DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Odalys Fernandez/99689-004
FCI Tallahassee
Federal Correctional Institution
501 Capitol Circle, NE
Tallahassee, FL 32301

09-08-2014

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2014-N-0563

Dear Ms. Fernandez:

This letter is to inform you that the Food and Drug Administration ("FDA" or "the Agency") is proposing to issue an order debarring you for a period of six years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted under federal law of five felony counts for conduct involving health care fraud and one count of conspiracy to commit health care fraud. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On November 9, 2012, the United States District Court for the Southern District of Florida entered judgment against you after a jury found you guilty of five counts of health care fraud in violation of 18 U.S.C. § 1347, and one count of conspiracy to commit health care fraud, in violation of 18 U.S.C. § 1349. The underlying facts supporting this conviction are as follows.

You were a registered nurse working for Ideal Home Health Inc. (Ideal) which was a business in Miami-Dade County, Florida. Ideal purportedly provided skilled nursing services to Medicare beneficiaries who required home health services. Medicare is a federally funded program governed by federal statutes and regulations and overseen by the Center for Medicare and Medicaid Services, an agency of the Department of Health and Human Services. As a registered nurse in the home health field, it was your duty to provide skilled nursing services to patients and maintain proper documentation of all treatments provided to patients.

From on or about August 17, 2007, and continuing through on or about March 19, 2009, you conspired with others to defraud Medicare. You and your co-conspirators, among other things, submitted and caused the submission of false and fraudulent claims to Medicare, and concealed the submission of these false and fraudulent claims.

You and your co-conspirators falsified and caused Medicare beneficiaries to falsify weekly visit/time record sheets, falsified skilled nursing progress notes representing that you had administered insulin

injections and provided various other medical services to Medicare beneficiaries, and you caused Ideal to submit false and fraudulent claims to Medicare for home health benefits by falsely representing that you had provided these home health services. As a result of these fraudulent claims, you caused Medicare to make payments to Ideal, which amounted to approximately $82,040.

FDA's Findings

Section 306(b)(2)(B)(ii)(I) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act" or "the Act") (21 U.S.C. § 335a(b)(2)(B)(ii)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a felony under Federal law which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, and the agency finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements under the FD&C Act relating to drug products.

The conduct that forms the basis of your convictions occurred in the course of your profession, the practice of nursing. In the course of this practice, you had legal and professional obligations to ensure that you submitted accurate medical claims for services you provided, as well as to ensure that you provided the appropriate drug products to your patients. Instead, you submitted and caused to be submitted false weekly visit/time record sheets and false daily blood sugar/insulin log sheets. You engaged in this conduct repeatedly over a period of approximately 19 months. Your convictions indicate that you knowingly and willfully disregarded your legal and professional obligations to keep accurate medical records and to submit accurate claims for the services you provided.

Having considered the conduct that forms the basis of your conviction and the fact that this conduct occurred in the course of your profession and showed a disregard for the obligations of your profession and the law, FDA finds that you have demonstrated a pattern of conduct sufficient to find that there is reason to believe that, if you were to provide services to a person that has an approved or pending drug application, you may violate requirements under the Act relating to drug products. Accordingly, the Agency finds that you are subject to debarment under section 306(b)(2)(B)(ii)(I).

The maximum period of debarment for each offense under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years, and the Agency may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors to be considered by the Agency in determining the appropriateness and length of your debarment. The factors applicable here include: (1) nature and seriousness of the offense involved, (2) nature and extent of management participation in this offense, (3) nature and extent of voluntary steps to mitigate the impact on the public and (4) prior convictions under the Act or involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

You were convicted of five felony counts of health care fraud and one count of conspiracy to commit health care fraud. As described in detail above, you submitted and caused to be submitted

false weekly visit/time record sheets and false daily blood sugar/insulin log sheets. In addition, you caused Ideal to submit false and fraudulent claims to Medicare for home health benefits by falsely representing that home health services had been provided to home health eligible Medicare beneficiaries.

Your actions have the potential for causing significant loss of public confidence in the healthcare system. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. The nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether institutional controls contributed to the offense.

There is nothing in the record addressing the nature and extent of any management participation in the offenses. Accordingly, this factor is not applicable here.

3. The nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health.

Rather than taking any actions to mitigate the impact of your offenses on the public, you continued your scheme over a period of approximately 19 months. Accordingly, the Agency considers your failure to take effective voluntary steps to mitigate the offenses you committed to be an unfavorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA is unaware of any prior convictions. The Agency will consider this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA has concluded that the unfavorable factors cumulatively outweigh the favorable factors and that debarment is appropriate. Accordingly, FDA proposes to issue an order under section 306(b)(2)(B)(ii)(I) of the Act (21 U.S.C. § 335a(b)(2)(B)(ii)(I)) debarring you for a period of six years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of five felony counts of health care fraud and one count of conspiracy to commit health care fraud. Based on the factors discussed above, FDA proposes that each offense be accorded a debarment period of three years. In the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively (21 U.S.C. § 335a(c)(2)(A)). FDA has concluded that the three-year period of debarment for each of the six offenses of conviction need not be served consecutively, which would result in a period of debarment of 18 years. Rather, FDA has

concluded that the three-year periods of debarment for the five counts of health care fraud shall run concurrently. The three-year period of debarment for the conspiracy conviction shall run consecutively to the periods of debarment for the health care fraud convictions, resulting in a total debarment period of six years.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. You should understand that the facts underlying your conviction are not at issue in this proceeding. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2014-N-0563 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR § 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement & Import Operations within the Food and Drug Administration.

Sincerely,

Douglas Stearn
Director
Office of Enforcement & Import Operations

cc:

Thomas South
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