



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Armando Santos/94995-004
FDC Miami
Federal Detention Center
P.O. Box 019120
Miami, FL 33101

04 - 09 - 2014

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2013-N-1106

Dear Mr. Santos:

This letter is to inform you that the Food and Drug Administration (“FDA” or “the Agency”) is proposing to issue an order debaring you for a period of twelve 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 of seven felony counts under Federal law for conduct involving health care fraud, conspiracy to commit health care fraud, and false statements related to health care matters. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On May 26, 2011, you were found guilty of seven felonies. On August 15, 2011, the United States District Court for the Southern District of Florida entered judgment against you for one count of conspiracy to commit health care fraud in violation of 18 U.S.C. § 1349, four counts of health care fraud in violation of 18 U.S.C. § 1347, and two counts of false statements related to health care matters in violation of 18 U.S.C. § 1035(a)(2). The underlying facts supporting this conviction are as follows.

You were a registered nurse employed by a local home health agency. 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 June 29, 2007, and continuing through on or about March 13, 2009, in the Southern District of Florida, you knowingly and willfully conspired with others to defraud Medicare, a health care benefit program. Through a nursing staffing company and a Miami-Dade County home health agency, you submitted and caused the submission of false and fraudulent claims to Medicare, and paid kickbacks and bribes to Medicare beneficiaries in exchange for the use of their Medicare beneficiary numbers as the bases of claims filed for home health care. You and your co-conspirators signed patient assessment forms falsely certifying that Medicare beneficiaries were in need of home health services that were medically unnecessary. You created false weekly visit/time records in which you claimed to be providing skilled nursing services to two separate Medicare beneficiaries at

the same time. On four separate occasions, you submitted and caused the submission of false and fraudulent claims to Medicare, representing that you had provided various home health services to beneficiaries pursuant to physicians' plans of care. You caused a home health agency to submit approximately \$230,315 in false and fraudulent claims to Medicare for home health services allegedly rendered to Medicare beneficiaries, when such home health services were not medically necessary and had not been provided. As a result of these fraudulent claims, you caused Medicare to make payments of approximately \$152,664 to a Miami-Dade County home health agency

In addition, on or about July 28, 2007, and November 9, 2007, you knowingly and willfully made materially false statements and representations, in connection with the delivery of and payment for health care benefits, items, and services. Specifically, you prepared documents titled "Skilled Nursing Progress Note[s]" which falsely stated that you had injected Medicare beneficiaries with insulin on July 28, 2007, and November 9, 2007, when you knew you had not performed these services.

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 it 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 Act relating to drug products. The conduct that forms the basis of your conviction 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 kept accurate medical records for each patient and to ensure that you submitted accurate claims for services you provided. Instead, you signed patient assessment forms falsely certifying that Medicare beneficiaries were in need of home health services that were medically unnecessary, and you submitted false weekly visit/time records. In addition, you prepared false "Skilled Nursing Progress Note[s]" stating that you had injected two Medicare beneficiaries with insulin when you had not done so. You also submitted and caused the submission of false and fraudulent claims to Medicare. You engaged in this conduct repeatedly over a period of almost two years. Your convictions indicate that you knowingly and willingly disregarded your legal and professional obligations to keep accurate medical records and to submit accurate claims for your services. 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 of the obligations of your profession, 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 should 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 seven felony counts of health care fraud, making false statements related to health care matters and conspiracy to commit health care fraud. As described in detail above, you created and submitted false documentation of visits to Medicare beneficiaries (including false certifications that Medicare beneficiaries were in need of home health services, false weekly visit/time records, and false "Skilled Nursing Progress Note[s]"). In addition, you submitted and caused the submission of false and fraudulent claims to Medicare.

You were a healthcare professional who breached your position of trust, you engaged in a conspiracy, and you committed perjury and showed no remorse for your illegal actions. 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 inadequate 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 years. You took no steps to mitigate the impact on the public of your offenses; in fact, the district court justified an upward variance from the sentencing guidelines in sentencing you because (among other reasons) you perjured yourself at trial and showed no remorse for your illegal actions. 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 determined that debarment is appropriate, and 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 12 years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of four counts of health care fraud, two counts of false statements related to health care matters, and one count of conspiracy to commit health care fraud, Federal felony offenses. Based on the factors discussed above, FDA proposes that each felony offense be accorded a debarment period of four 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 four-year period of debarment for each of the 7 offenses of conviction need not be served consecutively, which would result in a period of debarment of 28 years. FDA has concluded that the purposes of the debarment provision of the Act will be served if: (1) the four-year periods of debarment for counts 2-5 run concurrently, and (2) the four-year periods of debarment for counts 6-7 run concurrently. The two periods of debarment described in the preceding sentence shall run consecutively to each other and shall run consecutively to the four-year period of debarment for count 1, resulting in a total debarment period of 12 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-2013-N-1106 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 §

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Docket No. FDA-2013-N-1106

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,

A handwritten signature in cursive script, appearing to read "Dou Stearn".

Douglas Stearn
Director
Office of Enforcement & Import Operations

Armando Santos
Docket No. FDA-2013-N-1106

cc:

HFC-300/ Thomas South
GCF-1/ Denise Esposito
HFD-1/Dr. John Jenkins
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFC-2/ Michael Verdi
HF-22/Matthew Warren

Joanne Less
Kathleen Pfaender
HFD-45/Constance Lewin
HFD-45/Susan K. Cummins
HFD-45/David Burrow
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF