UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at LEXINGTON

UNITED STATES OF AMERICA, Plaintiff, v. APPALACHIAN REGIONAL HEALTHCARE, INC., Defendant.	)	Civil Case No. 5:16-cv-00132-JMH **MEMORANDUM OPINION & ORDER**

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I. Introduction

This matter is before the Court upon Defendant Appalachian Regional Hospital, Inc.'s ("ARH") Motion to Dismiss for Failure to State a Claim [DE 6]. ARH has also filed an alternative Motion to Strike Complaint and for Partial Summary Judgment [DE 5]. The United States having filed its Response to both Motions [DE 14], and ARH having submitted its Reply [DE 16, 17], this matter is now ripe for the Court's review. For the reasons stated herein, ARH's Motions are **DENIED IN FULL**.

II. Factual and Procedural Background

ARH is a healthcare system that operates medical centers, hospitals, and clinics throughout Eastern Kentucky. [DE 1, p. 2, ¶ 7]. It also oversees several pharmacies affiliated with these facilities, including Harlan ARH Hospital Pharmacy, Hazard ARH Regional Medical Center Clinic Pharmacy, Hazard ARH Regional

Medical Center Hospital Pharmacy, and Middlesboro ARH Pharmacy. [*Id.* at p. 2, ¶ 8].

Like all pharmacies, these entities were required to register with the Drug Enforcement Administration ("DEA") and follow the Controlled Substances Act's ("CSA") comprehensive regulatory scheme, which "tracks and traces controlled substances from manufacture to delivery to ensure that they are not illegally diverted for improper uses." [*Id.* at p. 3, ¶ 10]. This regulatory system permits pharmacies to dispense controlled substances to a patient, so long as that patient holds a prescription issued by a practitioner acting in his normal course of business for a legitimate medical purpose. [*Id.* at p. 4, ¶ 14]. Pharmacies may also distribute controlled substances to a practitioner upon request.[1] [*Id.*]. In either case, pharmacies must maintain detailed records of the transactions.[2] [*Id.* at p. 8, ¶ 39-40]. However, the precise recordkeeping requirements vary, depending on whether a transaction qualifies as a dispensation or a distribution. [*Id.*].

In 2010, a pharmacist at Harlan ARH Hospital Pharmacy notified the Director of Pharmacy, Angela Creech, that he had concerns about

[1] When pharmacies are distributing Schedule II substances, they must complete a special Form 222 issued by the DEA. [*Id.* at p. 8, ¶ 37-38].

[2] As indicated above, the CSA draws a distinction between "dispensing" a controlled substance, which means delivering a controlled substance to the ultimate user, and "distributing" the drug, which covers other types of delivery of a controlled substance. 21 U.S.C. § 802(10)-(11).

Phentermine prescriptions written by Dr. Donald F. Ramsey.[3] [*Id.* at p. 10, ¶ 56-57]. Phentermine, a Schedule IV controlled substance, is a stimulant intended to assist obese patients with weight loss when combined with diet and exercise.[4] [*Id.* at p. 9, ¶ 44-49]. The pharmacist noted that Dr. Ramsey was a physician in Harlan ARH Hospital's Emergency Room, and thus, did not have occasion to prescribe Phentermine in the normal course of his business. [*Id.* at p. 11, ¶ 58]. Many of these prescriptions were written for nurses and staff members who were not obese.[5] [*Id.* at p. 11, ¶ 60-61]. They were also written for twice the standard dosage of Phentermine. [*Id.* at p. 11, ¶ 59].

Around the same time, an employee informed Risk Manager Phyllis Wilson that a nurse had admitted to receiving and filling Phentermine prescriptions written by Dr. Ramsey. [*Id.* at p. 12-13, ¶ 70-71]. According to this source, the nurse had also indicated that she kept half of the pills and gave the other half to Dr. Ramsey. [*Id.*]. Wilson obtained a report from the pharmacy,

[3] In 2004, Dr. Ramsey began working in Harlan ARH Hospital's Emergency Room pursuant to a contract with Mountain Medical Enterprises, PLLC. [*Id.* at p. 10, ¶ 50-55]. According to the United States, ARH failed to properly credential Dr. Ramsey. [*Id.*]. Specifically, Dr. Ramsey did not obtain a DEA registration listing ARH as his place of business. [*Id.*]. Throughout his time at ARH, Dr. Ramsey's DEA registration indicated that he worked at a facility in Tennessee. [*Id.*].

[4] Controlled substances are divided into Schedules I through V, depending on the risk of abuse and dependence. 21 U.S.C. § 812(b)(1)-(5). Schedule II through V substances have accepted medical uses, while Schedule I substances do not. *Id.* Phentermine is chemically related to amphetamines. [*Id.* at p. 9, ¶ 45].

[5] Dr. Ramsey also wrote one Phentermine prescription for the spouse of a Harlan ARH Hospital employee. [*Id.* at p. 11, ¶ 61].

listing all recently filled Phentermine prescriptions, which supported these allegations. [*Id.* at p. 13, ¶ 72]. She then approached Hospital Administrator Dan Stone about the situation.[6] [*Id.* at p. 13, ¶ 73].

Despite these reports, Harlan ARH Hospital administrators never discussed the issue with Dr. Ramsey or instructed its pharmacists not to fill Phentermine prescriptions written by him. [*Id.* at 12, ¶ 67-68]. As a result, from January 17, 2012 to March 10, 2014, Harlan ARH Hospital Pharmacy filled 83 Phentermine prescriptions written by Dr. Ramsey to nurses, staff members, and their families.[7] [*Id.* at p. 14, ¶ 81].

Finally, in 2014, the Kentucky Board of Medical Licensure ("KBML") received an anonymous complaint about Dr. Ramsey's prescribing practices. [*Id.* at p. 17, ¶ 86]. During the ensuing investigation, eight employees, including five nurses, a licensed professional nurse, and a nursing services clerk, conceded that they obtained and filled Phentermine prescriptions written by Dr. Ramsey. [*Id.* at p. 17, ¶ 87]. Dr. Ramsey admitted to the same, indicating that he received and ingested some of the pills so that he could stay awake while working the night shift. [*Id.* at p. 18,

[6] Wilson also told Stone that she planned to discuss Dr. Ramsey's actions with Dr. Amir U. Ahmad, who owned Mountain Medical Enterprises, PLLC. [*Id.* at p. 74-78]. It is unclear whether such a conversation actually took place. [*Id.*].
[7] Although these employees used their insurance to pay for other pharmacy services, they routinely paid in cash when filling their Phentermine prescriptions. [*Id.* at p. 17, ¶ 83-84].

¶ 91]. Dr. Ramsey later entered into an agreement with the KBML, indefinitely terminating his ability to practice medicine. [*Id.* at p. 18, ¶ 93].

As part of a DEA audit, the United States later procured dispensing records for Harlan ARH Hospital Pharmacy, as well as Hazard ARH Clinic Pharmacy, Hazard ARH Hospital Pharmacy, and Middlesboro ARH Pharmacy. [*Id.* at 19, ¶ 95]. These records were often incomplete and inconsistent with each other, making it difficult to conduct an accurate audit. [*Id.* at 19-21, ¶ 98-103]. The audit also revealed that ARH pharmacies dispensed controlled substances for "office stock" to another registrant pursuant to a prescription and distributed Schedule II controlled substances without using a DEA Form 222. [*Id.* at p. 19-21, ¶ 95-101].

The United States now brings this civil enforcement action against ARH, seeking penalties and injunctive relief in connection with the aforementioned violations of the CSA. [*Id.* at 1, ¶ 1]. Count I alleges that ARH filled false or fraudulent prescriptions in violation of 21 U.S.C. § 842(a)(1), while Count II asserts that ARH failed to make and maintain complete and accurate records in violation of 21 U.S.C. § 842(a)(5). [*Id.* at p. 22-23, ¶ 104-113].

ARH urges the Court to dismiss Count I with prejudice because the relevant CSA provisions do not apply to the pharmacy itself. Moreover, ARH insists that the pharmacy cannot be held vicariously liable for the acts of the prescribing practitioner or pharmacist.

ARH argues that Count II should suffer the same fate because the United States has not plead a plausible claim of inaccurate recordkeeping. In the alternative, ARH contends that the United States cannot recover civil penalties on a "per occurrence" basis, and thus, it is entitled to partial summary judgment limiting the amount recoverable to $25,000 for all violations of the CSA plead in Count I and $10,000 for all violations alleged in Count II. Consistent with this conclusion, ARH asks the Court to strike all mention of "per occurrence" penalties from the Complaint. The Court will address each of these contentions in turn.

III. Principles of Statutory Construction

"It is a 'fundamental canon of statutory construction' that, 'unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.'" *Sandifer v. U.S. Steel Corp.*, 134 S. Ct. 870, 876 (2014) (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979)); *see also Norfolk S. Ry. Co. v. Perez*, 778 F.3d 507, 512 (6th Cir. 2015) ("We must presume that Congress says what it means and means what it says, and therefore must apply a statute as it is written, giving its terms the ordinary meaning that they carried when the statute was enacted.").

ARH's arguments, summarized above, hinge heavily on its reading of various federal statutes and regulations. The Court will therefore apply the aforementioned principles of statutory construction in evaluating ARH's Motions.

IV. ARH's Motion to Dismiss

A. Standard of Review

A Complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *see also* Fed. R. Civ. P. 12(b)(6). It should also include "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly v. Bell Atl. Corp.*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that a defendant is liable for the misconduct alleged." *Id.* "[A] formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

B. Count I—Filling False or Fraudulent Prescriptions

The CSA generally requires "[e]very person who manufactures or distributes any controlled substance," or proposes to engage in such activities, to obtain a registration issued by the Attorney General.[8] 21 U.S.C. § 822(a)(1). The same rule applies to "[e]very

[8] Under 21 U.S.C. § 822(c)(1)-(3), the following persons are exempted from registration: (1) an agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance … if such agent or employee is acting in the usual course of his business or employment; (2) a common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance … is in the usual course of his business or employment; and (3) an ultimate user who has lawfully obtained such substance.

person who dispenses, or proposes to dispense, any controlled substance." 21 U.S.C. § 822(a)(2). It is unlawful for registrants to distribute or dispense Schedule II, III, IV, or V controlled substances without a prescription. 21 U.S.C. § 829(a)-(c) (stating that such controlled substances must be dispensed pursuant to a prescription); 21 U.S.C. § 842(a)(1) (making it unlawful for any person to deviate from this procedure).

The CSA's underlying regulations further provide as follows:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a).

ARH argues that the United States' attempts to hold it liable under § 842(a)(1) and § 829(b) are misplaced because these provisions do not impose liability on corporate pharmacies. In support of this proposition, ARH notes that § 1306.04(a) refers to only two types of individuals—the practitioner and the pharmacist. Thus, when § 1306.04(a) states that the person knowingly filling

such a prescription shall be subject to penalties, ARH concludes that the word "person" refers to these two types of individuals.

Although § 1306.04(a) does not define "person," definitions from Part 1300 have been incorporated into Part 1306. 21 U.S.C. § 1306.02. In Part 1300, the term "[p]erson includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity." 21 U.S.C. § 1300.01. Thus, when § 1306.04(a) states that the person knowingly filling the prescription is subject to penalties, it contemplates liability for corporate entities as well.

ARH insists that such a reading is inconsistent with the remainder of § 1306.04(a), which is otherwise devoted to describing the responsibilities of practitioners and pharmacists in issuing and filling prescriptions. It also contends that this interpretation is contrary to other aspects of Part 1306. For example, § 1306.06 states that a prescription "may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy." Similarly, § 1306.03 states that only individual practitioners may issue prescriptions for controlled substances. If practitioners are the only ones who can issue prescriptions, and pharmacists are the only ones who can fill them,

then ARH posits that they are the only ones who can be held liable for knowingly issuing and filling invalid prescriptions.

The Court disagrees. First, it sees nothing inconsistent about articulating the responsibilities of individual practitioners and pharmacists while simultaneously indicating that other entities may be subject to penalties for their role in issuing and filling invalid prescriptions. Moreover, because Congress used the terms "practitioner" and "pharmacist" elsewhere in § 1306.04(a), it certainly could have used those words in lieu of the term "person" if it had truly intended to limit liability under these provisions to practitioners and pharmacists.

As a final matter, the Court notes that at least one court has held a pharmacy liable for violations of § 829(b) and § 842(a)(1). *See United States v. Poulin*, 926 F. Supp. 246, 252-53 (D. Mass. 1996). While *Poulin* did not address the precise argument raised by ARH in this case, it does suggest that liability may attach to pharmacies for such violations.[9] Thus, the Court concludes that ARH may be subject to liability under § 829(b) and § 842(a)(1).[10] ARH's Motion to dismiss must be denied as to Count I.

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[9] In *Poulin*, the defendants were also held strictly liable for failing to keep complete and accurate records under § 842(a)(10). *See* 926 F. Supp. at 253. Courts now require at least negligence for liability under 842(a)(10) to attach. *See United States v. Grab Bag Distrib.*, 189 F. Supp. 2d 1072, 1080-81.

[10] ARH also argued that it could not be held vicariously liable for the alleged CSA violations. Because the Court has already found that § 829(b) and § 842(a)(1) contemplate direct liability for pharmacies, and because the United

C. Count II—Failure to Maintain Records

The CSA requires registrants who dispense or distribute controlled substances to "make a complete and accurate record of all stocks [of controlled substances] on hand." 21 U.S.C. § 827(a)(1); *see also* 21 U.S.C. § 842(a)(5) (making it unlawful for "any person … to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter…"). However, these requirements vary, depending on whether the transaction is a dispensation or a distribution. 21 C.F.R. § 1304.22(b)-(c). As discussed earlier in this opinion, a dispensation occurs when the controlled substance is delivered to the ultimate user pursuant to a prescription or other lawful order of a practitioner. 21 U.S.C. § 802(10). By contrast, a distribution occurs when a controlled substance is otherwise delivered to another entity. 21 U.S.C. § 802(11).

Both dispensers and distributors must maintain records of the following information:

> (1) the name of the substance;
>
> (2) each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

States expressly alleges that ARH knew of Dr. Ramsey's prescribing practices and failed to take action, the Court finds it unnecessary to address the vicarious liability issue.

> (3) the number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person to whom the units were acquired;
>
> (4) the number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed; and
>
> (5) the number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant, including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

21 C.F.R. § 1304.22(a)(2),(b)-(c).

In addition to the aforementioned requirements, dispensers must also record "the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser."[11] *Id.*

According to the United States, the DEA audit of ARH pharmacies revealed that they failed to comply with the CSA's recordkeeping requirements. The United States points to a

[11] If applicable, distributors must also record the number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation. 21 C.F.R. § 1304.22(a)(2)(viii),(b).

handwritten "Requisition" form as an example of such inadequate recordkeeping, noting that it "do[es] not clearly identify which ARH entity originally possessed the controlled substance, who or which ARH entity received the substance, or when the controlled substance was transferred." [DE 1, p. 20, ¶ 100].

Additionally, the United States finds fault with "an unsigned prescription blank from an ARH physician with a sticker listing a physician's office and address as the recipient of the prescription, instead of a specific patient's name and address." [*Id.* at p. 20, ¶ 99]. The United States asserts that such transactions were sometimes treated as dispensations when they should have been recorded as distributions. [*Id.* at p. 21, ¶ 102]. It also alleges that ARH pharmacies failed to complete DEA Form 222's when distributing Schedule II controlled substances. [*Id.* at p. 21, ¶ 101].

ARH contends that these allegations fail to state a plausible claim for violations of § 827(a)(1) and § 842(a)(5), insisting that the examples cited in the Complaint satisfy the CSA's recordkeeping requirements. Specifically, ARH reads the "Requisition" form as stating that controlled substances were transferred to its Medical Mall Pharmacy on March 28, 2012. It also insists that the United States' only complaint about the use of the sticker on the prescription blank is that it does not show the name and address of the ultimate user. However, ARH says that

it is the dispensing physician's responsibility to keep records about the ultimate user.

The Court, having reviewed the examples at issue, agrees with the United States that the "Requisition" form is not clear. Although Medical Mall Pharmacy is listed on it, nothing on the form actually indicates whether Medical Mall is the transferor or transferee of the controlled substance. As for the prescription blank, the lack of information about the ultimate user is indicative of a larger problem. The United States used this record as a means to illustrate ARH's failure to distinguish between dispensation and distribution.

On one hand, the use of the prescription blank suggests that a dispensation took place. However, the recipient is a doctor's office, indicating that a distribution actually occurred. Because the recordkeeping requirements vary, depending on the nature of the transaction, this failure to distinguish between dispensation and distribution results in inconsistent, confusing, and potentially inaccurate records. These considerations, combined with the United States' allegations about the DEA Form 222's, are sufficient to state a plausible claim against ARH for faulty recordkeeping. Accordingly, ARH's Motion to Dismiss as to Count II must be denied.

IV. ARH's Motion for Partial Summary Judgment

Summary judgment is appropriate when there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). If there is a dispute over facts that might affect the outcome of the case under governing law, then entry of summary judgment is precluded. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The moving party has the ultimate burden of persuading the court that there are no disputed material facts and that he is entitled to judgment as a matter of law. *Id.* Once a party files a properly supported motion for summary judgment, "the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Id.* at 250.

Pursuant to 21 U.S.C. § 842(c)(1)(A), "any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000." However, "[i]n the case of a violation of paragraph (5) or (10) of subsection (a), the civil penalty shall not exceed $10,000." 21 U.S.C. § 842(c)(1)(B). Based on this language, the United States asserts that it is entitled to civil penalties, not to exceed the aforementioned amounts, "per occurrence." [DE 1, p. 22-23, ¶ 108-113].

ARH insists that § 842(c) caps the total penalty for filling false prescriptions and failing to keep accurate records at $25,000 and $10,000 respectively. In support of this proposition, ARH

notes that these subsections do not expressly authorize the recovery of "per occurrence" penalties. However, § 842(c)(1)(A) states that "any person who violates this section shall, *with respect to any such violation*, be subject to a civil penalty of not more than $25,000."

The phrase "with respect to any such violation" could be read as stating that this provision applies with equal force to any aspect of § 842. However, this is already made clear by the preceding clause, which subjects "any person who violates this section" to the civil penalty. Thus, the Court concludes that the phrase "any such violation" indicates that each violation may result in a civil penalty of up to $25,000. Because § 842(c)(1)(B) supplements this language, referring back to "the civil penalty" first mentioned in § 842(c)(1)(A), the Court concludes that Congress intended the same with respect to it.

Nevertheless, ARH insists that § 842(c)(1)(A) and (B) cannot be read as imposing "per occurrence" penalties because they do not include the "per violation" language found in neighboring provisions § 842(c)(1)(C) and (D). While the latter sections use different terminology, the Court does not see this as proof that § 842(c)(1)(A) and (B) cap penalties as ARH suggests. Congress added these two provisions to address concerns about anabolic steroid abuse. *See* H.R. Rep. No. 113-587, pt. 2, at 5 (2014). The House Report indicates that these new sections "build upon the

existing statutory framework for imposing civil penalties for this type of conduct." *Id.* This suggests that Congress intended its choice of language in § 842(c)(1)(C) and (D) to be consistent with its understanding of § 842(c)(1)(A) and (B). Stated another way, it seems that Congress understood 842(c)(1)(A) and (B) to impose "per occurrence" penalties, and adopted a similar approach in crafting § 842(c)(1)(C) and (D).

The Court is once again unaware of any cases explicitly discussing the argument proffered by ARH. However, it is worth noting that the Second Circuit has upheld an award of "per occurrence" penalties for negligent record keeping, which totaled over $2 million dollars. *See Advance Pharm., Inc. v. United* States, 391 F.3d 377, 399-400 (2d Cir. 2004). This holding lends further support to this Court's finding that "per occurrence" penalties may be recovered under § 842(c)(1)(A) and (B). The Court will therefore deny ARH's Motion for Summary Judgment in full.

V. ARH's Motion to Strike

Courts "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). This is "a drastic remedy to be resorted to only when required for the purposes of justice … [and] should be granted only when the pleading to be stricken has no possible relation to the controversy." *Brown v. Williamson Tobacco Corp. v. United States*, 201 F.2d 819, 822 (6th Cir. 1953); *see also*

Operating Eng'rs Local 324 Health Care Plan v. G&W Constr. Co., 783 F.3d 1045, 1050 (6th Cir. 2015) ("Motions to strike are viewed with disfavor and are not frequently granted.").

In this case, ARH asks the Court to strike those aspects of the Complaint that mention "per occurrence" penalties. Because this request proceeds on the assumption that ARH is entitled to partial summary judgment on the issue of "per occurrence" penalties, and because the Court has already reached the opposite conclusion, ARH's Motion to Strike must be denied.

VI. Conclusion

Accordingly, for the reasons stated herein,

IT IS ORDERED as follows:

(1) ARH's Motion to Dismiss [DE 6] is **DENIED**;

(2) ARH's Motion to Strike and for Partial Summary Judgment [DE 5] are **DENIED**; and

(3) ARH shall file an Answer to the Complaint **within fourteen (14) days** of the date of entry of this Order.

This the 30th day of March, 2017.

Signed By:
Joseph M. Hood
Senior U.S. District Judge