

DISTRICT OF COLUMBIA
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DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
Petitioner

v.

GRUBB'S PHARMACY OF D.C., INC.
t/a GRUBBS CARE PHARMACY
Respondent

Case No.: c
NOI No.: D100654

FINAL ORDER

I. Introduction

This case arises under the Civil Infractions Act of 1985, as amended (D.C. Official Code §§ 2-1801.01 - 1802.05). By Notice of Infraction (the “NOI”) served on February 27, 2012, the Government charged Respondent, Grubb’s Pharmacy of D.C., Inc., with violating 22 District of Columbia Municipal Regulations (“DCMR”) 1502.1¹ (the “Regulation”) by failing to keep records, maintain inventories, and file reports as required by federal law. The Government alleged that the violation occurred on October 6, 2011, at 326 East Capital Street, N.E., and sought a \$2,000 fine.

On March 19, 2012, Respondent filed an answer with a Deny plea and I held an evidentiary hearing on April 17, 2012. At the hearing, Rudolf Schreiber, Assistant Attorney

¹ 22 DCMR 1502.1 provides:

Every registrant shall keep records, maintain inventories and file reports in conformance with the requirements of federal law including the requirements prescribed under Part 1304, 21 CFR.

General for the Department of Health (“DOH”), represented the Government and Shauna White, a DOH Investigator with the Health Care Regulation and Licensing Administration, Pharmaceutical Control Division, appeared as the Government’s witness. Respondent’s owner, Michael Kim, appeared for Respondent and DeLisa Winston, its Chief Pharmacist, testified.

Based upon the testimony at the hearing, my evaluation of the witnesses’ credibility, the documents admitted into evidence, and the entire record in this matter, I make the following findings of fact and conclusions of law.

II. Findings of Fact

1. Respondent operates a pharmacy at 326 East Capital Street, N.E (the “Pharmacy”) and at all relevant times was registered to dispense controlled substances under D.C. law.
2. On October 6, 2011, Investigator White inspected the Pharmacy and at that time deferred determining whether Respondent had kept accurate records and maintained inventories regarding schedule II controlled substances (“CS II”) pending Respondent’s completion of a CS II audit. Petitioner’s Exhibit (“PX”) 100.
3. Respondent provided its independent controlled substance audit by letter dated October 31, 2011. Respondent’s Exhibit (“RX”) 200 It reflected, based upon its opening and closing inventories, and all recorded purchases and sales between the dates of these inventories, shortages in the amounts indicated for the following CS II medications: (i) Methadone 10 mg – 30 tablets short; (ii) Methadone Liquid 10 mg/ml - 63 ml short; (iii) Methadone (Intensol) 30 ml - 1 ml short; (iv) Methadone Powder – 4 grams short; (v) Dilaudid Liquid 1mg/ml – over 165 ml short; and (v) Oxycodone IR 20 mg – 4 tablets short. *Id.*

4. Due to these discrepancies, Ms. White determined that Respondent's records did not provide an accurate record of all controlled substances it had received, sold, delivered or disposed of and issued the NOI.
5. The Drug Enforcement Administration – Diversion Control Pharmacist Manual (the “DEA Manual”) provides procedures for identifying a “significant loss.” RX 204. However, Respondent did not adopt the procedures described in the manual.

III. Conclusions of Law

The Government alleged that Respondent violated 22 DCMR 1502.1 which states:

Every registrant shall keep records, maintain inventories and file reports in conformance with the requirements of federal law including the requirements prescribed under Part 1304, 21 CFR.

Respondent concedes that its records fail to fully account for all controlled substances it had purchased, sold, or disposed of, during the audited period. But Mr. Kim argued that under 21 CFR 1304.11, Respondent must merely maintain inventories that accurately reflect the controlled substances on hand as of the audit. Under his interpretation, only a failure to provide an accurate inventory, not shortages and overages occurring between inventories, violates the Regulation.

Mr. Kim's reliance on § 1304.11, which specifically addresses inventory requirements, ignores the more pertinent *continuing* record keeping requirements outlined in 21 CFR 1304.21. This provision requires all prescription-dispensing entities to "maintain, on a current basis, a complete and accurate record of each [controlled] substance" that it has "received, sold, delivered, exported, or otherwise disposed of...." Because Respondent is unable to explain or account for the shortages reflected in its controlled substances audit, it has not maintained a

complete and accurate record of each controlled substance it received, sold, delivered, or otherwise disposed of.

Mr. Kim also contends that when viewed in light of Respondent's large business volume, the discrepancies in its records were not significant. However, in imposing record-keeping requirements, the Regulation draws no distinction based upon a pharmacy's business volume and makes no allowance for "insignificant" discrepancies. Instead, the Regulation incorporates federal law that requires a "complete and accurate record." *Id.* For this same reason, I do not find persuasive the provisions of the DEA Manual that Respondent contends provides procedures for identifying "significant loss." RX 204. This is especially true when, as in this case, the pharmacy has not followed the procedures described in the manual.

I therefore conclude that at the Pharmacy on October 6, 2011, Respondent violated the Regulation by failing to maintain a current, accurate record of controlled substances in conformance with the requirements of federal law including those prescribed under Part 1304, 21 CFR. A violation of the Regulation is a Class 1 civil infraction punishable by a \$2,000 fine for a first offense. 16 DCMR 3201.1(a)(1); 16 DCMR 3616.1(e). I will impose a fine in that amount.

IV. Order

Based on the above findings of fact, conclusions of law, and the entire record in this matter, it is this _____ day of _____ 2012:

ORDERED, that Respondent is **LIABLE** for violating 22 DCMR 1502.1, as charged in the Notice of Infraction; and it is further

ORDERED, that Respondent shall pay a fine in the amount of **TWO THOUSAND DOLLARS (\$2,000)** in accordance with the attached instructions within twenty (20) calendar days of the date of mailing of this Order (15 calendar days plus 5 days for service by mail pursuant, to D.C. Code, 2001 Ed. §§ 2-1802.04 and 2-1802.05); and it is further

ORDERED, that if Respondent fails to pay the above amount in full within 20 calendar days of the date of mailing of this Order, by law, interest shall accrue on the unpaid amount at the rate of 1½ % per month or portion thereof, beginning with the date of this Order, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i)(1); and it is further

ORDERED, that failure to comply with the attached payment instructions and to remit a payment within the time specified will authorize the imposition of additional sanctions, including the suspension of either or both Respondent's licenses or permits, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(f), the placement of a lien on real or personal property owned by Respondent, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i), and the sealing of Respondent's business premises or work sites, pursuant to D.C. Code, 2001 Ed. § 2-1801.03(b)(7); and it is further

ORDERED, that the reconsideration and appeal rights of any person aggrieved by this Order are stated below.

Louis J. Burnett
Administrative Law Judge