

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FORM APPROVED

CENTERS FOR MEDICARE & MEDICAID SERVICES

OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15K097	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 07/10/2024	
NAME OF PROVIDER OR SUPPLIER 4U HOME HEALTH INC		STREET ADDRESS, CITY, STATE, ZIP CODE 8870 ZIONSVILLE RD, STE #300, INDIANAPOLIS, IN, 46268		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS - REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
E0000	<p>Initial Comments</p> <p>This was a Post-Condition revisit for an Emergency Preparedness Survey conducted on 05/22/2024 by the Indiana Department of Health in accordance with CFR 484.102.</p> <p>Survey Dates: 07/08, 07/09, and 07/10/2024</p> <p>Active Census: 18</p> <p>At this Post-Condition revisit Emergency Preparedness survey, 4U Home Health Inc. continued to be out of compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 484.102.</p> <p>QR completed by Area 3 on 7-16-2024.</p>	E0000		

E0001	<p>Establishment of the Emergency Program (EP)</p> <p>483.73</p> <p>\$403.748, \$416.54, \$418.113, \$441.184, \$460.84, \$482.15, \$483.73, \$483.475, \$484.102, \$485.68, \$485.542, \$485.625, \$485.727, \$485.920, \$486.360, \$491.12</p> <p>The [facility, except for Transplant Programs] must comply with all applicable Federal, State and local emergency preparedness requirements. The [facility, except for Transplant Programs] must establish and maintain a [comprehensive] emergency preparedness program that meets the requirements of this section.* The emergency preparedness program must include, but not be limited to, the following elements:</p> <p>* (Unless otherwise indicated, the general use of the terms "facility" or "facilities" in this Appendix refers to all provider and suppliers addressed in this appendix. This is a generic moniker used in lieu of the specific provider or supplier noted in the regulations. For varying requirements, the specific regulation for that provider/supplier will be noted as well.)</p> <p>*[For hospitals at §482.15:] The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:</p> <p>*[For CAHs at §485.625:] The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a</p>	E0001	<p>How are you going to correct the deficiency?</p> <p>4U Home Health has reached out to Indiana District 5 Healthcare Coalition on 7/16/2024 for assistance in developing an Emergency Program. We have setup an online account and their Planning Manager has provided contact details for their subcommittee chair for Home Health emergency planning. Administrator has sent emails out on 7/18/2024 and 7/23/2024. We have also called the Planning Manager for more guidance after not hearing back from the subcommittee for Home Health emergency planning. We will continue to follow up for help with emergency planning. 4U Home Health expects to have the program in place by 8/09/2024.</p> <p>Once the program is ready, we will educate all employees on the new program and expect to have that complete by 8/09/2024.</p> <p>How are you going to prevent the deficiency from recurring in the future?</p> <p>Annual testing exercise will be placed on the calendar. Results from annual testing will be discussed and reviewed in the next QAPI meeting. Any changes that need to be made to our EP as a result of our testing exercises will be discussed during our QAPI meeting and all staff will then be educated on any changes to the program that are made.</p> <p>Who is going to be responsible for ensuring that the Plan of Correction is implemented? Administrator will be responsible for educating and re-educating employees regarding the Emergency Preparedness Plan. Also to schedule annual testing exercises. QAPI Committee along with our governing body will be responsible for the review of the testing results and making recommendations for changes to the program.</p>	2024-08-09
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program, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

Based on record review and interview the agency failed to ensure an Emergency Preparedness Program was in place; the agency failed to evidence an Emergency Preparedness Plan had been developed, maintained, reviewed and updated every two(2) years (E0004), failed to evidence a risk assessment had been conducted (E0006), failed to address patient population, the types of services the agency had the ability to provide in an emergency, continuity of operations, delegation of authority and succession plans (E0007), failed to evidence a process for cooperation and collaboration with local tribal, regional, State and Federal emergency preparedness officials' efforts to to maintain an integrated response during an disaster or emergency situation (E0009), failed to evidence policies and procedures based on the emergency plan were reviewed and updated at least every two(2) years (E0017), failed to evidence procedures to inform

<p>State/Local officials regarding homebound patients in need of evacuation from their residences at any time due to an emergency, based on the patient's medical, psychiatric condition, and home environment (E0019), failed to evidence procedures to follow up with on-duty staff and patients to determine services needed during an emergency, and for informing the State and local officials of any on-duty staff or patients they are unable to contact (E0021), failed to evidence a process or procedure to secure and maintain availability of records during an emergency (E0023), failed to evidence use of volunteers or other emergency staffing to address surge needs during an emergency (E0024), failed to evidence an emergency communication plan (E0029), failed to evidence names and contact information for staff, entities providing services under arrangement, patients' physicians, other agencies, and volunteers (E0030), failed to evidence emergency officials' contact information: Federal, State, tribal, regional, and local emergency preparedness staff,</p>			
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and other sources of assistance (E0031), failed to evidence a method for sharing information and medical documentation for patients, with other health providers to maintain the continuity of care (E0033), failed to evidence a means of providing information about the agency's needs during an emergency and its ability to provide assistance during to the authority having jurisdiction, the Incident Command Center, or designee (E0034), failed to evidence Emergency Preparedness Testing and Training were conducted based on the emergency preparedness plan, risk assessment, policies and procedures, and communication plan (E0036), failed to evidence an Emergency Preparedness Training Program (E0037), and failed to evidence an Emergency Preparedness Testing Program (E0039).

The cumulative effect of these systemic problems resulted in the agency being found out of compliance with the condition /Emergency Preparedness, requirement for Medicare Participating Providers and Suppliers, for Home Health

Agencies /at /42 CFR 484.102.

Findings include:

1. On 07/08/2024 at 9:42 AM, Admin 5 presented the Agency's Emergency Preparedness Plan (EP), indicated that they had initiated the EP plan but hadn't completed it.
2. On 07/08/2024 a review of a document titled '4 U Home Health Emergency Preparedness Plan' revealed, "... If phone are not available, the information officer will contact two (2) prearranged radio stations (xxx;xxx) with an announcement for staff and patients ... If phone lines are down listen to radio stations (xxx;xxx) for instructions ... Emergency Assessments Each nurse or aide making home visits to patients must check in with the Agency office with an update _____ (frequency) [left blank] ... Emergency Supply Storage Area An emergency supplies storage area will be maintained at the Agency office for employees during the time period that they are working in the event of an emergency, and will be updated and maintained by _____

	<p>(assigned)[left blank] ..."</p> <p>3. The review of the EP Plan failed to evidence which radio stations were to be utilized, no frequency was listed for nurses or aides to check in with the office, and no one was assigned to the emergency supplies storage.</p> <p>4. On 07/10/2024 at 12:26, Admin Staff 5 indicated they didn't know which parts in the Plan they needed to utilize or delete, and that this plan was somewhat of a template for them to develop an EP Plan.</p>			
G0000	<p>INITIAL COMMENTS</p> <p>This Post-Condition Revisit was for a Federal Recertification and State Re-licensure survey of a Home Health Provider.</p> <p>Survey Dates: 07-08-2024, 07-09-2024, and 07-10-2024.</p> <p>12-Month Unduplicated Skilled Admission: one (1)</p> <p>One (1) previously cited condition was removed. One (1) previously cited condition was re-cited. Five (5) previous citations were removed. Two (2)</p>	G0000		

	<p>Two (2) new citations were cited.</p> <p>During this Post Condition Revisit survey, 4U Home Health Inc. continued to remain out of compliance with Condition of Participation CFR 484.102 Emergency Preparedness.</p> <p>4 U Home Health Inc. continues to be precluded from operating a home health aide training, skills competency and/or competency evaluation programs for a period of two years beginning 05-22-2024 and continuing through 05-20-2026.</p> <p>QR completed by Area 3 on 7-16-2024.</p>			
G0574	<p>Plan of care must include the following</p> <p>484.60(a)(2)(i-xvi)</p> <p>The individualized plan of care must include the following:</p> <p>(i) All pertinent diagnoses;</p> <p>(ii) The patient's mental, psychosocial, and cognitive status;</p> <p>(iii) The types of services, supplies, and equipment required;</p>	G0574	<p>How are you going to correct the deficiency? Administrator and RN will review 100% of patients' medication lists to verify that data in the medical record matches the medication lists sent from physicians' offices. If there is a discrepancy, or if medication instructions are unclear, RN will send a communication note to the patient's physician for clarification.</p> <p>How are you going to prevent the deficiency from recurring in the future? Administrator will monitor 100% of all charts and verify that changes to the medication profile match the medication list sent from a physician's office. Clinical Manager will provide education to RN's regarding</p>	2024-08-09

(iv) The frequency and duration of visits to be made;

(v) Prognosis;

(vi) Rehabilitation potential;

(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 or allowed practitioner may choose to include.

Based on record review and interview the agency failed to ensure the Plan of Care included all medications were included in 1 of 5 records reviewed. (Patient #3)

Findings include:

1. Review of an agency document revised December 2014, titled 'Plan of Care 700' revealed, "PROCEDURE ... 3. The 485, which includes the following Plan of Care elements

410 IAC 17-13-1(a)(1)(B)
410 IAC 17-13-1(a)(1)(C)
410 IAC 17-13-1(a)(1)(D)(i-xiii)

All education documentation will be placed in the RN's employee file.

Who is going to be responsible for ensuring that the Plan of Correction is implemented? Administrator

with ... physician ... and will serve as the initial plan of care: ... medications ..."

2. A review of the clinical record for Patient #3 revealed a document titled, 'HOME HEALTH CERTIFICATION AND PLAN OF CARE' for the certification period of 06/12/2024 through 08/10/2024, signed by the Clinical Supervisor, dated 06/10/2024, with diagnoses but not limited to hypertension (high blood pressure) and contracture (a permanent tightening of the muscles, tendons, skin and nearby tissues that causes the joints to shorten and become very stiff and often causes pain) of right hand and which evidenced the following medication but not limited to Fish Oil (used to but not limited to reduce inflammation, lower blood pressure, and to manage arthritis) 1000 milligram oral capsule 1 capsule daily.

3. On 07/08/2024 at 11:39 AM during an interview with Person B, indicated they would send a medication list with the current medications Patient #3 was to be currently taking.

4. A review of the medication list provided by Person B from Entity A evidenced but not limited to Fish Oil 1000 milligrams 1 capsule 2 times a day, and Propranolol (used for but not limited to Hypertension, heart arrhythmia, and angina) 20 milligrams tablet 1 tablet by mouth every day.

The Plan of Care failed to contain the correct medications and the correct dosage of the Fish Oil.

5. On 07/10/2024 at 11 AM, RN 1 indicated Patient #3 only took the Fish Oil 1000 milligrams 1 time a day, and only will take the Propranolol if they're feeling chest tightness or felt like their blood pressure was too high. RN 1 further indicated they needed to reach out to Entity A for clarification on the medications.

410 IAC 17-13-1(a)(1)(B)

410 IAC 17-13-1(a)(1)(C)

410 IAC 17-13-1(a)(1)(D)(i-xiii)

G0654

Track adverse patient events

G0654

How are you going to correct the deficiency?
Administrator and Admin 5 have developed a

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484.65(c)(2)

Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.

Based on record review and interview the agency failed to ensure their Quality Assurance Performance Improvement (QAPI) program included a method to track adverse patient events, analyze their causes, and implement preventative actions, for 1 of 1 home health agency.

Findings include:

1. Review of an agency document 'Rev. 06/2024' titled 'Quality Assessment and Performance Improvement (QAPI) Policy 000' stated, "... 2. The HHA (Home Health Agency) will measure, analyze, and track quality indicators, including adverse patient events and other performance aspects to assess processes of care, services, and operations ..."

2. Review of an agency document dated 06-03-2024, titled 'INCIDENT LOG' contained an entry which indicated Patient #6 had a fall on 05-28-2024.

3. Review of the agency's QAPI

spreadsheet to track quality indicators. Data sources were noted for each indicator to make it easier to update spreadsheet for quarterly meetings. Templates for Agenda and Meeting Minutes were developed to ensure consistency. Agenda will include tracking spreadsheet, active PIPs, and time for additional comments from each member. Initial QAPI committee meeting has taken place and documented with agenda and approved meeting minutes. Meeting minutes includes attending committee members which include office staff, RN, and HHA.

How are you going to prevent the deficiency from recurring in the future? Tracking spreadsheet includes data sources so Admin 5 will know where to gather data for each meeting. Meeting minutes for each meeting will include date for next meeting. This will be saved to calendar for a reminder. Committee members are allowed to attend via phone to prevent missed meetings. Data will be reviewed and discussed at each meeting. Current PIP's will be reviewed and discussed. If PIP has met its goal, then it will be closed and a new PIP will be chosen from collected data.

Who is going to be responsible for ensuring that the Plan of Correction is implemented? Administrator will be responsible for holding meetings. Admin 5 will be responsible for documenting meetings. Admin5 will work with Administrator to keep tracking spreadsheet updated for each meeting.

program failed to evidence data, including adverse events, were being tracked. The QAPI program failed to evidence documentation of Patient #6's fall on 05-28-2024.

4. On 07-08-2024 at 9:35 AM, the Administrator and Administrative Personnel 5 (Admin 5) indicated the agency was just getting their QAPI program started, as they had not had one in place previously, and indicated they recognized there were components of the program still lacking and planned to rectify this.

5. On 07-10-2024 at 12:20 PM, Admin 5 indicated the QAPI committee members had not yet been solidified but would include the Clinical Manager, Administrator, Alternate Administrator, and Admin 5, and a Home Health Aide they had not yet chosen. When queried as to when the committee would meet to discuss and review any tracked data such as adverse events, incidents, falls, and hospitalizations the Administrator indicated a meeting would occur soon, and

	be aggregated and utilized for this. 410 IAC 17-12-2(a)			
G0682	<p>Infection Prevention</p> <p>484.70(a)</p> <p>Standard: Infection Prevention.</p> <p>The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.</p> <p>Based on record review, observation, and interview the agency failed to ensure infection control measures, hand hygiene, and personnel protective equipment (PPE) were appropriately performed/utilized in 1 of 5 home visits observed. (Clinical Manager)</p> <p>Findings include:</p> <p>1. Review of an agency document, 'reviewed 01-07-2015, titled 'Standard Precautions ADM2045' stated, "PURPOSE To reduce the risk of</p>	G0682	<p>How are you going to correct the deficiency? Administrator will educate RN on policy Dress Code which includes the requirement to wear closed-toe shoes. Administrator will educate RN on policy ADM 2047 Hand Hygiene which states hand hygiene is to be performed after any glove removal. RN will be shown a video on how to perform proper hand hygiene. Education will also include requirement to wait for hand sanitizer to dry rather than fanning site to increase drying speed. Policy ADM2045 Standard Precautions will be updated to include the use of Chucks Pads while filling pillboxes to contain any spills to a clean area. Administrator will present policy to Governing Body, and after approval, will educate RN on policy.</p> <p>How are you going to prevent the deficiency from recurring in the future?Administrator will observe type of shoes worn by RN during work hours and will remind RN of Dress Code if open-toe shoes are observed. Administrator will supply RN with Chuck Pads for use when filling pillboxes.</p> <p>Annual in-services on infection control will be mandatory for all visiting staff. Education will be documented and placed in employee files.</p> <p>Who is going to be responsible for ensuring that the Plan of Correction is implemented?Administrator</p>	2024-08-09

infections when caring for patients ... PROCEDURE ... Personal Protective Equipment

1. Gloves: ... gloves are to be worn when: ... iii. Touching contaminated items or surfaces ... c. Gloves are to be changed: ... i. in between tasks on the same patient ..."

2. Review of an agency document, 'Rev. 09/2014', titled 'Hand Hygiene ADM 2047' stated, "... Hand decontamination using an alcohol-based hand rub should be performed when: ... g. when removing gloves ..."

3. Review of an agency document, 'Rev. 09/2014', titled 'Dress Code 000' stated, "... As specified by OSHA standards, personnel providing direct patient care wear socks or stockings and shoes with permeable enclosed toes ..."

4. On 07-08-2024 at 10:30 AM, during a home visit, the Clinical Director was observed providing medication set-up for Patient #1. The Clinical Director was wearing open-toed sandals for the visit, the toes were painted with white polish. The nurse sanitized her hands and

donned pink gloves then attended to a plastic pillbox on Patient #1's dining table. The nurse proceeded to handle the box and open each compartment which could hold seven days worth of medication. The nurse handled each prescription bottle in the process, used both hands to open the bottles, poured each medication into the bottle's cap, used the right gloved thumb and first finger to retrieve individual pills from the cap, then placed each pill into the corresponding pillbox slot. During the visit, a bottle of metformin was accidentally tipped over, most of the contents of the bottle spilled out onto the surface of the table. The nurse proceeded to scoop up the spilled pills, place them back into the bottle, and continued to fill the pillbox from that same bottle. During the visit, the nurse doffed gloves, failed to perform hand hygiene, donned new gloves, then entered her nursing bag. Later in the visit the nurse again doffed gloves, failed to perform hand hygiene, then donned new gloves. The nurse prepared to perform a fingerstick to the patient's left forefinger and

used an alcohol swab to scrub the pad of the finger before pricking. The nurse fanned her gloved hand rapidly over the area in order to dry it, and did not allow it to air dry.

5. On 07-08-2024 at 11:22 AM, during an interview with the Clinical Manager, when queried as to wearing open-toed shoes, the Clinical Director indicated the dress code was unclear about this, but indicated should wear closed-toed shoes for home visits with patients. When queried as to how medication should be transferred to the pillbox, indicated the 'perfect way' was 'in the lid' and indicated acknowledgment that the pills had been contaminated. When queried as to when hand hygiene should be performed, indicated understood this should occur after removing gloves, and before applying new gloves.

6. On 07-09-2024 at 10:01 AM, in an interview with the Clinical Manager, when discussing the fingerstick performed for Patient #1 and the nurse fanning the site to dry with her hand, the Alternate

	<p>this was wrong, and the Clinical Manager indicated the area should have been allowed to air dry.</p> <p>410 IAC 17-12-1(m)</p>			
G0984	<p>In accordance with current clinical practice</p> <p>484.105(f)(2)</p> <p>All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.</p> <p>Based on record review, observation, and record review the agency failed to ensure the Registered Nurse prepared a medication planner by referencing the patient's medication list, 1 of 4 home visits observed. (Clinical Manager)</p> <p>Findings include:</p> <p>1. Review of an agency document, 'reviewed' 09-30-2013, titled 'Medication Profile CLIN 2028' stated, "... 3. During subsequent home visits the medication profile will be used ... to ensure the patient and family/ caregiver as well as</p>	G0984	<p>How are you going to correct the deficiency? Administrator will educate RN on policy CLIN 2028 – Medication Profile. RN will communicate with patients' physicians if medication list needs to be updated and will document via communication note.</p> <p>How are you going to prevent the deficiency from recurring in the future? RN will use the Medication List which is located in each patient's folder at their house when filling pillboxes instead of relying on memorization. Administrator or RN will print new Medication Lists to update patients' folders when there is an update. Administrator will monitor that there is documented communication notes if medication list is updated.</p> <p>Clinical Manager will perform supervisory visits on each patient who has a med board set up in the next 30 days to ensure that policy is being followed. If policy is followed at 100% of visits, then clinical manager will perform a supervisory visit on 5 patients every quarter. If 100% of the visits are compliant, then clinical manager will perform a supervisory review on 2 patients every quarter. If non-compliance is noted, the clinical manager will return to supervisory visits on all med-board set ups.</p> <p>Who is going to be responsible for ensuring that the Plan of Correction is implemented? Administrator, Clinical Manager</p>	2024-08-09

medication regimen ..."

2. On 07-08-2024 at 10:30 AM, the Clinical Manager (who is also a Registered Nurse (RN)) was observed providing medication set up for Patient #1. The RN filled the patient's pill box with seven days worth of medication and failed to follow a medication list to ensure accuracy. During the visit the nurse was queried as to this practice and indicated she did not use the medication list because she knew them 'by heart' and had been seeing the patient for many years.

3. On 07-10-2024 at 10:42 AM, when queried as to the practice of filling of patient's pill boxes, the Clinical Manager indicated she does not always use a medication list, and reiterated she had worked with the agency's patients 'for years' and indicated 'know[s] their medications by heart'.

4. On 07-10-2024 at 11:10 AM the Clinical Manager indicated understanding of best practice was to fill patients pill box utilizing their updated medication lists, and indicated did not know if the agency had

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a policy concerning medication
planner/pill box management.

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

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

Leonid Grishin

TITLE

Administrator

(X6) DATE

7/29/2024 3:31:07 PM