprehensive assessment, the alternate clinical director stated "If I find something that's different or out of the ordinary." During this time, concerns were shared about nurses not actually contacting physicians for plan of care orders after a comprehensive assessment was done, and not actually contacting the physician for orders being written, the alternate clinical director stated "I get what you're saying."	G 584		
G 588	Reviewed, revised by physician every 60 days CFR(s): 484.60(c)(1) The individualized plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure the individualized plans of care were reviewed and revised by the certifying physician and the agency's registered nurse as frequently as the patient's condition or needs required, but no less frequently than once every 60 days for 1 of 10 records reviewed. (#1) Findings include: Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised as often as the client's condition warrants due to a major decline or improvement in health status ... To identify decline or improvement ... are reassessed	G 588		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 588	Continued From page 147	G 588		

when significant changes occur in their condition ... [or] diagnosis ... at least every fifty six to sixty (56-60) days ...."

Review of an undated copyrighted Briggs Healthcare policy C-580 titled "Plan of Care [POC]" stated "... Home Nursing Services staff to develop a plan of care individualized to meet [patient] specific identified needs ... and will be updated as necessary, but at least every sixty (60) days ...."

The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021, which evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 10/5/2020 - 12/3/2020, and stated "... SN [skilled nurse] monthly for full assessment with vital signs and ... foley catheter change ... Coordination of Care: SN will report changes in condition to MD, Client has Home attendant services from [entity B, a personal services agency] and they are responsible for these services [personal care and hygiene] ... friendly and pleasant during visit ... catheter ... draining thick, dark, gold-colored urine ... Foul smelling wound to the groin remains ... Advised POA [power of attorney] to have MD [physician] assess wound at appointment next week ...." The document failed to evidence the physician reviewed and approved the plan of care.

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 588	Continued From page 148	G 588		

[Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She stated they might have. Also asked about adding protein to the diet, niece stated she does not remember for sure, maybe ...." The document failed to evidence the nurse contacted the physician for review of the plan of care.

During an interview on 12/28/2020 at 11:26 AM, the alternate clinical director indicated she didn't know who the patient's certifying physician was, and stated "I do not know off the top of my head.", she didn't speak with the certifying physician after she saw the patient on 12/22/2020, and stated "No ma'am.", and indicated she only spoke with the certifying physician after completing a comprehensive assessment "If I find something that's different or out of the ordinary."

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 1/1/2021 - 3/1/2021 was signed by a registered nurse on 1/11/2021, stated

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 588	Continued From page 149 "... [skilled nursing orders] ... one visit ... every 2 weeks ... medication tray set-up, to monitor compliance ... physical assessment, and report any abnormal findings to MD ...." The document failed to evidence the physician reviewed or approved the plan of care. During an interview on 12/18/2020 at 1:00 p.m., the clinical manager indicated employee L (indicate title) didn't complete the comprehensive assessment document (for patient #1) due to the comprehensive assessment being behind and the agency wanted it done so it was sent to employee N (indicate title) for completion. The clinical manager indicated employee N was not the nurse that had initiated the comprehensive assessment but had seen the patient on 12/15/20 and this represented the completion of the comprehensive assessment which was initially conducted on 12/03/2020 (12 days after the initial comprehensive assessment). The clinical manager then indicated there were multiple incomplete assessments unfinished by employee L which were being completed / "fixed" by other clinicians who had not conducted the visits / assessments. At 1:38 p.m., a document was received from the clinical manager which evidenced 33 patients from 12/01/2020 - 12/18/2020 had incomplete assessments with no updated plan of care.	G 588		
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.	G 590		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 150	G 590		

This ELEMENT is not met as evidenced by:
Based on record review and interview, the agency failed to promptly alert the physician to changes in the patient's condition that suggested the plan of care should have been altered for 3 of 10 records reviewed (#1, 7, 9).

Findings include:

1. Review of an undated copyrighted Briggs Healthcare policy C-580 titled "Plan of Care" stated "... Home Nursing Services staff to develop a plan of care individualized to meet [patient] specific identified needs ... to include ... specific procedures ... medications, treatments, and procedures ... other appropriate items ... professional staff shall promptly alert the physician to any changes that suggest a need to alter the Plan of Care ...."

2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021, which evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 10/5/2020 - 12/3/2020, and stated "... SN [skilled nurse] monthly for full assessment with vital signs and ... foley catheter change ... Coordination of Care: SN will report changes in condition to MD, Client has Home attendant services from [entity B, a personal services agency] and they are responsible for these services [personal care and hygiene] ... friendly and pleasant during visit ... catheter ... draining thick, dark, gold-colored urine ... Foul smelling wound to the groin remains ... Advised POA [power of attorney] to have MD [physician] assess wound at appointment next week ...." The plan of care failed to evidence care

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 151	G 590		

coordination with the physician, or wound clinic.

Review of a document titled "Skilled Nurse Visit Note" dated 11/5/2020 stated "... Skin/Wounds ... Turgor [skin elasticity] [box checked] Poor [clinical indication of dehydration] ... [box checked] See Wound Location Assessment ... Hydration adequate [box checked] No ...." The document failed to evidence the physician was contacted.

Review of a document titled "Wound Location Assessment" dated 11/5/2020 stated "... Location: left [sic] groin ... Wound type: unknown ... Date originally reported: 2/3/2020 ... Comments: Small open area to the right groin area ... Client is being treated at the wound clinic for this wound ... Location: left buttocks ... Wound type: Pressure ... Date originally reported: 4/3/2020 ... Small reddened area on the buttocks ... Area is healed ...." The document failed to evidence the physician was contacted for change in wound status.

Review of a document titled "Skilled Nurse Visit Note" dated 12/3/2020 stated "... Heart sounds ... [box checked] Regular ... Skin/Wounds ... Turgor: [box checked] Poor ... [box checked] See Wound Location Assessment ... encouraged to increase fluids ... Hydration adequate [box checked] No ...." The document failed to evidence the physician was contacted.

Review of a document titled "Wound Location Assessment" dated 12/3/2020 stated "... Location: left [sic] groin ... Wound type: unknown ... Date originally reported: 2/3/2020 ... Comments: Small open area to the right groin area ... Treatments to the area continue with [entity C- a wound clinic] ... Location: left buttocks

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 152 ... Wound type: Pressure ... Date originally reported: 4/3/2020 ... Small reddened area on the buttocks ... Treatments to the area continue by family at home following wound clinic orders ...." The document failed to evidence the physician was contacted. Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/3/2020 stated "... Client has a pressure ulcer on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs. These are both being treated by the [entity C, wound clinic]. At time of assessment, the wounds were covered and not able to be assessed ...." The document failed to evidence entity C or the physician was contacted. During an interview on 12/16/2020 at 2:16 PM, when asked if their clinic records evidenced communication or care coordination with Home Nursing Services, a staff member at entity C stated "I don't see any communication with home care ... not sure we even knew he had home health care." Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose	G 590		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 153	G 590		

bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

During an interview on 12/17/2020 at 3:44 PM, the clinical director agreed the certifying physician would not be able to provide/approve orders to meet the patient's needs without complete and accurate assessment findings. During this time, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No."

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 154	G 590		

the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She stated they might have. Also asked about adding protein to the diet, niece stated she does not remember for sure, maybe ...." The document failed to evidence the nurse contacted the physician.

During an interview on 12/28/2020 at 11:26 AM, the alternate clinical director indicated she didn't know who the patient's certifying physician was, and stated "I do not know off the top of my head.", she didn't speak with the certifying physician after she saw the patient on 12/22/2020, and stated "No ma'am.", and indicated she only spoke with the certifying physician after completing a comprehensive assessment "If I find something that's different or out of the ordinary."

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.

Review of a document dated 11/11/2020 titled "Skilled Nurse Visit Note" evidenced the patient had signs/symptoms of urinary tract infection (UTI), and stated "... urinating through penis and around [catheter] ... Draining freely dark yellow, cloudy urine." The document failed to evidence the physician was notified.

Review of a document dated 12/8/2020 titled "Skilled Nurse Visit Note" stated " Client had urine from penis, has yellow purulence around foley [sic- suprapubic catheter insertion site]

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 155 ...Location: left heel ... wound type: pressure ... date originally reported: 6/26/2020 ... Comments: wound remains to the left heel ... Location: BLE [bilateral lower extremities]; 4th toes and left heel ... Wound type: unknown ... Date originally reported: 12/8/2020 ...." The document failed to evidence the physician was notified of new open area(s) and signs and symptoms urinary tract infection. During an interview on 1/11/2021 at 2:23 PM regarding the 12/8/2020 skilled nursing visit, the alternate clinical director agreed there was no evidence the physician was contacted, and indicated the hospitalization for UTI was potentially avoidable. Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021. Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician will added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.	G 590		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 156	G 590		

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was a high risk for skin breakdown, stated "... Does this patient have a stasis ulcer? ... Yes ... Current number of Stasis Ulcers that are observable ... 4 ... status of most problematic ... Not Healing ... Location ... right big toe ... right second toe ... left second toe ... left third toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... wife cleanses, applies medihoney dresses every other day and will see wound clinic 1/14/20 [sic] ...." The document evidenced the certifying physician was contacted for orders, but the clinical record failed to evidence orders dated 1/5/2021.

Review of a document dated 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, applying an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received. Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated she did not know the name of the ointment the spouse applied to the wound(s).

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), the administrator, and the alternate administrator stated "... 1-10-2021, 12:20pm. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her home remedy for his back is working ... She does not need me to stop by today to help her ...." The

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 157	G 590		

document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified the wife was applying a home remedy to his wound(s). Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), employee D (medical records coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021, or the certifying physician was notified.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order.

4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.
Review of a document titled "SN Re-Cert

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 158	G 590		

[recertification] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 11/1/2020 "... right second toe amputation ... Non-removable dressing present. Wound managed by orthopedics ... Report any abnormal findings to VA [veterans affairs] MD ... skilled nurse ... physical assessment ... and notify MD of any abnormal findings ... had his right second toe amputated ... His 3rd right toe is black and shriveled ...." The document also evidenced the patient had diagnoses (but not limited to) atherosclerotic heart disease (hardening of the arteries causing impaired circulation), and diabetes with diabetic neuropathy (diabetes with damage to nerves in your legs and feet, causing pain and numbness in your legs and feet). The document failed to evidence the physician was notified of the change in condition of the wound.

Review of a document dated 11/2/2020 titled "Skilled Nurse Visit Note" stated "... Right second toe amputation site not healing. 3rd toe black and very painful ...." The document failed to evidence the nurse notified the physician for the change in the patient's integumentary or pain status.

Review of a document dated and signed by employee M 11/16/2020 titled "Skilled Nurse Visit Note" stated "... "posterior foot blackening about an 1 1/2 inch on ball of right foot, 3rd toe black and shriveled, outer edge of 5th toe; see diagram" The document failed to evidence the physician was notified of the declining wound status.

During an interview on 1/6/2021 at 3:56 PM, when asked if the physician should have been notified of the change in wound status on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 159	G 590		

11/16/2020, the alternate director of nursing stated "He should be, I don't know if she did call." When asked if this failure to contact the physician could have potentially led to a negative outcome for the patient, she stated "Yes".

Review of a document dated and signed by employee M on 11/30/2020 titled "Skilled Nurse Visit Note" stated "...: "No fever, No cough, No complaints, Right foot, big toe starting to blacken, middle to black and shriveled. Per wife, US [ultrasound] showed multiple blockages and patient may lose foot d/t [due to] occlusions ...." The document failed to evidence the physician was notified of the declining wound status.

Review of a document dated and signed by employee M on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE Femoral Endarterectomy on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain. Pain 10/10. Taking Norco for pain. 2 weeks of meds set-up. 100% medication compliant. The document failed to evidence the physician was notified of the declining wound status or severe pain.

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence the certifying physican was notified.

Review of a document titled "Skilled Nurse Visit Note" dated 12/28/2020 stated "... returned from

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 160 hospital S/P [after] Right femoral endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] and Right partial amputation of foot. Right groin incision C/D/I [clean, dry, and intact] no redness, no draining, no swelling. OTA [open to air]. Right foot dressing C/D/I with orders not to remove same until f/u [follow up] with Podiatry 1/4/21. Plavix [medication to prevent formation of blood clots and to keep blood vessels open after surgical procedures, and may cause easy bleeding/bruising] ... added to medication regimine [sic] ... Client is NWB [non-weight bearing] R foot ...." The document failed to evidence the physician was notified for report and resumption of care orders. Review of a document dated 12/28/2020 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which previously had not been identified), and the nurse failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the physician was notified. Review of a document dated 12/28/2020 titled "SN ROC OASIS and Comprehensive Assessment" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without devices in his home ... Has had no ...	G 590		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 161	G 590		

hospitalizations ...." The document failed to evidence the physician was notified for report and resumption of care orders.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/28/2020 (additional document for same nurse visit same day) stated "... Pain Assessment: ... right foot. Severity (0-10), 6 ... Cardiovascular Assessment: ... blood thinners ... Plavix ... Integumentary [skin] Assessment: No issues noted ... incisions ... open to air ... right foot ... surgical dressing in place ...." The document failed to evidence the physician was notified for report and resumption of care orders.

During an interview on 1/5/2021 at 1:29 PM person F (staff at entity E) indicated the patient was seen 1/4/2021 for surgical follow up. When asked if she received any communication/coordination from the agency, she stated "On 12/29 [2020] we got a call from [employee M] to request PT/OT [physical and occupational therapy] order. That's the only thing I see ...."

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2021), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 590	Continued From page 162 During an interview on 1/12/2021 at 1:50 PM, regarding the skilled nursing visit on 11/16/2020, employee M indicated she did not contact the physician, he was already aware, it (the wound/blackening of toe/foot) started as just the tip, and it was an ongoing process; regarding the skilled nursing visit on 12/14/2020, she stated "I did not call the physician ...."	G 590		
{G 592}	Revised plan of care CFR(s): 484.60(c)(2) A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals 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 all patients' revised plans of care reflect current information from the patient's updated comprehensive assessment, and contained information concerning the patient's progress toward the measurable outcomes and goals identified by the agency and patient in the plan of care for 5 of 10 records reviewed (#1, 2, 7, 9, 10). 1. Review of an undated copyrighted Briggs Healthcare policy C-580 titled "Plan of Care" stated " ... The Plan of Care ... will be consistently reviewed to ensure that client needs are met, and will be updated as necessary ... At the time of ... recertification, a written summary of the client's current status ... are submitted with the plan of care ... The summary shall include ... client	{G 592}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 592}	Continued From page 163	{G 592}		

response to care/services and outcome of care and services ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 12/4/2020 - 2/1/2021, which failed to evidence current interventions indicated on the comprehensive re-assessment, and failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals.

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021, which failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals.

4. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 12/11/2020 - 2/8/2021, which failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals.

5. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 12/31/2020 -

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 592}	Continued From page 164	{G 592}		

2/28/2021, which failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals.

6. The clinical record review for patient #8 was completed on 1/11/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 9/23/2020 - 11/21/2020, which failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals. The record also evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/22/2020 - 1/20/2021, which also failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals.

7. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/2/2020 - 12/31/2020, which failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals. The record also evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 1/1/2021 - 3/1/2021, which also failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals.

During an interview at 12:17 at 2:34 PM, 11/19/2020, the clinical director indicated she

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 592}	Continued From page 165 didn't know who took care of the patient's foot ulcer, and regarding the goal to have average blood sugar less than 150, she stated "We don't monitor it." 8. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/14/2020 - 1/12/2021, which failed to evidence skilled interventions for measurable outcomes, or progress toward measurable outcomes and goals. 9. During an interview on 1/12/2021 at 12:48 PM, employee M (registered nurse) stated "I try not to set goals I cannot control."	{G 592}		
G 604	Integrate all orders CFR(s): 484.60(d)(2) Integrate orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to integrate orders from all physicians involved in the plan of care to assure the coordination of all services and interventions were provided to the patient for 2 of 10 records reviewed (#7, #9) Findings include: 1. The clinical record of patient #7, start of care 5/26/2016, was reviewed on 1/11/2021 and 1/12/2021. Review of plans of care for certification periods 11/1/2020 - 12/30/2020 and 12/31/2020 - 2/28/2021.	G 604		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 604	Continued From page 166	G 604		

Review of a document (not part of the agency's clinical record) from entity Q (a wound clinic) dated 11/24/2020 stated "... Follow up with the wound care clinic in 4 week(s) [sic]. Wash wound(s) with mild soap and water, then pat dry. Place Medihoney and cover with ABD [thick gauze] pad. Change dressing daily ... Home Healthcare to visit for wound care 2-3 [times] weekly and PRN [as needed] wound care/dressing changes ... wound location ... left lower extremity ... right lower extremity ...." The record failed to evidence the wound care orders were integrated into the patient's plan of care.

During an interview on 12/17/2020 at 2:34 PM, employee M (registered nurse) submitted a list which evidenced (but not limited to) 10 patients with wounds. Employee M indicated all were managed by wound clinics, the agency did not coordinate with the wound clinics, and there we no wound clinic notes in any of the patients' charts.

The clinical record also evidenced a document dated 1/2/2021 titled "Care Coordination Note" which evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 604	Continued From page 167	G 604		

assist wound healing, dietician will added Juven (nutritional supplement) twice daily to assist wound healing. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine. The record failed to evidence discharge orders were integrated into the patient's plan of care.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't."

2. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 1/1/2021 - 3/1/2021.

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2020), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 604	Continued From page 168 patient was to continue to remain non-weight bearing on the right foot. The record failed to integrate post-hospital orders on the plan of care.	G 604		
{G 608}	3. 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 coordination of care activities. This ELEMENT is not met as evidenced by: Based on record review and interview, the home health agency failed to complete coordination of care with other agencies or entities who provided services to the agency's patients for 6 of 10 records reviewed (#1, 2, 7, 8, 9, 10). Findings include: 1. Review of an undated copyright Briggs Healthcare policy C-300 titled "Clinical Supervision" stated "... The Clinical Director shall coordinate the day-to-day operation of the organization and work with the Administrator ...." Review of an undated copyright Briggs Healthcare policy C-360 titled "Coordination of Client Services" stated "... Each staff Registered Nurse shall meet with the Clinical Director/Designee weekly or as necessary to review all areas of client needs ...." 2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021. The record evidenced entity C (a	{G 608}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 608}	Continued From page 169	{G 608}		

wound care clinic), and had home attendant services from entity B (a personal services agency). The record failed to evidence documentation of care coordination with either agency.

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021. The record evidenced entity R (a home health agency) provided wound management, and entity Q (a wound clinic) also provided wound management. The record failed to evidence documentation of care coordination with the agencies.

4. The clinical record of patient #7, start of care 5/26/2016, certification period 12/31/2020 - 2/28/2021, was reviewed on 1/11/2021 and 1/12/2021, and evidenced a document dated 1/2/2021 titled "Care Coordination Note" which evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician will added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 608}	Continued From page 170	{G 608}		

of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked what kind of bed the patient had (he was bedbound and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted.

5. The clinical record review for patient #8 was completed on 1/11/2021, certification period 11/22/2020 - 1/20/2021. The record evidenced entity Q managed the patient's wound(s), and entity S (a behavioral center) managed the patient's behaviors. The record failed to evidence documentation of care coordination with the agencies.

During an interview on 12/17/2020 at 2:34 PM, when asked which wound clinic managed patient #8's wound, the clinical director indicated she did not know.

During an interview on 12/17/2020 at 3:44 PM,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 608}	Continued From page 171	{G 608}		

when asked who performed patient #8's wound care, the clinical director indicated staff at entity O (group home) did the wound care. When asked if the staff were clinicians, she stated "No, they do have a nurse that floats to the different houses. I'm not sure she's involved." When asked at what point do you get involved, she stated "When they need a skilled nurse to take over." During this interview, the administrator asked the clinical director "Do we receive wound clinic follow up?", she stated "No."

6. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of hospital (entity D) documentation (not part of the agency clinical record) evidenced the patient was hospitalized from 12/18/2020 - 12/28/2020. The record failed to evidence the agency coordinated with the hospital.

7. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, certification period 11/14/2020 - 1/12/2021 evidenced the patient had a wound managed by a wound clinic, but failed to evidence coordination with the wound clinic.

Review of a document received from entity C (a wound care clinic), not part of the agency clinical record, evidenced the patient was seen for wound management on 12/8/2020.

8. During an interview on 12/17/2020 at 2:34 PM, employee M (registered nurse) submitted a list which evidenced (but not limited to) 10 patients with wounds. Employee M indicated all were

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 608}	Continued From page 172 managed by wound clinics, the agency did not coordinate with the wound clinics, and there we no wound clinic notes in any of the patients' charts. During an interview on 1/11/2021 at 10:50 AM, the alternate clinical director indicated they received wound clinic coordination/notes for all but one patient requested, and coordination of care with other entities involved with agency patients was not complete, and would be completed by 1/22/2021. During an interview on 12/28/2020 at 11:26 AM, when asked if the agency contacted a hospital to coordinate care and obtain hospital paperwork to relay information to the certifying physician, the clinical director stated "We usually don't, because they usually come home with papers." When asked how the hospital would know the patient was getting home care services, she stated "Through the client or the client's family."	{G 608}		
G 610	Patients receive education and training CFR(s): 484.60(d)(5) Ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure all patients and/or caregivers received ongoing education and training regarding the needs of the patient as identified in the plans of care, and failed to	G 610		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 173	G 610		

evidence patient and caregiver responses and comprehension of any training provided for 9 of 10 records reviewed (#1, 2, 3, 4, 5, 7, 8, 9, 10) and 1 of 1 patients (without clinical record review) identified during an interview that verbalized no teaching had ever been completed (#12).

Findings include:

1. Review of an undated agency policy C-400 copyright Briggs Healthcare titled "Client/Family Education" stated "... Clients and their families will be provided with information necessary to make decisions and to take responsibility for self-management activities related to their needs ... will target the clients [sic] ability to improve outcomes through promotion of healthy behavior and involvement in their care, treatment, and service decisions ... All client and/or caregiver education and instruction, as well as their perceived comprehension and demonstrated competency, as appropriate, will be documented in the client's record ...."

Review of an undated agency policy C-580 copyright Briggs Healthcare titled "Plan of Care" stated "... The Plan of Care shall be completed in full to include: ... Instructions to client/caregiver, as applicable ... All of the above items must always be addressed on the plan of care ...."

Review of an agency policy dated 06/2000 titled "Home Nursing Services Job Description Registered Nurse" stated "... Provides instruction to the client and the client's family on areas listed on the plan of care, documents what is taught, and lists the client and/or family's response ...."

Review of an undated agency policy titled "Home

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 174	G 610		

Nursing Services Job Description Licensed Practical Nurse [LPN]" stated "... Will teach the client and care giver [sic] in the areas on the plan of care, document what is taught and their response ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a plan of care (POC) for certification period 12/4/2020 - 2/1/2021, with primary diagnosis Diabetes with diabetic peripheral angiopathy (blood vessel disease caused by high blood sugar levels), and other pertinent diagnoses chronic obstructive pulmonary disease, essential (primary) hypertension, hyperlipidemia (high cholesterol), peripheral vascular disease (impaired circulation), depression, neuromuscular dysfunction of bladder, urinary incontinence, anemia, chronic atrial fibrillation, nicotine dependence (cigarettes), history of falling, encounter for fitting and adjustment of urinary device, acquired absence of right leg below knee, and acquired absence of left leg below knee.

The POC also evidenced a section titled "Professional Service Orders" which stated "RN [registered nurse] Orders: ... periodic planned and unplanned supervisory visits ... 1x/month for indwelling catheter change ...." The section titled "60 Day Summary" evidenced the patient had open wounds which required wound care, an indwelling urinary catheter, he was a non-compliant diabetic, he was incontinent and wore briefs, and his niece was his primary caregiver.

The POC failed to evidence skilled nursing interventions for patient and caregiver education

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 175	G 610		

and training based on the needs identified on the POC, such as, but not limited to, teaching the caregiver proper wound treatment/dressing changes, signs or symptoms of infection, importance of following a diabetic diet, indwelling urinary catheter management, signs and symptoms of urinary tract infection (UTI), prevention of new or worsening skin breakdown, or COVID-19 precautions. The record review failed to evidence patient or caregiver training was performed, or the patient/caregiver response to the training.

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

3. The clinical record of patient #2, start of care

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 176	G 610		

9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021 with primary diagnosis unspecified injury at C6 (6th cervical vertebrae) level of spinal cord, and other pertinent diagnoses of unspecified injury at C7 (7th cervical vertebrae) level of spinal cord, laceration (cut) without foreign body of left buttock, presence of urogenital implants, autonomic dysreflexia, hyperlipidemia, muscle spasm, iron deficiency, constipation, essential (primary) hypertension, and unspecified cataract.

The POC also evidenced a section titled "Professional Service Orders" which stated "HHA [home health aide] ... 7 days a week ... SN [skilled nurse] Orders: ... 1 visit every other day ...."

The POC also evidenced a section titled "60 Day Summary" which evidenced the patient had a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock, the agency performed wound care as needed, and the patient had a suprapubic catheter (a tube inserted into a hole in the lower abdomen into the bladder to drain urine).

The POC failed to evidence skilled nursing interventions for patient and caregiver education and training based on the needs identified on the POC, such as, but not limited to, teaching the caregiver proper wound treatment/dressing changes, signs or symptoms of infection, indwelling urinary catheter management, signs and symptoms of urinary tract infection (UTI), prevention of new or worsening skin breakdown, or COVID-19 precautions. The record review

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 177	G 610		

failed to evidence patient or caregiver training was performed, or the patient/caregiver response to the training.

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 12/17/2020 - 2/14/2021 with primary diagnosis of cerebral palsy, and other pertinent diagnoses of profound intellectual disabilities, hearing loss, asthma, chronic obstructive pulmonary disease, attention and concentration deficit, sleep apnea, gastro-esophageal reflux disease without esophagitis, restlessness and agitation, impulse disorder, attention-deficit hyperactivity disorder, predominantly hyperactive type, seizures, constipation, other specified nonpsychotic mental disorders, seasonal allergies, gastrostomy (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.) status, and tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) status.

The POC evidenced the patient received skilled nursing services (but not limited to) for tracheostomy care, g-tube, administer medications via g-tube, breathing treatments via nebulizer machine, and personal care.

The POC failed to evidence skilled nursing interventions for patient and caregiver education and training based on the needs identified on the POC, such as, but not limited to, teaching the caregiver tracheostomy management,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 178	G 610		

gastrostomy management, aspiration precautions, signs or symptoms of infection, seizure precautions, or COVID-19 precautions. The record review failed to evidence caregiver training was performed, or the caregiver response to the training.

5. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 12/17/2020 - 2/14/2021 with primary diagnosis of paraplegia, and other pertinent diagnoses of essential (primary) hypertension, anxiety disorder, fusion of spine-lumbar region, and incontinence without sensory awareness.

The POC evidenced the patient received skilled nursing services (but not limited to) 3 times per week for wound care. The section titled "60 Day Summary" evidenced the patient had an open wound.

The POC failed to evidence skilled nursing interventions for patient and caregiver education and training based on the needs identified on the POC, such as, but not limited to, teaching the patient/caregiver signs or symptoms of wound infection, prevention of new or worsening skin breakdown, foods to avoid for patients with high blood pressure, or COVID-19 precautions. The record review failed to evidence patient/caregiver training was performed, or the patient/caregiver response to the training.

6. The clinical record of patient #5, start of care 3/14/2019, was reviewed on 1/12/21, evidenced a document titled "Home Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 179	G 610		

Certification/Recertification Plan of Care Order" for certification period 11/3/2020 - 1/1/2021 which evidenced orders for skilled nursing monthly for to "change central line dressing and cap; blood lab draw of CBC w diff [complete blood count with differential], CMP [sic comprehensive metabolic panel], trig. [sic triglycerides], magnesium, phosphurus [sic] every week and teach caregiver on TPN [total parenteral nutrition], and g tube [gastrostomy -tube inserted through the belly that brings nutrition directly to the stomach] maintenance. Call physician with any concerns or changes. Weekly weights to be called into pharmacy ..."

Review of documents titled "Skilled Nurse Visit Note" for dates 11/3/2020, 11/10/2020, 11/17/2020, 11/24/20, 12/1/2020, 12/8/2020, and 12/29/2020 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The section was blank for all notes, and all notes failed to evidence any skilled nursing teaching interventions.

7. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification dates 12/31/2020 - 2/28/2021. The document evidenced the patient received, but not limited to, skilled nursing every other week to complete a full head to toe assessment,vital signs, and change the patient's suprapubic catheter (a tube inserted into an opening in the lower abdomen directly into the bladder to drain urine), and home health aide (HHA) services for personal care "up to 60 hours", evidenced diagnoses listed (but not

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 180	G 610		

limited to) unspecified stroke and unspecified convulsions; and the section for the 60 day summary indicated (but not limited to) the patient had a wound on his tailbone, the wife performed the wound care, he was incontinent of bowel and bladder, had fragile skin, had diabetes, depression, chronic lung disease and used oxygen, and had chronic pain. The document failed to evidence any skilled nursing teaching interventions such as seizure precautions, infection control precautions, COVID-19 precautions, oxygen prevention of skin breakdown, or signs and symptoms of UTI, wound infection or respiratory issues to report to the nurse or physician.

Review of documents titled "Skilled Nurse Visit Note" for dates 11/11/2020, 11/27/2020, and 12/23/2020 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The section was blank for all notes, and all notes failed to evidence any skilled nursing teaching interventions were performed.

8. The clinical record review for patient #8 was completed on 1/11/2021, and evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification dates 11/22/2020 - 1/20/2021. The document evidenced the patient received HHA (home health aide) services 2 hours per day, five days per week, RN to supervise patient to ensure needs and goals were met (no frequency evidenced), diagnoses list included (but not limited to) diabetes, moderate intellectual disability, chronic lung disease, high blood sugar, high blood pressure; and the section for the 60 day summary indicated (but not limited to) the patient resided in a group home managed by

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 181	G 610		

entity O, he smoked, had anxiety at times, constipation at times, blood sugars fluctuate between 74-344, had a diabetic foot ulcer on the left foot, and had a previous ulcer that resulted in a partial foot amputation. Goals included (but not limited to) safe and free from injury, unlabored respirations and oxygen saturation 90% or above, and blood sugars less than 150. The document failed to evidence any skilled nursing teaching interventions for the group home caregivers such as signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and regularly checking blood sugars, infection control, COVID-19 precautions, prevention of new skin breakdown, or signs and symptoms of wound infection or respiratory issues to report to the nurse or physician.

9. The clinical record of patient #9, start of care 9/9/2019, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/2/2020 - 12/31/2020. The document evidenced the patient received skilled nursing services every two weeks to fill and organize medication delivery system as scheduled and when medications were changed; and the section for the 60 day summary indicated (but not limited to) the patient had a non-removable surgical dressing on his right second toe (amputation), his 3rd right toe was black and shriveled, and a goal was set to follow a diabetic diet. Listed diagnoses included (but not limited to) hardening of the arteries, high cholesterol, high blood pressure, progressive systemic sclerosis (a condition associated with thickening of the skin and tethering to subcutaneous tissues as well as smooth muscle waste and fibrosis of internal organs such as the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 182	G 610		

gastrointestinal tract, lungs, heart, and kidneys), and chronic lung disease, and the patient was a moderate fall risk. Goals stated (but not limited to) "... proper, safe and effective administration of meds ... remain safe in current living situation with agency caregiver assistance ... maintained at current status of physical and medical well-being through our assistance with obtaining proper nutrients, medications, and safe activity levels." The document failed to evidence any skilled nursing teaching interventions such as teaching caregiver proper medication administration, how to fill medication box, signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and regularly checking blood sugars, infection control, COVID-19 precautions, prevention of new skin breakdown, or signs and symptoms of wound infection or respiratory issues to report to the nurse or physician.

During an interview on 1/12/2021 at 12:48 PM, When asked how she ensured goals were being met on the plan of care, employee M (registered nurse) stated "The wife makes sure he takes his vitamins and his meds, he is only standing and pivoting. I would like to get him some therapy at home. Hoping the VA will provide that." When asked what interventions were completed to address his moderate fall risk, she stated "Clear pathways, coral the dogs so he doesn't trip, bedside commode next to bed, he does not stand or transfer by himself, he has a ramp going into the house, his wife has purchased a transport wheelchair for him." When asked how are goals established if there are no interventions, she stated "I try not to set goals I cannot control. I don't have control over the healing of the incision."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 183	G 610		

10. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/14/2020 - 1/12/2021. The document evidenced skilled nursing services every other week to include, but not limited to, set up medications in medication boxes, perform a system assessment, make sure needs are being addressed and goals are being met, and notify doctor of changes in condition. Listed diagnoses included (but not limited to) heart failure, kidney failure (unspecified stage), abdominal wound, high blood pressure chronic lung disease, diabetes, and cervicalgia (neck pain); and the section for the 60 day summary stated "... a history of non-compliance with taking oral meds ... Efforts are being made at education to improve her compliance ... open wound on her abdomen that is non-healing and getting progressively worse ... Will also set a pain management goal ...." The document evidenced goals including (but not limited to) pain level at 4 or less (verbal pain scale 0-10, with 0 being no pain, and 10 being worst pain ever), wound to decrease in size by 2.0 centimeters in length, and blood sugar levels at 140 or less. The document failed to evidence any skilled nursing teaching interventions such as signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and regularly checking blood sugars, infection control, prevention of new skin breakdown, signs and symptoms of wound infection, non-medicinal methods to mitigate pain, importance of medication compliance, or signs and symptoms to immediately report to the nurse or physician.

Review of documents titled "Skilled Nurse Visit

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 184	G 610		

Note" for dates 12/4/2020 and 12/19/2020 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The section was blank for all notes, and all notes failed to evidence any skilled nursing teaching interventions such as signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and regularly checking blood sugars, infection control, prevention of new skin breakdown, signs and symptoms of wound infection, non-medicinal methods to mitigate pain, importance of medication compliance, or signs and symptoms to immediately report to the nurse or physician.

Review of a document titled "Skilled Nurse Visit Note" dated 1/6/2021 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The document evidenced the nurse instructed the patient when to call physician and stated "... Client weak and called wound clinic and they advised client to go to the ED [emergency department] to r/o [rule out] infection. Client states she's lost about 30 lbs [pounds] with in [sic] the past month ...."

11. During an interview with patient #12 (no record review) on 12/29/2020 at 1:19 PM, when asked what teaching the nurses have done, she indicated she didn't need any teaching, she didn't need help, and she used to be a QMA (Qualified Medication Aide). When asked what the agency nurse did for her, she indicated she took her vital signs, filled her pill box, and checked if more medications needed to be ordered.

12. During an interview on 1/6/21 at 2:45 PM when asked if they would expect to see interventions for goals established on the plans of

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 610	Continued From page 185 care, the clinical director and alternate clinical director both stated "Yes." During an interview on 1/11/2021 at 3:35 PM, When asked if documentation of patient/caregiver education/teaching and correct return demonstration of a task/skill performed should be documented, the alternate clinical director stated "Correct." When asked if the agency had a policy regarding this, the clinical director and alternate clinical director both stated "No." During an interview on 1/12/21 12:48 PM, when asked if a nurse instructed a patient to take a particular medication, would she expect to see an order for the medication, employee M stated "You have to have an order before you instruct a patient to do anything." When asked if a nurse provided skilled care to a patient, would she expect to see orders for care/treatment on the plan of care, she stated "Yes."	G 610		
{G 682}	Infection Prevention CFR(s): 484.70(a) Standard: Infection Prevention. The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases. This STANDARD is not met as evidenced by: Based on observation and record review, the agency failed to ensure all staff followed the infection control policies and standard precautions for 2 of 3 home visits observed (#3, 4). Findings include:	{G 682}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 682}	Continued From page 186 1. Review of an agency policy D-330 dated 10/30/2020, copyright Briggs Healthcare titled "Handwashing/Hand Hygiene stated "... Indications for hand washing ... Between tasks on the same client ... After removing gloves ... After touching objects that are potentially contaminated ...." 2. During a home visit observation on 12/17/2020 at 9:50 AM with patient #3 (start of care 1/21/2003), Employee V, LPN (licensed practical nurse) was observed providing skilled nursing care. Employee V did not complete hand hygiene between glove changes, did not wear a face shield, and did not complete hand hygiene when removing gloves; after oral suction care was provided. Employee V failed to follow the agency's infection control policy. 3. During a home visit observation on 12/30/2020 at 10:30 AM with patient #4 (start of care 8/19/2019), Employee K, LPN (licensed practical nurse) was observed providing skilled nursing care. Employee K did not perform hand hygiene before donning gloves. Employee K used scissors to cut off old dressing and did not sanitize them prior to cutting supplies for new dressing and did not perform hand hygiene after removing old dressing and applying new dressing. Employee K recapped a single-use syringe after completing wound care. Employee K failed to follow the agency's infection control policy.	{G 682}		
G 714	Patient and caregiver education CFR(s): 484.75(b)(5) Patient and caregiver education; This ELEMENT is not met as evidenced by:	G 714		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 187	G 714		

Based on record review and interview, the registered nurse (RN) clinical director failed to ensure education was provided to patients/caregivers based on interventions evidenced in the plan of care for 9 of 10 records reviewed (#1, 2, 3, 4, 5, 7, 8, 9, 10).

Findings include:

1. Review of an undated agency policy C-400 copyright Briggs Healthcare titled "Client/Family Education" stated "... Clients and their families will be provided with information necessary to make decisions and to take responsibility for self-management activities related to their needs ... will target the clients [sic] ability to improve outcomes through promotion of healthy behavior and involvement in their care, treatment, and service decisions ... All client and/or caregiver education and instruction, as well as their perceived comprehension and demonstrated competency, as appropriate, will be documented in the client's record ...."

Review of an agency policy dated 06/2000 titled "Home Nursing Services Job Description Registered Nurse" stated "... Provides instruction to the client and the client's family on areas listed on the plan of care, documents what is taught, and lists the client and/or family's response ...."

Review of an undated agency policy titled "Home Nursing Services Job Description Licensed Practical Nurse [LPN]" stated "... Will teach the client and care giver [sic] in the areas on the plan of care, document what is taught and their response ...."

2. The clinical record of patient #1, start of care

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 188	G 714		

12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 12/4/2020 - 2/1/2021 evidenced skilled nursing monthly for indwelling catheter change and physical assessment, report any abnormal findings to MD, and stated "... RN will supervise patient to make sure needs are being addressed and goals are being met ...." The document also evidenced listed diagnoses of (but not limited to) diabetes, chronic lung disease, current smoker, peripheral vascular disease (impaired circulation to the lower extremities), amputations of both lower extremities, and depression; and the section for the 60 Day Summary evidenced the patient had an indwelling foley catheter (a tube inserted from the urethra into the bladder to drain urine), a wound to the right groin from pressure/friction due to wearing incontinence briefs, a wound to the left lower extremity stump, and non-compliance with diabetes. Goals included the patient would increase his protein intake by 18 grams per day, be safe and free from injury, free of UTIs (urinary tract infections), all for the certification period. The document failed to evidence any skilled nursing teaching interventions such as infection control, foley catheter management, nutrition, wound management, prevention of new skin breakdown, smoking cessation, diabetes management, and signs and symptoms of disease exacerbation to report to the nurse or physician.

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 189	G 714		

[Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today [12/22/2020] to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... His catheter bag [bag connected urine drain tube] was stuffed an opening [sic] in the side of his wheelchair. The urine in the tube was pale yellow with sediment present ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She indicated they might have. Also asked about adding protein to the diet, niece indicated she did not remember for sure, maybe." The document failed to evidence the skilled nurse provided education to the caregiver to meet the patient's needs, such as (but not limited to), education to mitigate worsening or new skin breakdown, education on proper placement of the urine drainage bag below the bladder to avoid urine back up into the bladder, which would increase risk of urinary tract infection, nutrition teaching for food sources high in protein, or wound care/management, to also include signs or symptoms of worsening wound status to report to nurse or physician.

3. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 190	G 714		

again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/16/2020 - 1/14/2021. The document evidenced the patient received skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock, and home health aide services 3 times per day for 2 hours each visit, 7 days per week for personal care, evidenced listed diagnoses of (but not limited to) C7 spinal cord injury (paralyzed from the neck down, may have limited upper extremity movement), autonomic dysreflexia (a condition in which your involuntary nervous system overreacts to external or bodily stimuli, such as an overfull urinary catheter bag, pressure on bony area(s) from not turning or re-positioning, which causes a dangerous spike in blood pressure and slow heartbeat), constipation, high blood pressure and anemia (low red blood cell count), evidenced the patient had an indwelling urinary catheter, evidenced nutritional requirements to encourage fluids and increase protein intake, and stated "... Client was having issues with autonomic dysreflexia and was put on [11/13/2020] Nitro-BID topical ointment PRN [as needed], no issues recently. He has had an increase [dose] in his Baclofen [medication for spasms] ...." The document also evidenced goals (but not limited to) for the wound to remain free of infection, patient to remain free of UTI, increase pre-albumin levels (by increasing protein intake), and free from infection. The document failed to evidence any skilled nursing teaching interventions such as infection control, foley catheter management, nutrition, wound management, prevention of new skin breakdown,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 191	G 714		

prevention of autonomic dysreflexia, and signs and symptoms of disease exacerbation to report to the nurse or physician.

Review of documents titled "Skilled Nurse Visit Note" for dates 11/16/2020, 11/18/2020, 11/20/2020, 11/22/2020, 11/24/2020, 11/26/2020, 11/28/2020, 11/30/2020, 12/2/2020, 12/4/2020, 12/6/2020, 12/8/2020, 12/10/2020, and 12/12/2020 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The section was blank for all notes, and all notes failed to evidence any skilled nursing teaching interventions such as infection control, foley catheter management, nutrition, wound management, prevention of new skin breakdown, prevention of autonomic dysreflexia, and signs and symptoms of disease exacerbation to report to the nurse or physician.

4. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification dates 12/17/2020 - 2/14/2021. The document evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (a tube inserted directly into the stomach to administer nutrition, fluids and medications), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care, 6 hours per day, 5 days per week, he lived in a group home managed by entity O, evidenced listed diagnoses of (but not limited to) cerebral palsy, profound intellectual disability, seizures, g-tube, tracheostomy, constipation, asthma, and chronic lung disease. Goals included (but not

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 192	G 714		

limited to) to remain safe in home environment by lack of hospitalizations due to injuries from falls and/or infections, maintain oxygen saturation levels of at least 95%, and no weight loss. The document also evidenced the patient was a high fall risk, and a high risk for aspiration (fluid or objects ingested directly into the lungs). The document failed to evidence any skilled nursing teaching interventions for the family/caregivers such as fall precautions, infection control precautions, aspiration precautions, or lung precautions such as avoidance of aerosol sprays, heavy perfumes/scents to avoid bronchiospasm.

5. The clinical record review of patient #4, start of care date 8/19/2019, was completed on 1/12/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification dates 12/11/2020 - 2/8/2021. The document evidenced the patient received, but not limited to, skilled nursing visits 3 times weekly for wound care (2 wounds) and physical assessment, and to alert MD for any abnormal findings, evidenced diagnoses (but not limited to) paraplegia (paralysis from the waist down), high blood pressure, anxiety disorder; and the section for the 60 day summary indicated the patient self-catheterized himself (scheduled insertion of a urinary drainage tube directly into the bladder to drain urine, which is removed once bladder is empty), and he had a wound on his right heel. The document also evidenced nutritional requirements to increase fluids, he was a fall risk, and had fragile skin. Goals included (but not limited to) no new open skin areas, no infection, have social, spiritual/physical/emotional and medical needs met. The document failed to evidence any skilled nursing teaching interventions such as fall precautions, infection

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 193	G 714		

control precautions, prevention of skin breakdown, or signs and symptoms to report to the nurse or physician.

6. The clinical record of patient #5, start of care 3/14/2019, was reviewed on 1/12/21, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/3/2020 - 1/1/2021 which evidenced orders for skilled nursing monthly for to "change central line dressing and cap; blood lab draw of CBC w diff [complete blood count with differential], CMP [sic comprehensive metabolic panel], trig. [sic triglycerides], magnesium, phosphurus [sic] every week and teach caregiver on TPN [total parenteral nutrition], and g tube [gastrostomy -tube inserted through the belly that brings nutrition directly to the stomach] maintenance. Call physician with any concerns or changes. Weekly weights to be called into pharmacy ..."
Review of documents titled "Skilled Nurse Visit Note" for dates 11/3/2020, 11/10/2020, 11/17/2020, 11/24/20, 12/1/2020, 12/8/2020, and 12/29/2020 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The section was blank for all notes, and all notes failed to evidence any skilled nursing teaching interventions.

7. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification dates 12/31/2020 - 2/28/2021. The document evidenced the patient received, but not limited to, skilled nursing every other week to complete a full head to toe

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 194	G 714		

assessment,vital signs, and change the patient's suprapubic catheter (a tube inserted into an opening in the lower abdomen directly into the bladder to drain urine), and home health aide (HHA) services for personal care "up to 60 hours", evidenced diagnoses listed (but not limited to) unspecified stroke and unspecified convulsions; and the section for the 60 day summary indicated (but not limited to) the patient had a wound on his tailbone, the wife performed the wound care, he was incontinent of bowel and bladder, had fragile skin, had diabetes, depression, chronic lung disease and used oxygen, and had chronic pain. Goals included (but not limited to) remain free of infection, and maintain optimal gas exchange (no breathing issues) with oxygen saturation reading 95% or above. The document failed to evidence any skilled nursing teaching interventions such as seizure precautions, infection control precautions, oxygen prevention of skin breakdown, or signs and symptoms of UTI, wound infection or respiratory issues to report to the nurse or physician.

Review of documents titled "Skilled Nurse Visit Note" for dates 11/11/2020, 11/27/2020, and 12/23/2020 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The section was blank for all notes, and all notes failed to evidence any skilled nursing teaching interventions were performed.

8. The clinical record review for patient #8 was completed on 1/11/2021, and evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification dates 11/22/2020 - 1/20/2021. The document evidenced the patient received HHA

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 195	G 714		

(home health aide) services 2 hours per day, five days per week, RN to supervise patient to ensure needs and goals were met (no frequency evidenced), diagnoses list included (but not limited to) diabetes, moderate intellectual disability, chronic lung disease, high blood sugar, high blood pressure; and the section for the 60 day summary indicated (but not limited to) the patient resided in a group home managed by entity O, he smoked, had anxiety at times, constipation at times, blood sugars fluctuate between 74-344, had a diabetic foot ulcer on the left foot, and had a previous ulcer that resulted in a partial foot amputation. Goals included (but not limited to) safe and free from injury, unlabored respirations and oxygen saturation 90% or above, and blood sugars less than 150. The document failed to evidence any skilled nursing teaching interventions for the group home caregivers such as signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and regularly checking blood sugars, infection control, prevention of new skin breakdown, or signs and symptoms of wound infection or respiratory issues to report to the nurse or physician.

9. The clinical record of patient #9, start of care 9/9/2019, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/2/2020 - 12/31/2020. The document evidenced the patient received skilled nursing services every two weeks to fill and organize medication delivery system as scheduled and when medications were changed; and the section for the 60 day summary indicated (but not limited to) the patient had a non-removable surgical dressing on his

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 196	G 714		

right second toe (amputation), his 3rd right toe was black and shriveled, and a goal was set to follow a diabetic diet. Listed diagnoses included (but not limited to) hardening of the arteries, high cholesterol, high blood pressure, progressive systemic sclerosis (a condition associated with thickening of the skin and tethering to subcutaneous tissues as well as smooth muscle waste and fibrosis of internal organs such as the gastrointestinal tract, lungs, heart, and kidneys), and chronic lung disease, and the patient was a moderate fall risk. Goals stated (but not limited to) "... proper, safe and effective administration of meds ... remain safe in current living situation with agency caregiver assistance ... maintained at current status of physical and medical well-being through our assistance with obtaining proper nutrients, medications, and safe activity levels." The document failed to evidence any skilled nursing teaching interventions such as teaching caregiver proper medication administration, how to fill medication box, signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and regularly checking blood sugars, infection control, prevention of new skin breakdown, or signs and symptoms of wound infection or respiratory issues to report to the nurse or physician.

During an interview on 1/12/2021 at 12:48 PM, When asked how she ensured goals were being met on the plan of care, employee M (registered nurse) stated "The wife makes sure he takes his vitamins and his meds, he is only standing and pivoting. I would like to get him some therapy at home. Hoping the VA will provide that." When asked what interventions were completed to address his moderate fall risk, she stated "Clear pathways, coral the dogs so he doesn ' t trip,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 197	G 714		

bedside commode next to bed, he does not stand or transfer by himself, he has a ramp going into the house, his wife has purchased a transport wheelchair for him." When asked how are goals established if there are no interventions, she stated "I try not to set goals I cannot control. I don ' t have control over the healing of the incision."

10. The clinical record review for patient #10 was completed on 1/6/2021 and again on 1/12/2021, start of care date 8/23/2013, evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/14/2020 - 1/12/2021. The document evidenced skilled nursing services every other week to include, but not limited to, set up medications in medication boxes, perform a system assessment, make sure needs are being addressed and goals are being met, and notify doctor of changes in condition. Listed diagnoses included (but not limited to) heart failure, kidney failure (unspecified stage), abdominal wound, high blood pressure chronic lung disease, diabetes, and cervicalgia (neck pain); and the section for the 60 day summary stated "... a history of non-compliance with taking oral meds ... Efforts are being made at education to improve her compliance ... open wound on her abdomen that is non-healing and getting progressively worse ... Will also set a pain management goal ...." The document evidenced goals including (but not limited to) pain level at 4 or less (verbal pain scale 0-10, with 0 being no pain, and 10 being worst pain ever), wound to decrease in size by 2.0 centimeters in length, and blood sugar levels at 140 or less. The document failed to evidence any skilled nursing teaching interventions such as signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 198	G 714		

regularly checking blood sugars, infection control, prevention of new skin breakdown, signs and symptoms of wound infection, non-medicinal methods to mitigate pain, importance of medication compliance, or signs and symptoms to immediately report to the nurse or physician.

Review of documents titled "Skilled Nurse Visit Note" for dates 12/4/2020 and 12/19/2020 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The section was blank for all notes, and all notes failed to evidence any skilled nursing teaching interventions such as signs and symptoms of high and low blood sugar, importance of maintaining a diabetic diet and regularly checking blood sugars, infection control, prevention of new skin breakdown, signs and symptoms of wound infection, non-medicinal methods to mitigate pain, importance of medication compliance, or signs and symptoms to immediately report to the nurse or physician.

Review of a document titled "Skilled Nurse Visit Note" dated 1/6/2021 evidenced a section titled "Interventions/Instructions", which stated "... Observe/Teach: ...." The document evidenced the nurse instructed the patient when to call physician, and stated "... Client weak and called wound clinic and they advised client to go to the ED [emergency department] to r/o [rule out] infection. Client states she's lost about 30 lbs [pounds] with in [sic] the past month ...."

11. During an interview with patient #12 (no record review) on 12/29/2020 at 1:19 PM, when asked what teaching the nurses have done, she indicated she didn't need any teaching, she didn't need help, and she used to be a QMA (Qualified

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 714	Continued From page 199 Medication Aide). When asked what the agency nurse did for her, she indicated she took her vital signs, filled her pill box, and checked if more medications needed to be ordered. During an interview on 1/6/21 at 2:45 PM when asked if they would expect to see interventions for goals established on the plans of care, the clinical director and alternate clinical director both stated "Yes." During an interview on 1/11/2021 at 3:35 PM, When asked if documentation of patient/caregiver education/teaching and correct return demonstration of a task/skill performed should be documented, the alternate clinical director stated "Correct." When asked if the agency had a policy regarding this, the clinical director and alternate clinical director both stated "No." During an interview on 1/12/21 12:48 PM, when asked if a nurse instructed a patient to take a particular medication, would she expect to see an order for the medication, employee M stated "You have to have an order before you instruct a patient to do anything." When asked if a nurse provided skilled care to a patient, would she expect to see orders for care/treatment on the plan of care, she stated "Yes."	G 714		
G 726	Nursing services supervised by RN CFR(s): 484.75(c)(1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k). This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure nursing services were	G 726		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 726	Continued From page 200	G 726		

provided under the supervision of a registered nurse.

Review of an undated copyright Briggs Healthcare policy D-220 titled "Competency Evaluation of Home Care Staff" stated, "... assessment of the person's ability to perform required activities ... assessment will verify and focus on the individual staff knowledge and skill appropriate to assigned responsibilities ... Competencies will address ... Age/type of client ... High risk procedures ... All competencies will be documented ... To assure the personnel providing services to home care clients are trained, competent and able to respond to needs of clients in safe and effective manor ... All new employees will be assessed for competency ... A Home Health Aide will not be permitted to provide ... services until evidence of adequate training and/or competency has been determined ... There must be evidence of ... competency in the delegated tasks ...."

Review of an undated copyright Briggs Healthcare policy D-180 titled "Personnel Records" stated, "... personnel record may include, but not limited to: ... Competency testing for home health aides and specific competencies per job title ... competency reviews ...."

During an interview on 1/11/2021 at 3:35 PM, the clinical director indicated the agency does not require competency evaluations for agency staff.

During an interview on 1/11/2021 at 4:00 PM, when asked what kind of patents she saw for this agency, employee O (registered nurse) stated "From peds to elderly." When asked if she had competency evaluations when she started this

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 726	Continued From page 201 job, she stated "I already had PALS [pediatric advanced life support] from past nursing jobs." When asked if she had competency evaluations for pediatric patients with this agency, she stated "No." During an interview on 1/12/2021 11:54 AM, when asked who did her last performance evaluation and when was it done, employee K (licensed practical nurse) stated "I believe that was [the clinical director], and I am not sure the last time it was done, longer than a year." When asked what kind of patents she saw for this agency, she indicated from pediatrics to adult. When asked if she had completed competency evaluations at this agency for pediatric patients, she stated "I do not with this company, but I staff primarily for a peds [pediatric] company outside of here and have been with them for 5.5 years." When asked when she started working here, shgge stated "November of 2011. When asked who did her initial competency evaluation, she stated "It would ' ve been [employee F, not a registered nurse] from HR [human resource] in Fort Wayne." During an interview on 1/12/2021 at 12:48 PM, when asked who did her last performance evaluation and when was it done, employee M (registered nurse) stated "It would be [the clinical director], and I don't remember [when it was last done]." When asked when she started working here, she stated "April, 2018."	G 726		
G 768	Competency evaluation CFR(s): 484.80(c)(1)(2)(3) Standard: Competency evaluation. An individual may furnish home health services on behalf of an HHA only after that individual has	G 768		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 768	Continued From page 202	G 768		

successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient, or with a pseudo-patient as part of a simulation.

(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.
This STANDARD is not met as evidenced by:
Based on record review and interview, the agency failed to ensure all agency home health aides successfully completed a competency evaluation by a registered nurse for the care of its patients prior to providing care for 1 of 1 home health aide records reviewed (employee J).

Findings include:

Review of an undated copyright Briggs Healthcare policy D-220 titled "Competency Evaluation of Home Care Staff" stated, "... assessment of the person's ability to perform required activities ... To assure the personnel providing services to home care clients are

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 768	Continued From page 203	G 768		

trained, competent and able to respond to needs of clients in safe and effective manor ... All new employees will be assessed for competency ... A Home Health Aide will not be permitted to provide ... services until evidence of adequate training and/or competency has been determined ... There must be evidence of ... competency in the delegated tasks ...."

Review of an undated copyright Briggs Healthcare policy D-180 titled "Personnel Records" stated, "... personnel record may include, but not limited to: ... Competency testing for home health aides and specific competencies per job title ... competency reviews ...."

During an interview and personnel file review on 1/11/2021 at 1:58 PM, employee F (human resource coordinator) acknowledged there was no competency evaluation for the care of a suprapubic catheter (a tube inserted directly into the bladder via a hole surgically created in the lower abdomen to drain urine) for employee J (patient #7's primary home health aide, who had a suprapubic catheter). Employee J emptied the urinary catheter drainage bag and washed around catheter insertion site every aide visit.

During an interview on 1/11/2021 at 3:35 PM, the clinical director indicated the agency does not require competency evaluations for agency staff.

During an interview on 1/11/2021 at 4:00 PM, when asked if an aide was assigned to clean around a catheter insertion site and perform catheter care, would she expect the aide had a competency evaluation prior to performing the tasks on a patient, employee O (registered nurse) stated "Yes."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 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 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 record review and interview, the agency failed to ensure a registered nurse assigned home health aides (HHAs) to all its patients, and failed to ensure the HHA care plan was individualized with specific, not generic, tasks to be completed for 2 of 3 records reviewed that were assigned home health aides (#2, 7). Findings include: 1. Review of an undated copyright Briggs Healthcare policy C-100 titled "Services Provided" stated "... Services will be coordinated by the Registered Nurse managing the care. This will include ... scheduling of visits ...." Review of an undated agency policy C-340 copyright Briggs Healthcare titled "Home Health Aide Supervision," stated " ... Home Nursing Services shall provide Home Health Aide services under the direction and supervision of a Registered Professional Nurse ... Special Instructions ... The Nursing Supervisor or designated Registered Nurse will give the Home Health Aide direction for client care by way of the Service Plan ...."	{G 798}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 798}	Continued From page 205	{G 798}		

2. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock, and HHA 2 hours in the AM, 2 hours in the afternoon, and 2 hours in the evening, 7 days per week to provide bathing, dressing, hair care, skin care, pressure area checks, shave, groom, deodorant, nail care, oral care, elimination assist, catheter care, ambulation assist, mobility assist, ROM (range of motion exercises), positioning, exercise, meal prep, and maintaining a clean and safe environment. The record evidenced bed bath - partial (or) bed bath - complete, but failed to evidence indications for each. The record also failed to evidence type of elimination assist (such bedside commode, toilet, incontinence brief), specific ROM exercises and to which parts of the body, how often to turn the patient, or specific equipment care.

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/1/2020 - 12/30/2020, which evidenced the patient had (but not limited to) a history of stroke with left sided paralysis, indwelling urinary catheter, oxygen use for chronic lung disease. He was also incontinent

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 798}	Continued From page 206 of bowel, and had a wound on his coccyx (tailbone). The document also evidenced orders for skilled nursing services every other week, and HHA up to 60 hours per month scheduled at wife's request, for assist with bathing, dressing, hair, skin, oral, and foot care, checking pressure areas, grooming, deoderant, elimination assist, catheter care, ROM, repositioning, meal preparation, encouraging fluids, laundry, and light housekeeping. The record also evidenced bed bath - partial (or) bed bath - complete, but failed to evidence indications for each, and failed to evidence type of elimination assist (such bedside commode, toilet, incontinence brief), specific ROM exercises and to which parts of the body, or how often to turn the patient. 4. During an interview on 1/11/2021 at 4:00 PM-4:17 PM, when asked who assigned home health aides to patients, employee O (registered nurse) stated "I believe it's our scheduler, [employee Q, home health aide]." During an interview on 1/12/2021 at 11:54 AM, when asked who made schedules, employee K (licensed practical nurse) stated "[Employee P, home health aide] at the auburn office." During an interview on 1/12/2021 at 12:48 PM, when asked who assigned home health aides to patients, employee M (registered nurse) stated "The scheduler, [employee Q, home health aide]."	{G 798}		
{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;	{G 800}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 800}	Continued From page 207	{G 800}		

(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 record review the home health aides (HHA) failed to follow the plan of care for 2 of 3 records reviewed that were assigned home health aides (#2, 7), and practiced outside of the home health aide scope of practice/without a physician order for 1 of 3 incident reports reviewed with home health aide involvement on or after 11/3/2020 which affected patient (#14).

Findings include:

1. Review of an undated copyright Briggs Healthcare policy C-340 titled "Home Health Aide Supervision," stated "Home Nursing Services shall provide Home Health Aide services ... when personal care services are indicated and ordered by the physician ...."

Review of an undated copyright Briggs Healthcare policy C-100 titled "Services Provided" stated "... Services will be coordinated by the Registered Nurse managing the care ...."

Review of an internet reference document https://cnazone.com/Tests/Materials/C031materials.pdf titled "Therapeutic Use of Heat and Cold" stated "... These are best used by a health care professional as they require special equipment and traaining in order to use them correctly and safely ... Only apply heat or cold if you are directed to do so by your supervisor or if hese therapies have been ordered by a physician ...."

2. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 800}	Continued From page 208	{G 800}		

again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock, and HHA 2 hours in the AM, 2 hours in the afternoon, and 2 hours in the evening, 7 days per week to provide bathing, dressing, hair care, skin care, pressure area checks, shave, groom, deodorant, nail care, oral care, elimination assist, catheter care, ambulation assist, mobility assist, ROM (range of motion exercises), positioning, exercise, meal prep, and maintaining a clean and safe environment. The record evidenced bed bath - partial (or) bed bath - complete, but failed to evidence indications for each. The record also failed to evidence type of elimination assist (such bedside commode, toilet, incontinence brief), specific ROM exercises and to which parts of the body, how often to turn the patient, or specific equipment care.

Review of a document titled "Daily Visit Sheet [HHA] for 12/10/2020" evidenced an AM visit was completed and task to shampoo hair during the AM visit was assigned. The visit was performed by the registered nurse case manager (RNCM), and stated "... Hair shampooed only when client requests - as needed ... [filing nails] ... not needed ... Grocery shopping ... 1 x [time per] week task ...." The record failed to evidence the registered nurse modified the aide plan of care.

Review of a document titled "Home Nursing Services Report of Missed Visit" evidenced a

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 800}	Continued From page 209	{G 800}		

home health aide visit was missed on 12/10/2020 due to "no coverage" (no agency staff available). The record evidenced an AM and PM visit for 12/10/2020, but failed to evidence 3 visits were made on that date as ordered.

Review of a document titled "Home Nursing Services Report of Missed Visit" evidenced a home health aide visit was missed on 12/11/2020 due to "no coverage". The record evidenced an AM and PM visit for 12/11/2020, but failed to evidence 3 visits were made on that date as ordered.

Review of a document titled "Daily Visit Sheet for 12/12/2020" evidenced a PM visit was made by the RNCM. The document evidenced the client was independent with brushing his teeth, he did not eat before bed/at bedtime, and grocery shopping was once per week. The record failed to evidence the registered nurse modified the aide plan of care. The record also evidenced only 2 aide visits were made on 12/12/2020. The record also evidenced only 1 visit was made on 12/13/2020.

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/1/2020 - 12/30/2020, which evidenced the patient had (but not limited to) a history of stroke with left sided paralysis, indwelling urinary catheter, oxygen use for chronic lung disease. He was also incontinent of bowel, and had a wound on his coccyx (tailbone). The document also evidenced orders for skilled nursing services every other week, and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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{G 800}	Continued From page 210	{G 800}		

HHA up to 60 hours per month scheduled at wife's request, for assist with bathing, dressing, hair, skin, oral, and foot care, checking pressure areas, grooming, deodorant, elimination assist, catheter care, ROM, repositioning, meal preparation, encouraging fluids, laundry, and light housekeeping. The record also evidenced bed bath - partial (or) bed bath - complete, but failed to evidence indications for each, and failed to evidence type of elimination assist (such bedside commode, toilet, incontinence brief), specific ROM exercises and to which parts of the body, or how often to turn the patient.

Review of documents dated 12/9/2020, 12/10/2020, 12/11/2020, 12/12/2020, and 12/13/2020 titled "Daily Visit Sheet for ...." (HHA visit sheets) all evidenced (but not limited to) the aide was to wash around the stoma (hole in lower abdomen that a tube is inserted in directly to the bladder to drain urine) every visit, but it failed to evidence what the aide should use to wash it, failed to assist the patient with dressing. failed to perform nail care, failed to groom, and failed to shave the patient.

4. Review of an agency document dated 11/3/2020 titled "Home Nursing Services Incident Report" for patient #14 stated "... Date of incident 11/3/2020 ... Witness of Incident [employee R, HHA] ... Description of Incident ... Client dropped laundry basket on her toe. Toe is bruised ... HHA applied ice ...." The home health aide failed to follow the plan of care (applied ice to the patient's toe, there was no order to apply ice, and this was outside of the scope of practice for a home health aide).

Review of a document titled "Daily Visit Sheet for

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 800}	Continued From page 211 11/3/2020" (HHA visit form) signed by employee R failed to evidence the change in the patient's condition, failed to evidence she reported the change to an RN, and failed to document the date, time, and person the HHA notified the change to.	{G 800}		
{G 804}	Aides are members of interdisciplinary team CFR(s): 484.80(g)(4) Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures. This ELEMENT is not met as evidenced by: Based on record review and interview, the home health aide (HHA) failed to report a change in the patient's condition to a registered nurse (RN), and failed to document the date, time, and person the HHA notified the change to, for 3 of 3 incident reports reviewed with home health aide involvement on or after 11/3/2020 which affected patients (#14, 15, 16). Findings include: 1. An agency job description with date amended 10/23/2020 titled "Home Health Aide," stated "... Reports any observed or reported changes in the client's condition and/or needs to the Registered Nurse ...." 2. Review of an agency document dated 11/3/2020 titled "Home Nursing Services Incident Report" for patient #14 stated "... Date of incident 11/3/2020 ... Witness of Incident [employee R, HHA] ... Description of Incident ... Client dropped	{G 804}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 804}	Continued From page 212	{G 804}		

laundry basket on her toe. Toe is bruised ... reported incident to [patient's] sister ...." The document failed to evidence the HHA reported a change in the patient's condition to an RN, and failed to document the date, time, and person the HHA notified the change to. The document also failed to evidence who reported the incident.

Review of a document titled "Daily Visit Sheet for 11/3/2020" (HHA visit form) signed by employee R failed to evidence the change in the patient's condition, failed to evidence she reported the change to an RN, and failed to document the date, time, and person the HHA notified the change to.

3. Review of an agency document dated 11/11/2020 titled "Home Nursing Services Incident Report" for patient #15 stated "... Date of incident 11/7/2020 ... Witness of Incident ... No visual witness, [employee S, HHA] assisted the client when she arrived for her HHA visit ... Description of Incident ... The client stated she lost her balance while walking and fell to the floor ... no injury ... client reported the fall to this writer [employee T, registered nurse] on 11/11/2020. Aide reported the event on 11/7/2020 ...." The document failed to evidence the HHA reported a change in the patient's condition to an RN, and failed to document the date, time, and person the HHA notified the change to. The document also failed to evidence who reported the incident.

Review of a document titled "Daily Visit Sheet for 11/7/2020" signed by employee S failed to evidence the change in the patient's condition (fall), failed to evidence she reported the change to an RN, and failed to document the date, time, and person the HHA notified the change to.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 804}	Continued From page 213 4. Review of an agency document dated 12/3/2020 titled "Home Nursing Services Incident Report" for patient #16 stated "... Date of incident 12/3/2020 ... Witness of Incident ... none ... Other individuals that are involved and may not be a witness [employee U, HHA], [and] client's daughter ... Description of Incident ... Client was found on the floor next to his bed by HHA at 5 AM when she arrived at his home to begin her shift ... there is an abrasion above his [right] eye ... and on the bridge of his nose ...." The document failed to evidence the HHA reported a change in the patient's condition to an RN, and failed to document the date, time, and person the HHA notified the change to. The document also failed to evidence who reported the incident. Review of a document titled "Daily Visit Sheet for 12/3/2020" signed by employee U failed to evidence the change in the patient's condition (fall), failed to evidence she reported the change to an RN, and failed to document the date, time, and person the HHA notified the change to. 5. During an interview on 12/18/2020 at 1:32 PM, at the clinical director indicated the incident reports lacked follow up, and there was no evidence the aides notified the nurse for changes in condition.	{G 804}		
{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	{G 940}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 940}	Continued From page 214 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 minutes failed to evidence information regarding policy review, updates, and approvals (See G942); the administrator failed to be responsible for the day to day functions of the agency (See G948); the clinical director (CD) failed to make patient and personnel assignments (See G960); the CD failed to coordinate patient care for the agency (See G962); the CD failed assure patient needs were continuously assessed (See G966); the CD failed to assure patient plans of care were implemented, and updated to ensure the needs of the patient were being met (See G968); the agency failed to report a branch location to the state survey agency (See G972); and the agency failed to maintain primary responsibility for all patients' care, and failed to ensure it provided all care and treatment necessary to meet the patients' needs (See G980). The cumulative effect of this systemic problem resulted in the agency being out of compliance with the Condition of Participation 42 CFR 484.105 Organization and administration of services.	{G 940}		
G 942	Governing body	G 942		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 942	Continued From page 215 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 Governing Body failed to periodically review and approve the agency's operational policies and review and approve updated/new policies. Findings include: Review of an undated copyright Briggs Healthcare policy B-100 titled "Governing Body" stated "... The Governing Body shall assume full legal authority and responsibility for the operation of Home Nursing Services ... The duties of the Governing Body shall include ... Adopt and periodically review and approve the administrative and personnel policies, client care policies and procedures ... as required by state licensure ...." Review of an undated copyright Briggs Healthcare policy B-210 titled "Policy Development" stated "... All policies will be incorporated into Home Nursing Services policy manual. Selected policies will be reviewed and revised at least annually ... The Governing Body makes final approval ... New or revised policies will be approved ... Policy reviews will be documented ...."	G 942		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 942	Continued From page 216	G 942		

Review of an agency policy excerpt (as indicated by the administrator) submitted on 1/12/2021 at 1:30 PM from the employee handbook titled "Progressive Discipline" evidenced an amended date of 10/23/2020.

Review of an agency policy titled "Client Incident/Accident" evidenced an amended date of 10/23/2020.

Review of agency policies titled "Dress Code", "Home Nursing Services Job Description: Home Health Aide", and "Home Nursing Services Job Description: Homemaker", all evidenced amendment date 10/23/2020.

Review of a copyright Briggs Healthcare policy D-325 titled "Exposure to Coronavirus (COVID-19): Disease Response and Management" evidenced a date of 11/3/2020.

Review of an agency document dated 2/28/2020 titled "Written Consent to Resolutions of the Board of Directors of Home Nursing Services, Inc." failed to evidence agency policies were reviewed and approved,

Review of an agency document dated 6/5/2020 titled "Written Consent to Resolutions of the Board of Directors of Home Nursing Services, Inc." failed to evidence agency policies were reviewed and approved.

During an interview on 1/6/2021 at 12:01 PM, the administrator submitted Governing Body minutes and meetings from 2/28/2020 and 6/5/2020. When asked if the submitted documents included all minutes and meetings from 2/28/2020 to present (1/6/2021), the administrator stated "Yes."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Responsible for all day-to-day operations CFR(s): 484.105(b)(1)(ii) (ii) Be responsible for all day-to-day operations of the HHA; This ELEMENT is not met as evidenced by: Based on record review and interview, the administrator failed to be responsible for all day-to-day operations of the agency; failed to have systems in place to monitor ongoing staff performance to ensure comprehensive assessments were being conducted and documented; failed to ensure staff received appropriate competency evaluations prior to providing patient care; failed to ensure staff were not documenting in the electronic medical record as other nursing staff (not themselves); and failed to ensure staff did not modify clinical documentation without prior approval from the assessing clinician, all which led to employees continuation of working without discipline, appropriate competency, and training which led to new or worsening wounds, urinary tract infection, hospitalization, amputation, and/or death to 3 of 7 patients (#1, 7, and 9) who had wounds. This practice had the potential to affect all agency patients. Findings include: 1. Review of an agency employee handbook policy amended 10/23/2020 titled "Progressive Discipline" stated "... it should be understood that certain conduct will not be tolerated and will subject an employee to warning, discipline or immediate discharge, depending on the severity of the circumstance ... any employee actions which compromise the health and safety of the clients will also be cause for immediate termination."	G 948		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 218 Review of an undated copyright Briggs Healthcare policy C-873 titled "Documentation of Changes to the Medical Record" stated, "... If it is necessary to make an addition to a previous entry, this must be done using an addendum to the record. The entry will be marked as an addendum and must include the date it is written and the visit date that the entry relates to ... Changes to OASIS documentation ... The clinician who completes the assessment form is responsible for making changes (corrections, revisions, or additions) to the document. The clinical supervisor or designee may enter changes based on the review of the assessment. These changes must be documented in the record identifying the reason for the changes and the communication of those changes to the authoring clinician ... Records sourced from electronic systems containing amendments, corrections or delayed entries must: Distinctly identify any amendment, correction or delayed entry ... Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the records ... Auditors including recovery auditors shall NOT consider any entries that do not comply with these principles ...." Review of an undated copyright Briggs Healthcare policy D-220 titled "Competency Evaluation of Home Care Staff" stated, "... assessment of the person's ability to perform required activities ... assessment will verify and focus on the individual staff knowledge and skill appropriate to assigned responsibilities ... Competencies will address ... Age/type of client ... High risk procedures ... All competencies will be documented ... To assure the personnel providing	G 948		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 219	G 948		

services to home care clients are trained, competent and able to respond to needs of clients in safe and effective manor ... All new employees will be assessed for competency ... A Home Health Aide will not be permitted to provide ... services until evidence of adequate training and/or competency has been determined ... There must be evidence of ... competency in the delegated tasks ...."

Review of an undated copyright Briggs Healthcare policy D-180 titled "Personnel Records" stated, "... personnel record may include, but not limited to: ... Competency testing for home health aides and specific competencies per job title ... competency reviews ...."

2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021.
Review of a document received on 12/28/2020 titled "SN [skilled nurse] SOC [start of care] OASIS and Comprehensive Assessment" dated 12/10/2019 evidenced the patient had no wounds, and failed to evidence a Braden scale (a comprehensive assessment for predicting pressure sore risk) was completed by the registered nurse. The assessment further evidenced the patient had (but not limited to) diabetes with peripheral angiopathy (a blood vessel disease caused by high blood sugar), amputations of both legs below the knees, and had an indwelling urinary catheter (a tube inserted into to bladder to drain urine). The patient was alert and oriented to person, place, and time, without confusion or disruptive behaviors. Upon admission on 12/10/2019, the patient had no open skin areas or wounds.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 220 Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4). During the entrance conference interview on 12/15/2020 at 11:00 AM, the clinical director indicated the agency used both paper and electronic charting. When asked the process for making corrections in the clinical record, the clinical director indicated the document would be taken to the RNCM (registered nurse case manager) to discuss, then it would be a late entry, line through, corrected, then initialed. When asked the timeframe for documents to be incorporated into the patients' medical records, the clinical director stated, "Fourteen days."	G 948		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 221 During an interview on 12/17/2020 at 3:44 PM, the clinical director stated the comprehensive assessment for patient #1 dated and signed by employee L on 12/3/2020 was actually completed on that date (12/17/2020), and the plan of care was also completed that date (12/17/2020) and sent to the physician. Both were reviewed and approved by employee M (registered nurse). It was verified by the clinical director and the administrator that employee L (registered nurse) initiated the comprehensive assessment on 12/3/2020 but didn't complete it, and she did not assess the wounds. When asked, the clinical director agreed the certifying physician would not be able to provide/approve orders to meet the patient's needs without complete and accurate assessment findings. During this time, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No." During an interview on 12/18/2020 at 1:00 PM, when asked who finished the comprehensive assessment for patient #1 dated 12/3/2020, the director of nursing stated "[employee N-registered nurse]." When asked if she was the nurse that initiated the comprehensive assessment on 12/3/2020, the director of nursing stated "No." When asked why employee L didn't complete the assessment, the director of nursing stated "We discovered she was behind, we wanted to get it done, so we sent it to [employee N]." She also indicated employee N saw the patient on 12/15/2020, and that visit represented completion of the comprehensive assessment dated 12/3/2020. When asked if there were other incomplete patient assessments that employee L failed to complete that someone else was finishing, the administrator stated, "I believe so."	G 948		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 948	Continued From page 222	G 948		

When asked when the agency noticed employee L's had incomplete/late assessments, the clinical Director stated "Monday [12/14/2020]". When asked if the agency had a list of additional patients that other nurses were "fixing or have fixed" for employee L, the clinical director stated "Yes." The administrator indicated employee H (office staff) completed billing every week, and every week she checked in the paperwork. During this interview (at 1:23 PM), the list of all patients re-assigned to other nurses to finish was requested, and was received at 1:38 PM. The list evidenced (but not limited to) 33 patients from 12/1/2020 - 12/18/2020 which had incomplete assessments.

During an interview on 12/18/2020 at 3:20 PM, when asked which nurse did which portions of the comprehensive assessment dated 12/3/2020, the administrator stated "I can only tell [employee L] visited [the patient] on the 3rd, started writing [on the assessment on] 11th, [employee N] saw the patient on the 15th, and employee M reviewed and approved the assessment document on the 17th ... [employee M] signed the plan of care." The administrator also indicated he didn't know who did the wound assessments, or when the wounds were last assessed by staff. When asked if there had been any discipline for employee L, the administrator stated, "I don't know."

During an interview on 12/18/2020 at 3:53 PM, the clinical director indicated employee L was going to be fired next week. When asked why she was allowed to see patients this week, the clinical director indicated employee L kept saying she was going to finish the paperwork, the clinical director further stated she was going to terminate employee L's employment this week, and stated

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 223	G 948		

"... but because Indiana department of health is here, it's next week".

Review of employee L's employee file on 12/18/2020, hire date 6/4/2019, evidenced a pattern of poor work performance evidenced by (including but not limited to) a document dated 2/7/2020 titled "Case Conference" which stated "... During her time as a Registered Nurse Case Manager ... [employee L] has struggled to perform her duties satisfactorily ... Due to infection control concerns, she is no longer permitted to work on [entity H intravenous infusion company] cases ... She demonstrates very little initiative or urgency about her work ...." An additional email document dated 4/30/2020 evidenced the alternate clinical director was notified by person G that employee L, while in the office, referred to a pediatric patient as a "little brat ...", person G indicated she told employee L the patient was just a baby, and employee L stated "I don't care she is still a little brat ...." The file failed to evidence any disciplinary action taken.

Review of an untitled agency document received on 12/15/2020 evidenced a calendar for the month of December 2020. The clinical director indicated this was the agency on-call log. The document evidenced employee L was scheduled to be on call from 12/1/2020 - 12/31/2020.

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated patient #1 expired in the hospital on 12/27/2020.

During an interview with the alternate clinical director (clinical director also present) on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 224	G 948		

12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head." When asked why there was no follow up visit scheduled to assess the patient's wounds after 12/22/2020, she stated "... planned on going back after the holidays." When asked if it was appropriate to wait so long to assess wounds (as part of the comprehensive assessment), she stated "Yes ...." When asked if she spoke with the certifying physician after she saw the patient on 12/22/2020, she stated "No ma'am." When asked if she should speak with the certifying physician after completing a comprehensive assessment, she stated "If I find something that's different or out of the ordinary." When asked if measurements from wound clinic documentation counted as part of her comprehensive assessment, she stated "No, but I was going to go back after the holiday." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted.

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.
Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/1/2020 - 12/30/2020 stated "... [skilled nursing orders] System

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 225	G 948		

assessment with each skilled nursing visit ... report any abnormal findings to [physician] ... open area on coccyx that is being treated by the wound clinic ...." the document failed to evidence current wound care orders, wounds listed on comprehensive assessment (left foot- all toes, right foot- all toes), and failed to evidence skilled nursing interventions to mitigate wound status or prevention of new pressure sores. The document also evidenced the patient had (but not limited to) a history of stroke with left sided paralysis, indwelling urinary catheter, oxygen use for chronic lung disease. He was also incontinent of bowel, and had a wound on his coccyx (tailbone).

Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 10/30/2020 stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... 1 ... Stage 3 ... 1 ... Stage 1 ... 1 ... Location ... left foot (all toes) ... right foot ... all toes ... left upper coccyx ... HNS [agency name] is not responsible for wound care ... Bedfast, unable to transfer and is unable to turn and position self ... unable to be up in a chair ..." The assessment failed to identify stage of each wound, assessment or measurements, or evidence education was provided to the caregiver to mitigate worsening or new skin breakdown.

Review of a document dated 11/11/2020 titled "Skilled Nurse Visit Note" stated "... Urinating through penis and around [catheter] ... [after catheter change] ... Draining freely dark yellow, cloudy urine ...." The document failed to evidence wounds were assessed, failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, or infection control teaching related to the urinary

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 226	G 948		

catheter, including (but not limited to) signs and symptoms of clogged tubing or infection.

Review of a wound clinic document dated 11/24/2020 (obtained by the wound clinic, not from clinical record) titled "Wound Treatment #1 (Order 262060966)" stated "... Wash wound(s) with mild soap and water, then pat dry. Place Medihoney [wound bed ointment] and cover with ABD [surgical absorbent gauze pad]. Change dressing daily ... Home Healthcare to visit for wound care 2-3 [times] weekly and PRN [as needed] wound care/dressing changes ... left lower extremity ... right lower extremity ...." The agency record failed to evidence it provided skilled nursing visits 2-3 times weekly.

Review of a document dated 11/27/2020 titled "Skilled Nurse Visit Note" failed to evidence wounds were assessed or treated by the nurse, and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown.

Review of a document dated 12/8/2020 titled "Skilled Nurse Visit Note" stated "...Location: left heel ... wound type: pressure ... date originally reported: 6/26/2020 ... Comments: wound remains to the left heel ... Location: BLE [bilateral lower extremities]; 4th toes and left heel ... Wound type: unknown ... Date originally reported: 12/8/2020 ... Purulence [thick and milky discharge from a wound, often indicates an infection and needs treatment as soon as possible] drainage and scant blood around suprapubic stoma/foley [insertion site on abdomen for direct access to bladder with urinary drainage tube] ...." The document failed to evidence wounds were assessed/measured or treated by the nurse, the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 227	G 948		

physician was notified of new open area(s) and signs of infection at suprapubic insertion site, and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown or signs and symptoms of infection.

Review of a document dated 12/23/2020 titled "Skilled Nurse Visit Note" failed to evidence wounds were assessed or treated by the nurse, and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown.

Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... [blank] ... Stage 3 ... [blank] ... Unstageable [full thickness skin and tissue loss in which the extent of the damage within the ulcer cannot be determined due to scabbing or dead fibrous tissue; once removed to expose wound, a stage 3 or 4 would be revealed] ... Stage 1 ... 0 ... Does this patient have a stasis ulcer [ulcer caused by impaired circulation]? ... Yes ... Current number of Stasis Ulcers that are observable ... 3 ... status of most problematic ... Not Healing ... Location ... left second toe ... left third toe ... right second toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... Integument [skin] Impression: ... unstable ... in need of skilled intermittent care ... Will continue to monitor during regular visits, but not be a focus of care ... Will require a lot of attention ... Current possible UTI [urinary tract infection] symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The document also evidenced the patient was a high risk for skin breakdown. The document failed to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 228	G 948		

evidence the wounds were treated by the nurse, or education was provided to the caregiver to mitigate worsening or new skin breakdown, or signs and symptoms of UTI.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for the newest certification period 12/31/2020 - 2/28/2021 stated "... [skilled nursing orders] System assessment with each skilled nursing visit ... full head to toe assessment ... Teach/train in proper positioning to reduce pressure on pressure prone areas ... Assess wound for infection and healing ... [home health aide] up to 60 hr/month ... assist with ... catheter care ...." The document failed to evidence current wound care orders or treatment performed by nurse, all wounds listed on comprehensive assessment, and failed to evidence skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote wound healing, frequent turning schedule, padding of bony prominences, or catheter management and signs and symptoms to report to agency and/or physician.

During an interview and personnel file review on 12/30/2020 at 2:00 PM, employee F (human resource coordinator) acknowledged there was no competency evaluation for the care of a suprapubic catheter (a tube inserted directly into the bladder via a hole surgically created in the lower abdomen to drain urine) for employee J (patient #7's primary home health aide). Employee J emptied the urinary catheter drainage bag and washed around catheter insertion site every aide visit.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 229	G 948		

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI and would likely be discharged 1/4/2021 or 1/5/2021. Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician will added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

Review of a document titled "SN ROC [skilled nursing resumption of care] OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was a high risk for skin breakdown, stated "... Does this patient have a stasis ulcer? ... Yes ... Current number of Stasis Ulcers that are observable ... 4 ... status of most problematic ... Not Healing ... Location ... right big toe ... right second toe ... left second toe ... left third toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... wife cleanses, applies medihoney dresses every other day and will see wound clinic 1/14/20 [sic] ...." The document failed to evidence contact precautions for VRE, skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote wound healing, frequent turning schedule, or

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 230	G 948		

padding of bony prominences, or wound care was performed by the nurse. The document evidenced the certifying physician was contacted for orders, but the clinical record failed to evidence a resumption of care order dated 1/5/2021.

Review of a document dated by the clinical director on 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, and applied an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received. Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated she did not know the name of the ointment the spouse applied to the wound(s).

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), the administrator, and the alternate administrator stated "... 1-10-2021, 12:20 PM. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her home remedy for his back is working ... She does not need me to stop by today to help her ...." The document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified the wife was applying a home remedy to his wound(s). Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 231	G 948		

(registered nurse), employee M (registered nurse), employee D (medical records coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound with wounds, and a new wound that developed post-hospitalization, and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted.

4. The clinical record of patient #9, start of care

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 232	G 948		

9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document titled "SN Re-Cert [recertification] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 11/1/2020 "... right second toe amputation ... Non-removable dressing present. Wound managed by orthopedics ... Report any abnormal findings to VA [veterans affairs] MD ... skilled nurse ... physical assessment ... and notify MD of any abnormal findings ... had his right second toe amputated ... His 3rd right toe is black and shriveled ...." The document also evidenced the patient had diagnoses (but not limited to) atherosclerotic heart disease (hardening of the arteries causing impaired circulation), and diabetes with diabetic neuropathy (diabetes with damage to nerves in your legs and feet, causing pain and numbness in your legs and feet). The document failed to evidence the physician was notified of the change in condition of the wound.

Review of a document dated 11/2/2020 titled "Skilled Nurse Visit Note" stated "... Right second toe amputation site not healing. 3rd toe black and very painful ...." The document failed to evidence the nurse measured the wounds, performed wound care, or notified the physician for the change in the patient's integumentary or pain status.

Review of a document dated and signed by employee M on 11/16/2020 titled "Skilled Nurse Visit Note" stated "... "posterior foot blackening about 1 1/2 inch on ball of right foot, 3rd toe black and shriveled, outer edge of 5th toe; see

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 233	G 948		

diagram" The clinical record failed to evidence a diagram of the wound, or failed to evidence the physician was notified of the declining wound status.

During an interview on 1/6/2021 at 3:56 PM, when asked if the doctor should have been notified of the change in wound status on 11/16/2020, the alternate clinical director stated "He should be, I don't know if she did call." When asked if this failure to contact the physician could have potentially led to a negative outcome for the patient, she stated "Yes".

Review of a document dated and signed by employee M on 11/30/2020 titled "Skilled Nurse Visit Note" stated "... "No fever, No cough, No complaints, Right foot, big toe starting to blacken, middle toe black and shriveled. Per wife, US [ultrasound] showed multiple blockages and patient may lose foot d/t [due to] occlusions ...." The document failed to evidence the physician was notified of the declining wound status.

Review of a document dated and signed by employee M on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE [right lower extremity] Femoral Endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain. Pain 10/10. Taking Norco for pain. 2 weeks of meds set-up. 100% medication compliant ...." The document failed to evidence the physician was notified of the declining wound status or severe pain.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 234	G 948		

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to [sic] femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence the agency coordinated with the hospital to provide patient's current status or request hospital records.

Review of a document titled "Skilled Nurse Visit Note" dated 12/28/2020 stated "... returned from hospital S/P [after] Right femoral endarterectomy and Right partial amputation of foot. Right groin incision C/D/I [clean, dry, and intact] no redness, no draining, no swelling. OTA [open to air]. Right foot dressing C/D/I with orders not to remove same until f/u [follow up] with Podiatry 1/4/21. Plavix [medication to prevent formation of blood clots and to keep blood vessels open after surgical procedures, and may cause easy bleeding/bruising] ... added to medication regimine [sic] ... Client is NWB [non-weight bearing] R foot ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document dated 12/28/2021 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 235	G 948		

previously had not been identified), and the nurse failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the nurse instructed on non-weight bearing status to the right foot, which could potentially have a negative outcome on the surgical healing process, failed to evidence the nurse assessed the left second toe pain, and failed to evidence the physician was notified.

Review of a document dated 12/28/2021 titled "SN ROC OASIS and Comprehensive Assessment" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without devices in his home ... Has had no ... hospitalizations ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/28/2021 (additional document for same nurse

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 236	G 948		

visit same day) stated "... Pain Assessment: ... right foot. Severity (0-10), 6 ... Cardiovascular Assessment: ... blood thinners ... Plavix ... Integumentary [skin] Assessment: No issues noted ... incisions [groin] ... open to air ... right foot ... surgical dressing in place ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection, nutritional requirements for wound healing, or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and recertification care orders.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 1/1/2021 - 3/1/2021 stated "... [skilled nursing orders] ... one visit ... every 2 weeks ... medication tray set-up, to monitor compliance ... physical assessment, and report any abnormal findings to MD ...." The document failed to evidence skilled nursing interventions such as wound care/treatments, patient/family education for wound care/treatment, interventions to mitigate new or worsening skin breakdown, appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, or signs and symptoms of infection, nutritional requirements for wound healing or other indications that should be reported to the agency and/or physician.

During an interview on 1/5/2021 at 1:29 PM person F (staff at entity E-podiatrist office) indicated the patient was seen 1/4/2021 for

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 237	G 948		

surgical follow up. When asked if she received any communication/coordination from the agency, she stated "On 12/29 [2020] we got a call from [employee M] to request PT/OT [physical and occupational therapy] order. That's the only thing I see ...."
Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2021), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.

During an interview on 1/6/2021 at 3:56 PM, the clinical director and alternate clinical director confirmed the skilled nursing frequency remained every two weeks since hospital discharge. When asked if waiting two weeks to see this patient could lead to a potentially negative outcome, they both stated "Yes."

During an interview on 1/12/2021 at 1:50 PM, regarding the skilled nursing visit on 11/16/2020, employee M indicated she did not contact the physician, he was already aware, it (the wound/blackening of toe/foot) started as just the tip, and it was an ongoing process; regarding the skilled nursing visit on 12/14/2020, she stated "I did not call the physician ...."

5. During an interview on 1/11/2021 at 3:35 PM, the clinical director indicated the agency does not

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 948	Continued From page 238 require competency evaluations for agency staff.	G 948		
G 960	Make patient and personnel assignments, CFR(s): 484.105(c)(1) Making patient and personnel assignments, This ELEMENT is not met as evidenced by: Based on record review and interview, the clinical director failed to ensure a registered nurse (RN) assigned all patient and personnel assignments. Findings include: Review of an undated copyright Briggs Healthcare policy C-100 titled "Services Provided" stated "... Services will be coordinated by the Registered Nurse managing the care. This will include ... scheduling of visits ...." During an interview on 1/11/2021 at 4:00 PM-4:17 PM, when asked who assigned home health aides to patients, employee O (registered nurse) stated "I believe it's our scheduler, [employee Q, home health aide]." During an interview on 1/12/2021 at 11:54 AM, when asked who made schedules, employee K (licensed practical nurse) stated "[Employee P, home health aide] at the auburn office." During an interview on 1/12/2021 at 12:48 PM, when asked who assigned home health aides to patients, employee M (registered nurse) stated "The scheduler, [employee Q, home health aide]."	G 960		
G 962	Coordinate patient care CFR(s): 484.105(c)(2) Coordinating patient care,	G 962		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 962	Continued From page 239	G 962		

This ELEMENT is not met as evidenced by:
Based on record review and interview, the clinical director failed to ensure all agency patients received effective coordination of care.

Findings include:

Review of an undated copyright Briggs Healthcare policy C-360 titled "Coordination of Client Services" stated "... Each staff Registered Nurse shall meet with the Clinical Director/Designee weekly or as necessary to review all areas of client needs ...."

During an interview on 12/17/2020 at 2:34 PM, employee M (registered nurse) submitted a list which evidenced (but not limited to) 10 patients with wounds. Employee M indicated all were managed by wound clinics, the agency did not coordinate with the wound clinics, and there we no wound clinic notes in any of the patients' charts.

During an interview on 12/17/2020 at 2:34 PM, when asked which wound clinic managed patient #8's wound, the clinical director indicated she did not know.

During an interview on 12/17/2020 at 3:44 PM, when asked who performed patient #8's wound care, the clinical director indicated staff at entity O (group home) did the wound care. When asked if the staff were clinicians, she stated "No, they do have a nurse that floats to the different houses. I'm not sure she's involved." When asked at what point do you get involved, she stated "When they need a skilled nurse to take over." During this interview, the administrator asked the clinical director "Do we receive wound clinic follow up?",

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 962	Continued From page 240 she stated "No." During an interview on 12/28/2020 at 11:26 AM, when asked if the agency contacted a hospital to coordinate care and obtain hospital paperwork to relay information to the certifying physician, the clinical director stated "We usually don't, because they usually come home with papers." When asked how the hospital would know the patient was getting home care services, she stated "Through the client or the client's family." During an interview on 1/11/2021 at 10:50 AM, the alternate clinical director indicated they received wound clinic coordination/notes for all but one patient requested, and coordination of care with other entities involved with agency patients was not complete, and would be completed by 1/22/2021.	G 962		
G 966	Assure patient needs are continually assessed CFR(s): 484.105(c)(4) Assuring that patient needs are continually assessed, and This ELEMENT is not met as evidenced by: Based on record review and interview, the clinical director failed to ensure the registered nurse (RN) continually assessed and accurately described the patient's status, which led to new or worsening wounds, urinary tract infection, hospitalization, amputation, and/or death for 3 of 7 patients' records reviewed with wounds (#1, 7, and 9). This practice had the potential to affect all 11 patients identified with wounds. Findings include: 1. Review of an undated agency policy C-155	G 966		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 241	G 966		

copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised as often as the client's condition warrants due to a major decline or improvement in health status ... To identify decline or improvement ... are reassessed when significant changes occur in their condition ... [or] diagnosis ... [and] at least every fifty six to sixty (56-60) days ...."

Review of agency policy dated 6/2000 titled "Home Nursing Services Job Description: Registered Nurse" stated "... Becomes familiar with the diagnostic services available for home health care and follows the directions of the Clinical Director in utilizing these services to meet the needs of the client ... Documents fully and accurately to record a complete, total picure of the client's status and progress, and gives a complete synopsis of the care provided by the skilled registered nurse ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021.

Review of a document received on 12/28/2020 titled "SN [skilled nurse] SOC [start of care] OASIS and Comprehensive Assessment" dated 12/10/2019 evidenced the patient had no wounds, and was alert and oriented to person, place, and time, without confusion or disruptive behaviors.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 10/3/2020 (for certification period 10/5/2020-12/3/2020) evidenced the patient was fully oriented and able to make own decisions,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 242	G 966		

normal behavior, and had a wound on his right groin area. The document stated "... Right groin ... Irtritation [sic] from brief rubbing on the area ... scabbed over area ... measurements: 1x2 ... Overall, the level of function has been: Slowly deteriorating ... Does the physician-ordered plan of care include the following ... Interventions to prevent pressure ulcer (wound) ... [box checked] Yes ... now has home attendant from entity B [personal care services] ... and they are responsible for these services ... heavy smoker ... observed foul smelling wound to the groin. Area appears dark red in color with puss [sic]-like drainage present. Advised POA [power of attorney- family member] to keep all follow-up appointments with the wound clinic due to possible infection to the area ... complete depandence [sic] on nece [sic] for all care ... Any immediate concerns or issues to be resolved before next visit: No ... Next visit [skilled nurse] planned to occur: 11/3/2020 [one month later] ...." The document also evidenced a Braden scale was completed, with a score of 16 (patients with a total score of 16 or less are considered to be at risk for developing pressure ulcers; 15 or 16 = low risk, 13 or 14 = moderate risk, and 12 or less = high risk.) The assessment evidenced (but not limited to) the patient's skin was occasionally moist, requiring a linen change approximately once a day (score of 3), and evidenced the patient moved in bed and chair independently and could maintain good positioning in bed or chair (score 3). However, the assessment also evidenced the patient was incontinent of stool more often than once daily, which would require linen changes more than once daily (score 2 - skin is often, but not always moist), and he was a bilateral amputee and unable to sit unsupported, major physical limitations, was dependent for all

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 243	G 966		

personal care, and was unable to transfer self from bed to chair (score 1 - requires moderate to maximum assistance in moving). The adjusted score would have been 13 (moderate risk). The document failed to evidence wound diagnoses, failed to evidence the physician was contacted to report wound assessment findings (with possible infection), and wound treatment orders, failed to evidence entity B was contacted for care coordination regarding the wound and possible incorrect application of brief (too tight causing pressure/friction), and failed to evidence the niece (primary caregiver) was educated on signs or symptoms of infection (redness, heat, pain, foul odor, pus-like drainage, fever), wound care/treatment, or correct application of briefs, and failed to evidence a timely skilled nursing follow up visit was scheduled to re-assess the wound, ensure treatment orders were received, and the family member was competent in performing the treatment(s). No other wounds were identified during this assessment.

The clinical record contained a plan of care for the certification period of 12/4/2020 - 2/1/2021 which indicated orders for skilled nursing once per month for indwelling catheter change and system assessment with vital signs.

Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/3/2020 stated "... Client has a pressure ulcer on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs. These are both being treated by the [entity C- wound clinic]. At time of assessment, the wounds were covered and not able to be assessed ...." The document failed to evidence wound diagnoses or assessment.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 244 During an interview on 12/16/2020 at 2:16 PM, when asked if their clinic records evidenced communication or care coordination with Home Nursing Services, a staff member at entity C stated "I don't see any communication with home care ... not sure we even knew he had home health care." Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4). During an interview on 12/17/2020 at 3:44 PM, the comprehensive assessment for patient #1 dated 12/3/2020 was completed today (12/17/2020), and the plan of care was completed today (12/17/2020) and sent to the physician.	G 966		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 245	G 966		

Both were reviewed and approved by employee M (registered nurse) It was verified by the clinical director and the administrator that employee L (registered nurse) initiated the comprehensive assessment on 12/3/2020 but didn't complete it, and she did not assess the wounds. When asked, the clinical director agreed the certifying physician would not be able to provide/approve orders to meet the patient's needs without complete and accurate assessment findings. During this time, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No."

During an interview on 12/18/2020 at 1:00 PM, when asked who finished the comprehensive assessment dated 12/3/2020, the director of nursing stated "[employee N- registered nurse]." When asked if she was the nurse that initiated the comprehensive assessment on 12/3/2020, the director of nursing stated "No." When asked why employee L didn't complete the assessment, the director of nursing stated "We discovered she was behind, we wanted to get it done, so we sent it to [employee N]." She also indicated employee N saw the patient on 12/15/2020, and that visit represented completion of the comprehensive assessment dated 12/3/2020. When asked if the patient's electronic clinical record evidenced education for mitigation of pressure ulcers/wounds, the clinical director stated "No, but I can get the [paper portion] chart." Employee M retrieved it. When asked if the chart evidenced education for mitigation of pressure ulcers/wounds, employee M stated "No, looks like he goes to the wound clinic and they just advise him to keep his appointments."

During an interview on 12/18/2020 at 3:20 PM,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 246	G 966		

when asked which nurse did which portions of the comprehensive assessment dated 12/3/2020, the administrator stated "I can only tell [employee L] visited [the patient] on the 3rd, started writing [on the assessment on] 11th, [employee N] saw the patient on the 15th, and employee M reviewed and approved the assessment document on the 17th ... [employee M] signed the plan of care." The administrator also indicated he didn't know who did the wound assessments, or when the wounds were last assessed by staff. When asked if there had been any discipline for employee L, the administrator stated, "I don't know."

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today [12/22/2020] to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... His catheter bag [bag connected urine drain tube] was stuffed an opening [sic] in the side of his wheelchair. The urine in the tube was pale yellow with sediment present ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 247	G 966		

supplements of Vitamin C and Zinc for wound healing. She indicated they might have. Also asked about adding protein to the diet, niece indicated she did not remember for sure, maybe." The document failed to evidence wound diagnoses, failed to evidence the nurse and patient's niece scheduled a follow up visit to assess the wounds, failed to evidence the nurse followed up with the physician regarding orders for supplemental vitamins or additional protein diet, failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, and failed to evidence education was provided to the caregiver on proper placement of the urine drainage bag below the bladder to avoid urine back up into the bladder, which would increase risk of urinary tract infection.

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated patient #1 expired in the hospital on 12/27/2020.

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head." When asked why there was no follow up visit scheduled to assess the patient's wounds after 12/22/2020, she stated "... planned on going back after the holidays." When asked if it was appropriate to wait so long to assess wounds (as

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 248	G 966		

part of the comprehensive assessment), she stated "Yes ...." When asked if she spoke with the certifying physician after she saw the patient on 12/22/2020, she stated "No ma'am." When asked if she should speak with the certifying physician after completing a comprehensive assessment, she stated "If I find something that's different or out of the ordinary." When asked if it was out of the ordinary for the patient to resist/refuse assessment of vital signs and not interact with the nurse during the assessment on 12/22/2020, she indicated it was not out of the ordinary. However, all other clinical notes evidenced the patient was cooperative during skilled nursing visits. When asked if measurements from wound clinic documentation counted as part of her comprehensive assessment, she stated "No, but I was going to go back after the holiday." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted.

Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...."

Review of a document titled "Care Coordination Note" dated 12/28/2020 stated "... [nurse] made a visit on Tuesday [12/22/2020] ... The client was resistive of being touched and could not hear the conversation ... The client continued to be tired and not wanting to get out of bed on Wednesday [12/23/2020] ... niece called EMS to take the client to the hospital due to him not acting right ...."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 249	G 966		

Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020 ...."

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 10/30/2020 stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... 1 ... Stage 3 ... 1 ... Stage 1 ... 1 ... Location ... left foot (all toes) ... right foot ... all toes ... left upper coccyx ... HNS [name of agency] is not responsible for wound care ... Chronic UTI ... Yes ... Supra pubic [sic] catheter which is changed every two weeks ... Bedfast, unable to transfer and is unable to turn and position self ... unable to be up in a chair ..." The document failed to identify stage of each wound, assessment or measurements, or evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, or infection control teaching related to the urinary catheter. The document evidenced the patient had diagnoses (but not limited to) of history of stroke with left sided paralysis, indwelling urinary catheter, oxygen use for chronic lung disease, incontinent of bowel. The record failed to include diagnosis for wound on coccyx or other area(s).

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 250	G 966		

Review of a document dated 11/11/2020 titled "Skilled Nurse Visit Note" stated "... Urinating through penis and around [catheter] ... [after catheter change] ... Draining freely dark yellow, cloudy urine ...." The document failed to evidence wounds were assessed, failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown, or infection control teaching related to the urinary catheter, including (but not limited to signs and symptoms of clogged tubing or infection.

Review of a wound clinic document dated 11/24/2020 (obtained by the wound clinic, not from clinical record) titled "Wound Treatment #1 (Order 262060966)" stated "... Wash wound(s) with mild soap and water, then pat dry. Place Medihoney [wound bed ointment] and cover with ABD [surgical absorbent gauze pad]. Change dressing daily ... Home Healthcare to visit for wound care 2-3 [times] weekly and PRN [as needed] wound care/dressing changes ... left lower extremity ... right lower extremity ...." The agency record failed to evidence it provided skilled nursing visits 2-3 times weekly.

Review of a document dated 12/8/2020 titled "Skilled Nurse Visit Note" stated "...Location: left heel ... wound type: pressure ... date originally reported: 6/26/2020 ... Comments: wound remains to the left heel ... Location: BLE [bilateral lower extremities]; 4th toes and left heel ... Wound type: unknown ... Date originally reported: 12/8/2020 ... Purulence [thick and milky discharge from a wound, often indicates an infection and needs treatment as soon as possible] drainage and scant blood around suprapubic stoma/foley [insertion site on abdomen for direct access to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 251 bladder with urinary drainage tube] ...." The document failed to evidence wounds were assessed/measured or treated by the nurse, the physician was notified of new open area(s) and signs of infection at urinary insertion site, and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown or signs and symptoms of infection. Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... [blank] ... Stage 3 ... [blank] ... Unstageable [full thickness skin and tissue loss in which the extent of the damage within the ulcer cannot be determined due to scabbing or dead fibrous tissue; once removed to expose wound, a stage 3 or 4 would be revealed] ... Stage 1 ... 0 ... Does this patient have a stasis ulcer [ulcer caused by impaired circulation]? ... Yes ... Current number of Stasis Ulcers that are observable ... 3 ... status of most problematic ... Not Healing ... Location ... left second toe ... left third toe ... right second toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... Integument [skin] Impression: ... unstable ... in need of skilled intermittent care ... Will continue to monitor during regular visits, but not be a focus of care ... Will require a lot of attention ... Current possible UTI symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The document also evidenced the patient was a high risk for skin breakdown. The document failed to evidence the wounds were treated by the nurse, or education was provided to the caregiver to mitigate worsening or new skin breakdown.	G 966		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 252	G 966		

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician will added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was a high risk for skin breakdown, stated "... Does this patient have a stasis ulcer? ... Yes ... Current number of Stasis Ulcers that are observable ... 4 ... status of most problematic ... Not Healing ... Location ... right big toe ... right second toe ... left second toe ... left third toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... wife cleanses, applies medihoney dresses every other day and will see wound clinic 1/14/20 [sic] ...." The document failed to evidence contact precautions for VRE, skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 253	G 966		

wound healing, frequent turning schedule, or padding of bony prominences, or wound care was performed by the nurse. The document evidenced the certifying physician was contacted for orders, but the clinical record failed to evidence orders dated 1/5/2021.
Review of a document dated 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, applying an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received. Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated she did not know the name of the ointment the spouse applied to the wound(s).

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), the administrator, and the alternate administrator stated "... 1-10-2021, 12:20pm. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her home remedy for his back is working ... She does not need me to stop by today to help her ...." The document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified the wife was applying a home remedy to his wound(s). Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), employee D (medical records

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 254	G 966		

coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound with wounds, and a new wound that developed post-hospitalization, and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted.

4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 255	G 966		

1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document titled "SN Re-Cert [recertification] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 11/1/2020 "... right second toe amputation ... Non-removable dressing present. Wound managed by orthopedics ... Report any abnormal findings to VA [veterans affairs] MD ... skilled nurse ... physical assessment ... and notify MD of any abnormal findings ... had his right second toe amputated ... His 3rd right toe is black and shriveled ...." The document also evidenced the patient had diagnoses (but not limited to) atherosclerotic heart disease (hardening of the arteries causing impaired circulation), and diabetes with diabetic neuropathy (diabetes with damage to nerves in your legs and feet, causing pain and numbness in your legs and feet). The document failed to evidence the physician was notified of the change in condition of the wound.

Review of a document dated 11/2/2020 titled "Skilled Nurse Visit Note" stated "... Right second toe amputation site not healing. 3rd toe black and very painful ...." The document failed to evidence the nurse measured the wounds, performed wound care, or notified the physician for the change in the patient's integumentary or pain status.

Review of a document dated and signed by employee M 11/16/2020 titled "Skilled Nurse Visit Note" stated "... "posterior foot blackening about an 1 1/2 inch on ball of right foot, 3rd toe black and shriveled, outer edge of 5th toe; see diagram" The clinical record failed to evidence a diagram of the wound, or failed to evidence the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 256	G 966		

physician was notified of the declining wound status.

During an interview on 1/6/2021 at 3:56 PM, when asked if the doctor should have been notified of the change in wound status on 11/16/2020, the alternate clinical director stated "He should be, I don't know if she did call." When asked if this failure to contact the physician could have potentially led to a negative outcome for the patient, she stated "Yes."

Review of a document dated and signed by employee M on 11/30/2020 titled "Skilled Nurse Visit Note" stated "...: "No fever, No cough, No complaints, Right foot, big toe starting to blacken, middle toe black and shriveled. Per wife, US [ultrasound] showed multiple blockages and patient may lose foot d/t [due to] occlusions ...." The document failed to evidence the physician was notified of the declining wound status.

Review of a document dated and signed by employee M on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE [right lower extremity] Femoral Endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain. Pain 10/10. Taking Norco for pain. 2 weeks of meds set-up. 100% medication compliant. The document failed to evidence the physician was notified of the declining wound status or severe pain.

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 257	G 966		

client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence the agency coordinated with the hospital to provide patient's current status or request hospital records.

Review of a document titled "Skilled Nurse Visit Note" dated 12/28/2020 stated "... returned from hospital S/P [after] Right femoral endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] and Right partial amputation of foot. Right groin incision C/D/I [clean, dry, and intact] no redness, no draining, no swelling. OTA [open to air]. Right foot dressing C/D/I with orders not to remove same until f/u [follow up] with Podiatry 1/4/21. Plavix [medication to prevent formation of blood clots and to keep blood vessels open after surgical procedures, and may cause easy bleeding/bruising] ... added to medication regimine [sic] ... Client is NWB [non-weight bearing] R foot ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document dated 12/28/2020 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which previously had not been identified), and the nurse

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 258	G 966		

failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the nurse instructed on non-weight bearing status to the right foot, which could potentially have a negative outcome on the surgical healing process, failed to evidence the nurse assessed the left second toe pain, and failed to evidence the physician was notified.

Review of a document dated 12/28/2020 titled "SN ROC OASIS and Comprehensive Assessment" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without devices in his home ... Has had no ... hospitalizations ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/28/2020 (additional document for same nurse visit same day) stated "... Pain Assessment: ...

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 259	G 966		

right foot. Severity (0-10), 6 ... Cardiovascular Assessment: ... blood thinners ... Plavix ... Integumentary [skin] Assessment: No issues noted ... incisions ... open to air ... right foot ... surgical dressing in place ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection, nutritional requirements for wound healing, or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and recertification care orders.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 1/1/2021 - 3/1/2021 stated "... [skilled nursing orders] ... one visit ... every 2 weeks ... medication tray set-up, to monitor compliance ... physical assessment, and report any abnormal findings to MD ...." The document failed to evidence skilled nursing interventions such as wound care/treatments, patient/family education for wound care/treatment, interventions to mitigate new or worsening skin breakdown, appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, or signs and symptoms of infection, nutritional requirements for wound healing or other indications that should be reported to the agency and/or physician.

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 260	G 966		

patient/caregiver upon hospital discharge on 12/28/2020), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.

During an interview on 1/6/2021 at 3:56 PM, the clinical director and alternate clinical director confirmed the skilled nursing frequency remained every two weeks since hospital discharge. When asked if waiting two weeks to see this patient could lead to a potentially negative outcome, they both stated "Yes."

During an interview on 1/12/2021 at 1:50 PM, regarding the skilled nursing visit on 11/16/2020, employee M indicated she did not contact the physician, he was already aware, it (the wound/blackening of toe/foot) started as just the tip, and it was an ongoing process; regarding the skilled nursing visit on 12/14/2020, she stated "I did not call the physician ...."

During the entrance conference on 12/15/2020 at 11:00 AM, when asked how the agency determined when there has been a major decline or improvement in the patient's health status, the clinical director stated, "Through nursing assessment."

During an interview on 12/18/2020 at 1:00 PM, when asked the purpose of the comprehensive assessment, the clinical director stated, "To develop the plan of care." When asked if it was her expectation for staff to look at entire head to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 966	Continued From page 261 toe for comprehensive assessment, the clinical director stated, "Yes."	G 966		
G 968	Assure implementation of plan of care CFR(s): 484.105(c)(5) Assuring the development, implementation, and updates of the individualized plan of care. This ELEMENT is not met as evidenced by: Based on record review and interview, the clinical director failed to ensure all patients' records identified that had wounds, or were high risk for skin breakdown, included skilled nursing interventions such as wound care/treatments, patient/family education for wound car/treatment, care coordination/orders from physicians or wound clinics, or interventions to mitigate new or worsening skin breakdown that led to new or worsening wounds, urinary tract infection, hospitalization, amputation, and/or death for 3 of 7 patients' records reviewed with wounds (#1, 7, and 9). This practice had the potential to affect all 11 patients identified with wounds. Findings include: 1. Review of an undated copyrighted Briggs Healthcare policy C-580 titled "Plan of Care" stated "... Home Nursing Services staff to develop a plan of care individualized to meet [patient] specific identified needs ... to include ... specific procedures ... medications, treatments, and procedures ... other appropriate items ... professional staff shall promptly alert the physician to any changes that suggest a need to alter the Plan of Care ...." Review of an undated copyrighted Briggs Healthcare policy C-100 titled "Services Provided"	G 968		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 262	G 968		

stated "... Services will be coordinated by the Registered Nurse managing the care. This will include implementing, revising, and updating the Plan of Care; physician conferencing ... conferencing with health team members to plan and evaluate client [patient] care ...."

Review of an undated copyrighted Briggs Healthcare policy C-360 titled "Coordination of Client Services" stated "... to ensure appropriate, quality care is being provided to clients ... to establish effective interchange, reporting and coordination of client care does occur ... Coordination with other agencies and institutions ... alert physician to changes in client condition ...."

Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Skilled Nursing Services" stated "... Skilled nursing services will be provided ... In determining whether a service requires the skills of a Nurse, the inherent complexity of the service, condition of the client ... Regularly reevaluates the client needs ... Initiates the Plan of Care and necessary revisions and updates to the plan of care ... Provides services requiring specialized nursing skill and initiates appropriate preventive and rehabilitative nursing procedures ... Informs the physician and other personnel of changes in the client condition and needs ... Counsels the client and family/caregivers in meeting their needs ... Prepares clinical and progress notes ...."

2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 263	G 968		

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 10/5/2020 - 12/3/2020 stated "... SN [skilled nurse] monthly for full assessment with vital signs and ... foley catheter change ... Coordination of Care: SN will report changes in condition to MD, Client has Home attendant services from [entity B] and they are responsible for these services [personal care and hygiene] ... friendly and pleasant during visit ... catheter ... draining thick, dark, gold-colored urine ... Foul smelling wound to the groin remains ... Advised POA [power of attorney] to have MD [physician] assess wound at appointment next week ...." The plan of care failed to evidence care coordination with the physician, entity B, or wound clinic, and failed to evidence skilled nursing interventions to mitigate wound status or prevention of new pressure sores or urinary tract infection.

Review of a document titled "Skilled Nurse Visit Note" dated 11/5/2020 stated "... Skin/Wounds ... Turgor [skin elasticity] [box checked] Poor [clinical indication of dehydration] ... [box checked] See Wound Location Assessment ... Hydration adequate [box checked] No ...." The document failed to evidence the physician was contacted for potential dehydration or wound treatment orders.

Review of a document titled "Wound Location Assessment" dated 11/5/2020 stated "... Location: left [sic] groin ... Wound type: unknown ... Date originally reported: 2/3/2020 ... Comments: Small open area to the right groin area ... Client is being treated at the wound clinic for this wound ... Location: left buttocks ... Wound type: Pressure ... Date originally reported: 4/3/2020 ... Small reddened area on the buttocks ... Area is healed

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 264 ...." The document failed to evidence wound measurements, the physician was contacted for change in wound status, or education was provided to the caregiver to mitigate worsening or new skin breakdown. Review of a document titled "Skilled Nurse Visit Note" dated 12/3/2020 stated "... Heart sounds ... [box checked] Regular ... Skin/Wounds ... Turgor: [box checked] Poor ... [box checked] See Wound Location Assessment ... encouraged to increase fluids ... Hydration adequate [box checked] No ...." The document failed to evidence the physician was contacted for ongoing potential dehydration, wound treatment orders, or education was provided to the caregiver to mitigate worsening or new skin breakdown or signs and symptoms of dehydration to report to agency or physician. Review of a document titled "Wound Location Assessment" dated 12/3/2020 stated "... Location: left [sic] groin ... Wound type: unknown ... Date originally reported: 2/3/2020 ... Comments: Small open area to the right groin area ... Treatments to the area continue with [entity C- a wound clinic] ... Location: left buttocks ... Wound type: Pressure ... Date originally reported: 4/3/2020 ... Small reddened area on the buttocks ... Treatments to the area continue by family at home following wound clinic orders ...." The document failed to evidence wound measurements, the physician was contacted for change in wound status, or wound treatment orders. Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/3/2020 stated "... Client has a pressure ulcer	G 968		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 265	G 968		

on the bottom of his left stump and a friction ulcer from in his right groin from where his brief rubs. These are both being treated by the [entity C]. At time of assessment, the wounds were covered and not able to be assessed ...." The document failed to evidence care coordination with entity C or the physician for new home care orders, which included but not limited to wound care orders.

During an interview on 12/16/2020 at 2:16 PM, when asked if their clinic records evidenced communication or care coordination with Home Nursing Services, a staff member at entity C stated "I don't see any communication with home care ... not sure we even knew he had home health care."

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4),

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 266	G 968		

and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

Review of a document received on 12/28/2020 at 12:01 PM dated 12/22/2020 titled "Follow Up Assessment (FUA) Non-Recert OASIS" stated "... A general assessment was completed due to the findings of the State ... This client uses HNS [Home Nursing Services] for a monthly catheter change ... The physician or family have not requested the assistance of this agency for his wounds ... The state feels that HNS should be involved in the wound care. The state wants total client care not just cath [catheter] care ... The client went today to the clinic and the niece declined to allow this nurse to visualize the wounds ... The niece stated that an appointment [with agency nurse] can be set up to see wounds at a further date ... The niece changes the dressings daily to the wounds, she state [sic] the wounds look the same to her except this morning the area to the stump had changed for the worse ... Writer [registered nurse] asked [niece] if the clinic recommended about adding vitamins and supplements of Vitamin C and Zinc for wound healing. She stated they might have. Also asked about adding protein to the diet, niece stated she does not remember for sure, maybe ...." The document failed to evidence the nurse and patient's niece scheduled a follow up visit to assess the wounds, failed to evidence the nurse followed up with the physician regarding orders for supplemental vitamins or additional protein diet, and failed to evidence education was provided to the caregiver to mitigate worsening or new skin breakdown.

During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 267 indicated patient #1 expired in the hospital on 12/27/2020. During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head." When asked why there was no follow up visit scheduled to assess the patient's wounds after 12/22/2020, she stated "... planned on going back after the holidays." When asked if it was appropriate to wait so long to assess wounds (as part of the comprehensive assessment), she stated "Yes ...." When asked if she spoke with the certifying physician after she saw the patient on 12/22/2020, she stated "No ma'am." When asked if she should speak with the certifying physician after completing a comprehensive assessment, she stated "If I find something that's different or out of the ordinary." When asked if measurements from wound clinic documentation counted as part of her comprehensive assessment, she stated "No, but I was going to go back after the holiday." During this time, when asked the last time wounds were assessed by agency nurses, the clinical director stated "I don't have that information. I'd have to look." No further information was submitted. Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency)	G 968		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 268	G 968		

OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...."

Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020 ...."

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 11/1/2020 - 12/30/2020 stated "... [skilled nursing orders] 1 visit every other week ... physical assessment ... and to change suprapubic catheter ... with each skilled nursing visit ... report any abnormal findings to [physician] ... RHHA [respite home health aide] up to 60 hr/month ... catheter care ... open area on coccyx that is being treated by the wound clinic ...." the document failed to evidence current wound care orders, wounds listed on comprehensive assessment (left foot- all toes, right foot- all toes), and failed to evidence skilled nursing interventions to mitigate wound status or prevention of new pressure sores, and failed to educate patient/caregiver on signs and symptoms of urinary tract infection, and when to notify

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 269 agency/physician. Review of a document dated 11/11/2020 titled "Skilled Nurse Visit Note" failed to evidence wounds were assessed, and failed to evidence education was provided to the caregiver to mitigate worsening, signs and symptoms of infection, dehydration, urinary tract infections or new skin breakdown. Review of a wound clinic document dated 11/24/2020 (obtained by the wound clinic, not from clinical record) titled "Wound Treatment #1 (Order 262060966)" stated "... Wash wound(s) with mild soap and water, then pat dry. Place Medihoney [wound bed ointment] and cover with ABD [surgical absorbent gauze pad]. Change dressing daily ... Home Healthcare to visit for wound care 2-3 [times] weekly and PRN [as needed] wound care/dressing changes ... left lower extremity ... right lower extremity ...." The agency record failed to evidence it provided skilled nursing visits 2-3 times weekly. Review of a document dated 12/8/2020 titled "Skilled Nurse Visit Note" stated " Client had urine from penis, has yellow purulence around foley [sic- suprapubic catheter insertion site] ...Location: left heel ... wound type: pressure ... date originally reported: 6/26/2020 ... Comments: wound remains to the left heel ... Location: BLE [bilateral lower extremities]; 4th toes and left heel ... Wound type: unknown ... Date originally reported: 12/8/2020 ...." The document failed to evidence wounds were assessed/measured or treated by the nurse, the physician was notified of new open area(s), and failed to evidence education was provided to the caregiver to mitigate worsening, signs and symptoms of	G 968		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 968	Continued From page 270	G 968		

infection, dehydration, urinary tract infections or new skin breakdown.

Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage ... Stage 2 ... [blank] ... Stage 3 ... [blank] ... Unstageable [full thickness skin and tissue loss in which the extent of the damage within the ulcer cannot be determined due to scabbing or dead fibrous tissue; once removed to expose wound, a stage 3 or 4 would be revealed] ... Stage 1 ... 0 ... Does this patient have a stasis ulcer [ulcer caused by impaired circulation]? ... Yes ... Current number of Stasis Ulcers that are observable ... 3 ... status of most problematic ... Not Healing ... Location ... left second toe ... left third toe ... right second toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... Integument [skin] Impression: ... unstable ... in need of skilled intermittent care ... Will continue to monitor during regular visits, but not be a focus of care ... Will require a lot of attention ... Current possible UTI symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The document also evidenced the patient was a high risk for skin breakdown. The document failed to evidence the wounds were treated by the nurse, or education was provided to the caregiver to mitigate worsening or new skin breakdown.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 12/31/2020 - 2/28/2021 stated "... [skilled nursing orders] 1 visit every other week x 9 weeks ... System assessment with each skilled nursing visit ... full head to toe

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 968	Continued From page 271	G 968		

assessment ... change suprapubic catheter ... RHHA up to 60hr ... catheter care ... Teach/train in proper positioning to reduce pressure on pressure prone areas ... Assess wound for infection and healing ...." The document failed to evidence current wound care orders or treatment performed by nurse, all wounds listed on comprehensive assessment, and failed to evidence skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote wound healing, frequent turning schedule, or padding of bony prominences, signs and symptoms of UTI, and catheter management.

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021. The document also evidenced the patient had chronic wounds to both feet, inadequate protein intake related to foot wounds and diabetes, need for more protein to assist wound healing, dietician will added Juven (nutritional supplement) twice daily to assist wound healing. No wounds on back/coccyx were evidenced in the documentation. The document also evidenced the patient required contact isolation (frequent handwashing and disinfection of bathroom) due to VRE (Vancomycin Resistant Enterococcus Infection) of the urine.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 272	G 968		

Review of a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient was a high risk for skin breakdown, stated "... Does this patient have a stasis ulcer? ... Yes ... Current number of Stasis Ulcers that are observable ... 4 ... status of most problematic ... Not Healing ... Location ... right big toe ... right second toe ... left second toe ... left third toe ... left foot (all toes) ... right foot (all toes) ... left upper coccyx ... wife cleanses, applies medihoney dresses every other day and will see wound clinic 1/14/20 [sic] ...." The document failed to evidence contact precautions for VRE, skilled nursing interventions to mitigate wound status or prevention of new pressure sores such as specialized diet and supplements to promote wound healing, frequent turning schedule, or padding of bony prominences, or wound care was performed by the nurse. The document evidenced the certifying physician was contacted for orders, but the clinical record failed to evidence orders dated 1/5/2021.
Review of a document dated 1/8/2021 titled "Skilled Nursing Visit Note" evidenced documentation of wounds on right big toe, left 2nd toe, left heel, and back left buttock, and indicated the wife performed the wound care, applying an ointment to the wounds. The document failed to evidence the physician was notified of the new wound(s), or new orders were received.

Review of an email document dated 1/11/2021 at 9:49 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), the administrator, and the alternate administrator stated "... 1-10-2021, 12:20pm. I spoke with [patient's wife], regarding his new wound on his back. She said he is fine ... Her

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 273	G 968		

home remedy for his back is working ... She does not need me to stop by today to help her ...." The document failed to identify the ingredient(s) of the "home remedy", or that the physician was notified the wife was applying a home remedy to his wound(s). Additionally, during the exit interview on 1/12/2021 at 2:50 PM, the clinical director indicated the home remedy was urine.

Review of an email document dated 1/11/2021 at 10:12 AM from the clinical director to employee C (registered nurse), employee M (registered nurse), employee D (medical records coordinator), employee H (office staff), the administrator, and the alternate administrator, stated "... new wound on left lower back reported to [wound clinic] ... [wound clinic] ordered daily wound care starting today ...." The clinical record failed to evidence a wound care order with increased skilled nursing frequency dated 1/11/2021.

During an interview on 1/11/2021 at 2:23 PM, when asked if the agency requested and received hospital paperwork for admission on 1/2/2021, the alternate director of nursing stated "I don't know. I don't know if she [assessing nurse on 1/5/2021] called the hospital." When asked if the agency did any coordination with the hospital to obtain the hospital paperwork, she stated "I didn't." When asked where the resumption of care orders (1/5/2021) were located, she indicated they were in the comprehensive assessment. The record failed to evidence a physician's order. When asked what kind of bed the patient had (he was bedbound and would benefit from a specialized mattress to decrease risk of skin breakdown), the clinical and alternate clinical directors both indicated they did not know.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 968	Continued From page 274 During an interview on 1/12/2021 at 10:50 AM, the alternate clinical director stated a nurse was going to see the patient today (1/12/2021), and she still did not know what kind of mattress the patient had. Upon exit, no further information was submitted. 4. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021. Review of a document titled "SN Re-Cert [recertification] OASIS [outcome and assessment information set] and Comprehensive Assessment" dated 11/1/2020 "... right second toe amputation ... Non-removable dressing present. Wound managed by orthopedics ... Report any abnormal findings to VA [veterans affairs] MD ... skilled nurse ... physical assessment ... and notify MD of any abnormal findings ... had his right second toe amputated ... His 3rd right toe is black and shriveled ...." The document also evidenced the patient had diagnoses (but not limited to) atherosclerotic heart disease (hardening of the arteries causing impaired circulation), and diabetes with diabetic neuropathy (diabetes with damage to nerves in your legs and feet, causing pain and numbness in your legs and feet). The document failed to evidence the physician was notified of the change in condition of the wound. Review of a document dated 11/2/2020 titled "Skilled Nurse Visit Note" stated "... Right second toe amputation site not healing. 3rd toe black and very painful ...." The document failed to evidence the nurse measured the wounds, performed wound care, or notified the physician for the	G 968		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 275	G 968		

change in the patient's integumentary or pain status.

Review of a document dated and signed by employee M 11/16/2020 titled "Skilled Nurse Visit Note" stated "... "posterior foot blackening about an 1 1/2 inch on ball of right foot, 3rd toe black and shriveled, outer edge of 5th toe; see diagram" The clinical record failed to evidence a diagram of the wound, or failed to evidence the physician was notified of the declining wound status.

During an interview on 1/6/2021 at 3:56 PM, when asked if the doctor should have been notified of the change in wound status on 11/16/2020, the alternate director of nursing stated "He should be, I don't know if she did call." When asked if this failure to contact the physician could have potentially led to a negative outcome for the patient, she stated "Yes".

Review of a document dated and signed by employee M on 11/30/2020 titled "Skilled Nurse Visit Note" stated "...: "No fever, No cough, No complaints, Right foot, big toe starting to blacken, middle to black and shriveled. Per wife, US [ultrasound] showed multiple blockages and patient may lose foot d/t [due to] occlusions ...." The document failed to evidence the physician was notified of the declining wound status.

Review of a document dated and signed by employee M on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE Femoral Endarterectomy on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain. Pain 10/10.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 276	G 968		

Taking Norco for pain. 2 weeks of meds set-up. 100% medication compliant. The document failed to evidence the physician was notified of the declining wound status or severe pain.

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence the agency coordinated with the hospital to provide patient's current status or request hospital records.

Review of a document titled "Skilled Nurse Visit Note" dated 12/28/2020 stated "... returned from hospital S/P [after] Right femoral endarterectomy [a surgical procedure to remove plaque inside the superficial femoral artery] and Right partial amputation of foot. Right groin incision C/D/I [clean, dry, and intact] no redness, no draining, no swelling. OTA [open to air]. Right foot dressing C/D/I with orders not to remove same until f/u [follow up] with Podiatry 1/4/21. Plavix [medication to prevent formation of blood clots and to keep blood vessels open after surgical procedures, and may cause easy bleeding/bruising] ... added to medication regimine [sic] ... Client is NWB [non-weight bearing] R foot ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G 968	Continued From page 277	G 968		

was notified for report and resumption of care orders.

Review of a document dated 12/28/2020 titled "Pain Location Assessment" evidenced the patient now had left second toe pain (which previously had not been identified), and the nurse failed to evidence further pain/physical assessment of the toe. The document also evidenced right foot (surgical) pain, and stated "... almost constantly ... sharp ... throbbing ... Intensity 5 [pain scale 0-10, with 0 being no pain, 10 being worst/most severe pain ever] ... worst pain over last 48 hours 10 ... best pan over last 48 hours 5 ... What makes pain worse? ... [box checked] Activity with affected area ... Changing position ... Comments ...." The document failed to evidence the nurse instructed on non-weight bearing status to the right foot, which could potentially have a negative outcome on the surgical healing process, failed to evidence the nurse assessed the left second toe pain, and failed to evidence the physician was notified.

Review of a document dated 12/28/2020 titled "SN ROC OASIS and Comprehensive Assessment" (additional document for same nurse visit same day) stated "... had his right second toe amputated ... ambulates without devices in his home ... Has had no ... hospitalizations ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 278	G 968		

was notified for report and resumption of care orders.

Review of a document titled "SN Re-Cert OASIS and Comprehensive Assessment" dated 12/28/2020 (additional document for same nurse visit same day) stated "... Pain Assessment: ... right foot. Severity (0-10), 6 ... Cardiovascular Assessment: ... blood thinners ... Plavix ... Integumentary [skin] Assessment: No issues noted ... incisions ... open to air ... right foot ... surgical dressing in place ...." The document failed to evidence the nurse educated the patient/caregiver on appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, nutritional requirements for wound healing, signs and symptoms of infection or other indications that should be reported to the agency and/or physician, and failed to evidence the physician was notified for report and resumption of care orders.

Review of a document titled "Home Health Certification/Recertification Plan of Care Order" for certification period 1/1/2021 - 3/1/2021 stated "... [skilled nursing orders] ... one visit ... every 2 weeks ... medication tray set-up, to monitor compliance ... physical assessment, and report any abnormal findings to MD ...." The document failed to evidence skilled nursing interventions such as wound care/treatments, patient/family education for wound care/treatment, interventions to mitigate new or worsening skin breakdown, appropriate post-surgery instructions/precautions such as (but not limited to) non-weight bearing status and other physical restrictions, bleeding precautions, nutritional requirements for wound

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 279	G 968		

healing, or signs and symptoms of infection or other indications that should be reported to the agency and/or physician.

During an interview on 1/5/2021 at 1:29 PM person F (staff at entity E) indicated the patient was seen 1/4/2021 for surgical follow up. When asked if she received any communication/coordination from the agency, she stated "On 12/29 [2020] we got a call from [employee M] to request PT/OT [physical and occupational therapy] order. That's the only thing I see ...."

Review of documents received from person E (Podiatrist) on 1/5/2021 at 2:04 PM (not part of agency clinical record) included hospital discharge paperwork (given to the patient/caregiver upon hospital discharge on 12/28/2021), which indicated (but not limited to) the patient was not to bear weight on the right foot, and post-surgical education/instructions/limitations. Also included was a document dated 1/4/2021 titled "Progress Notes", which indicated (but not limited to) the patient was to continue to remain non-weight bearing on the right foot.

During an interview on 1/6/2021 at 3:56 PM, the clinical director and alternate clinical director confirmed the skilled nursing frequency remained every two weeks since hospital discharge. When asked if waiting two weeks to see this patient could lead to a potentially negative outcome, they both stated "Yes."

During an interview on 1/12/2021 at 1:50 PM, regarding the skilled nursing visit on 11/16/2020, employee M indicated she did not contact the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 968	Continued From page 280 physician, he was already aware, it (the wound/blackening of toe/foot) started as just the tip, and it was an ongoing process; regarding the skilled nursing visit on 12/14/2020, she stated "I did not call the physician ...."	G 968		
{G 972}	Report all branch locations to SA CFR(s): 484.105(d)(1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch. This ELEMENT is not met as evidenced by: Based on observation, record review, and interview, the home health agency failed to report a branch location to the state survey agency for 1 of 1 branch locations observed. Findings include: Review of a plan of corrections from a survey conducted on this agency completed 8/27/2020 stated "... The agency does not maintain branch locations, and instead operates convenience sites for employees ... No agency employees will be based in the branch offices of [entity K -a personal services agency (PSA), with same owners as agency being surveyed] ...." During the entrance conference on 12/15/2020 at 11:00 AM, the clinical director indicated the agency had no branch offices. During an interview on 12/15/2020 at 4:02 PM, the alternate clinical director submitted 2 untitled calendars dated 12/2020. She indicated they represented the agency's on call schedules,	{G 972}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 972}	Continued From page 281	{G 972}		

indicated one was for the "north area", and one was for the "south area". When asked the difference between the north and south areas, she stated "Oh, that's just [entity K] up there ... no charts there ... Like a nurse might go in there to chart or whatever." The "north" on call schedule evidenced employee L was on call 12/1/2020 through 12/31/2020.

During a home visit with patient #9 on 12/30/2020 at 9:45 AM, the patient indicated he was unaware his nurse (employee K -licensed practical nurse who regularly saw patient #9) worked for Home Nursing Services, and he thought all the staff coming to his house worked "locally" at entity K.

During an on-site visit to a branch office of entity K on 12/30/2020 at 11:20 AM, the surveyor observed 3 Home Nursing Services cars in the parking lot of the entity. Person I (Director from entity K) indicated 1 car was a "spare", 1 car was dropped off by employee L (a registered nurse who was recently terminated), and employee C (registered nurse with Home Nursing Services) was "here now" charting, which accounted for the third car. Person I also indicated there were no Home Nursing Services clinical records at this location, and stated "... They're all in Fort Wayne." During a tour of the branch office, person I opened an unlocked door to an office which evidenced multiple unsecured documents and folders which contained Home Nursing Services' patients' clinical documents sitting on top of desks. Greater than 40 documents and/or folders were observed, with some being copies, and some being original clinical record documents, dating back to 06/2020. Person I pointed to a desk and stated "That's [employee L's] desk ... This is the office/room for Home Nursing

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 972}	Continued From page 282 Services. I don't really mess with this stuff ....", and acknowledged Home Nursing Services employees worked in this space. During an interview on 12/30/2020 at 2:38 PM, the clinical director acknowledged patient clinnical documents were at entity K's branch location in Auburn, and stated they were "... just nurses' copies." She also agreed the documents should be removed from that location. A review of the agency's Electronic Medical Record (EMR) was conducted on 1/6/2021 at 12:38 PM. The EMR evidenced directions to patient #9's house with a starting point from entity K During an interview on 1/12/2021 at 11:54 AM, employee K (licensed practical nurse who regularly saw patient #9) stated "I use the auburn [branch]." During the exit conference on 1/12/2021 at 2:50 PM, the clinical director indicated the patient records were not removed from entity K's Auburn branch.	{G 972}		
{G 980}	Primary HHA is responsible for patient care CFR(s): 484.105(e)(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to assume primary responsibility care of its patients, and failed to provide all needed services and or treatments for 3 of 10	{G 980}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 980}	Continued From page 283	{G 980}		

records reviewed. (#1, 3, 7), and 1 document submitted for a patient without record review (#11). This practice had the potential to affect all agency patients.

Findings include:

1. Review of an undated agency policy C-120 copyright Briggs Healthcare titled "Admission Policy" stated "... Clients are accepted for treatment in the home on the basis of reasonable criteria and under the expectation that the client's medical, nursing, and social needs can be met adequately by Home Nursing Services in the client's place of residence ...."

Review of an undated agency policy C-100 copyright Briggs Healthcare titled "Services Provided" stated "... All services not furnished directly, are monitored and controlled by the parent Home Nursing Services ...."

2. The clinical record of patient #1, start of care 12/10/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "SN [skilled nurse] Re-Cert [recertification] OASIS [Outcome and Assessment Information Set] and Comprehensive Assessment" dated 12/3/2020 evidenced skilled nursing monthly for indwelling catheter change and physical assessment, report any abnormal findings to MD, evidenced the patient had a wound, and evidenced the niece lived with the patient and was his primary caregiver.

Review of a document dated 12/17/2020 titled "Coordination of Care Between Entities" evidenced Home Nursing Services (HNS) designated entity P (a state funded program,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 980}	Continued From page 284	{G 980}		

which allows a non-skilled caregiver, such as, but not limited to, adult children of aging parents to receive compensation for having their aging parent live with them and being their primary caregiver) as the primary entity, and identified HNS as the secondary entity (not primarily responsible for the patient). Entity P was the niece of the patient, and was a non-skilled caregiver. The agency failed to assume primary responsibility for care of this patient.

3. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, personal care, and evidenced the patient lived in a group home.

Review of a document dated 12/17/2020 titled "Coordination of Care Between Entities" evidenced HNS designated entity O (a group home with non-skilled caregivers) as the primary entity, and identified HNS as the secondary entity (not primarily responsible for the patient). The agency failed to assume primary responsibility for care of this patient.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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 980}	Continued From page 285 4. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021 evidenced a document titled "SN ROC OASIS and Comprehensive Assessment" dated 1/5/2021 evidenced the patient received, but not limited to, skilled nursing every other week to complete a full head to toe assessment,vital signs, and change the patient's suprapubic catheter (a tube inserted into an opening in the lower abdomen directly into the bladder to drain urine), and home health aide (HHA) services for personal care "up to 60 hours", and evidenced the patient had wounds. Review of a document dated 12/21/2020 titled "Coordination of Care Between Entities" evidenced HNS designated entity Q (a wound clinic) as the primary entity, and identified HNS as the secondary entity (not primarily responsible for the patient). The agency failed to assume primary responsibility for care of this patient. 5. Review of an agency clinical document for patient #11 (no clinical record review) received from the alternate clinical director on 1/28/2020 at 11:25 AM dated 12/21/2020 titled "Coordination of Care Between Entities" evidenced HNS designated entity Q (a wound clinic) as the primary entity, and identified HNS as the secondary entity (not primarily responsible for the patient). The agency failed to assume primary responsibility for care of this patient.	{G 980}		
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	G1012		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1012	Continued From page 286	G1012		

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 all patients current comprehensive assessments, including all of the comprehensive assessments were present in the clinical records for 3 of 10 records reviewed (#2, 3, 6).

Findings include:

1. Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Skilled Nursing Services" stated "... Skilled nursing services will be provided ... In determining whether a service requires the skills of a Nurse, the inherent complexity of the service, condition of the client ... Prepares clinical and progress notes ...."

Review of an undated agency policy C-155 copyright Briggs Healthcare titled "Client Reassessment/Update of Comprehensive Assessment" stated "... Comprehensive Assessment will be updated and revised as often as the client's condition warrants due to a major decline or improvement in health status ... To identify decline or improvement ... are reassessed when significant changes occur in their condition ... [or] diagnosis ... [and] at least every fifty six to sixty (56-60) days ...."

2. The clinical record of patient #2, start of care 9/23/2019, was reviewed on 12/18/2020, and again on 1/12/2021 evidenced a document titled "Home Health Certification/Recertification Plan of Care Order" for dates 11/16/2020 - 1/14/2021. The document evidenced the patient received (but not limited to) skilled nursing services to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1012	Continued From page 287	G1012		

administer a bowel program (insertion of rectal suppository to facilitate a bowel movement), and to perform wound care to a stage 4 (full thickness with tendon and/or bone exposed) pressure injury to the left buttock. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

3. The clinical record review of patient #3, start of care date 1/21/2003, was completed on 1/12/2021, which evidenced documents titled "Home Health Certification/Recertification Plan of Care Order" for dates 10/18//2020 - 12/16/2020, and dates 12/17/2020 - 2/14/2021. The documents evidenced the patient received skilled nursing services (but not limited to) for tracheostomy (an incision in the windpipe made to relieve an obstruction to breathing) care, g-tube (tube inserted through the wall of the abdomen directly into the stomach. It allows air and fluid to leave the stomach and can be used to give drugs and liquids, including liquid food, to the patient.), administer medications via g-tube, breathing treatments via nebulizer machine, and personal care. The record failed to evidence any comprehensive assessments or comprehensive re-assessments were performed by a registered nurse.

4. The clinical record of patient #6 was reviewed on 1/12/21 and indicated a start of care date of 8/8/20. The record contained a plan of care for the certification period of 12/4/21-2/1/21 which failed to evidence a comprehensive assessment or comprehensive re-assessment was completed.

During an interview on 12/28/20 at 3:20 PM, while

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1012	Continued From page 288 reviewing the patient's EMR (electronic medical record), employee E (administrator) agreed no comprehensive assessments on patient #6 were performed and present in the EMR for the past 3 certification periods (180 days).	G1012		
G1022	Discharge and transfer summaries CFR(s): 484.110(a)(6)(i-iii) (i) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient's discharge; or (ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or (iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer. This ELEMENT is not met as evidenced by: Based on record review and interview, the agency failed to ensure a completed transfer summary was sent to the physician or receiving facility within 2 business days of a planned transfer, or a completed transfer summary was sent to the physician or receiving facility within 2 business days of becoming aware of an unplanned transfer, for 3 of 3 records reviewed with patient transfers to an inpatient facility (#1, 7, 9), and 1 of 1 patients (without clinical record review) identified during an interview who was previously hospitalized, and subsequently sent back to the emergency room (#11).	G1022		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

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HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1022	Continued From page 289	G1022		

Findings include:

1. Review of an undated copyrighted Briggs Healthcare policy C-840 titled "Transfer Policy" stated "... A client may be transferred ... identified need that cannot be met by Home Nursing Services ... A transfer summary shall be completed by the registered nurse ... form shall be sent to the new provider or facility ... a copy shall be retained for the client's chart ... discussed with the physician and orders obtained approving the client's transfer ...."

2. The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 - 2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021. During the morning conference with the agency on 12/28/2020 at 10:27 AM, the clinical director indicated the patient expired in the hospital on 12/27/2020.

During an interview with the alternate clinical director (clinical director also present) on 12/28/2020 at 11:26 AM when asked which doctor she spoke with today (12/28/2020) to inform of patient's death, she indicated she spoke to the wound clinic. When asked who specifically she spoke to, she stated "The nurse. I don't know her name." When asked if she spoke with any other physicians, she stated "No ma'am." When asked who the patient's certifying physician was, she stated "I do not know off the top of my head."

Review of hospital record received 12/29/2020, dated 12/23/2020 evidenced the patient was admitted to the hospital on 12/23/2020, and stated "... critical care was necessary for dehydration, Patient does appear to be septic from a urinary tract infection related to a foley

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G1022	Continued From page 290	G1022		

catheter ... presented to the [emergency department] with reports of increasing confusion ... this evening ... disoriented ... poorly healing wound to left stump ... date of death 12/27/2020 ...."

Review of a document received on 12/29/2020 at 11:30 AM, dated 12/28/2020, and titled "Transfer to Inpatient Facility (Discharged From Agency) OASIS" stated "... The niece called [12/28/2020] and stated the client passed away on Sunday 12-27-2020 ...." The record failed to evidence a transfer summary, or that a transfer summary was sent to the physician. Upon exit, nothing further was submitted.

3. The clinical record of patient #7, start of care 5/26/2016, certification period 11/1/2020 - 12/30/2020, was reviewed on 12/18/2020, and again on 1/11/2021. Review of a document titled "SN [skilled nurse] Re-Cert OASIS and Comprehensive Assessment" dated 12/29/2020 (after the IJ was called) stated "... Current possible UTI (urinary tract infection) symptoms: Wife stated client has been sleeping more and usually a sign of UTI ...." The record also evidenced a document titled "Transfer to Inpatient Facility (Not Discharged) OASIS [outcome and assessment information set]" was completed and dated 1/2/2021, but failed to evidence a transfer summary, or that a transfer summary was sent to the physician or receiving facility.

Review of a document dated 1/2/2021 titled "Care Coordination Note" evidenced the patient was admitted to the hospital 1/2/2021 for UTI (urinary tract infection) and would likely be discharged 1/4/2021 or 1/5/2021.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1022	Continued From page 291	G1022		

Review of documents received from entity D (hospital) on 1/5/2021 (not part of agency clinical record) evidenced the patient was admitted 1/2/2021 for sepsis (systemic infection)/ UTI, and was discharged 1/5/2021.

Review of a document dated 1/5/2021 titled "Physician Order" stated "... Please place client on HOLD [sic] as of 1/2/2021 due to being inpatient at ... to treat UTI ...."

3. The clinical record of patient #9, start of care 9/9/2019, certification period 11/2/2020 - 12/31/2020, was reviewed on 12/18/2020, 1/6/2021, 1/11/2021 and 1/12/2021.

Review of a document dated and signed by employee M (registered nurse) on 12/14/2020 titled "Skilled Nurse Visit Note" stated "... No cough, No fever. Client having RLE [right lower extremity] Femoral Endarterectomy on Friday 12/18/20. Right foot and toes continue to blacken. There is now a foul odor associated with foot. Foot is starting to get wet and drain ...."

During an interview on 1/12/2021 at 1:10 PM, employee M stated "I didn't contact the physician [on 12/14/2020] because he already had an appointment scheduled [for 12/18/2020] and the [physician] was already aware."

Review of a document dated 12/23/2020 titled "Care Coordination Note" stated "Spoke with client's wife. Client went into hospital to femoral endarterectomy. Decided to move ahead with partial amputation of right foot. Client remains in hospital. Wife will call when client home." The clinical record failed to evidence a transfer summary was sent to the hospital or certifying

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1022	Continued From page 292 physician. 5. During an interview on 1/6/2021 2:45 PM the alternate clinical director indicated she received report this morning/today (1/6/2021) from employee M's (registered nurse), and indicated patient (#11-no clinical record review) went to the emergency room (ER) today. She also indicated an agency aide reported it to employee M, the patient had fempop bypass (Femoral popliteal bypass surgery which requires a stay in the hospital) about two weeks ago, and he was still having pain. The clinical director and alternate clinical director indicated they did not know if the aide saw the patient today, did not know when the patient was last seen by a nurse, didn't know if the agency had hospital paperwork regarding the hospitalization for bypass surgery, and the agency was previously unaware the patient was hospitalized. When asked if the hospital was contacted today and a summary was sent, the alternate clinical director stated "No. She said they were just sending him." When asked if the physician was contacted, she stated "I don't know. She was out in the field. ....", and indicated it was employee M's job to coordinate with the physician.	G1022		
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:	G1024		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1024	Continued From page 293	G1024		

Based on record review and interview, the agency failed to ensure all clinical record entries were complete, and appropriately authenticated, dated, and timed for 1 of 10 records reviewed (#1). This practice had the potential to affect all agency patients.

Findings include:

Review of an undated copyright Briggs Healthcare policy C-873 titled "Documentation of Changes to the Medical Record" stated, "... If it is necessary to make an addition to a previous entry, this must be done using an addendum to the record. The entry will be marked as an addendum and must include the date it is written and the visit date that the entry relates to ... Changes to OASIS documentation ... The clinician who completes the assessment form is responsible for making changes (corrections, revisions, or additions) to the document. The clinical supervisor or designee may enter changes based on the review of the assessment. These changes must be documented in the record identifying the reason for the changes and the communication of those changes to the authoring clinician ... Records sourced from electronic systems containing amendments, corrections or delayed entries must: Distinctly identify any amendment, correction or delayed entry ... Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the records ... Auditors including recovery auditors shall NOT consider any entries that do not comply with these principles ...."

The clinical record of patient #1, start of care 12/10/2019, certification period 12/4/2020 -

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

(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
G1024	Continued From page 294	G1024		

2/1/2021, was reviewed on 12/18/2020, and again on 1/12/2021.
Review of a document received on 12/28/2020 titled "SN [skilled nurse] SOC [start of care] OASIS and Comprehensive Assessment" dated 12/10/2019 evidenced the patient had no wounds and failed to evidence a Braden scale (a comprehensive assessment for predicting pressure sore risk) was completed by the registered nurse. The assessment further evidenced the patient had (but not limited to) diabetes with peripheral angiopathy (a blood vessel disease caused by high blood sugar), amputations of both legs below the knees, and had an indwelling urinary catheter (a tube inserted into to bladder to drain urine). The patient was alert and oriented to person, place, and time, without confusion or disruptive behaviors. Upon admission on 12/10/2019, the patient had no open skin areas or wounds.

Review of documents received from wound clinic on 12/16/2020 at 3:23 PM (not part of agency clinical record) included (but not limited to) physician wound progress notes. Review of a document titled "[entity C] Progress Note" dated 11/10/2020 evidenced the patient had a stage 3 (full thickness through skin to fatty tissue) pressure injury to the right thigh, no pressure injury to the left [sic- should state 'right'] lower extremity stump (previous below knee amputation), and two deep wounds to the right [sic- should state 'left'] lower extremity stump "... I fear more aggressive debridment [sic] will expose bone ...." Review of another document titled "[entity C] Progress Note" dated 11/24/2020 evidenced the left lower extremity pressure ulcers were worsening stage 4 (full thickness with bone or tendon exposed), and pressure ulcer to right

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G1024	Continued From page 295	G1024		

groin remained (stage 3). Review of the last document titled "[entity C] Progress Note" dated 12/8/2020 evidenced the right groin was worsening with deep tendon exposed (stage 4), and the left stump pressure ulcer now had sharp bone exposed (worsening stage 4).

During the entrance conference interview on 12/15/2020 at 11:00 AM, the clinical director indicated the agency used both paper and electronic charting. When asked the process for making corrections in the clinical record, the clinical director indicated the document would be taken to the RNCM (registered nurse case manager) to discuss, then it would be a late entry, line through, corrected, then initialed.

During an interview on 12/17/2020 at 3:44 PM, the clinical director stated the comprehensive assessment for patient #1 dated and signed by employee L on 12/3/2020 was actually completed on that date (12/17/2020), and the plan of care was also completed that date (12/17/2020) and sent to the physician. Both were reviewed and approved by employee M (registered nurse). It was verified by the clinical director and the administrator that employee L (registered nurse) initiated the comprehensive assessment on 12/3/2020 but didn't complete it, and she did not assess the wounds. When asked, the clinical director agreed the certifying physician would not be able to provide/approve orders to meet the patient's needs without complete and accurate assessment findings. During this time, the administrator asked the director of nursing if the agency obtained wound clinic follow up. The director of nursing stated "No."

During an interview on 12/18/2020 at 1:00 PM,

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	157211	A. BUILDING _____ B. WING _____	R-C 01/12/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOME NURSING SERVICES	528 W WASHINGTON BLVD FORT WAYNE, IN 46802

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G1024	Continued From page 296	G1024		

when asked who finished the comprehensive assessment for patient #1 dated 12/3/2020, the director of nursing stated "[employee N-registered nurse]." When asked if she was the nurse that initiated the comprehensive assessment on 12/3/2020, the director of nursing stated "No." When asked why employee L didn't complete the assessment, the director of nursing stated "We discovered she was behind, we wanted to get it done, so we sent it to [employee N]." She also indicated employee N saw the patient on 12/15/2020, and that visit represented completion of the comprehensive assessment dated 12/3/2020. When asked if there were other incomplete patient assessments that employee L failed to complete that someone else was finishing, the administrator stated, "I believe so." When asked when the agency noticed employee L's had incomplete/late assessments, the clinical Director stated "Monday [12/14/2020]". When asked if the agency had a list of additional patients that other nurses were "fixing or have fixed" for employee L, the clinical director stated "Yes." The administrator indicated employee H (office staff) completed billing every week, and every week she checked in the paperwork. During this interview (at 1:23 PM), the list of all patients re-assigned to other nurses to finish was requested, and was received at 1:38 PM. The list evidenced (but not limited to) 33 patients from 12/1/2020 - 12/18/2020 which had incomplete assessments.

During an interview on 12/18/2020 at 3:20 PM, when asked which nurse did which portions of the comprehensive assessment dated 12/3/2020, the administrator stated "I can only tell [employee L] visited [the patient] on the 3rd, started writing [on the assessment on] 11th, [employee N] saw the

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G1024	Continued From page 297 patient on the 15th, and employee M reviewed and approved the assessment document on the 17th ... [employee M] signed the plan of care." The administrator also indicated he didn't know who did the wound assessments, or when the wounds were last assessed by staff. When asked if there had been any discipline for employee L, the administrator stated, "I don't know."	G1024		
G1028	Protection of records CFR(s): 484.110(d) Standard: Protection of records. The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding protected health information set out at 45 CFR parts 160 and 164. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the agency failed to ensure all patients' clinical records, contents, and information contained therein was safeguarded against loss or unauthorized use. Findings include: Review of an undated copyright Briggs Healthcare policy C-420 titled "Clinical Record Removal" stated "... Original clinical records ... may not be removed from Home Nursing Services at any time except in the event of potential defacement, damage from weather ... Specific components of the record that must be updated at the time of the visit and that must reflect information present in the home record may be taken on visits, but must be returned on the same business day ... To assure that	G1028		

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G1028	Continued From page 298	G1028		

reasonable security measures are implemented to protect clinical record information ... to assure that protected records are not lost or made available to outside sources without client consent ... Employees will safeguard photocopies of the clinical record. They will transport client records in closed files in the trunk of the car. Records shall not be left in automobiles overnight ... At the time of client discharge from Home Nursing Services, all copies of the record should be returned to Home Nursing Services for destruction."

Review of a plan of corrections from a survey conducted on this agency completed 8/27/2020 stated "... The agency does not maintain branch locations, and instead operates convenience sites for employees ... No agency employees will be based in the branch offices of [entity K -a personal services agency (PSA), with same owners as agency being surveyed] ...."

During the entrance conference on 12/15/2020 at 11:00 AM, the clinical director indicated the agency had no branch offices.

During an interview on 12/15/2020 at 4:02 PM, the alternate clinical director submitted 2 untitled calendars dated 12/2020. She indicated they represented the agency's on call schedules, indicated one was for the "north area", and one was for the "south area". When asked the difference between the north and south areas, she stated "Oh, that's just [entity K] up there ... no charts there ... Like a nurse might go in there to chart or whatever." The "north" on call schedule evidenced employee L (agency registered nurse) was on call 12/1/2020 through 12/31/2020.

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G1028	Continued From page 299	G1028		

During a home visit with patient #9 on 12/30/2020 at 9:45 AM, the patient indicated he was unaware his nurse (employee K -licensed practical nurse who regularly saw patient #9) worked for Home Nursing Services, and he thought all the staff coming to his house worked "locally" at entity K.

During an on-site visit to a branch office of entity K on 12/30/2020 at 11:20 AM, the surveyor observed 3 Home Nursing Services cars in the parking lot of the entity. Person I (Director from entity K) indicated 1 car was a "spare", 1 car was dropped off by employee L (a registered nurse who was recently terminated), and employee C (registered nurse with Home Nursing Services) was "here now" charting, which accounted for the third car. Person I also indicated there were no Home Nursing Services clinical records at this location, and stated "... They're all in Fort Wayne." During a tour of the branch office, person I opened an unlocked door to an office which evidenced multiple unsecured documents and folders which contained Home Nursing Services' patients' clinical documents sitting on top of desks. Greater than 40 documents and/or folders were observed, with some being copies, and some being original clinical record documents, dating back to 06/2020. Person I pointed to a desk and stated "That's [employee L's, who was terminated on 12/19/2020] desk ... This is the office/room for Home Nursing Services. I don't really mess with this stuff ....", and acknowledged Home Nursing Services employees worked in this space.

During an interview on 12/30/2020 at 2:38 PM, the clinical director acknowledged patient clinical documents were at entity K's branch location in Auburn, and stated they were "... just nurses'

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G1028	Continued From page 300 copies." She also agreed the documents should be removed from that location. A review of the agency's Electronic Medical Record (EMR) was conducted on 1/6/2021 at 12:38 PM. The EMR evidenced directions to patient #9's house with a starting point from entity K During an interview on 1/12/2021 at 11:54 AM, employee K (licensed practical nurse who regularly saw patient #9) stated "I use the auburn [branch]." During the exit conference on 1/12/2021 at 2:50 PM, the clinical director indicated the patient records were still not removed from entity K's Auburn branch.	G1028		
{E 000}	Initial Comments An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 484.102. Survey Dates: December 15, 16, 17, 18, 28, 29, 30 (2020); and January 4, 5, 6, 7, 11, 12, (2021) Facility Number: IN005372 Provider Number: 157211 Active Census: 143 At this Emergency Preparedness survey, Home Nursing Services was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 484.102.	{E 000}		

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