

IN THE MATTER OF

\*

BEFORE THE

NEWCARE HOME HEALTH SERVICES, INC.

\*

MARYLAND STATE

\*

BOARD OF PHARMACY

Permits No.: PW0101/D00652

\*

Respondent Pharmacy/Distributor

\*

\* \* \* \* \*

**ORDER FOR SUMMARY SUSPENSION**

Pursuant to Md. State Govt. Code Ann. § 10-226 (c) (2004 Repl. Vol.), the State Board of Pharmacy (the "Board") hereby suspends the pharmacy and distributor permits issued to NewCare Pharmacy Services (the "Respondent-Pharmacy"), under the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. §§ 12-101, *et seq.* (2005 Repl. Vol.). This Order is based on the following investigative findings, which the Board has reason to believe are true:

**Findings**

1. At all times relevant, 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 a waiver under permit number PW0101, and a permit to distribute drugs under permit number D00652. NewCare's October 2005 Renewal Application to the Board was signed by Steven A. Sodipo, Pharm.D. NewCare is owned and/or operated by pharmacists Steven Abiodun Sodipo (License Number 11532) and/or Callixtus Onigbo Nwaehiri (License Number 10899) and is the location where both pharmacists were actively engaged in the practice of pharmacy.

2. 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 its 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 that NewCare was not conducting any internet pharmacy business. 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.

3. Information from the United States Drug Enforcement Administration ("DEA") revealed the following:

a. In 2003, NewCare purchased approximately 4,200 dosage units of

Hydrocodone<sup>1</sup> 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 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 (7.5/500mg, 7.5/750 mg, 10/325 mg, 10/500 mg, 10/650 mg, all marked "Watson").

---

<sup>1</sup> Schedule III Controlled Substance.

(2) Approximately 1,362 prescription labels were discovered in NewCare's trash.<sup>2</sup> 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* signature<sup>3</sup> 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 identified as the prescribers for the customers. None of the physicians listed on the labels were Maryland physicians. The majority were located in Florida.

4. 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

---

<sup>2</sup> 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[.]"

<sup>3</sup> 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."

inventory and seizing NewCare's Controlled Dangerous Substances (CDS) that were on hand in the pharmacy. Federal agents arrested Mr. Sodipo and Mr. Nwaehiri.

5. Pursuant to a federal Indictment, Mr. Sodipo and Mr. Nwaehiri, 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).

6. The federal Indictment also included a provision governing the forfeiture to the United States of property belonging to 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.

7. Both Mr. Sodipo and Mr. Nwaehiri 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. Mr. Nwaehiri – As a condition of his release, Mr. Nwaehiri 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.

8. 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<sup>4</sup> of drugs on NewCare's stock shelves intermingled with NewCare's medication stock.<sup>5</sup> 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

---

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

<sup>5</sup> 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."

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 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 Mr. Sodipo had a replacement server with limited information.

### Discussion

The two pharmacist owners of NewCare, Mr. Sodipo and Mr. Nwaehiri, have been federally indicted for illegally dispensing and distributing approximately 8 million doses of hydrocodone, a Schedule III controlled dangerous substance ("CDS"). It is alleged that Mr. Sodipo and Mr. Nwaehiri have illegally utilized the pharmacy and distributor permits issued to NewCare to dispense and distribute millions of doses of controlled dangerous substances to individuals throughout the United States via the internet. At this juncture, NewCare has had its controlled dangerous substance inventory seized by both the DEA and the State's Division of Drug Control. Mr. Sodipo and Mr. Nwaehiri have both been arrested and released under certain conditions. In the federal court order, one of those conditions prohibits both pharmacists from dispensing narcotics unless they receive approval from the Board.<sup>6</sup>

NewCare is currently operating a pharmacy under a waiver permit issued by the Board that restricts its operations to long-term care, internet, durable medical supplies and

---

<sup>6</sup> Contemporaneous with this Order, the Board has issued orders continuing the summary suspensions against Mr. Sodipo and Mr. Nwaehiri, prohibiting them from practicing pharmacy in any capacity.



home infusion services. Although NewCare's counsel has indicated that it is no longer engaging in internet activities, without taking action against NewCare's permit, the Board cannot prohibit such activity. In addition, as of December 2005, DDC reported that NewCare was not actively engaged in home infusion services. The remaining significant specialty area of pharmacy under NewCare's waiver permit is long-term care.

As stated above, NewCare's CDS inventory has been seized by the DEA and the Division of Drug Control. Without a CDS inventory, it is impossible to render comprehensive services to those long-term care facilities and institutional facilities currently under contract with NewCare. There are numerous federal and Medicare requirements regarding the provision of pharmacy services to long-term care facilities. Indeed, it is a federal requirement that any pharmacy that contracts pharmacy services with a nursing home be able to provide full and timely pharmaceutical services. Clearly, NewCare is not in a position to provide such services. As residents in nursing facilities are generally vulnerable adults with compromised health conditions, it is imperative for their health, safety and continuity of care that the contract pharmacy be able to provide the full spectrum of pharmacy needs. In addition, a contract pharmacy that can only provide non-controlled medications disrupts the continuity of care for these elderly patients as well as severely hindering the pharmacy's the ability to perform adequate drug regimen reviews. Furthermore, the contract pharmacy is responsible for establishing a system of receipt and disposition of controlled drugs to enable an accurate reconciliation of controlled substances dispensed to the long-term care facility. In light of the misconduct at issue, it is wholly inappropriate and poses substantial risk to nursing home residents to allow NewCare to perform these services.

Lastly, the recent DDC inspections clearly evidence that NewCare is in a state of disarray, (e.g., allowing delivery person to package medications, maintaining unlabeled drug products, and violating confidentiality by inappropriately discarding patient sensitive information) and is incapable of providing even marginal services to long-term care facilities.

As the Board has summarily suspended the pharmacists' licenses of both Mr. Sodipo and Mr. Nwaehiri, it is impossible for the Board to protect the public by allowing both pharmacists continued access to NewCare, the very pharmacy which was used to dispense 8 million doses of controlled substances in less than 2 years. Although the controlled substances have been seized, many non-controlled substances have significant street value, such as Viagra, Soma and Promethazine. Although the federal court has released Mr. Sodipo and Mr. Nwaehiri pursuant to certain conditions, such release does not relieve the Board of its commensurate responsibility to protect the public from the substantial likelihood of risk posed by the continued operation of NewCare.

### **Conclusion**

Based on the foregoing, the Board finds that the public health, safety or welfare imperatively requires emergency action, pursuant to Md. St. Govt. Code Ann. § 10-226(c)(2) (2004 Repl. Vol.).

### **ORDER**

Based on the foregoing, and after a Show Cause Hearing was held in which the Respondent-Pharmacy was given the opportunity to be heard as to whether a Summary

Suspension should be executed, on this 5 day of JANUARY, 2007, by an affirmative vote of majority of the Board, by authority granted to the Board by Md. Code Ann., State Gov't Art. § 10-226(c)(2) (2004 Repl. Vol.), it is hereby,

**ORDERED** that the permits held by the Respondent to operate NewCare Pharmacy Services, Inc. (Permits No. PW0101/D00652) are hereby **SUMMARILY SUSPENDED**, such suspension to be effective thirty (30) days from the date of this Order; and be it further,

**ORDERED** that the Respondent-Pharmacy shall close in accordance with the requirements set forth in Code Md. Regs. tit. 10, § 34.14 and shall not accept any new business; and be it further,

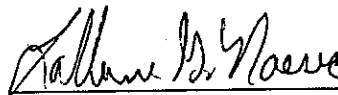
**ORDERED** that as of the effective date of this Order, the Respondent-Pharmacy is prohibited from operating as a pharmacy or distributing prescription drugs in the State of Maryland; and be it further,

**ORDERED** that the permit holder shall return all permits and renewal permits pertaining to the Respondent-Pharmacy, within five (5) days of the effective date of this Order; 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 effective date of this Order shall constitute a waiver of any evidentiary hearing; and be it further

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

JANUARY 5, 2006  
Date



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