BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: ALLWELL PHARMACY AND MEDICAL SUPPLIES, LLC; CLETUS UCHE DURU, MEMBER AND PHARMACIST-IN-CHARGE Pharmacy Permit No. PHY 50426 and CLETUS UCHE DURU Pharmacist License No. RPH 46402 Respondents.	Case No. 6012 OAH No. 2017060170

DECISION AFTER RECONSIDERATION (AS TO RESPONDENT ALLWELL PHARMACY AND MEDICAL SUPPLIES, LLC ONLY)

The California State Board of Pharmacy (Board) issued a Decision and Order in this matter on April 24, 2018, which was set to be effective at 5 p.m. on May 24, 2018. The Decision and Order adopted the February 22, 2018, Proposed Decision of the administrative law judge.

Prior to the effective date, respondent Allwell Pharmacy and Medical Supplies, LLC (respondent Allwell) timely requested reconsideration of the decision, requesting that the revocation of the pharmacy permit be modified. Specifically, respondent Allwell requested a stay of the effective date revoking the pharmacy permit to allow for the sale of the pharmacy.

On May 24, 2018, the Board granted reconsideration as to respondent Allwell, only, and further stayed the decision as to that respondent until the Board issued its decision after reconsideration.[1] Both parties were invited to submit written argument.

Respondent Allwell submitted a letter argument dated June 28, 2018, indicating that the owner wished to withdraw his request for reconsideration because he had sold the pharmacy.

[1] The Board's decision became effective as to respondent Duru's pharmacist license, at 5 p.m. on May 24, 2018.

Good cause appearing, on reconsideration, the Board upholds its May 24, 2018, Decision and Order adopting the Proposed Decision.

IT IS SO ORDERED this 1st day of August, 2018.

This Decision and Order will be effective at 5 p.m. on August 10, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Victor Law, R.Ph.
Board President

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: ALLWELL PHARMACY AND MEDICAL SUPPLIES, LLC; CLETUS UCHE DURU, MEMBER AND PHARMACIST-IN-CHARGE Pharmacy Permit No. PHY 50426 and CLETUS UCHE DURU Pharmacist License No. RPH 46402 Respondents.	Case No. 6012 OAH No. 2017060170

ORDER GRANTING PETITION FOR RECONSIDERATION, IN PART

On April 24, 2018, the California State Board of Pharmacy issued a Decision and Order adopting the Proposed Decision as its decision in this matter. The decision was set to become effective at 5 p.m. on May 24, 2018.

Pursuant to Government Code section 11521, respondents timely requested reconsideration of the decision as to Allwell Pharmacy and Medical Supplies, LLC, License No. PHY 50426. Good cause appearing, IT IS HEREBY ORDERED:

(1) That reconsideration of the decision be, and is, hereby granted, as to respondent Allwell Pharmacy and Medical Supplies, LLC (PHY 50426), only, and that the decision is hereby further stayed as to PHY 50426 until the board renders its decision on reconsideration;

(2) That reconsideration will be based on the pertinent parts of the record. No new evidence will be allowed. The board will not order a copy of the transcript of the hearing, but the parties are invited to submit written argument. The parties are encouraged to address arguments raised in the petition for reconsideration.

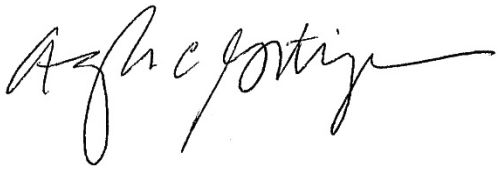
(3) The parties shall submit written argument, if any, on or before June 25, 2018. Any argument shall be served on the board at 1625 N. Market Blvd, Suite N219,

Sacramento, CA, 95834, Attention: Susan Cappello, Enforcement Manager. Each party shall provide the other party with a copy of any written argument filed with the board.

The portion of the April 24, 2018, Decision and Order related to Respondent Cletus Uche Duru's pharmacist license (RPH 46402), shall become effective at 5:00 p.m. on May 24, 2018, as previously ordered.

IT IS SO ORDERED this 24th day of May 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By _____
Amy Gutierrez, Pharm.D.
Board President

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: ALLWELL PHARMACY AND MEDICAL SUPPLIES, LLC; CLETUS UCHE DURU, MEMBER AND PHARMACIST-IN-CHARGE Pharmacy Permit No. PHY 50426 and CLETUS UCHE DURU Pharmacist License No. RPH 46402 Respondents.	Case No. 6012 OAH No. 2017060170

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter

This Decision shall become effective at 5:00 p.m. on May 24, 2018.

It is so ORDERED on April 24, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: ALLWELL PHARMACY AND MEDICAL SUPPLIES, LLC; CLETUS UCHE DURU, MEMBER AND PHARMACIST-IN-CHARGE Pharmacy Permit No. PHY 50426 and CLETUS UCHE DURU Pharmacist License No. RPH 46402 Respondents.	Case No. 6012 OAH No. 2017060170

PROPOSED DECISION

Administrative Law Judge Tiffany L. King, Office of Administrative Hearings, State of California, heard this matter on January 16 and 17, 2018, in Sacramento, California.

Mabel Lew, Deputy Attorney General, represented Virginia Herold (complainant), Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs (Department), State of California.

Attorney Adam J. Richards represented respondents Allwell Pharmacy and Medical Supplies, LLC (Allwell) and Cletus Uche Duru (respondent Duru). Respondent Duru was present, throughout the hearing.

Evidence was received, the record was closed, and the matter was submitted for decision on January 17, 2018.

SUMMARY

Complainant seeks to discipline Allwell's permit based a number violations of federal and state law. Complainant also seeks to discipline respondent Duru's license as he was the pharmacist-in-charge when the violations occurred. Additionally, complainant alleges respondent Duru individually violated his corresponding duty by distributing numerous prescriptions for controlled substances written by a physician, whose office was in Fresno, as well as numerous other suspicious prescriptions. Cause for discipline was established by clear and convincing evidence. Respondent Duru introduced sufficient evidence of his continued fitness to perform the duties of a pharmacist, pursuant to certain terms and conditions, including a prohibition from owning or operating his own pharmacy.

FACTUAL FINDINGS

1. On August 16, 1993, the Board issued Pharmacist License Number RPH 46402 (license) to respondent Duru. Said license will expire on May 31, 2019, unless renewed or revoked. On November 1, 2010, the Board issued Pharmacy Permit Number PHY 50426 (permit) to Allwell for its location at 5611 Stockton Boulevard in Sacramento, California. The permit will expire on November 1, 2018, unless renewed or revoked. Respondent Duru is listed as the sole member and pharmacist-in-charge (PIC) of Allwell. In 2013, the license and permit were cited and fined for violating pharmacy law by filling a prescription with an incorrect prescriber name. Respondents have no other history of discipline.

2. Complainant, acting solely in her official capacity, signed the Accusation on June 13, 2017. The Accusation seeks to discipline respondent Duru's license and Allwell's permit based on numerous violations of federal and state laws and regulations governing pharmacy. Respondents timely filed a Notice of Defense. The matter was set for an evidentiary hearing before an Administrative Law Judge of the Office of Administrative Hearings, an independent adjudicative agency of the State of California, pursuant to Government Code section 11500, et seq.

The Board's Investigation

3. Steven Kyle has been an inspector with the Board for approximately three years. He received his Doctorate of Pharmacy (Pharm D.) in 1996 and is a licensed pharmacist in California. He worked as a pharmacist for 18 years for numerous pharmacies, and as a PIC for ten years. Inspector Kyle has inspected more than 100 pharmacies. He is assigned to the prescription drug abuse team and his duties include investigating and inspecting pharmacies and licensees regarding their compliance with pharmacy laws and regulations.

4. In 2016, the Board received information that Jose Flores, M.D., who practiced in Fresno, had surrendered his medical license due, in part, to the improper prescribing of

controlled substances.[1] Inspector Kyle was assigned to investigate the matter. As part of his investigation, Inspector Kyle ordered a Controlled Substance Utilization Review & Evaluation System (CURES) report for Dr. Flores, showing all prescriptions dispensed from pharmacies under his name for the period of April 1, 2013 to April 1, 2016. The report revealed that Allwell had dispensed a large number of Dr. Flores's prescriptions, notwithstanding it was located more than 160 miles from Fresno. It further revealed that Allwell dispensed more controlled substance prescriptions for Dr. Flores than any other pharmacy, including local pharmacies in Fresno. Inspector Kyle then ordered a CURES report for Allwell, which showed the pharmacy placed orders for unusually large quantities of promethazine with codeine.[2]

5. On May 5, 2016, Inspector Kyle and another board inspector, Irina Top, Pharm. D., conducted an inspection of Allwell during business hours. Upon their arrival, the following personnel were present: respondent Duru as the PIC; one pharmacy technician; and four pharmacy clerks.

UNLICENSED ACTIVITY

6. The inspectors observed Gloria Sanchez, a pharmacy clerk, at the prescription filling counter. Ms. Sanchez opened a prescription drug container of amlodipine 5mg, poured the drug on a counter tray, and began counting the tablets with a spatula. On the counter in front of her was a prescription label for amlodipine 5mg for a patient. The inspectors interviewed Ms. Sanchez, who told them she had worked at the pharmacy for five years and had always counted drugs for prescriptions. She confirmed she had never been trained as a pharmacy technician. At that time, respondent Duru walked to the counter and interrupted the interview. He told the inspectors that Ms. Sanchez was not "filling" prescriptions, but was only counting tablets, which he had authorized her to do. The inspectors explained to respondent Duru that pharmacy clerks were prohibited by law from counting prescription medications, as they are not licensed pharmacy technicians. The inspectors requested and reviewed Allwell's pharmacy technician policy, and confirmed it was consistent with the laws regulating pharmacy technicians.

DRUG LOSS

7. Inspector Kyle asked respondent Duru if he had experienced any recent losses of controlled substances. Respondent Duru reported that, in 2012, the pharmacy was robbed during store hours and the assailants stole approximately six pint-size (480ml) bottles of promethazine with codeine. Respondent Duru filed a police report and called the Drug

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[1] Dr. Flores surrendered his medical license pursuant to a stipulated settlement with the Medical Board of California (Medical Board) on April 9, 2014.

[2] Promethazine with codeine (also known as Phenergan with Codeine Syrup) is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1).

Enforcement Administration (DEA). However, the DEA advised him that he was not required to report the drug loss to the Board, because it was too insignificant an amount. Respondent Duru admitted he did not make a drug loss report to the Board, noting he was unaware he was required to do so.

8. At hearing, Inspector Kyle explained the average prescription for promethazine with codeine is much less than a pint, and the maximum daily dose is 30ml. He further explained the drug is a Schedule V controlled substance which is highly sought after on the street for abuse, and bears the street names, "Sizzurp" and "Purple Drank." Depending on the geographic area, a one-pint bottle of the drug has a street value from $250 up to $1,000.

9. Respondent Duru admitted to the inspectors he did not perform a controlled substances inventory immediately following the robbery. He was further unable to provide the inspectors with any documents or records, such as the police report, concerning the theft. Inspector Kyle requested respondent Duru send him any additional information he subsequently found regarding any controlled substance losses. On May 27, 2016, the Board received a handwritten letter from respondent Duru. In the letter, respondent Duru asserted the 2012 theft was the only controlled substance loss, that approximately "7-8 16 oz bottles were taken," but that he did not know what portion of the stolen bottles contained promethazine with codeine.

QUALITY ASSURANCE PROGRAM

10. Pharmacy law requires each pharmacy to establish or participate in a Quality Assurance Program to document medication errors and assess an appropriate response to prevent future errors. (Cal. Code Regs., tit. 16, § 1711.) During the May 5, 2016 inspection, Inspectors Kyle and Top requested to review the pharmacy's records of medication errors. Respondent Duru provided a binder containing the pharmacy's Quality Assurance Program policy and incident reporting forms. The binder also included one completed report of a medication error dated August 1, 2012. Inspector Kyle found it very unusual that the pharmacy had only one reported medical error over a four-year period, given the high number of prescriptions Allwell dispensed in that time period. Respondent Duru then told the inspectors about another error he had discovered "a few months" earlier. On August 18, 2015, the pharmacy dispensed the wrong package of Apidra to a patient (in pen rather than vial form). The pharmacy discovered the error when the patient returned the medication. Respondent Duru did not document the error in an incident report.

11. Inspector Kyle asked respondent Duru if there were any other medication errors at the pharmacy. Respondent Duru stated he believed that there were, but that he could not recall the details and did not document them in an incident report. Allwell's Quality Assurance Program policy provided: "A pharmacist MUST complete a Prescription Incident Report whenever an error is discovered AFTER the patient has left the pharmacy, regardless of whether the medication was ingested or not." Notwithstanding the policy, Inspector Kyle found that Allwell did not follow its own Quality Assurance Program policy

and therefore failed to participate in a Quality Assurance Program in a manner aimed at preventing future errors. Specifically, the pharmacy did not keep all of the following records in an immediately retrievable form for at least one year: the date, location, and participants in the quality assurance review; the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact; the findings and determinations generated by the quality assurance review; and, recommended changes to pharmacy policy, procedure, systems, or processes.

PRESCRIPTION LABELS

12. Pharmacy law requires prescription labels to contain specific information in the following order: (1) patient's name; (2) name and strength of the drug; (3) direction for use; and, (4) the condition or purpose for which the drug was prescribed, if the condition or purpose is indicated on the prescription. (Cal. Code Regs., tit. 16, § 1707.5, subd. (a).) The purpose of said labeling requirements is to create uniformity and a standard of effective communication with patients regarding what medication they are receiving.

13. While on-site, Inspectors Kyle and Top reviewed a sample Allwell prescription label provided by respondent Duru. The inspectors noted that while the label contained all the information required by law, the information was out of order, listing the name and strength of the drug last.

BIENNIAL INVENTORY AND RECORD REQUIREMENTS

14. State and federal law require pharmacies to perform a biennial inventory of controlled substances in the pharmacy. The report must identify: all Schedule II through V drugs and the date the inventory was completed. The report must also indicate whether the inventory was completed before opening or after closing close of the pharmacy to ensure there were no pending prescription transactions. Finally, inventory reports must be maintained by the pharmacy for at least three years.

15. Upon request, respondent Duru provided Allwell's 2015 inventory report to Inspector Kyle. The report had a handwritten notation, "May/June," on the top of the page. It identified only Schedule II drugs, and did not list any Schedule III through V controlled substances. The report also did not indicate the date the inventory was completed, or whether it was completed before opening or after closing of the pharmacy. Inspector Kyle asked to review another inventory report, and respondent Duru provided him with a 2014 report. The 2014 report had a date/time stamp of May 5, 2014, 11:10 a.m.; but it was unclear whether this referred to the time of printing or the time the inventory was conducted. Because the last page of the report listed a different time, Inspector Kyle assumed the May 5, 2014 date was the print date. The 2014 report also did not indicate when the inventory was performed, or if it was completed prior to opening or after closing of the pharmacy. Respondent Duru could not recall when he performed either the 2014 or 2015 inventories, but stated it was his practice to begin the inventory in the morning and complete it over the course of several days. Inspector Kyle reviewed with respondent Duru the biennial inventory

requirements. Because Allwell did not have a valid inventory completed within the past two years, Inspector Kyle directed respondent Duru to complete one and sent it to him.

16. On May 8, 2016, respondent Duru sent Inspector Kyle a copy of the pharmacy's 2016 inventory report. However, the report was not legible and Inspector Kyle requested another copy. On May 27, 2016, respondent Duru provided Inspector Kyle a USB drive with a copy of Allwell's dispensing records from April 1, 2013 through May 9, 2016. Inspector Kyle reviewed it and noted the 2016 inventory report was deficient because it did not indicate when the inventory was conducted, or if it was performed before opening or after closing of the pharmacy. In addition, the inventory was missing entries for the following common controlled substances: hydrocodone/APAP 10/325; methadone 10mg; oxycodone 15 mg and 30mg; and oxycodone APAP 10/325.[3] A review of Allwell's records indicated these medications were regularly dispensed. Therefore, the 2016 inventory was inaccurate and incomplete.

CONTROLLED SUBSTANCE PRESCRIPTIONS

17. Pharmacy law requires prescription forms for controlled substances to contain 14 security features. (Health & Saf. Code, § 11162.1.) During the Board's inspection, Inspector Kyle found Allwell had dispensed controlled substances for prescriptions written on forms which did not contain all of the security features. Specifically, on February 5, 2015, Allwell dispensed prescriptions written by Thomas McIlraith, M.D., for alprazolam[4] 2mg and hydrocodone/APAP 10/325 mg. The prescription forms were missing the following security features: (1) a watermark stating "California Security Prescription" on the back of the form; (2) the number of the security printer approved by the Department of Justice; and (3) the lot number printed on the form. On February 19, 2015, Allwell dispensed a prescription written by Darla Duran, M.D., for alprazolam 2mg. The prescription form was missing the following required security features: (1) a watermark on the back of the form; (2) the number of the approved security printer; and (3) the lot number printed on the form.

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[3] Hydrocodone/APAP 10/325 (commonly known as Norco or Lortab) is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e)(5). Methadone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c)(14). Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M). APAP refers to acetaminophen.

[4] Alprazolam (commonly known as Xanax) is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1). Alprazolam is used to control anxiety and is highly sought after on the street, where it bears the nicknames "bars" or "ladders."

CORRESPONDING RESPONSIBILITY FOR LEGITIMACY OF PRESCRIPTION

18. When a prescription for controlled substances raises "red flags" regarding its legitimacy, the pharmacist has a corresponding responsibility to verify the prescription was issued for a legitimate medical purpose and was by a physician in the normal course of his or her professional practice. The pharmacist can cross-check the prescription with the patient's CURES report or the CURES records of the prescribing physician to see if the prescription appears legitimate. He may also call the prescribing physician to resolve any irregularities with the prescription. However, if after making reasonable attempts to verify its legitimacy, the pharmacist continues to doubt the legitimacy of a prescription, he is obligated to reject the prescription and not fill it.

19. Inspector Kyle reviewed the Dr. Flores's CURES records from April 1, 2013 through April 11, 2016, for all controlled substance prescriptions filled at Allwell. During that time period, Allwell dispensed controlled substances for 653 prescriptions written by Dr. Flores, 591 (90.5 percent) of which were paid for with cash; Allwell was the top pharmacy for dispensing controlled substance prescriptions by Dr. Flores. All 34 patients lived in or around Sacramento area, an urban area, yet traveled more than 160 miles to Dr. Flores for treatment. Additionally, all 34 patients were prescribed oxycodone, hydrocodone/APAP, and carisoprodol in the highest strength and for the maximum dosage available. There were also numerous instances in which groups of similar or identical prescriptions were filled on the same day or within a short time span, and paid for mostly by cash. Inspector Kyle explained that all of these factors were "red flags" of abuse for which Allwell should have taken steps to validate the prescriptions. However, a review of Allwell's patient prescription records found no evidence that Allwell took any steps to verify that the prescriptions were for a legitimate medical purpose.

20. Between April 2013 and May 2016, Allwell dispensed at least 70 prescriptions for promethazine with codeine written by Sen Jone, M.D. The prescription forms were missing the number of the approved security printer, and the lot number printed on the form. Inspector Kyle also noted the prescriptions were for full pints (480 ml), which is the amount commonly ordered by wholesalers. Promethazine with codeine is typically prescribed for cough relief and in amounts of 240 ml or less. The high quantity of the amount prescribed, in addition to defects in the prescription forms, were indications that the prescriptions were possibly illegitimate and being diverted for abuse.

21. In other instances, Allwell filled several prescriptions for high dosages of methadone or other opioids and dispensed them to patients who were considered opioid naïve,[5] based on their CURES data, or who exhibited other red flags of opioid abuse. In nearly all of these instances, the patients were new to Allwell, paid in cash only, had prescriptions from out-of-town doctors, and requested high starting dosages of the controlled

[5] An opioid-naïve patient is one who has not taken certain dosages of opioid for at least a week prior to being given the dosage prescribed.

substance prescribed. The following are examples of suspicious prescriptions filled by Allwell.

a. Jerome F.

Date	Days Supply	Quantity	Drug	Prescribing Physician
11/25/13	30	90	Hydrocodone/APAP 10/325 mg	Sultan Sultan
11/25/13	30	90	Oxycodone 30 mg	Sultan Sultan
01/29/14	30	180	Methadone 10 mg	Carol Jessop
01/29/14	30	180	Oxycodone 30 mg	C. Jessop

Jerome F. was considered opioid-naïve at the time he received the prescriptions from Dr. Jessop, and therefore, the dosage of methadone was considered high. Inspector Kyle also noted the following irregularities regarding Jerome F.'s prescriptions: (1) Dr. Jessop's office was located in Oakland, 90 miles away from Allwell; (2) the drug name and direction information was preprinted or rubberstamped on the prescription form; and (3) the prescriptions were paid for in cash. Additionally, the prescription document had a notation on the front indicating some information as preprinted due to Dr. Jessop having a broken wrist. However, handwritten on the form was the patient's name, drug quantity and strength, dosage and frequency.

b. Brandon T.

Date	Days Supply	Quantity	Drug	Prescribing Physician
04/09/14	30	120	Methadone 10 mg	Ronald Chambers

Brandon T. had no prior medication history at Allwell and he paid with cash. The high starting dosage of methadone was more than four times the recommended dose. Finally, the patient's CURES report showed he had been supplied with methadone six days previously by a different pharmacy.

c. Norman A.

Date	Days Supply	Quantity	Drug	Prescribing Physician
09/24/14	30	120	Methadone 10 mg	Allen Hassan

Norman A, had no prior medication history with Allwell and he paid with cash. The high starting dosage of methadone was more than four times the recommended dose.

Additionally, Dr. Hassan's medical license was on probation by the Medical Board, due in part to repeated gross negligence in the prescribing of controlled substances.

d. Torrell F.

Date	Days Supply	Quantity	Drug	Prescribing Physician
06/06/14	30	120	Methadone 10 mg	Allen Hassan

Torrell F. was considered opioid-naïve based on his CURES report, which revealed a previous oxycodone 30 mg prescription by Dr. Hassan filled by Wal-Mart on April 24, 2014. Therefore, the starting dose of methadone was considered high. Torrell F. also had no medication history with Allwell and he paid with cash. Finally, as noted earlier, Dr. Hassan's medical license was on probation.

e. Edwin B.

Date	Days Supply	Quantity	Drug	Prescribing Physician
03/19/14	30	120	Alprazolam 2 mg	Octavio Camasura
03/19/14	30	120	Carisoprodol	Octavio Camasura
03/19/14	23	180	Hydrocodone/APAP 10/325 mg	Octavio Camasura

Based on his CURES history, Edwin B. had been supplied with Alprazolam and Carisoprodol six days previously by a different pharmacy. He was new to Allwell and paid with cash. Dr. Camasura was located in Marysville, north of Sacramento. Edwin B. lived in Sacramento, but north of the pharmacy. He would have had to travel a total of 105 miles to visit the physician then return to Allwell to fill the prescription. There were numerous other pharmacies in close proximity to the patient's residence. Additionally, Dr. Camasura's medical license had been disciplined by the Medical Board for prescribing medicinal marijuana without a proper medical exam, indicating a past practice of disregarding prescription rules and requirements.

f. Bruce (aka John) O.

Date	Days Supply	Quantity	Drug	Prescribing Physician
06/09/14	30	120	Oxycontin 80 mg	Allen Hassan
07/03/14	25	100	Oxycontin 80 mg	Allen Hassan

Bruce O. was a new patient to Allwell. The patient's CURES report showed he received prescriptions for Oxycodone 30 mg on June 2, 2014 and again on June 28, 2014,

from different physicians and filled at a different pharmacy. The dosage and frequency of Oxycontin prescribed was unusually high; it was also prescribed at the maximum strength. As noted earlier, Dr. Hassan's medical license was on probation. The prescription directed the patient to take the Oxycontin every six hours, though this medication is intended to be taken every 12 hours. The dispensing pharmacy is required to provide a medication guide describing the risks and give instructions directly to the patient.

Respondent's Evidence

22. Respondent obtained his bachelor of science in pharmacy in 1987 from the University of Benin in his home country of Nigeria. He immigrated to the United States in 1991. After passing the Board's pharmacist exam in 1993, he worked as a pharmacist for several national pharmacies, including Rite Aid (formerly, "Thrifty Payless"), where respondent was a PIC and ran his own store.

23. In 2000, respondent Duru moved with his wife to New York, so the latter could attend her medical residency in family medicine. Respondent Duru became licensed in New York and continued to work as a pharmacist and PIC for Rite Aid. In 2004, he and his wife returned to California and respondent Duru continued his employment with Rite Aid.

24. In 2010, respondent wanted to open his own pharmacy in a neighborhood where he could make an impact on the community. He started Allwell "from the ground up" in November 2010. Allwell is located right across from a Rite Aid store in a low to middle income neighborhood with a mixed demographic. In his first month, respondent Duru employed two employees and dispensed roughly 50 prescriptions. He now employs seven employees and dispenses more than 4,000 prescriptions each month. In addition, respondent Duru employs a relief pharmacist who works at the pharmacy two days a week. As owner and PIC, respondent Duru described his duties as "everything from janitorial to managing inventory, order[ing] supplies, ensur[ing the] system is functional, hiring/firing, and administrative issues."

25. At hearing, respondent admitted he had an unlicensed person performing the duties of a licensed pharmacy technician when the Board inspectors arrived on May 5, 2016. He explained he was unaware he was violating the law before Inspector Kyle advised his interpretation of the law was incorrect. Following the Board's inspection, Allwell was also inspected by the DEA. Respondent Duru met with all of his employees to discuss the changes needed at the pharmacy. Since that time, no unlicensed personnel has performed any tasks for which a license is required.

26. Respondent Duru also admitted that, in the past, Allwell did not always adhere to its Quality Assurance Program policy. Respondent Duru kept notes of medication errors in a basket so he would not forget about them, but he did not always fill out an incident report. Since the inspection, Allwell documents medication errors in an incident report as soon as respondent Duru learns of it.

27. Further, respondent Duru also admitted the Allwell prescription labels inspected by Inspectors Kyle and Top did not meet the legal requirements. He subsequently called the software vendor which fixed the issue. Allwell's prescription labels currently meet all legal requirements.

28. Respondent Duru testified regarding the 2012 robbery, which he described as a "grab and run." He did not see the suspects steal any medication, but saw them carrying bottles when he reviewed the security video. He did not know whether they stole controlled substances, noting only that they stole promethazine[6] products based upon the location of the missing bottles. He admitted that, at that time, he had "an unsophisticated system to track inventory," and therefore, he could not confirm what had been taken. He called the police but believed they minimized the case because no one was killed or injured. He also reported the robbery to the DEA because he was uncertain what the suspects had taken. Respondent Duru testified he was aware of his duty to report a controlled substance loss to the Board, but did not in this case because he did not know if controlled substances had been taken. He denied telling Inspector Kyle that 6-8 bottles of promethazine with codeine were stolen. Since the inspection, Allwell has taken steps to prevent robberies in the future including, hiring an inventory manager to keep track of inventory, moving the promethazine with codeine products to another location within the pharmacy, and storing opioids in a locked box.

29. Respondent Duru testified he prefers to conduct controlled substances inventories on Sundays when the pharmacy is closed and no deliveries are made. Respondent Duru performs the inventory himself on an annual basis. He denied failing to conduct any biennial inventory.

30. Respondent Duru admitted he erred in not checking for all the required security features on some of the prescription forms for controlled substances. He asserted that technology is continuously changing and it can be difficult to differentiate between real and fake forms. Although he makes his best effort to do so, he admitted "some things slip through." In the past, respondent Duru asserted the pharmacy contacted the prescriber if it detected any irregularities in the prescription. Today, the pharmacy runs a CURES report for every controlled substance prescription and any new patient. If any irregularities are noticed, the pharmacy contacts the prescribing doctor's office.

31. Respondent Duru testified Allwell contacted Dr. Flores's office several times to verify prescriptions presented by patients. Dr. Flores had an active medical license during this time, so respondent Duru did not believe he could refuse to fill the prescription. Additionally, Dr. Flores did not accept certain insurances. Patients requested Allwell match the insurance price and then paid with cash. Respondent Duru did not suspect the prescriptions from Dr. Flores were illegitimate because they were consistent with his pain management practice. Respondent Duru testified Allwell also contacted other physicians

[6] Promethazine, by itself, is not a controlled substance and therefore is not required to be reported in the event of loss.

when irregularities were found in the prescription forms. He denied the pharmacy ever dispensed a prescription which respondent Duru knew to be deficient or fraudulent.

32. Respondent Duru submitted several letters of support from his professional colleagues, friends and family.[7]

a. Okwudili B. Ahiligwo is a pharmacist at Bidwell Pharmacy in Chico. He has known respondent Duru for more than 30 years, as a friend and colleague. They previously worked together at Rite Aid and respondent Duru was instrumental in Mr. Ahiligwo's transition to the retail pharmacy. Mr. Ahiligwo described respondent Duru as possessing "steadfastness, uprightness, honesty, commitment and humility," and that he is the "epitome of all that a good pharmacist should strive for . . . ." When Mr. Ahiligwo learned the Board was investigating respondent Duru and Allwell, he was filled with shock, surprise, and disbelief.

b. Dr. Chimezie Ubbaonu[8] is respondent's brother-in-law. They described respondent Duru as "very motivated and disciplined," and as having "outstanding character."

c. Ugochukwu Ubbaonu[9] has known respondent Duru for over 15 years, noting respondent Duru supported and helped him when he immigrated to the United States to pursue a legal career. He described respondent Duru as dependable and having a "passion to succeed."

d. Isaac Erinmwingbovo has known respondent Duru for over twenty years as a friend and colleague. He extolled respondent Duru as a "consummate professional, [who is] ethical and practices his profession with [the] utmost care for his patient." He further praised respondent Duru as a "strong family man and man of faith," and noted he is highly involved in his community and youth education.

Discussion

33. The evidence established Allwell violated pharmacy law by: (1) allowing a non-licensed person to perform activities required to be performed by a licensed pharmacy technician; (2) failing to include on its prescription labels the required information in the designated order; (3) failing to promptly document medication errors and to adhere to its

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[7] These letters were admitted as "administrative hearsay" and considered to the extent permitted under Government Code section 11513, subdivision (d).

[8] In his letter, Dr. Ubbaonu did not identify what type of doctorate he holds.

[9] The record did not reflect whether Mr. Ubbaonu has any relation to Dr. Ubbaonu.

Quality Assurance Program policy; and, (4) failing to ensure prescription forms for controlled substances contained certain security features required by law.

34. The evidence further established that Allwell failed to perform and maintain accurate and complete biennial inventories of controlled substances during the time period relevant to the Accusation. Additionally, Allwell failed to report a controlled substance loss to the Board following a 2012 robbery.

35. Respondent Duru's testimony that he did not know what type of promethazine was stolen, or any controlled substances were taken, was not credible. He reported the robbery to the DEA, which only requires loss of controlled substances be reported. During the May 5, 2016 inspection, he indicated to Inspector Kyle that promethazine with codeine had been stolen. Finally, it is worth noting that had Allwell maintained accurate and complete biennial inventories, respondent Duru would have been able to verify easily what drugs had been stolen, the amount stolen, and whether any controlled substances were taken.

36. Allwell and respondent Duru owed a corresponding duty to verify that the controlled substance prescriptions presented by patients were written for a legitimate medical purpose and by a physician in the normal course of his or her professional practice. While this corresponding duty does not make the pharmacy nor the pharmacist a guarantor that every prescription filled was in fact written for a legitimate medical purpose, it requires respondent Duru (as PIC) to exercise professional judgment in assessing the legitimacy of each prescription presented. If respondent Duru held doubts as to the legitimacy of a prescription, after making reasonable attempts to verify its legitimacy, he is obligated to reject the prescription and not fill it. Respondent Duru seemed ignorant of this fact.

37. Information regarding the prescriptions described in Findings 18 through 21 revealed multiple "red flags" that should have raised respondents' suspicions about numerous prescriptions. Many of the prescription forms lacked the required security features. Several were for unusually high doses of opioids prescribed for opioid-naïve patients, who were new to Allwell and paid in all cash. Prescription forms that were lacking required security features prescribed an unusually high amount of promethazine with codeine, a commonly abused drug sold on the street. Hundreds of prescriptions were written by Dr. Flores, whose practice was located 160 miles from Allwell, for patients residing in Sacramento. Dr. Flores also prescribed the same or similar controlled substances, or combinations of the same, for the maximum strength, to different patients on the same day. Finally, many of the prescriptions were written by doctors whose licenses were disciplined by the Medical Board, or surrendered under threat of discipline for overprescribing controlled substances.

38. Despite these red flags, respondents did not fulfill their corresponding duty by taking steps to confirm the legitimacy of the prescriptions. While none of the red flags by themselves constituted conclusive evidence of a fraudulent prescription, each was sufficient to raise enough suspicion such that respondents were obligated to make a reasonable inquiry to determine the legitimacy of the prescription. Respondents failed to introduce persuasive

evidence of their efforts to confirm the legitimacy of any of the above-referenced prescriptions, such as asking the patients why they were paying for their prescription with cash, or why they were driving what appeared to be a long distance to obtain and fill the prescription, or contact their prescribing physician to confirm the legitimacy of the prescriptions.

39. The Board has adopted disciplinary guidelines (Guidelines) for consideration when determining the appropriate discipline to impose for a violation of pharmacy law. (Cal. Code Regs., tit. 16, § 1760.) The guidelines categorize different violations of pharmacy law into one of four categories, and recommends a range of discipline for each. Each of the violations committed by respondents fall under Category I, II or III. The recommended discipline for the Category I ranges from revocation stayed, one year's probation, all standard terms and conditions, and all appropriate optional terms and conditions to outright revocation. And the recommended discipline for the latter categories ranges from revocation stayed, 90-day actual suspension, three to five years' probation, all standard terms and conditions, and all appropriate optional terms and conditions to outright revocation.

40. The Guidelines also provide criteria for consideration when determining the specific discipline imposed for the particular category violated. Relevant criteria include: (1) actual or potential harm to the public or any consumer; (2) prior disciplinary record or warnings; (3) number or variety of current violations; (4) nature and severity of the acts or crimes under consideration; (5) evidence of aggravation, mitigation, or rehabilitation; (6) time passed since the act or offense; (7) whether the conduct was intentional or negligent, or demonstrated incompetence; and (8) whether respondent financially benefitted from the misconduct.

41. Respondents repeatedly violated pharmacy laws and regulations regarding controlled substances and aimed at ensuring such medications are aimed at ensuring such medications are prescribed for a legitimate medical purpose and preventing their diversion for abuse. These violations were serious and presented an actual and potential harm to the public insofar as respondents dispensed hundreds of prescriptions for controlled substances which were not validated and were not appropriately inventoried, and in a manner which made it likely that the controlled substances were being diverted for abuse. While there was no evidence that respondents' actions were intentional, the evidence as a whole established that respondents' conduct was negligent or demonstrated incompetence.

42. Respondent has been a licensed pharmacist for more than 30 years. Other than a citation and fine in 2013 for filling a prescription with an incorrect prescriber name, he has had no other Board discipline. Respondent Duru took responsibility for several pharmacy law violations, though he continues to deny responsibility for others. (*Seide v. Committee of Bar Examiners of the State Bar of California* (1989) 49 Cal.3d 933, 940-941 [acknowledging the wrongfulness of one's past conduct is an essential element of rehabilitation].) It has been less than three years since the Board's inspection and investigation of Allwell. While respondent Duru's proficiency with pharmacy law appeared to be lacking during the inspection, he made changes after the inspectors informed him of the various violations. For

example, Allwell has updated policies and re-educated its staff, hired a relief pharmacist and inventory manager, performed annual controlled substance inventories and began securing opioids in a locked box. Furthermore, Respondent Duru is open to being placed on probation with any conditions that the Board deems appropriate to place on his license and permit.

43. The purpose of license discipline is not to punish the licensee, but to protect the public. When all the evidence is considered, it would not be contrary to the public interest to allow respondent to maintain his pharmacist license on a restricted basis, subject to certain terms and conditions including a prohibition from owning or operating his own pharmacy Therefore, Allwell's permit should be revoked.

Costs

44. Complainant has requested that respondent be ordered to pay investigation and enforcement costs in the total amount of $37,755.50 pursuant to Business and Professions Code section 125.3. This amount consists of costs incurred directly by the Board ($19,480.5) as well as costs incurred by the Office of the Attorney General and billed to the Board ($18,275).[10] At hearing, complainant introduced a signed Certification of Costs of Investigation by Agency Executive Officer as well as supporting declarations by Supervising Inspector Ngondara, Inspector Kyle, and Inspector Top. Complainant also introduced a Certification of Prosecution Costs: Declaration of Mabel Lew. The declaration attached a computer printout of the tasks the Attorney General's office performed, the amount of time spent performing these tasks, and the amounts charged. Respondent did not object to any of complainant's evidence of costs, and did not introduce any evidence of his inability to pay them.

45. Complainant established that the requested costs are reasonable in light of the allegations and issues in this matter. Complainant's request for costs is further addressed in the Legal Conclusions below.

LEGAL CONCLUSIONS

1. Complainant bears the burden of proving each of the grounds for discipline alleged in the Accusation by clear and convincing evidence. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) Clear and convincing evidence requires proof that is so clear as to leave no substantial doubt and sufficiently strong to command the

[10] The Certification asserted its total investigative costs as $19, 512.25 based on 10 Supervising Inspector hours at $127 per hour, and 150.5 Inspector hours at $121 per hour. However, the itemization of time spent per task in Supervising Inspector Antony Ngondara's declaration totals 10 hours, rather 10.25. The Declaration of Mabel Lew asserted the Office of the Attorney General billed the Board a total of $18,515 (through December 13, 2017). However, the itemization of hours attached to her declaration lists a total amount of $18,275. The amount of investigation and prosecution costs was thus adjusted accordingly.

unhesitating assent of every reasonable mind. (*Katie V. v. Superior Court* (2005) 130 Cal.App.4th 586, 594.)

Applicable Law

DUTIES OF A PHARMACIST-IN-CHARGE

2. "'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy." (Bus. & Prof. Code, § 4036.5.) Business and Professions Code section 4113, subdivision (c), provides: "the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

PHARMACIST'S CORRESPONDING DUTY

3. Health and Safety Code section 11153 imposes a corresponding duty on pharmacists to confirm prescriptions for controlled substances are issued only for legitimate medical purposes as follows:

> A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

4. California Code of Regulations, title 16, section 1761, defines a pharmacist's corresponding duty as follows:

> (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such

prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

5. Business and Professions Code section 4081 states, in relevant part:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every . . . pharmacy . . . who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy . . . shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

Cause for Discipline

6. Pursuant to Business and Professions Code section 4301, the Board is authorized to discipline a permit or license if the permit holder or licensee is guilty of unprofessional conduct, which includes:

[¶] . . . [¶]

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

[¶] . . . [¶]

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

[¶] . . . [¶]

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

7. Additionally, Business and Professions Code section 4306.5 defines unprofessional conduct for a pharmacist as including:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

UNLICENSED ACTIVITY

8. A pharmacy technician may perform "packaging, manipulative, repetitive, or other nondiscretionary tasks" while assisting, and under the supervision of a pharmacist. (Bus. & Prof. Code, § 4115, subd. (a).) Said "nondiscretionary tasks" include: removing the drug or drugs from stock; counting, pouring or mixing pharmaceuticals; placing that product into a container; affixing a label or labels to the container; and, packaging and repackaging. (Cal. Code Regs., tit. 16, § 1793.2.) It is unlawful for a pharmacy to employ any person to act as a pharmacy technician who is not a pharmacy technician. (Bus. & Prof. Code, § 4115, subd. (e).) As set forth in Finding 6, Allwell employed an unlicensed person to perform the duties of a pharmacy technician, including opening, counting, and repackaging prescription medication. Therefore, cause exists to discipline Allwell's permit pursuant to Business and

Professions Code section 4301, subdivision (o), as that statute relates to Business and Professions Code section 4115 and California Code of Regulations, title 16, section 1793.2.

9. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 8, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

REPORTING DRUG LOSS

10. A pharmacy owner "shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths." (Cal. Code Regs., tit. 16, § 1715.6.) As set forth in Findings 7 through 9, and 34, Allwell failed to report the loss of controlled substances to the Board within 30 days of discovery. Therefore, cause exists to discipline Allwell's permit pursuant to Business and Professions Code section 4301, subdivision (o).

11. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 10, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

FAILURE TO PARTICIPATE IN QUALITY ASSURANCE PROGRAM

12. Every pharmacy "shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy services and prevent errors." (Cal. Code Regs., tit. 16, § 1711, subd. (a).) "Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form." (Cal. Code Regs., tit. 16, § 1711, subd. (c)(1).) Each medication error shall be investigated as soon as reasonably possible, but no later than two business days from the date of discovery. All medication errors are subject to a quality assurance review, the record of which should contain: the date, location, and participants in the review; the pertinent data and other information relating to the medication error; the findings and determinations generated by the review; and any recommended charges to pharmacy policies, procedures, and processes. (Cal. Code Regs., tit. 16, § 1711, subds. (d) and (e).)

13. As set forth in Findings 10, 11 and 33, Allwell failed to participate in an established quality assurance program, and failed to follow its own policy regarding the same, by failing to document and assess medication errors. Therefore, cause exists to discipline Allwell's permit pursuant to Business and Professions Code section 4301, subdivision (o), as that section relates to California Code of Regulations, title 16, section 1711.

14. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 13, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

REQUIREMENTS FOR PATIENT-CENTERED PRESCRIPTION LABELS

15. Labels on prescription drug containers dispensed to patients in California must list information in the following order: the name of the patient; the name and strength of the drug; the directions for use of the drug; and the condition or purpose for which the drug was prescribed if so stated on the prescription. (Cal. Code Regs., tit. 16, § 1707.5, subd. (a).) Said information must be "clustered into one area of the label that comprises at least 50 percent of the label." (*Id.*)

16. Allwell used prescription labels which did not list the above information in the required order. (Findings 12 and 13). Accordingly, cause exists to discipline Allwell's permit pursuant to Business and Professions Code section 4301, subdivision (o), as that section relates to California Code of Regulations, title 16, section 1707.5, subdivision (a).

17. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 16, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

BIENNIAL INVENTORY AND RECORD REQUIREMENTS

18. A pharmacy is required to make a biennial inventory of all controlled substances it maintains. (21 C.F.R. § 1304.11(c).) The inventory shall include the name of each drug, the form in which it is kept (e.g., pill, capsule, or liquid), the number of units or volume of each drug, and the number of commercial containers of each drug. (21 C.F.R. § 1304.11(e)(1)(iii), (6).) Additionally, pharmacies must maintain a current inventory[11] of all dangerous drugs it maintains. (Bus. & Prof. Code, § 4081, subd. (a).) Any person who fails, neglects, or refuses to maintain these required records or to produce them for an inspection within a reasonable time, is guilty of a misdemeanor. (Bus. & Prof. Code, § 4332.)

19. At a minimum, as of May 5, 2016, Allwell failed to make a biannual inventory of all controlled substances it maintained as explained in Factual Findings 14 through 16, and 34. Accordingly, cause exists to discipline Allwell's permit pursuant to Business and Professions Code section 4301, subdivision (o), as that section relates to Business and Professions Code sections 4081 and 4332, California Code of Regulations, title 16, section 1718, and 21 Code of Federal Regulations part 1304.11.

[11] "Current inventory," as used in Business and Professions Code sections 4081 and 4332, includes "complete accountability for all dangerous drugs handled by every licensee enumerated" therein. (Cal. Code Regs., tit. 16, § 1718.)

20. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 19, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

CONTROLLED SUBSTANCE PRESCRIPTIONS

21. Health and Safety Code section 11164 provides:

> [N]o person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.
>
> (a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
>
> (1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

22. In February 2015, Allwell dispensed controlled substances pursuant to prescription forms that were missing required security features, as explained in Findings 17, 19, and 33. Therefore, cause exists to discipline Allwell's permit pursuant to Business and Professions Code section 4301, subdivision (o), as that section relates to Health and Safety Code section 11164.

23. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 22, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

CORRESPONDING RESPONSIBILITY FOR LEGITIMACY OF PRESCRIPTIONS

24. As set forth in Findings 18 through 21, and 36 through 38, Allwell failed to fulfill its corresponding responsibility to ensure the controlled substance prescriptions it filled were issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Accordingly, cause exists to discipline

Allwell's permit pursuant to Business and Professions Code section 4301, subdivision (o), as that section relates to Health and Safety Code section 11153, and California Code of Regulations, title 16, section 1761.

25. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 24, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

UNPROFESSIONAL CONDUCT

26. As set forth in the Findings and Legal Conclusions as a whole, Allwell engaged in unprofessional conduct by operating in a grossly negligent manner, violating laws and regulations governing the controlled substances and the practice of pharmacy, and clearly furnishing excessive amounts of controlled substances without exercising its corresponding responsibility to dispense only medically legitimate prescriptions. (Bus. & Prof. Code, § 4301, subds. (a), (d), (j), and (o).)

27. Respondent Duru was the PIC of Allwell at all relevant times. Therefore, cause also exists to discipline his license pursuant to Legal Conclusion 26, and Business and Professions Code sections 4036.5 and 4113, subdivision (c).

Appropriate Discipline

28. When all the evidence is considered, and for the reasons set forth in Findings 32 through 41, Allwell's permit shall be revoked. Respondent Duru's license shall be revoked, the revocation shall be stayed, and the license placed on probation for a period of five years, subject to the terms and conditions set forth below.

Costs

29. Pursuant to *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, various factors must be considered in determining the amount of costs to be assessed. The Board must not assess the full costs of investigation and prosecution when to do so will unfairly penalize a licensee who has committed some misconduct, but who has used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed. The Board must consider the licensee's subjective good faith belief in the merits of his or her position, as well as whether the licensee has raised a colorable challenge to the proposed discipline. The Board must determine that the licensee will be financially able to make later payments. Finally, the Board may not assess the full costs of investigation and prosecution when it has conducted a disproportionately large investigation to prove that a licensee engaged in relatively innocuous misconduct.

30. As discussed in Findings 44 and 45, complainant's request that respondent reimburse the Board $37,755.50 for its costs to investigate and enforce this matter is reasonable. Respondents provided no evidence of any basis to reduce these costs, for which

they are jointly and severally liable. Respondents shall be ordered to pay the Board's costs in the total amount of it $37,755.50, pursuant to a payment plan approved by the Board.

ORDER

1. Pharmacy Permit Number 50426 issued to respondent Allwell Pharmacy and Medical Supplies, LLC, listing Cletus Uche Duru as member and pharmacist-in-charge, is hereby REVOKED.

Respondent owner shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five days of disposition.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding 60 days.

2. Pharmacist License No. RPH 46402 issued to Cletus Uche Duru is REVOKED; however, the revocation is stayed and respondent is placed on probation for five years upon the following terms and conditions.

(1) Obey All Laws: Respondent shall obey all state and federal laws and regulations. Respondent shall report any of the following occurrences to the board, in writing, within 72 hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime

- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

(2) **Report to the Board:** Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

(3) **Interview with the Board:** Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

(4) **Cooperate with Board Staff:** Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

(5) **Continuing Education:** Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

(6) **Notice to Employers:** During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6012 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within 30 days of the effective date of this decision, and within 15 days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6012, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 6012 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within 30 days of the effective date of this decision, and within 15 days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 6012 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

(7) **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant:** During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

(8) **Reimbursement of Board Costs:** As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $37,755.50. Respondent shall make said payments pursuant to a payment plan approved by the board.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

(9) **Probation Monitoring Costs:** Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its

designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

(10) **Status of License:** Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

(11) **License Surrender While on Probation/Suspension:** Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

(12) **Notification of a Change in Name, Residence Address, Mailing Address or Employment:**

Respondent shall notify the board in writing within 10 days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within 10 days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

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(13) **Tolling of Probation:**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within 10 days of the cessation of practice, and must further notify the board in writing within 10 days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding 36 months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

(14) **Violation of Probation:** If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

(15) **Remedial Education:**

Within 90 days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education regarding state and federal law governing controlled substances. The program of remedial education shall consist of at least 40 hours, which shall be completed within one year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

(16) **Supervised Practice:**

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

- Continuous - At least 75% of a work week
- Substantial - At least 50% of a work week
- Partial - At least 25% of a work week
- Daily Review – Supervisor's review of probationer's daily activities within 24 hours

Within 30 days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 6012 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within 15 days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 6012 and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within 10 days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Failure to comply with this suspension shall be considered a violation of probation.

(17) **No Ownership of Licensed Premises:**

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within 90 days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

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(18) **Completion of Probation:** Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

DATED: February 22, 2018

DocuSigned by:
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TIFFANY L. KING
Administrative Law Judge
Office of Administrative Hearings

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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ALLWELL PHARMACY AND MEDICAL SUPPLIES, LLC; CLETUS UCHE DURU, MEMBER AND PHARMACIST-IN-CHARGE** **5611 Stockton Blvd.** **Sacramento, CA 95824** **Pharmacy Permit No. PHY 50426,** **and** **CLETUS UCHE DURU** **5611 Stockton Blvd.** **Sacramento, CA 95824** **Pharmacist License No. RPH 46402** Respondents.	Case No. 6012 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about November 1, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50426 to Allwell Pharmacy and Medical Supplies, LLC (Respondent Allwell) with

Cletus Uche Duru as a Member and as Pharmacist-In-Charge (PIC). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2017, unless renewed.

3. On or about August 16, 1993, the Board of Pharmacy issued Pharmacist License Number RPH 46402 to Cletus Uche Duru (Respondent Duru). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2017, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 4300 of the Code states, in pertinent part:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

7. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or

who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

8. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the

customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

9. Section 4081 of the Code states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

10. Section 4113 of the Code states, in pertinent part:

(a) Every pharmacy shall designate a pharmacist-in-charge ...

...

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

11. Section 4115 of the Code states, in pertinent part:

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

...

(e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

12. Section 4306.5 of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

13. Section 4332 of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

HEALTH AND SAFETY CODE

14. Section 11153 of the Health and Safety Code states, in pertinent part:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

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15. Section 11164 of the Health and Safety Code states, in pertinent part:

[N]o person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

FEDERAL REGULATION

16. Section 1304.11 of title 21 of the Code of Federal Regulations (21 CFR 1304.11) states, in pertinent part:

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. ... The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

...

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

CALIFORNIA REGULATIONS

17. Section 1707.5 of title 16 of the California Code of Regulations (16 CCR 1707.5) states, in pertinent part:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient.

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

18. 16 CCR 1711 states, in pertinent part:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

...

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

...

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

19. 16 CCR 1715.6 states: "The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

20. 16 CCR 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

21. 16 CCR 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

22. 16 CCR 1793.2 states:

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

(a) removing the drug or drugs from stock;

(b) counting, pouring, or mixing pharmaceuticals;

(c) placing the product into a container;

(d) affixing the label or labels to the container;

(e) packaging and repackaging.

CONTROLLED SUBSTANCES

23. Alprazolam is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(1), and is sold under the brand name Xanax.

24. Clonazepam is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(7), and is sold under the brand name Klonopin.

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25. Diazepam is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(9), and is sold under the brand name Valium.

26. Hydrocodone/APAP 10/325 is a Schedule III controlled substance as designated by Health and Safety Code section 11056(e)(5), and is sold under the brand names Norco or Lortab.

27. Methadone is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (c)(14).

28. Oxycodone is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(M).

29. Promethazine/codeine is a Schedule V controlled substance as designated by Health and Safety Code section 11058, subdivision (c)(1) and is sold under the brand name Phenergan with Codeine Syrup.

COST RECOVERY

30. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CAUSES FOR DISCIPLINE

Allwell Pharmacy and Medical Supplies, LLC (Allwell)

FIRST CAUSE FOR DISCIPLINE

(Unlicensed Activity)

31. Respondent Allwell is subject to disciplinary action under Code section 4115, subdivisions (a) and (e) and 16 CCR 1793.2, by and through Code section 4301(o), in that Respondent allowed unlicensed staff to perform the duties of a pharmacy technician. The circumstances are as follows:

32. On or about May 5, 2016 and during a subsequent investigation, Respondent had an unlicensed pharmacy clerk perform the duties of a pharmacy technician, including opening a stock prescription bottle, pouring the drug onto a counting tray, counting the drug to be dispensed

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to a patient, placing the counted drug into a container, and sealing the container. This was confirmed to be a standard workflow practice at Respondent pharmacy.

SECOND CAUSE FOR DISCIPLINE

(Reporting Drug Loss)

33. Respondent Allwell is subject to disciplinary action under 16 CCR 1715.6, by and through Code section 4301(o), in that Respondent failed to report the loss of controlled substances, including their amounts and strengths, to the Board within thirty (30) days. The circumstances are as follows:

34. On or about May 5, 2016, and during a subsequent investigation, it was found that in 2012, six to eight pint-size bottles of promethazine/codeine, a Schedule V controlled substance, were stolen from Respondent during business hours. Respondent was aware of the theft and did not report the loss to the Board.

THIRD CAUSE FOR DISCIPLINE

(Failure to Participate in Quality Assurance Program)

35. Respondent Allwell is subject to disciplinary action under 16 CCR 1711, by and through Code section 4301(o), in that Respondent failed to participate in an established quality assurance program. The circumstances are as follows:

36. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy made a medication error on or about August 18, 2015. Prescription number 740903 was dispensed in error to a patient for the wrong package of Apidra, a dangerous drug. The prescription was returned to the pharmacy by the patient when the error was discovered. Respondent pharmacy did not document an incident report of the error, as required by the Quality Assurance Policy. It was also found that other medication errors had occurred within the past year and no documentation of the errors was completed and kept on file so as to have complete details, conduct a review, and prevent a recurrence of the error, as required by the policy.

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FOURTH CAUSE FOR DISCIPLINE

(Requirements for Patient-Centered Labels for Prescriptions)

37. Respondent Allwell is subject to disciplinary action under 16 CCR 1707.5, subdivision (a), by and through Code section 4301(o), in that Respondent failed to comply with the requirements for patient-centered labels on drug containers. The circumstances are as follows:

38. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy labeled prescriptions in a format with the name of the drug and strength of the drug listed after the directions for use of the drug, in violation of the required order.

FIFTH CAUSE FOR DISCIPLINE

(Biennial Inventory and Record Requirements)

39. Respondent Allwell is subject to disciplinary action under Code section 4081, 16 CCR 1718, and 21 CFR 1304.11, by and through Code section 4301(o), in that Respondent failed to comply with the requirements for maintaining an inventory of controlled substances and completing a biennial inventory. The circumstances are as follows:

40. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy had a controlled substance inventory on file which indicated it was printed on November 5, 2014 without an indication of the completion date or if the inventory was completed as of opening or close of business. Respondent pharmacy also had a controlled substance inventory on file dated May/June 2015. There was no indication of an exact date completed or if the inventory was completed as of opening or close of business. After a controlled substance inventory was requested from Respondent pharmacy, a controlled substance inventory was provided which was dated May 8, 2016, a Sunday when the pharmacy was closed. The inventory did not have any entries for the following controlled substances: hydrocodone/APAP 10/325; methadone 10 mg; oxycodone 30 mg; and oxycodone APAP 10/325. Respondent pharmacy's records indicated that these controlled substances were regularly dispensed. Thus, this was not a complete current inventory of all drug stocks on hand. Respondent did not complete a biennial inventory every two years and have the inventory on file.

SIXTH CAUSE FOR DISCIPLINE

(Requirements for Controlled Substance Prescriptions)

41. Respondent Allwell is subject to disciplinary action under Health and Safety Code section 11164, by and through Code section 4301(o), in that Respondent pharmacy dispensed controlled substances using prescription forms that were missing required features. The circumstances are as follows:

42. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy dispensed controlled substance prescriptions for alprazolam 2 mg and hydrocodone/APAP 10/325 mg on February 5, 2015, and alprazolam 2 mg on February 19, 2015, pursuant to prescription forms that were missing the following required features: 1. Watermark printed on back of prescription blank stating "California Security Prescription"; 2. Identifying number assigned to the approved security printer by the Department of Justice; 3. The lot number printed on the form. Furthermore, between May 10, 2013, and February 21, 2014, Respondent pharmacy dispensed controlled substances pursuant to at least thirty (30) prescriptions from Sen Jone, MD, that were missing the following required features: 1. Identifying number assigned to the approved security printer by the Department of Justice; 2. The lot number printed on the form.

SEVENTH CAUSE FOR DISCIPLINE

(Corresponding Responsibility for Legitimacy of Prescription)

43. Respondent Allwell is subject to disciplinary action under Health and Safety Code section 11153 and 16 CCR 1761, by and through Code section 4301(o), in that Respondent pharmacy failed to fulfill its corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The circumstances are as follows:

44. On or about May 5, 2016, and during a subsequent investigation which reviewed dispensing data and records from April 1, 2013, to May 5, 2016, it was found that Respondent pharmacy dispensed excessive controlled substances prescriptions with irregularities and red flags of abuse without ensuring the prescriptions were issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Respondent pharmacy dispensed controlled substances after ignoring, or not being aware of, objective factors

which were irregular from medically legitimate prescriptions. The objective factors of illegitimacy, irregularity, and abuse included but were not limited to:

a. The invalid nature of prescription documents which did not have required features, were fraudulent, or not issued in the usual course of professional practice.

b. Unusually high doses of opioids for opioid naïve patients.

c. Doctor prescribing trends seemingly inconsistent with the primary area of practice for a surgeon who prescribed a high percentage of promethazine/codeine prescriptions on invalid controlled substance forms.

d. Unusually high cash payment profiles from patients obtaining controlled substances with red flags of abuse, such as out-of-the-area prescriber, invalid forms, high initial doses of opioids, and no previous history with the pharmacy.

e. Patients presenting prescriptions from a doctor whose office was over 160 miles from the pharmacy.

f. Many patients receiving the same or similar controlled substances, or combinations of controlled substances, from a doctor whose office was over 160 miles from the pharmacy.[1] On many occasions, the pharmacy dispensed the same combination of controlled substances written by the same prescriber to different patients on the same day, sometimes within minutes of one another.

g. Near uniformity in prescribing trends of controlled substances for a doctor whose office was over 160 miles from the pharmacy.

h. Many patients receiving the highest table strength of controlled substances with no upward titration from a lower dose for prescriptions from a doctor whose office was over 160 miles from the pharmacy, e.g. highest tablet strength of oxycodone, methadone, alprazolam, diazepam, and clonazepam.

i. Many controlled substance prescriptions dispensed from doctors whose licenses became surrendered, revoked, or put on probation.

[1] In three years, Respondent dispensed 653 prescriptions for controlled substances from this doctor, more than any other pharmacy; of those prescriptions, 90.5% were paid in cash.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

45. Respondent Allwell is subject to disciplinary action under Code section 4301, subdivisions (a), (d), (j) and (o), in that Respondent pharmacy committed unprofessional conduct by operating in a grossly negligent manner, violating laws and regulations governing the practice of pharmacy, violating laws and regulations regulating controlled substances, and clearly excessive furnishing of controlled substances without the exercise of its corresponding responsibility to only dispense medically legitimate prescriptions. Respondent pharmacy's conduct constituted gross negligence by operating in violation of the laws and regulations intended to ensure the safe practice of pharmacy and the safe distribution of controlled substances. Respondent pharmacy operated in a manner that was a gross deviation from the standard of safe pharmacy practice, and which could cause harm to patients or other persons. The circumstances are set forth in paragraphs 32, 34, 36, 38, 40, 42, and 44 and its subparts, above.

Cletus Uche Duru

46. Respondent Cletus Uche Duru has been the designated Pharmacist-In-Charge for Allwell Pharmacy and Medical Supplies, LLC under Code section 4113(a) since November 1, 2010. As pharmacist-in-charge for Allwell, Respondent Duru was responsible for Allwell's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

NINTH CAUSE FOR DISCIPLINE

(Unlicensed Activity)

47. Respondent Duru is subject to disciplinary action under Code section 4115, subdivisions (a) and (e) and 16 CCR 1793.2, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, allowed unlicensed staff to perform the duties of a pharmacy technician. The circumstances are set forth in paragraph 32 above.

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TENTH CAUSE FOR DISCIPLINE

(Reporting Drug Loss)

48. Respondent Duru is subject to disciplinary action under 16 CCR 1715.6, by and through Code section 4301(o), in that that he, as pharmacist-in-charge for Allwell, failed to report the loss of controlled substances, including their amounts and strengths, to the Board within thirty (30) days. The circumstances are set forth in paragraph 34 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Participate in Quality Assurance Program)

49. Respondent Duru is subject to disciplinary action under 16 CCR 1711, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to participate in an established quality assurance program. The circumstances are set forth in paragraph 36 above.

TWELFTH CAUSE FOR DISCIPLINE

(Requirements for Patient-Centered Labels for Prescriptions)

50. Respondent Duru is subject to disciplinary action under 16 CCR 1707.5, subdivision (a), by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to comply with the requirements for patient-centered labels on drug containers. The circumstances are set forth in paragraph 38 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Biennial Inventory and Record Requirements)

51. Respondent Duru is subject to disciplinary action under Code section 4081, 16 CCR 1718, and 21 CFR 1304.11, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to comply with the requirements for maintaining an inventory of controlled substances and completing a biennial inventory. The circumstances are set forth in paragraph 40 above.

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FOURTEENTH CAUSE FOR DISCIPLINE

(Requirements for Controlled Substance Prescriptions)

52. Respondent Duru is subject to disciplinary action under Health and Safety Code section 11164, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, dispensed controlled substances using prescription forms that were missing required features. The circumstances are set forth in paragraph 42 above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Corresponding Responsibility for Legitimacy of Prescription)

53. Respondent Duru is subject to disciplinary action under Health and Safety Code section 11153 and 16 CCR 1761, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to fulfill his corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The circumstances are set forth in paragraph 44, and its subparts, above

SIXTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

54. Respondent Duru is subject to disciplinary action under Code section 4301, subdivisions (a), (d), (j) and (o), in that he, as pharmacist-in-charge for Allwell, committed unprofessional conduct by operating in a grossly negligent manner, violating laws and regulations governing the practice of pharmacy, violating laws and regulations regulating controlled substances, and clearly excessive furnishing of controlled substances without the exercise of its corresponding responsibility to only dispense medically legitimate prescriptions. Respondent Duru's conduct constituted gross negligence by operating in violation of the laws and regulations intended to ensure the safe practice of pharmacy and the safe distribution of controlled substances. Respondent Duru acted in a manner that was a gross deviation from the standard of safe pharmacy practice, and which could cause harm to patients or other persons. The circumstances are set forth in paragraphs 32, 34, 36, 38, 40, 42, and 44 and its subparts, above.

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OTHER MATTERS

55. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50426 issued to Allwell Pharmacy and Medical Supplies LLC, Allwell Pharmacy and Medical Supplies LLC shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if it is revoked.

56. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50426 issued to Allwell Pharmacy and Medical Supplies LLC, while Cletus Uche Duru has been a member and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Cletus Uche Duru shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 50426, issued to Allwell Pharmacy and Medical Supplies LLC;

2. Revoking or suspending Pharmacist License Number RPH 46402, issued to Cletus Uche Duru;

3. Prohibiting Allwell Pharmacy and Medical Supplies LLC from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if Pharmacy Permit Number 50426 issued to Allwell Pharmacy and Medical Supplies LLC is revoked;

4. Prohibiting Cletus Uche Duru from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit

Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if Pharmacy Permit Number 50426 issued to Allwell Pharmacy and Medical Supplies LLC is revoked;

5. Ordering Allwell Pharmacy and Medical Supplies LLC and Cletus Uche Duru to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

6. Taking such other and further action as deemed necessary and proper.

DATED: 3/18/17

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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