



Minnesota Board of Pharmacy

DISCIPLINARY ACTIVITY: February, 2018 through April, 2018

The Board took the following disciplinary actions involving **pharmacists** at its February, 2018 and April, 2018 meetings:

Low, Michael J., License # 119263. Licensee fraudulently created prescriptions for hydrocodone and methylphenidate, both DEA schedule II controlled substances, by printing them at home off the internet and forging the signature of a physician (“Fake Prescriptions”). The Fake Prescriptions were not written by or authorized by a physician. Licensee then brought the Fake Prescriptions to the Pharmacy for the purpose of filling them for purchase. Licensee created a fictitious patient profile within the Pharmacy’s computer prescription processing system, for the purpose of filling the Fake Prescriptions for controlled substances. Licensee was ingesting the drugs obtained through the use of the Fake Prescriptions for his personal use and not selling them. Licensee had created the Fake Prescriptions to obtain opioid analgesics and other controlled substances to treat pain that he was experiencing. Licensee obtained the methylphenidate to stay focused.

Licensee would sometimes place half of the pills in his pocket instead of a bottle. Licensee would sometimes split the pills between an amber bottle and stock bottle when he did not have enough cash to pay for the Fake Prescriptions.

On approximately twelve occasions, Licensee also took from the Pharmacy and

ingested multi-vitamins, magnesium, cetirizine, and sertraline while at work, without paying for them.

Licensee's diversion of controlled substances from the Pharmacy included the following losses attributed to employee pilferage by Licensee, which were valued at \$1,784.00:

- i. 240 tablets of Acetaminophen-codeine #3;
- ii. 390 tablets of Methylphenidate 20 mg;
- iii. 270 tablets of Methylphenidate ER 20 mg;
- iv. 450 tablets of Hydrocodone-acetaminophen 10-325 mg;
- v. 450 gm of Testosterone 50 mg/5gm pkt;
- vi. 154 tablets of Oxycodone 15 mg; and,
- vii. 110 tablets of Oxycodone 30 mg.

On October 11, 2017, the Pharmacy terminated Licensee's employment due to his diversion of controlled substances. Licensee signed a "Voluntary Statement Form" stating he "knowingly filled and purchased invalid prescriptions under a false name for personal use," "occasionally took some OTC meds from the OTC section," and that the "false prescriptions were not written or authorized by the physician."

Consequently, the Board issued a Stipulation and Consent Order reprimanding the Licensee, imposing a \$2,000 civil penalty, and suspending his license, but staying the suspension on condition that he participate in the Health Professionals Services Program, and comply with any requirements of the court, if convicted of a crime related to his diversion.

Ristau, Jeffrey A., License # 117496. On three separate occasions between mid-September and mid-October, 2017, licensee diverted for his own use a total of 35-40 tablets of lorazepam 1mg from a pharmacy at which he worked. Sometime between mid-September to mid-October, 2017, Licensee also diverted for his own use 4 tablets of lorazepam 2mg from a second pharmacy at which he worked. Consequently, the Board issued a Stipulation and Consent Order that reprimands the Licensee, imposes a civil penalty of \$1,000, and requires him to participate in the Health Professionals Services Program.

The Board took the following disciplinary actions involving **pharmacy technicians** at its February, 2018 and April, 2018 meetings:

Forss, Lindsey, Registration # 737543. Registrant was observed by a Pharmacy staff member, diverting a certain quantity of oxycodone/acetaminophen 5/325 tablets (a schedule II controlled substance), by pouring the tablets from a stock bottle into her hand, and then placing the tablets in her pocket. The Pharmacy Manager and a Pharmacy Asset Protection Manager both reviewed the Pharmacy's surveillance video. The surveillance video confirmed the following:

a. On November 30, 2017, on four separate occasions, Registrant is shown on video diverting certain quantities of schedule II controlled substance tablets. Registrant is shown pouring the tablets onto a counting tray. She proceeds to count out the tablets, as if filling a prescription. She then picks up some of the tablets with her right hand and places them into her pocket. Registrant is also shown consuming an unknown quantity by placing them directly into her mouth.

b. On December 5, 2017, on two occasions, Registrant is again shown on video diverting schedule II controlled substances in the same manner, by placing the tablets in her pocket.

After reviewing the surveillance video, law enforcement were notified and they arrived at the Pharmacy. Registrant was interviewed while still at the Pharmacy, and verbally admitted to diverting a variety of controlled substances on multiple occasions.

Pharmacy staff conducted an audit and determined the following controlled substances had been diverted:

- a. Oxycodone/acetaminophen 5/325mg tablets #358
- b. Hydrocodone/acetaminophen 10/325mg tablets #112
- c. Oxycodone 30mg tablets #88
- d. Oxycodone 5mg tablets #838
- e. Oxycodone 10mg tablets #157

The total value of the diverted controlled substances was \$1,326.58. As a result of her diverting the controlled substances, Registrant was discharged from her employment at the Pharmacy. Consequently, the Board adopted a Stipulation and Consent Order for Voluntary Surrender of Registration.

Goodermont, Larry E., Registration # 735694. On February 2, 2017, the California Board issued a Decision After Rejection and Order, ordering Registrant's California technician license revoked for no less than three years from the effective date

of the order and imposed a fine of \$1,600.00. The revocation was based on an arrest for methamphetamine possession that had occurred in 2013. The criminal case had been dismissed on October 24, 2014, following Registrant's successful completion of a court-ordered diversion program. Consequently, the Minnesota Board of Pharmacy issued a Stipulation and Consent Order suspending Registrant's pharmacy technician registration for a three-year period to run concurrently with the minimum three-year revocation imposed by the California Board. The Minnesota Board's Order further requires the Registrant to provide proof of paying the \$1,600 penalty imposed by the California Board.

Odenbreit, Tanya E., Registration # 730484. Registrant had a history of being convicted of charges related to driving motor vehicles under the influence of alcohol - in 2006 and 2008. After obtaining a registration as a pharmacy technician in July of 2014, registrant pleaded guilty to a charge of driving a snowmobile under the influence of alcohol. (On September 16, 2016). She had enrolled in the Health Professionals Services Program (HPSP) in December of 2015, after being charged with that crime. Registrant failed to submit required toxicology screens on November 30 and December 1, 2016. On December 9, 2016, respondent finally underwent a toxicology screen, which was positive for methamphetamine and amphetamine. She subsequently refused to undergo a chemical dependency evaluation and was discharged from HPSP. Consequently, the Board issued Findings of Fact, Conclusion and Final order, revoking her pharmacy technician registration.

The Board took the following disciplinary actions involving **pharmacies** at its February, 2018 and April, 2018 meetings:

Complete Pharmacy and Medical Solutions, License # 263608. On or about June 29, 2016, Licensee's Owner submitted to the Board an original Pharmacy Renewal Application ("Renewal Application"). On the Renewal Application, the Owner checked a box for "yes", in response to the question "are all prescriptions labeled and dispensed pursuant to a valid, patient specific prescription order that is received in advance of dispensing." The Renewal Application included a notification "for all pharmacies also licensed as manufacturers or outsourcing facilities" that included additional instructions, including "facilities licensed by the FDA as an Outsourcing Facility must be licensed as a manufacturer in Minnesota."

On or about July 3, 2016, the Board received Licensee's Application for Drug Manufacturer Licensure, and requested additional information from Licensee related to its corrective actions and responses to the FDA's 2014 Form 483 and Warning Letter.

On July 26, 2016, the Board notified the Owner that as an Outsourcer, Licensee also needed to complete and submit an Application for Drug Wholesaler License.

On or about December 9, 2016, the Board received information that Licensee distributed compounded drug products to a weight loss clinic located in Maple Grove, Minnesota ("Clinic") for office use. The Clinic then dispensed some of the compounded drug products to patients for self-administration.

On December 19, 2016, the Board requested Licensee provide information about the compounded drug products it prepares, including a list of compounded preparations shipped into Minnesota during the previous year.

On or about December 20, 2016, two Board Surveyors visited the Clinic, and identified the following within a medication room refrigerator:

a. Multiple full and open multi-dose vials of vitamin supplements (e.g. Lipovite #2165, Lipolean #2180, Ultra Burn #2174, MIC, etc.), bearing Licensee's label and "this is a compounded drug; not for resale."

b. None of the full and open multi-dose vials of vitamin supplements found in the Clinic refrigerator were properly labeled with a patient specific label containing all required information.

c. At the time, Licensee did not have an active manufacturer or wholesaler license within the State of Minnesota allowing for distribution of compounded drug products to the Clinic for office use.

On or about December 22, 2016, Respondent submitted distribution records specific to several lot numbers of injectable lyophilized human chorionic gonadotropin ("HCG"). The distribution records show the following:

a. On February 5, 2016, and again on March 3, 2016, Licensee distributed forty vials of HCG 11,000 IU/vial to the Clinic's Medical Director for office use; and,

b. On April 14, 2016, Licensee distributed ten vials of HCG 15,000 IU/vial, to the Clinic's Medical Director for office use.

c. HCG is a schedule III controlled substance in Minnesota.

A "Log of Scripts" for all prescriptions compounded and dispensed or distributed by Respondent into Minnesota between December 22, 2015 and December 22, 2016

shows Licensee also distributed multiple vials of the following compounded drug products to the Clinic's Medical Director on February 5, March 16, March 31, and June 1, 2016:

- a. M.I.C. (#1024) and (#504), 30 ml vials
- b. Lipolean (#2180), 30 ml vials
- c. Lipo-Vite (#2165), 30 ml vials
- d. Cyanocobalamin (#2532), 30 ml vials
- e. Ultra Burn (#2174), 30 ml vials

The Log of Scripts also showed Licensee distributed the following compounded drug products for office use to three other physicians located in Minnesota for office use, including:

Physician 1:

- a. Sixteen vials of HCG 11,000 units injectable on April 7, May 5, July 15, and November 29, 2016;
- b. Twenty vials of HCG 11,000 units injectable on August 1, August 25, September 21, October 19, and December 14, 2016;
- c. Sixteen vials of HCG 5,000 units injectable on June 9, 2016, and twenty vials on June 28, 2016; and,
- d. Two vials 30 ml of cyanocobalamin 1 mg/ml injectable #2532 on October 19, 2016, and four 30 ml vials on December 13, 2016.

Physician 2:

a. Two 30 ml vials of cyanocobalamin 1mg/ml injectable #2532 on August 22, 2016.

Physician 3:

a. Three 30 ml vials of LipoLean #2160 on September 29, 2016 and sixty vials on October 10, 2016.

Licensee provided a copy of a “Pharmacy Provider Agreement” signed by the Clinic’s CEO on September 24, 2015, including the printed name of the Medical Director, agreeing to several conditions including, but not limited to, the Clinic, as the “receiving party,” desires to arrange for Licensee to provide sterile and non-sterile compound preparations for office use and office administration.

On December 23, 2016, Licensee provided a copy of a “compounded lipotropic patient specific prescription order form” (“Order Form”) sent by the Minnesota Clinic on May 31, 2016, for ten vials of HCG 15,000 units and multiple vials of three different vitamin supplements, for subsequent distribution to the Clinic. The Order Form, signed by the Medical Director and not issued for an individual patient, did not include all required prescription information, such as a patient name and address, and adequate directions for use. The Order Form included checked boxes for “bill to office” and “ship to office.” Licensee provided copies of labels for the HCG 15,000 units showing it was labeled as “OFFICESTOCK” and “OFFICESTOCK ONLY NOT FOR RE-SALE,” with the instructions “use as directed.”

Consequently, the Board issued a Stipulation and Consent Order reprimanding the

Licensee and assessing a civil penalty in the amount of \$3,500.

Synergy Rx, License # 264695. On April 1, 2015, the Board licensed Licensee as a non-resident pharmacy in Minnesota. Licensee was licensed as a non-resident pharmacy that prepares nonsterile compounded drug products for dispensing to patients in Minnesota. On March 28, 2016, the Board received a letter and Licensee's Minnesota pharmacy license in the mail. The letter stated Licensee was ceasing all operations effective April 15, 2016. Subsequently, Licensee's license status was changed to "closed" by the Board.

On or about December 15, 2016, the Board received information that multiple patients had developed bacterial skin infections after self-injecting a medication into the skin of their abdomens. The medication was dispensed to the patients by a weight loss clinic ("Clinic") located in Maple Grove, Minnesota.

On or about December 20, 2016, two Board surveyors visited the Clinic, met with the Clinic's CEO and Owner ("Owner"), Clinical Nurse Manager ("RN Manager"), and Medical Assistant, and identified the following:

a. The Clinic is one of two weight loss clinic locations operated by the Owner in Minnesota. The Owner also has multiple other weight loss clinics located in Arizona.

b. Within a medication room refrigerator, the Surveyors found multiple un-reconstituted vials and one reconstituted vial of human chorionic gonadotropin ("HCG"). HCG is an unapproved product marketed for weight loss. There are no FDA-approved HCG products for weight loss.

c. The Owner stated the HCG vials were shipped to the Clinic by Licensee, and provided Licensee's invoice, dated December 13, 2016, showing twenty vials of "HCG 11,000 iu" were shipped and billed in the amount of \$612.75. A second Clinic copy of Licensee's invoice included written documentation that all twenty vials of HCG were received on December 15, 2016.

d. None of Licensee's HCG vials were properly labeled with a patient specific label containing all required information, and the HCG vials contained an extended beyond use date, resulting in the vials being misbranded. The HCG vials were labeled as follows:

- i. Rx #8564312;
- ii. HCG 11,000 iu Lyophilized Vial;
- iii. For office use only;
- iv. Lot #985476;
- v. Expiration 05-2017; and
- vi. The HCG vials did not include the name of a patient or prescriber,

or the name, address and phone number for Licensee.

e. The Owner stated the HCG vials were dispensed to multiple patients pursuant to a Clinic protocol. There were no patient specific prescriptions for the involved patients within the Clinic records. Clinic patient chart documents showed how many HCG vials were dispensed to each patient, the HGC lot number, and the number of days' supply.

f. At the time, Licensee did not have an active pharmacy, manufacturer or wholesaler license within the state of Minnesota, allowing for the distribution of HCG vials to the Clinic.

g. The Board Surveyor issued an Administrative Detention for the suspected adulterated and misbranded HCG vials.

On or about December 22, 2016, the Board notified Licensee it was the subject of a complaint investigation and subsequent investigation by the Board. A Board Surveyor spoke with Licensee's attorney to request additional information about drug products compounded and shipped by Licensee into Minnesota. Licensee's attorney sent the same Clinic copy of Licensee's invoice, dated December 13, 2016, to the Board Surveyor.

On December 23, 2016, the Board Surveyor sent an e-mail to Licensee and Licensee's attorney, requesting documentation for drug products compounded and shipped by Licensee into Minnesota, including but not limited to, batch records for compounding, sterility and endotoxin testing ("Compounding Documentation").

On December 27, 2016, the Board Surveyor sent another e-mail to Licensee and Licensee's attorney, requesting additional Compounding Documentation for five lot numbers of HCG identified within Clinic patient chart documents. On December 27, 2016, and again on December 28, 2016, Licensee's attorney responded to the Board Surveyor e-mail stating he was working on determining if the documents exist. On December 29, 2016, Licensee's attorney provided additional invoices for HCG vials shipped to the Clinic's Arizona location, for which documentation did not contain any lot numbers for those vials.

Between January 5, 2017 and January 19, 2017, the Board Surveyor contacted Licensee and Licensee's Attorney on multiple occasions to again request the Compounding Documentation. Licensee's Attorney again advised the Board Surveyor that he was working on reviewing the request from MN and doing what he could to obtain the information.

On or about February 14, 2017, by company announcement, Licensee issued a voluntary national recall, with the knowledge of the U.S. Food and Drug Administration ("FDA"), of all lots of HCG 5,000 units/vial and 11,000 units/vial to the retail level due to a lack of sterility assurance.

On or about February 17, 2017, by company announcement, Licensee expanded its voluntary national recall, with the knowledge of the Arizona Board of Pharmacy, to include sublingual tablets, HCG and HCG with resveratrol, and all strengths of nonsterile dermatology creams to the retail level due to a lack of quality assurance.

Consequently, the Board issued a Stipulation and Consent Order for Voluntary Surrender of Licensees' pharmacy license.