IN THE MATTER OF	*	**BEFORE THE**
CALLIXTUS ONIGBO NWAEHIRI, P.D.	*	**MARYLAND STATE**
LICENSE NO. 10899	*	**BOARD OF PHARMACY**
RESPONDENT	*	

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ORDER CONTINUING SUMMARY SUSPENSION

Pursuant to Md. Code Ann., State Gov't § 10-226(c) (2004 Repl. Vol.), and after a show cause hearing held on November 29, 2006, the Maryland Board of Pharmacy (the "Board") hereby continues the summary suspension of the license to practice pharmacy issued to CALLIXTUS ONIGBO NWAEHIRI, P.D. (the "Respondent"), under the Maryland Pharmacy Act (the "Act"), Title 12, Health Occupations Article (2005 Repl. Vol.).

Findings

The Board determines that the following findings, as originally set forth in the Board's Order for Summary Suspension, continue to warrant emergency action:

1. At all times relevant hereto, the Respondent was licensed to practice pharmacy in Maryland under License Number 10899.

2. At all times relevant hereto, 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 the

Respondent and/or Steven Abiodun Sodipo 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, NewCare submitted a request to the Board asking that it 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 DDC inspector was also provided with a

list of long-term facilities served by NewCare. It was later discovered that some of the facilities on that list were not actually long-term facilities and many did not have the number of beds as stated on the list.

4. Information from the United Stated Drug Enforcement Administration ("DEA") revealed the following:

a. In 2003, NewCare purchased approximately 4,200 dosage units of Hydrocodone[1] 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 4,000,000 tablets of Hydrocodone, making NewCare the number one purchaser of Hydrocodone of all pharmacies in 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 examinations 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.

[1] Schedule III controlled dangerous substance.

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

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 (7.5/500 mg, 7.5/750 mg, 10/325mg, 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 names, DEA number, address, and phone number. A large electronic signature[3] 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.

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[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."

(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 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 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",[4] 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 bail on October 12, 2006.

a. Mr. Sodipo – As a condition of his release, Mr. Sodipo was ordered to notify the Board of Pharmacy of the pending charges and is not to

[4] At the show cause hearing before the Board, NewCare's counsel indicated that NewCare's home health equipment has since been returned.

dispense and prescribe narcotic medication unless approved by the Maryland Board of Pharmacy.

b. 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 containers[5] of drugs on NewCare's stock shelves intermingles with NewCare's medication stock.[6] 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.

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

[6] 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."

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. The Respondent informed the DDC inspectors that NewCare would not be operating on Monday, October 16, 2006. Information was also received 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 Phamracy and observed a pharmacist and pharmacy technician 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.

DISCUSSION

The Respondent has been federally indicted for dispensing, not for a legitimate medical purpose, at least 8 million dosage units of Hydrocodone, a Schedule III controlled dangerous substance in less than two years. The Board finds that it is nearly impossible to justify dispensing such an excessive number of any controlled substance within such a short time period. In fact, it appears that the Respondent, along with his pharmacist business partner, was forced to create false long-term care facility clients in order to justify the purchasing of Hydrocodone in such large quantities.

In addition to the enormous quantities of controlled substances, the "patients" were located throughout the United States, and it appears that most of the prescribing physicians were in states other than the home state of the patient. It is, therefore, very difficult for the Board to accept that the Respondent believed that an actual physician-patient relationship truly existed in order to validate the millions of prescriptions for controlled substances.

The federal court order prohibits the Respondent from dispensing narcotics unless the Board grants approval. The Board, through this Order, is denying such approval. Furthermore, the Board finds there is a substantial likelihood that the Respondent would pose a risk to the public health, safety and welfare if the Respondent was permitted to dispense any prescription drugs, as even certain non-controlled substances have significant street value.

CONCLUSION OF LAW

Based upon the foregoing, the Board concludes that the public health, safety, and welfare imperatively require emergency action, pursuant to Md. Code Ann., State Gov't Article § 10-226(c)(2) (2004 Repl. Vol.).

ORDER

Based on the foregoing, and after a Show Cause Hearing was held in which the Respondent was given the opportunity to be heard as to whether the Summary Suspension should continue, on this 5 day of January, 2007, by an affirmative vote of majority of the Board, it is hereby,

ORDERED that the SUMMARY SUSPENSION of the Respondent's license to practice pharmacy in Maryland, License No. 10899, is CONTINUED; and be it further,

ORDERED that the Respondent may submit a written request to the Board within thirty (30) days of the date of this Order for an evidentiary hearing to be held before the Board on the summary suspension, which hearing may be

consolidated with a hearing on charges, should charges be issued. Failure to request a hearing within thirty (30) days of the date of this Order shall constitute a waiver of any evidentiary hearing; and be it further

ORDERED that this document constitutes a formal disciplinary action of the Maryland State Board of Pharmacy and is therefore a public document for purposes of public disclosure, pursuant to the Public Information Act., State Gov't § 10-611 *et seq.* and COMAR 10.34.01.12.

January 5, 2007
Date

LaVerne G. Naesea, Executive Director
for
Mark Levi, P.D.,
President, Board of Pharmacy