

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FORM APPROVED

CENTERS FOR MEDICARE &amp; MEDICAID SERVICES

OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  15K002	(X2) MULTIPLE CONSTRUCTION A. BUILDING  B. WING	(X3) DATE SURVEY COMPLETED  04/21/2022
NAME OF PROVIDER OR SUPPLIER  SUNSHINE HOME HEALTH CARE		STREET ADDRESS, CITY, STATE, ZIP CODE  302 E JEFFERSON BLVD, FORT WAYNE, IN, 46802		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC 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>This visit was for a Federal and State complaint survey of a Home Health Agency Provider.</p> <p>Survey Dates: 4/18, 4/19, 4/20, and 4/21/2022</p> <p>Complaint: IN00062528: Unsubstantiated. Federal deficiency, unrelated, was cited.</p> <p>Census: 76</p> <p>Sunshine Home Healthcare was found to be in compliance with 410 IAC 17 in regard to this allegation.</p>	G0000		2022-05-10
G0687	<p>COVID-19 Vaccination of Home Health Agency staff</p> <p>484.70 (d)-(d)(3)(i-x)</p> <p>§ 484.70 Condition of Participation: Infection Prevention and Control.</p> <p>(d) Standard: COVID-19 Vaccination of Home</p>	G0687	How are you going to correct the deficiency? If already corrected, include the steps taken and date of correction.	2022-05-10

(HHA) must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following HHA staff, who provide any care, treatment, or other services for the HHA and/or its patients:

(i) HHA employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following HHA staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the HHA that are performed exclusively outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as

Sunshine Home Health Care updated the COVID Vaccination policy on 5/5/2022 to clarify that medical exemption documentation needs to be based on recognized clinical contraindications to COVID-19 vaccines. Medical exemptions will only be approved if they meet recognized clinical contraindications to COVID-19 vaccines and the employee provides all required documentation. Administrator reviewed all medical exemptions that were previously granted. Only one medical exemption had been previously approved by Agency. The Administrator notified the employee that although the employee's medical exemption was previously approved, the documentation was not based on recognized clinical contraindications to the COVID-19 vaccines, therefore the approval had to be immediately withdrawn. The employee was notified that the employee was not able to work in the office, clients' homes, or have any contact with any employee or client until they were either fully vaccinated, including two week wait period, had an approved medical exemption based on recognized clinical contraindications to COVID-19 vaccine, or had an approved religious exemption.

recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the HHA and/or its patients;

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

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

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

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

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

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

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19

At the time the Employee was advised that her MedicalExemption would be withdrawn, the employee requested a religious accommodation inwriting. This was not a new request, buta renewal of her original request. Theemployee originally requested both a medical exemption and a religiousexemption. The Agency believes herreligious exemption to be sincere, as employee has been very vocal about herreligious objection to vaccines and has not received any vaccine that she canremember. We believed her request to besincere, but she had a medical request, and we did not see any need to processboth a medical and religious request. However, given the need to withdraw her medical exemption, we determinedwe needed to revisit her original religious exemption request. This was necessary, because CMS's guidanceand federal law require us to accommodate her sincerely held religiousbeliefs. For this reason, we reviewed therequest and credibility of the request on an objective basis. Agency believes that employee is credible inasking for request, since employee originally asked agency if she shouldcomplete both a religious and medical exemption because she felt she qualifiedfor both and Agency

medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

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

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

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

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

Review of an agency policy titled COVID Vaccination dated 01/18/2022, revealed a definition of an exempt staff member & means staff who are exempted from the requirements of this policy due to a medical contraindication, sincerely held religious belief or those staff for who the vaccination must temporarily be delayed due to clinical contraindications. The policy further revealed the medical exemption must be based on one of the three CDC contraindications

informed employee that only one exemption was required. Agency approved employee's religious accommodation request and granted an exemption to the COVID-19 vaccination policy. Employee was notified that religious accommodation was approved and educated on the additional precautions required for staff members that were not fully vaccinated due to an exemption.

How are you going to prevent the deficiency from recurring in the future?

All employees that have the authority to approve medical exemptions were re-educated by 5/10/2022 on the updated policy specifically on the requirement that medical approved exemptions must be based on recognized clinical contraindications to the COVID-19 vaccine and employee must submit documentation from a licensed practitioner, other than the person requesting the exemption that specifies: which of the authorized COVID-19 vaccines are clinically contraindicated, the recognized clinical reasons for the contraindications, a statement from the practitioner recommending that the staff

and stated, However, if a Covered Service Member produces documentation from their primary care practitioner & states it is the practitioner's medical opinion that due to another medical consideration or condition & request will be evaluated as a request for an accommodation under the ADA [Americans with Disabilities Act] &.

Review of the employee medical file for Employee C, revealed a document titled Exemption Decision and Communication Form that contained the exemption request of Medical Contraindication. The other options for a request were religious accommodation or disability. The exemption was granted by Employee B, the Alternate Administrator, and Employee I, Human Resources representative, based on a medical letter. Attached to the request was a letter from Physician A, dated 01/31/2022, which stated, [Employee C] has natural immunity to Covid. [He / she] doesn't require the Covid Vaccines.

During the daily conference, on 4/20/2022, employee B, the Alternate Administrator, indicated the letter followed the agency policy.

member be exempt from the Agency's COVID-19 vaccination requirements based on the recognized clinical contraindications, date, licensed practitioner's signature, and employee's full name. Education also included the CDC's Summary Document for Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Authorized or Approved in the United States. No medical exemption will be granted unless all of the required documentation is provided by the employee. The request for the medical exemption form has been updated to clearly indicate the above information is required for a medical exemption to be approved. These employees were also reeducated on our policies and procedures regarding exemptions for sincerely held religious beliefs and due to disabilities to ensure all appropriate and federally required exemption requests were granted.

Administrator will have final approval of all medical, religious and disability exemptions before they are granted to ensure that medical exemptions are only granted if they are based on recognized clinical contraindications to the COVID-19 vaccine and all required documentation

Alt.Administrator will audit 100% of active employee charts every quarter to ensure compliance with the COVID vaccination policy. The Administrator and/or Alt. Administrator will present audit findings quarterly to the QAPI Committee.

Who is going to be responsible for number 1 and 2 above; i.e., administrator, director, etc.?

The Administrator is responsible for ensuring ongoing compliance with G0687.

By what date are you going to have the deficiency corrected? You must provide a specific date the deficiency will be or has been corrected (example: June 30, 2000 or 06-30-00) in the "COMPLETION DATE" column. The correction time should be within thirty (30) days from the date of the survey.

The deficiency was corrected by 5/10/2022

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

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

TITLE

(X6) DATE