DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ehigiator O. Akhigbe
Registration Number 30118-016
FCI Morgantown
Federal Correctional Institution
P.O. Box 1000
Morgantown, WV 26507

SEP 13 2010

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0235

Dear Dr. Akhigbe:

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 twenty five 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 seventeen felonies under Federal law for conduct involving fraud, false statement and falsification or destruction of records. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On December 17, 2009, you were found guilty of seventeen felonies. On March 19, 2010, the United States District Court for the District of Columbia entered judgment against you for one count of health care fraud in violation of 18 U.S.C. § 1347, and sixteen counts of false statements in health care matters in violation of 18 U.S.C. § 1035. The underlying facts supporting this conviction are as follows.

You were a medical doctor with licenses to practice in the District of Columbia, Maryland, Pennsylvania, and Virginia. You owned and operated Mercigab Medical Center and Pain Clinic in the District of Columbia. The District of Columbia Medicaid Program contracted with Amerigroup Corporation (Amerigroup) to act as its fiscal agent for the processing and payment of claims submitted by Medicaid providers. On or about December 6, 2001, you entered into a Participating Physician Agreement with Amerigroup whereby you agreed to provide healthcare services to District of Columbia Medicaid beneficiaries.

You prepared and submitted your own billing to Amerigroup for medical services you purportedly provided to your patients. For each billed visit, you or others acting at your direction, generated insurance claim forms which included your certification that all of the information on the claim form was accurate. From on or about December 6, 2001, until the termination of your contract with Amerigroup on June 24, 2004, you submitted approximately 3,957 claims to Amerigroup for

services you purportedly provided to Medicaid patients and sought approximately $807,347.00 from Amerigroup. You received approximately $290,103.80 in payments from Amerigroup.

Beginning in approximately December 2002, and continuing to approximately May 2005, in the District of Columbia and elsewhere, you knowingly, willfully, and with intent to defraud, executed a scheme and artifice to defraud Amerigroup as to material matters in connection with the delivery of and payment for health care benefits, items, and services, and to obtain money from Amerigroup by means of material false and fraudulent pretenses and representations and the concealment of material facts in connection with the delivery of and payment for health care benefits, items, and services.

As part of the scheme you repeatedly prepared and submitted false claims in which you purported to have performed surgical or invasive medical procedures or other procedures on D.C. Medicaid patients that were never performed; you billed for office visits that never occurred; and you continued to bill for a period of time after a minor or major procedure during which no additional bills could be submitted, in violation of Global Billing rules.

In order to conceal from Amerigroup that you were billing for procedures that you had not performed, you created false progress notes indicating the dates, times and medical procedures that you claimed to have performed and inserted the false progress notes into your patients' medical files to corroborate a number of false claims.

FDA's Finding

Section 306(b)(2)(B)(ii)(I) of the Federal Food, Drug, and Cosmetic Act (FDCA 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. Each of the statutes under which you were convicted, 18 U.S.C. §§ 1347 and 1035, requires the government to prove that your actions were knowingly and willingly performed. Moreover, the criminal acts occurred in the course of your profession, the practice of medicine. 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 medical claims for procedures you performed. Your convictions indicate that you knowingly and willingly disregarded your legal obligation to submit accurate medical claims for reimbursement. Further, you disregarded your professional obligation to your patients to maintain their medical records in an accurate manner. 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 disregard of the obligations of your profession, FDA has 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 debarment is appropriate.

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 one felony count of health care fraud and sixteen felony counts of false statements in health care matters. The statutes under which you were convicted, 18 U.S.C. §§ 1347 and 1035 each require the government to prove that your actions were knowingly and willingly performed. The evidence at trial established that you personally prepared and submitted hundreds of false Medicaid claims over a number of years for medical services that you never performed on your D.C. Medicaid patients. You stipulated at sentencing that the loss amount was between $200,000 and $400,000. To further support your fraudulent billing scheme, you created false progress notes and inserted them in your patients' medical files. Your actions demonstrate that you were more concerned with making a profit than in taking care of the needs of your D.C. Medicaid patients. Your actions further demonstrate that you did not care whether your fraudulent billing scheme adversely impacted your patients' medical histories, nor did you give any consideration to whether the insertion of false progress notes into your patients' medical files would or could lead to future mis-diagnosis due to false medical histories. 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.

You owned and operated Mercigab Medical Clinic and Pain Clinic. In your position as the clinic owner, you prepared and submitted your own billing to Amerigroup, repeatedly submitting false claims in which you purported to have performed procedures that were never performed and you billed for office visits that never occurred. To substantiate the false billing, you created false progress notes indicating the dates, times and surgical procedures that you claimed to have performed and inserted the false progress notes into your patients' medical files to corroborate a number of false claims. You chose to engage in such criminal conduct intentionally and repeatedly. Accordingly, the Agency will consider the nature and extent of your participation as an unfavorable factor.

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.

As a trusted physician and D.C. Medicaid provider, you committed seventeen serious felony offenses. Your actions have the potential for causing significant loss of public confidence in the healthcare system, particularly by the poor who rely on Medicaid. As the Government argued in its sentencing memorandum, your actions demonstrate that you were more concerned with making a profit than in taking care of the needs of your D.C. Medicaid patients. Your actions further demonstrate that you did not care whether your fraudulent billing scheme adversely impacted your patients' medical histories, nor did you give any consideration to whether the insertion of false progress notes into your patients' medical files would or could lead to future mis-diagnosis due to false medical histories. Rather than taking any actions to mitigate the impact of your offenses on the public, you continued your scheme over a period of years. 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.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, 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 twenty-five years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of one count of health care fraud and sixteen counts of false statements in health care matters, Federal felony offenses. Based on the factors discussed above, FDA proposes that each felony offense be accorded a debarment period of five 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 five-year period of debarment for each of the 17 offenses of conviction need not be served consecutively, which would result in a period of debarment of 85 years. FDA has concluded that the purposes of the debarment provision of the Act will be served if: (1) the five-year periods of debarment for counts 2-6 run concurrently, (2) the periods of debarment for counts 7-10 run concurrently, (3) the periods of debarment for counts 11-14 run concurrently, and (4) the five year periods of debarment for counts 14-16 and 18 run concurrently. The four periods of debarment described in the preceding sentence shall run consecutively to each other and shall run consecutively to the five-year period of debarment for count 1, resulting in a total debarment period of twenty-five 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.

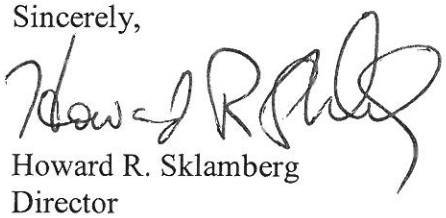
A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the 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.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment under section 306(b)(2)(B)(ii)(I) of the Act (21 U.S.C. 335a(b)(2)(B)(ii)(I) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2010-N-0235 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 within the Food and Drug Administration.

Sincerely,



Howard R. Sklamberg
Director
Office of Enforcement
Office of Regulatory Affairs