

IN THE MATTER OF

Callixtus Onigbo Nwaehiri, P.D.

LICENSE NUMBER: 10899

Respondent

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BEFORE THE
MARYLAND
STATE BOARD
OF PHARMACY

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ORDER FOR SUMMARY SUSPENSION

Pursuant to Md. State Govt. Code Ann. §10-226 (c) (2004 Repl. Vol.), the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. §§ 12-101 *et seq.* (2005 Repl. Vol.), Code Md. Regs. tit. 10, § 34.01.12, the State Board of Pharmacy (the "Board") hereby summarily suspends the license of Callixtus Onigbo Nwaehiri, P.D., License Number 10899, (the "Respondent"), to practice pharmacy under the Act. This Order is based on the following investigative findings, which the Board has reason to believe are true:

FINDINGS OF FACT

1. The Respondent is licensed to practice pharmacy in the State of Maryland under License Number 10899.

2. At all times relevant, NewCare Home Health Services, Inc. ("NewCare") was authorized to operate a pharmacy and distribute prescription drugs in the State of Maryland. NewCare currently holds a permit to operate a pharmacy with waiver under permit number PW0101, and a permit to distribute drugs under permit number D00652. NewCare is owned and/or operated by Steven Abiodun Sodipo and/or the Respondent and is the location where the Respondent is actively engaged in the practice of pharmacy.

3. At all times relevant, NewCare was operating a pharmacy and distributing prescription drugs at 3423-3425 Sinclair Lane, P.O. Box 4118, Baltimore, MD 21213.

a. In its "Application for Permit to Operate a Pharmacy in Maryland" and "Application for Waiver from Full Service Pharmacy Requirement" both dated August 1993, NewCare is listed as serving patients as an infusion pharmacy. In its 1993 "Application for Waiver" NewCare is listed as having vertical and horizontal laminar flow hoods.

b. In or about May 2005, the Respondent submitted a request to the Board asking that NewCare be allowed to add mail order/internet prescription services to NewCare's permit.

c. In its "Renewal Application for Waiver from Full Service Pharmacy Requirements" dated October 2005, NewCare's pharmaceutical specialty is listed as "Long-term pharmacy, IV Infusion, disposable medical supplies and internet pharmacy and mail order prescription services."

d. An inspector from the Maryland Division of Drug Control ("DDC") inspected NewCare in December 2005. The DDC inspector observed the IV pharmacy was not in service. The only recognized functions of the facility that were observed were Long-Term Care and Correctional pharmacy services. The DDC inspector was informed by Mr. Sodipo that NewCare was not conducting any internet pharmacy business. The Respondent signed off on a DDC inspection report from December 2005 indicating that internet business was not being conducted at NewCare. The DDC inspector was also provided with a list of Long-Term Care facilities served by NewCare. It was later

discovered that some of the facilities on that list were not actually Long-Term Care facilities and many did not have the number of beds as stated on the list.

4. Background information from the United States Drug Enforcement Administration ("DEA") revealed the following:

a. In 2003, NewCare purchased approximately 4,200 dosage units of Hydrocodone¹ for further distribution. In 2004, NewCare's orders of Hydrocodone rose to 4,600 dosage units. In 2005, NewCare ordered in excess of 4 million dosage units of Hydrocodone for further distribution. As of August 2006, NewCare has ordered in excess of 4 million tablets of Hydrocodone, making NewCare the number one purchaser of Hydrocodone of all pharmacies in the State of Maryland. In comparison, the number two purchaser of Hydrocodone in Maryland has purchased approximately 162,800 dosage units of Hydrocodone in the same time frame in 2006.

b. NewCare is distributing Hydrocodone to various locations around the United States via internet sales. Individuals are able to obtain Hydrocodone by accessing an internet website, furnishing cursory information, medical records, and paying for a phone consultation. An individual then contacts the customer for a consultation; however, no physical exams are conducted. The physicians issuing the prescriptions are not located in Maryland and the customers receiving the prescriptions are located all over the United States.

c. The investigation has also revealed that some of NewCare's Long-Term Care facilities are in fact local residences and incapable of holding the stated number of beds listed in NewCare's facility listing.

¹ Schedule III Controlled Substance.

d. On or about June 21, 2006, federal agents conducted a trash search of refuse removed from a trash dumpster used by NewCare. The following items were discovered:

(1) Approximately 250 empty 500-ct. Hydrocodone containers (7.5/500mg, 7.5/750 mg, 10/325 mg, 10/500 mg, 10/650 mg, all marked "Watson").

(2) Approximately 1,362 prescription labels were discovered in NewCare's trash.² Of those prescription labels approximately 1,225 were for combination Hydrocodone products, totaling 113,907 tablets. Each label was marked with the heading "Prescription." Each label contained an ID number, process date, and shipping date. Each label also contained patient names, addresses, phone numbers, dates of birth, allergies, specific medication and dose, directions for use, physician's name, DEA number, address, and phone number. A large *electronic* signature³ of the doctor is visible in the center portion of the page on each label. The labels also had markings indicating that they were internet orders.

(3) The prescription labels were for prescriptions filled on May 18, 2006, June 1, 7, 12, 14, 15, 16, 19, and 20, 2006. The majority of the prescriptions were filled on June 15 (523), June 16 (233), June 19 (287), and June 20 (293). The labels identified customers in 47 states and the District of Columbia. Eight physicians were

² Code Md. Regs. tit. 10, § 34.05.04A(1) "A pharmacy permit holder shall: (1) Prevent unauthorized disclosure or loss by securing all patient records[.]"

³ Code Md. Regs. tit. 10, § 19.03.09A(1) "A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner."

identified as the prescribers for the customers. None of the physicians listed on the labels were Maryland physicians. The majority were located in Florida.

5. On or about October 10, 2006, an inspector with the DDC accompanied members of various federal agencies to NewCare's pharmacy. The DDC inspector observed federal agents interviewing various employees and federal agents conducting an inventory and seizing NewCare's Controlled Dangerous Substances (CDS) that were on hand in the pharmacy. Federal agents arrested the Respondent and Mr. Sodipo.

6. Pursuant to a federal Indictment, the Respondent and Mr. Sodipo, among others, were charged with two counts:

Count One

did knowingly, intentionally, and unlawfully combine, conspire, confederate, and agree with each other and with other known and unknown to the Grand Jury to distribute and possess with intent to distribute, outside the scope of professional practice and not for a legitimate medical purpose, a controlled substance, that is, at least eight (8) million dosage units of hydrocodone, a Schedule III controlled substance, in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(D).

Count Two

did knowingly, intentionally, and unlawfully, combine, conspire, confederate, and agree with each other and with others known and unknown to the Grand Jury to commit the following offenses against the United States, in violation of Title 18, United States Code, Section 1956(a)(1):

to conduct and attempt to conduct financial transactions affecting interstate commerce that involved the proceeds of specified unlawful activities in connection with the distribution of hydrocodone, a Schedule III controlled substance, in violation of Title 21, United States Code, Sections 841 and 846, knowing that the funds involved in the financial transactions represented the proceeds of the specified unlawful activities, and with the intent to promote the carrying on of the specified unlawful activities, as set forth in Count One of this Indictment, in violation of Title 18, United States Code, Section 1956(a)(1)(A)(I); and knowing that the

transactions were designed in whole or in part to conceal or disguise the nature, the location, the source, the ownership, or the control of the proceeds of the specified unlawful activities, as set forth in Count One of this Indictment, in violation of Title 18, United States Code, Section 1956(a)(1)(B)(I).

7. The federal Indictment also included a provision governing the forfeiture to the United States of property belonging to the Respondent and/or NewCare. Specifically enumerated in the Indictment was the "property known as Newcare Pharmacy, and Newcare Home Health Services, Inc., located at 3423-25 Sinclair Lane, Baltimore City, Maryland," bank accounts, vehicles, and personal residences, among other things. The assets seized equaled approximately \$20 million in alleged illegal drug sales.

8. Both the Respondent and Mr. Sodipo were released on October 12, 2006.

a. Mr. Sodipo – As a condition of his release, Mr. Sodipo was ordered to notify the pharmacy board of the pending charges and is not to dispense and prescribe narcotic medication unless approved by the Maryland Board of Pharmacy.

b. The Respondent – As a condition of his release, the Respondent was also ordered to notify the Board of Pharmacy of the pending charges and is not to dispense and prescribe narcotic medication unless approved by the Maryland Board of Pharmacy.

9. A DDC inspector has performed random inspections at the NewCare facility since October 10, 2006.

a. On or about October 11, 2006, the DDC inspectors observed Pharmacist A attempting to fill non-CDS prescription medications at NewCare. The DDC inspectors began an inventory and discovered some CDS remaining in the pharmacy. DDC inspectors also observed several blister packages and prescription bottles from other

pharmacies, as well as misbranded containers⁴ of drugs on NewCare's stock shelves intermingled with NewCare's medication stock.⁵ Additionally, Pharmacist B was interviewed and explained he had never prepared IV medications and only remembers a few patients on IV infusion. Pharmacist B also stated NewCare's internet Pharmacy business started in approximately March of 2005. Pharmacist B acknowledged that the prescriptions were from a Florida Clinic and most of the prescriptions were for patients located outside of Maryland.

b. On or about October 12, 2006, the DDC inspectors observed limited activity at NewCare. A delivery driver was observed repacking some medications into unit dose packaging. The delivery driver did not wear gloves during this operation and failed to place information (name of drug, strength, expiration date, lot number) into the repackaging log book.

c. On or about October 13, 2006, in the morning hours, the DDC inspector observed pharmacy technicians repacking some drugs. A pharmacist was present and filled a few pending orders. All blister packaged medications from other pharmacies were removed from the shelves and boxed together. Later in the day, an impoundment order was issued by the DDC for "all controlled dangerous substances on the premises of NewCare." All CDS was impounded and the impound order was posted on the front and back entrances of NewCare. Mr. Sodipo informed the DDC inspectors that NewCare would not be operating on Monday, October 16, 2006. Information was also received

⁴ Some drugs were in bottles containing no lot numbers, expiration dates, and/or manufacturer names.

⁵ Code Md. Regs. tit. 10, § 34.22.09E(1) requires "[p]rescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier for proper disposal."

that NewCare would be closing down its operations as, due to the federal Indictment, no assets were available to pay employees or operate the business.

d. On or about October 16, 2006, a DDC inspector checked on the NewCare facility and confirmed it was not operating. No employees were observed at the facility and it remained locked with no activity in the building.

e. On or about October 17, 2006, a DDC inspector visited NewCare pharmacy and observed a pharmacist and pharmacy technicians filling orders for Long-Term Care facilities.

f. On or about October 20, 2006, Employee A was interviewed and stated that to her knowledge no new orders were received or processed by NewCare on October 20, 2006. Employee A also noted that she would have to basically start from scratch as the patient information was on a server seized by the DEA. Employee A noted the Respondent had a replacement server with limited information.

10. Specifically, the Board has cause to believe that the Respondent violated the following:

Md. Health Occ. Code Ann. § 12-313

(b) *In general.* -- Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant, reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the applicant or licensee:

- (2) Fraudulently or deceptively uses a license;
- (14) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;
- (15) Except as provided in § 12-506 of this title, unless an

authorized prescriber authorizes the refill, refills a prescription for any drug, device, or diagnostic for which a prescription is required;

- (20) Is professionally, physically, or mentally incompetent; [and]
- (24) Violates any rule or regulation adopted by the Board[.]

Code Md. Regs. tit. 10, § 34.10:

.01 Patient Safety and Welfare.

A. A pharmacist shall:

- (1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:
 - (a) United States Code, Title 21,
 - (b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,
 - (c) Health Occupations Article, Title 12, Annotated Code of Maryland,
 - (d) Criminal Law Article, Title 5, Annotated Code of Maryland, and
 - (e) COMAR 10.19.03;

...

B. A pharmacist may not:

...

- (3) Engage in unprofessional conduct.

Code Md. Regs. tit. 10, § 19.03.07C:

Purpose of Issue of Prescription (21 CFR § 1306.04).

- (1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual

practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501-5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of the law relating to controlled dangerous substances.

Code Md. Regs. tit. 10, § 19.03.09A:

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

CONCLUSIONS OF LAW

Based on the foregoing, the Board concludes that the public health, safety or welfare imperatively requires emergency action, pursuant to Md. St. Gov't. Code Ann. § 10-226(c)(2) (2004 Repl. Vol.).

ORDER

Based on the foregoing, it is therefore this 8 day of November 2006, by a majority vote of a quorum of the State Board of Pharmacy, by authority granted to the Board by Md. St. Gov't. Code Ann. § 10-226(c)(2) (2004 Repl. Vol.), hereby:

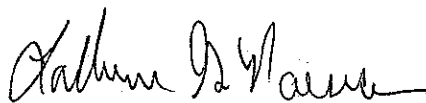
ORDERED that the license issued to the Respondent, Callixtus Onigbo Nwachiri, to practice pharmacy in the State of Maryland under License Number 10899 is hereby **SUMMARILY SUSPENDED**; and be it further

ORDERED that the Respondent is prohibited from practicing pharmacy in the State of Maryland; and be it further

ORDERED that the Respondent shall return his wall certificate and wallet licenses to the Board, within five days of the date this Order is signed by the Board; and be it further

ORDERED that a non-evidentiary Show Cause Hearing shall be scheduled for Wednesday, November 29, 2006, at 1:00 p.m. at the Board's offices, 4201 Patterson Avenue, Baltimore, Maryland 21215, at which the Respondent will be given an opportunity to be heard as to whether the Summary Suspension should be lifted/terminated; and be it further

ORDERED, that this document constitutes a final Order of the Board and is therefore a public document for purposes of public disclosure, as required by Md. State Gov't Code Ann. § 10-617(h) (2004 Repl. Vol.).



LaVerne Naesea, Executive Director
Maryland Board of Pharmacy

For

Mark Levi, President
Maryland Board of Pharmacy

NOTICE OF HEARING

A non-evidentiary Show Cause hearing to determine whether the Summary Suspension shall be lifted/terminated will be held before the Board at 4201 Patterson Avenue, Baltimore, 21215 on **Wednesday, November 29, 2006, at 1:00 p.m.** Failure to appear at the Show Cause Hearing will result in the Board continuing the suspension of your license.