

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: 157685	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 05/23/2023	
NAME OF PROVIDER OR SUPPLIER BAYADA PEDIATRICS		STREET ADDRESS, CITY, STATE, ZIP CODE 2415 DIRECTORS ROW SUITE H, INDIANAPOLIS, IN, 46241		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS - REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
G0000	<p>INITIAL COMMENTS</p> <p>This was a Federal complaint and State licensure complaint survey conducted at Bayada Pediatrics, a deemed home health agency, by the Indiana Department of Health (IDOH).</p> <p>Complaint: #98595 - deficiencies cited</p> <p>Survey Dates: May 22, 23 (2023)</p> <p>Facility ID: 013748</p> <p>Unduplicated Census for the past 12 months: 54</p> <p>This deficiency report also reflects State Findings cited in accordance with 410 IAC 17.</p> <p>Based on the Condition-level deficiencies cited during the 5/23/2023 survey, at 42 CFR §484.100 Condition of Participation: Compliance with</p>	G0000	See corrective actions detailed under G0848, G0860, G0940 and G1028.	

	<p>and Regulations Related to the Health and Safety of Patients, and 42 CFR §484.105 Condition of participation: Organization and Administration of Services, and pursuant to section 1891(c)(2)(D) of the Social Security Act on 5/23/2023, your agency is precluded from operating a home health aide training, skills competency and/or competency evaluation programs for a period of two years beginning 5/23/2023 and continuing through 5/22/2025.</p> <p>Quality Review Completed 06/08/2023</p>			
G0848	<p>Compliance with Federal, State, Local Law</p> <p>484.100</p> <p>Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.</p> <p>The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.</p> <p>Based on observation, record</p>	G0848	<p>G848</p> <p>The Agency did not comply with Federal, State and, Local Laws and regulations related to health and safety of patients by failing to ensure a branch location was licensed.</p> <p>See corrective actions listed under tag G860.</p>	2023-06-22

	<p>health agency failed to ensure its branch location was licensed as required by the State of Indiana (Please see tag G0860). This practice had the potential to affect all patients the agency served.</p> <p>The findings include:</p> <p>The cumulative effect of these systemic problems resulted in the home health agency's inability to ensure the provision of quality health care in a safe environment for the Condition of Participation 42 CFR §484.100: Compliance with Federal, State, and Local Laws and Regulations Related to the Health and Safety of Patients.</p>			
G0860	<p>Licensing</p> <p>484.100(b)</p> <p>(b) Standard: Licensing.</p> <p>The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.</p> <p>Based on observation, record review, and interview, the home health agency failed to ensure its branch location was licensed</p>	G0860	<p>G860</p> <p>Based on an analysis of the specific deficiencies cited,the corrective plan and actions taken are to address the lack of demonstratedknowledge resulting in failure to operate a drop site in accordance withFederal regulation when permitted to do so by state law. The plan of correctionwill be completed through comprehensive focused</p>	2023-06-22

as required by the State of Indiana.

The findings include:

Review of an agency policy, revised date 4/19/2018, titled "0-6885 Office Licensure Application Process", stated "... Bayada ... is responsible for the completion, submission and follow-up of all initial and renewal license applications ... Applications are completed for ... branch ... [Bayada corporate level] will follow-up with the State licensing authority until the application has been processed to completion"

Review of an agency policy, revised date 8/15/2022, titled "0-523 Ownership, Governance, and Administration: Bayada Home Health Care", stated, "... A copy of the state license, when required, is kept in the local office ... A structured relationship exists between parent and branch offices under the same Medicare certification number to ensure adequate oversight of the branch ... Parent offices provide supervision and administrative control of branch ... in order to meet the Medicare Conditions

education.

On 5/24/2023 the Administrator communicated to all Agency field staff that effective 5/29/2023, the drop site and drop box/mailbox located in Valparaiso would no longer be available for use and for all documentation to be mailed to the office located at 2415 Directors Row, Suite H-I, Indianapolis, IN 46241.

On 5/24/2023 Agency Administration initiated the process for removal of the Agency signage at the Valparaiso location. Removal of the Agency sign was completed on 6/5.

By 6/8/2023 the drop box/mailbox that was affixed to the Valparaiso location was removed.

By 6/22/2023, the Valparaiso location will have all items removed and will no longer be used by the Agency in any

of Participation"

During an observation on 5/22/2023, at 1:24 PM, the entrance doors were locked to the office located in Valparaiso, and no one was present to open the doors. A sign on the entrance doors was observed that stated, "For deliveries or any assistance, please call our Indianapolis office at 317-481-6800."

During an interview on 5/22/2023 at 1:37 PM, the Administrator indicated the red box affixed to the outside of the front of the building was used as a drop box/mailbox for submission of clinical record documents; at one point, the Valparaiso location was operating, but never became official, and was currently being managed by the Indianapolis home health agency.

During an interview on 5/22/2023 at 1:56 PM, Administrative Registered Nurse (RN) #4 indicated the Valparaiso office was a branch of the Indianapolis home health agency.

During an interview on

capacity.

By 6/22/2023 the Director, Regulatory Support and Guidance, will conduct mandatory, comprehensive education for all administrative staff of the Agency on federal, state, and local laws related to drop sites and licensure of home health agencies and branches. The curriculum includes the following:

- State Operations Manual publication 100-07, Chapter 2, Section 2182.4D - Drop Sites
- Policies: *Office Licensure Application Process*, 0-6885, *Ownership, Governance and Administration: BAYADA Home HealthCare*, 0-523, and *New Service Office Authorization*, 0-6684
- Indiana state regulation 410 IAC 17: 17-10-1(b)

Effective 6/22/2023 the Valparaiso location is no longer operational. Any future plans to establish a drop site or a new

Administrative RN #4 indicated there wasn't an Emergency Preparedness Plan for the Valparaiso office, as everything was done out of Indianapolis; and all patients served at the Valparaiso location were billed through the Indianapolis agency.

During an interview on 5/22/2023 at 2:39 PM, Administrative RN #4 indicated the Valparaiso location initially operated independently, but then corporate Bayada decided not to make the Valparaiso location an independent agency. Administrative RN #4 indicated the Valparaiso location operated "out of Indianapolis", and she was responsible to manage the Valparaiso patients.

During an interview on 5/22/2023 at 4:05 PM, the Administrator indicated the Valparaiso location originally operated independently in 2018, was currently managed and controlled by the Indianapolis agency, and staff was assigned to the Valparaiso location.

410 IAC 17: 17-10-1(b)

location will be monitored through the implementation of policy *New Service Office Authorization, 0-6684*. The expected compliance threshold will be 100%. Failure to achieve 100% will be addressed through focused education with the individual staff members by the Administrator/designee.

The Administrator has overall responsibility for implementation and oversight of the plan.

G0940	<p>Organization and administration of services</p> <p>484.105</p> <p>Condition of participation: Organization and administration of services.</p> <p>The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.</p> <p>Based on observation, record review, and interview, the home health agency failed to ensure its administrative and supervisory functions were not delegated to another individual, agency, or organization; and all services not furnished directly were monitored and controlled by the parent agency. This practice had the potential to affect all patients the agency served.</p> <p>The cumulative effect of these systemic problems resulted in the home health agency's inability to ensure the provision of quality health care in a safe</p>	G0940	<p>G940</p> <p>Based on an analysis of the specific deficiencies cited, the corrective plan and actions taken are to address the lack of demonstrated knowledge resulting in failure of Agency Administration to ensure its administrative and supervisory functions were not delegated to another individual, agency, or organization, and the failure for all services not furnished directly to be monitored and controlled by the parent agency. The plan of correction will be completed through comprehensive focused education.</p> <p>By 6/22/2023 the organizational chart will be updated to reflect Agency reporting structure in accordance with Indiana state regulations and federal conditions of participation.</p> <p>By 6/22/2023, <i>Supervising Nurse Position Description Supplement – Indiana, 0-9628</i> was updated to reflect oversight and supervision of Agency's clinical staff.</p>	2023-06-22

environment for the Condition of Participation 42 CFR §484.105: Organization and Administration of Services.

A standard level deficiency was also cited at this level.

The findings include:

During an interview on 5/22/2023, at 12:52 PM, the clinical manager indicated clinical records were not on site at the Valparaiso office. The clinical manager indicated nurses servicing patients from the Valparaiso office were never required to come to the Indianapolis office and come into the Valparaiso office for training and clinical competency with the clinical manager assigned to the Valparaiso office.

During an interview on 5/22/2023, at 1:27 PM, the administrator indicated to his knowledge, there were no clinical records at the Valparaiso location. The administrator was unsure of the exact date when he had last been to the Valparaiso location and

By 6/22/2023, the Director, Regulatory Support and Guidance, will educate the Supervising Nurse and Alternate Supervising Nurse on Indiana regulation 410 IAC 17-12-1 with emphasis on their role and responsibilities.

By 6/22/2023, the Director, Regulatory Support and Guidance, will conduct mandatory, comprehensive education for all administrative staff of the Agency on condition of participation 484.105, *Organization and Administration of Services*, and Indiana state regulations 410 IAC 17:17-12-1(a) and (b), *Home Health Agency Administration and Management*. The curriculum includes the following:

- Review of Organizational structure
- Roles and responsibilities as part of the licensed home health agency
- Oversight responsibilities
- Structure and mechanism for Administrator reporting to the Governing Body

sometime last year. At 2:17 PM, the administrator indicated he was unsure if the clinical manager and alternate clinical manager had ever been to the Valparaiso location.

During an observation at the Valparaiso location on 5/22/2023, at 1:56 PM, clinical records for Patient #1 and Patient #2 were observed on the desk unsecured in red binders. A stack of clinical documents was observed for Patient #3 with an agency discharge summary document on top of the stack on the desk unsecured. An agency assessment screening tool document was observed for Patient #4 in a bin unsecured on a desk. A room was observed containing medical supplies and equipment, which was identified by registered nurse #1, to be the simulator training lab for the nurses servicing the patients from the Valparaiso office.

Effective 6/22/2023, the Administrator will conduct weekly forward meetings with all administrative staff to organize and direct the Agency's ongoing functions. During weekly forward meetings, the Supervising Nurse will provide direction to and supervision of all Clinical Managers and oversight of nursing services by reviewing new cases, relevant updates to ongoing cases, and staffing needs. The expected compliance threshold will be 100%. Failure to achieve 100% will be addressed through focused education with the individual staff members by the Administrator/designee.

The Administrator has overall responsibility for implementation and oversight of the plan.

During an interview on 5/22/2023, at 2:28 PM, registered nurse (RN) #1 indicated she was responsible for the day-to-day operations of the Valparaiso location.

Review of an undated agency document on 5/22/2023, identified to be the agency's organization chart, indicated the administrator reported to Administrative Staff #1, who reported to Administrative Staff #2, who reported to Administrative Staff #3, who reported to Administrative Staff #4, who reported to Administrative Staff #5.

Review of an undated agency document on 5/22/2023, identified to be the governing body members, failed to evidence Administrative Staff #1, Administrative Staff #2, Administrative Staff #3, Administrative Staff #4, and Administrative Staff #5 were members of the governing body.

During an interview on 5/22/2023, at 2:50 PM, the administrator indicated he directly reported to Administrative Staff #1 and

indicated Administrative Staff #1 was not a member of the governing body. The administrator indicated he was unsure why he reported to someone who was not a member of the governing body and indicated corporate determined the organizational structure.

During an interview on 5/23/2023, at 10:30 AM, the administrator indicated he was unaware the agency sign and the red drop box was in still in place on the front of the building because he had not been to the Valparaiso location.

During an interview on 5/23/2023, at 1:54 PM, the clinical manager indicated RN #1 provided the clinical oversight of the patients serviced from the Valparaiso location and the client services manager provided oversight to the scheduling of the patients and staff. The clinical manager indicated she did not require the nurses from the Valparasio location to come to the Indianapolis location and indicated she has never been to the Valparasio location. The clinical manager indicated RN

#1 provided the training and competency validation for the nurses in Valparaiso and she did not do anything with the nurse training and competence for Valparaiso nurses.

Review of an agency policy with revised date 9/01/2014, titled "0-3070 Medicare Service Provision - Enrollment Requirements", stated, "... Ongoing compliance with the Medicare Conditions of Participation, State Regulations ... are monitored through BAYADA's Quality Assurance Program [corporate level]"

Review of an agency policy with revised date 8/15/2022, titled "0-523 Ownership, Governance, and Administration: Bayada Home Health Care", stated, "... Bayada ... has an ownership and governance structure, and meets administration requirements, in accordance with Delaware law ... The Governing Body ... is responsible for ... Appointing a qualified Administrator and designated back-up administrator ... and authorized in writing ... A structured relationship exists between

the same Medicare certification number to ensure adequate oversight of the branch ... Parent offices provide supervision and administrative control of branch ... in order to meet the Medicare Conditions of Participation"

Review of an agency policy dated 9/2018, titled "Administrator Position Description Supplement - Indiana", stated, "... direct the home health agency's ongoing functions ... Employ qualified personnel and ensure adequate staff education and evaluations ... Ensure the accuracy of public information materials ... Ensure that the home health agency meets all rules and regulations for licensure"

Review of an agency policy dated 9/2018, titled "Supervising Nurse Position Description Supplement - Indiana", stated, "... Supervise and direct nursing and other therapeutic services"

During an observation at the Valparaiso location on 5/22/2023 at 2:04 PM, a Bayada marketing pamphlet was

entrance, which indicated the agency provided hospice and therapy services (Physical, Occupational, and Speech Therapy)

During an interview on 5/23/2023 at 10:52 AM, the Administrator indicated there wasn't hospice or therapy services provided by the Indianapolis or Valparaiso locations, Bayada agencies in other states provided those services, corporate Bayada provided marketing pamphlets, and the pamphlets weren't specific to the services Indianapolis or Valparaiso provided.

410 IAC 17: 17-12-1(a)(1);
17-12-1(a)(2); and 17-12-1(b)

G1028

Protection of records

484.110(d)

Standard: Protection of records.

The clinical record, its contents, and the information contained therein must be

G1028

G1028

Based on an analysis of the specific deficiencies cited, the corrective plan and actions taken are to address the lack of demonstrated knowledge

2023-06-22

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.

Based on observation, record review, and interview, the home health agency failed to ensure all clinical records/clinical record documents were safeguarded against loss or unauthorized use, for 8 of 8 random patients' unsecured clinical records/clinical documents observed (Patient #1, 2, 3, 4, 5, 6, 7, 8).

The findings include:

During an observation on 5/22/2023, at 1:24 PM, the entrance doors were locked to the office located in Valparaiso, and no one was present to open the doors. A sign on the entrance doors was observed that stated, "For deliveries or any assistance, please call our Indianapolis office at 317-481-6800." Through the front window, red binders with the names of Patient #1 and Patient #2 on the outside of the binder. A red box affixed to the outside of the front of the building contained 3 envelopes addressed to the agency. Envelopes were visible from the outside of the box when the

resulting in failure to ensure all clinical

records/clinical record documents were safeguarded against loss or unauthorized use. The plan of correction will be completed through comprehensive focused education.

On 5/22/2023, an incident report was submitted for the breaches of client personal health information (PHI) that occurred during the survey.

On 5/24/2023 the Administrator communicated to all Agency field staff that effective 5/29/2023, the drop site and drop box/mailbox located in Valparaiso would no longer be available for use and for all documentation to be mailed to the office located at 2415 Directors Row, Suite H-I, Indianapolis, IN 46241.

By 6/8/2023 the drop box/mailbox that was affixed to

flap was opened and were retrieved through the slot. Upon entranced to the building at 1:56 PM, clinical records were observed unsecured on top of the desk in red binders for Patient #5 and Patient #6. A stack of clinical record documents with an agency discharge summary document on top were observed unsecured for Patient #3 on top of the desk. An agency assessment screening tool document for Patient #4 was observed in an open tray unsecured sitting on top of a table.

During an observation at the Valparaiso office on 5/23/2023 at 10:30 AM, clinical records for Patient #1, Patient #2, Patient #5, and Patient #6 were observed unsecured on top of the desk in the same position from the previous day.

During an interview on 5/22/2023, at 1:37 PM, the administrator indicated clinical records were to be stored in a locked filing cabinet.

Review of an agency policy, revised date 2/27/2012, titled "37-2197 Confidentiality of PHI

the Valparaiso location was removed.

By 6/22/2023, the Valparaiso location will have all items removed and will no longer be used by the Agency in any capacity.

By 6/22/2023, the Director, Regulatory Support and Guidance will educate all administrative staff of the Agency on policy *Confidentiality of Protected Health Information (PHI) – Communication and Client Charts: Access and Amendment and Disclosure, 37-2197* and the requirement to maintain the confidentiality of all Protected Health Information (PHI) of clients and employees and use of appropriate security measures to protect information against loss, defacement, tampering, and unauthorized disclosure or use. Education included the following requirements:

- All charts are to be maintained in secure

[protected health information] - Access and Disclosure", stated "Bayada Home Health Care maintains the confidentiality of all ... PHI of clients"

Review of an agency policy dated 11/2021, titled "Standards of Honesty & Confidentiality ... Bayada's Compliance Program", stated, "... protection and confidential handling of protected health information ... Examples of ... violations ... Unprotected storage of private health information"

Review of an agency policy, revised date 7/2021, titled "Client Bill of Rights", stated, Clients have the right to a confidential clinical record"

During an interview on 5/22/2023 at 1:37 PM, Administrative Registered Nurse (RN) #4 indicated the red box affixed to the outside of the front of the building was used as a drop box/mailbox for submission of clinical record documents.

During an observation on 5/22/2023 at 1:56 PM, Administrative RN #4 opened

when not in use,

- All offices are locked at the close of business each day, and

- Documents containing PHI are not to be open and available for observation when not being utilized by Agency staff to facilitate client care.

Effective 6/22/2023, the Administrator/designee will conduct weekly observations of the Agency during non-business hours to ensure the confidentiality of PHI is being maintained. The expected compliance threshold will be 100%. Failure to achieve 100% will be addressed through focused education with the individual staff members by the Administrator/designee.

The Administrator has overall responsibility for implementation and oversight of the plan.

the 3 envelopes retrieved from the drop box. Observed clinical visit notes for Patients #7, dated 3/25/2023, 3/27/2023 - 4/01/2023, and 5/01/2023 - 5/06/2023; and a six page medication and treatment administration record, dated 4/01/2023 - 4/30/2023, for Patient #8. Administrative RN #4 confirmed the envelopes from the drop box contained clinical record documents for Patients #7 and #8.

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

Logan Jost

TITLE

Director/Administrator

(X6) DATE

6/19/2023 11:31:21 AM