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DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
Petitioner

v.

STERLING PHARMACY
Respondent

Case No.: 2012-DOH-D100542
NOI No.: D100542

FINAL ORDER

I. Introduction

This matter arises under the Civil Infractions Act of 1985, as amended, (D.C. Official Code §§ 2-1801.01 *et seq.*) and Title 22-B, Chapters 15 and 19 of the District of Columbia Municipal Regulations (“DCMR”). By Notice of Infraction (No. D100542) served January 27, 2012, the Government charged Respondent Sterling Pharmacy with violating 22-B DCMR 1907.6 (failure to maintain adequate storage temperature) and 22B DCMR 1502.1 (failure to maintain adequate records).¹ The Government charged that the violation of 22-B DCMR 1907.6 occurred on July 12, 2011 at 1647 Benning Road, N.E. (the “Pharmacy”) and that the violation of 22-B DCMR 1502.1 occurred on August 1, 2011 at the Pharmacy. The Government sought a total fine of \$3,000 for these violations.

Respondent answered the charged violation of 22-B DCMR 1907.6 with a plea of Admit with Explanation, and the charged violation of 22-B DCMR 1502.1 with a plea of Deny.

¹ The Government originally charged Respondent with violating of 22-B DCMR 1503.1, but moved to amend the Notice of Infraction at the hearing without opposition from Respondent. The Government’s motion was therefore granted.

Accordingly, an evidentiary hearing was scheduled and held on April 24, 2012. Rudolph Schreiber, Esq., appeared on behalf of the Government, along with the Government's charging inspector, Michael Kosyak, who testified on behalf of the Government. OAH Rule 2833. Omololu Fatuksai, Pharmacy Manager for Respondent, appeared and testified on its behalf. OAH Rule 2835.6. Petitioner's Exhibit ("PX") 100 and Respondent's Exhibits ("RX") 100, 101, 102 and 103 were admitted into the record.

Based on the testimony of the witnesses and my evaluation of their credibility, and the admitted documentary evidence, I now make the following Findings of Fact and Conclusions of Law:

II. Findings of Fact

A. 22-B DCMR 1907.6

22-B DCMR 1907.6 provides:

Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the United States Pharmacopoeia/National Formulary (USP/NF) and/or the manufacturer's or distributor's labeling unless otherwise indicated by the Bureau of Food, Drug & Radiation Protection, Pharmaceutical Control Division.

On July 12, 2011, Respondent admitted that the refrigerator thermometer observed by Inspector Kosyak indicated that the Pharmacy's refrigeration unit was not maintaining an adequate temperature. PX100. Respondent later determined that one of its thermometers was malfunctioning.

B. 22-B DCMR 1502.1

22-B DCMR 1502.1 provides:

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

On July 12, 2011, Inspector Kosyak inspected the Pharmacy and determined there was a discrepancy in the on hand, physical count of the quantity of Oxycodone 30 mg tablets (a Schedule II Controlled Substance) and the number of tablets reflected in other computer invoice records. *See* PX 100, RX101 and RX103.

As a result of this discrepancy, Inspector Kosyak immediately requested an audit of selected Schedule II Controlled Substances. This audit included a review of detailed computer generated records, some of which were not available or updated at the time of inspection. Inspector Kosyak then issued a follow-up audit request for information related to Respondent's purchase and inventory of Oxycodone 30 mg tablets from the period September 22, 2010 through July 12, 2011. RX 100. Respondent issued its response on August 1, 2011 and addressed the Oxycodone 30 mg tablet inventory issue to Inspector Kosyak's satisfaction. *See* RX102 and RX103. The Government contends that the violation of 22-B DCMR 1502.1 occurred because the inventory on hand count of Oxycodone 30 mg tablets was incorrect when reviewing the Pharmacy's other documentation on July 12, 2011.

III. Conclusions of Law

A. 22-B DCMR 1907.6

By its answer and plea of Admit with Explanation, Respondent has admitted violating 22-B DCMR 1907.6 at the Pharmacy as charged in the Notice of Infraction. Respondent has accepted responsibility for the violation. A fine of \$1,000 is authorized for a violation of this

regulation which, in light of the mitigating factor noted herein as well as consideration of the seriousness of this violation, this administrative court shall reduce to \$900. 16 DCMR 3617.2(f)

B. 22-B DCMR 1502.1

The Government has charged Respondent with failing to keep adequate records consistent with the requirements of federal law, including those set forth in 21 C.F.R. Part 1304. The Government charged Respondent with this violation because Respondent could not provide the requested Controlled Substance II auditing information during the July 12, 2011 inspection, despite the fact that Respondent subsequently supplied that documentation on or about August 1, 2011. RX 101.

During the hearing, it was unclear precisely what records the Government required from Respondent to be available at the July 12, 2011 inspection for purposes of complying with 22-B DCMR 1502.1 and 21 C.F.R. Part 1304. Inspector Kosyak testified that the violation of 22-B DCMR 1502.1 occurred because the inventory on hand count of Oxycodone 30 mg tablets was incorrect when reviewing Respondent's other documentation.

Working from that charging theory, then, Part 1304 of the Code of Federal Regulations (which is referenced in 22-B DCMR 1502.1) provides detailed information regarding records to be kept and made available by registrants for inspection and copying. *See, e.g.*, 21 C.F.R. § 1304.04. In addition, section 1304.11 lists the inventory requirements for controlled substances:

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, type-written, or printed form at the registered location. . . **Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse**

on behalf of the registrant, and substances in possession of employees of the registrant and intended for distribution as complimentary samples...

(Emphasis supplied).

By definition, then, drugs may be deemed to be on hand even if they are not reflected in the count of what is in the registrant's physical possession. In this case, there appeared to be some initial confusion regarding what should be considered on hand for purposes of Respondent's inventory of Oxycodone 30 mg tablets, because the physical count of tablets did not match the count reflected in the available documentation. That confusion, however, was resolved by the follow-up information requested by the Government and duly submitted by Respondent. It is not clear on this record, therefore, that Respondent's inventory of Oxycodone 30 mg tablets that were on hand at the time of the July 12, 2011 inspection was improperly maintained, and, therefore, a basis for a violation of 22-B DCMR 1502.1.

Moreover, to the extent that the Government contends that certain of the follow-up records requested by Inspector Kosyak should have been immediately available on July 12, 2011, the Government has not established exactly what those records were and, even more important, how the immediate availability of those records is required by 21 C.F.R. Part 1304, portions of which recognize that, in certain situations, documentation may require additional time for registrants to produce for inspection. *See, e.g.,* 21 C.F.R. § 1304.04(b) (central recordkeeping registrants).

To the extent the Government required particular inventory documentation from a registrant by a date certain, and that registrant was unable to satisfactorily produce that documentation, the question of liability for violating 22-B DCMR 1502.1 would seem clearer. In this instance, however, Respondent maintained inventory documentation related to its

Oxycodone 30 mg tablets that were on hand at the Pharmacy as of July 12, 2011.² And, when requested by the Government to provide additional clarifying information in this regard by a date certain, Respondent did so to the satisfaction of the Government.

Therefore, because, for purposes of 21 C.F.R. Part 1304, the Government has not established what additional information Respondent was required to have available on July 12, 2011, and/or how Respondent's on hand inventory of Oxycodone 30 mg tablets was improperly maintained on that date, it has not met its burden under the Civil Infractions Act, and this charge must be dismissed. D.C. Official Code § 2-1802.03(a).

IV. Order

Based on the above findings of fact, conclusions of law, and the entire record in this matter, it is this 4th day of May 2012:

ORDERED, that Respondent is **NOT LIABLE** for violating 22 DCMR 1502.1 as charged in the above-captioned Notice of Infraction, and that charge shall be **DISMISSED WITH PREJUDICE**; and it is further

ORDERED, that Respondent is **LIABLE** for violating 22 DCMR 1907.6 as charged in the above-captioned Notice of Infraction; and it is further

ORDERED, that Respondent shall pay a total amount of **NINE HUNDRED DOLLARS (\$900)** in reduced fines in accordance with the attached instructions within 20 calendar days of the mailing date of this Order (15 days plus 5 days service time pursuant to D.C. Official Code §§ 2-1802.04 and 2-1802.05; and it is further

² Indeed, but for the invoice documentation supplied by Respondent, it is unclear to this administrative court whether the issue of a discrepancy in the physical count of tablets would have even arisen.

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 must accrue on the unpaid amount, or portion thereof, at the rate of 1½ % per month, beginning with the date of this Order, pursuant to D.C. Official Code § 2-1802.03(i)(1); and it is further

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

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

May 4, 2012

/s/ _____
Mark D. Poindexter
Deputy Chief
Administrative Law Judge

