

**UNITED STATES DISTRICT COURT
DISTRICT OF MAINE**

UNITED STATES OF AMERICA,)	
)	
PLAINTIFF)	
)	
v.)	CIVIL No. 05-163-P-H
)	
CAP QUALITY CARE, INC.,)	
)	
DEFENDANT)	

**ORDER AFFIRMING IN PART AND REJECTING IN PART
THE RECOMMENDED DECISION ON MOTIONS FOR
PARTIAL SUMMARY JUDGMENT**

Can the government recover Title 21 civil penalties from a methadone maintenance clinic that dispenses methadone in split doses (half the dose under supervision at the clinic; the other half unsupervised at home) when the clinic has not followed the “time-in-treatment” regulations that the Secretary of Health and Human Services has adopted under Title 42 for take-home methadone treatment?

Following oral argument on March 15, 2007, I conclude that Title 21 civil penalties are available for the Title 42 regulatory violation. I therefore **GRANT** partial summary judgment (liability only) for the government on Count 4 of the Amended Complaint, contrary to the Magistrate Judge’s recommendation. In all

other respects, I **ADOPT** the Magistrate Judge's Recommended Decision on Motions for Partial Summary Judgment (Docket Item 163) ("Recommended Dec.").

UNDISPUTED FACTS

The basic facts are undisputed for purposes of this ruling. Cap Quality Care Inc. ("CAP") is a methadone maintenance treatment clinic. Cap Quality Care's Additional Material Facts (Docket Item 144) ¶ 2 ("CAP Additional SMF"); Gov't Reply to CAP's Additional Statement of Fact (Docket Item 151) ¶ 2 ("Gov't's Additional Responsive SMF"). CAP uses methadone to treat patients who have been diagnosed with an opioid addiction. *Id.* CAP's position is that although most methadone patients require only one daily dosage of methadone, a single daily dose does not work well for patients who metabolize methadone rapidly. *Id.* ¶ 7. Accordingly, CAP has administered what it calls a "split-dose" to those patients: the patient ingests half the methadone dose at the clinic and takes the other half away from the clinic to ingest later in the day outside the clinic setting. *Id.* ¶ 10. CAP admits that it did not follow the Title 42 time-in-treatment regulations that govern unsupervised or take-home use, insisting instead that the "split-dose" is distinct from take-home or unsupervised use.¹

¹ I adopt Magistrate Judge Cohen's analysis at page 41 of the Recommended Decision, listing all the paragraphs in the government's statement of material facts showing that CAP violated the time-in-treatment regulations, along with the corresponding denials in CAP's response. The Magistrate Judge explained that CAP's denials addressed the legal question whether "split-dosing" is equivalent to "take-home" or "unsupervised use," but did not address the underlying factual allegations. Therefore, once the Magistrate Judge rejected CAP's legal argument, the fact that CAP failed to comply with the time-in-treatment regulations was appropriately deemed admitted. *(continued on next page)*

ANALYSIS

The Controlled Substances Act states that any person who violates 21 U.S.C. § 829 is subject to a civil penalty of up to \$25,000 per violation. 21 U.S.C. § 842(a)(1),(c)(1)(A). Section 829 provides:

Except when dispensed directly by a practitioner . . . to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §301 et seq.], may be dispensed without the written prescription of a practitioner

21 U.S.C. § 829(a). The parties agree that methadone is a schedule II controlled substance prescription drug. CAP Additional SMF ¶ 4; Gov't's Additional Responsive SMF ¶ 4. The issue on the cross motions for summary judgment on Count 4 is whether CAP's "split-doses" of methadone fit into either of the two statutorily enumerated exceptions to liability: dispensing methadone pursuant to a practitioner's written prescription; or a practitioner dispensing directly to an ultimate user.

1. WRITTEN PRESCRIPTION

Magistrate Judge Cohen denied summary judgment to the government on Count 4 because the record did not establish whether CAP had used written prescriptions in dispensing the methadone. In response, the government argues that the use of written prescriptions would have been illegal, thus still resulting in civil penalties. In the alternative, the government requests permission to

CAP did not object to the Magistrate Judge's treatment of the factual admissions. See Def.'s *(continued on next page)*

reopen the record to establish that there were no written prescriptions. CAP resists reopening the record. It does not assert that there were written prescriptions, but argues that if the record is reopened, the clinic should also be permitted to raise new factual issues. Def.'s Response to Pl.'s Partial Obj. to the Recommended Dec. (Docket Item 175) at 5.

The Title 21 regulations are clear on the illegality of written prescriptions for methadone used in detoxification or maintenance:

A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment"

21 C.F.R. § 1306.04(c)(2002).² I conclude that the government, therefore, is correct on the law (prescriptions for methadone are illegal)³, and that there is no need to reopen the record. I reject the Magistrate Judge's recommendation that summary judgment on Count 4 should be denied for lack of record evidence regarding written prescriptions for methadone.

Partial Obj. to the Mem. Dec. (Docket Item 167) at 6-11 ("Def.'s Obj.").

² The quoted language comes from the version of 21 C.F.R. § 1306.04 that was in effect at the time of the challenged conduct. The regulation was amended in 2005, but the amendment did not affect the prohibition against issuing written prescriptions for methadone for maintenance or detoxification treatment. See Authority for Practitioners to Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance and Detoxification Treatment, 70 F.R. 36338, 36339 (June 23, 2005) ("This rule does not affect the existing prohibition against prescribing any Schedule II narcotic controlled drugs for maintenance or detoxification treatment.").

³ The government's brief cites 21 C.F.R. § 1306.07, a regulation that only indirectly supports the prohibition. Pl.'s Partial Objection to the Recommended Dec. (Docket Item 165) at 4 ("Pl.'s Obj."). The more explicit prohibition of issuing written prescriptions for methadone for maintenance treatment is the regulation I quote in text, 21 C.F.R. § 1306.04(c).

2. DISPENSED DIRECTLY BY A PRACTITIONER

I therefore decide the question that Magistrate Judge Cohen did not address: do CAP's "split-doses" fit the other Section 829 exception to liability—a practitioner dispensing methadone directly to an ultimate user? I agree with the Magistrate Judge that CAP's "split-doses" of methadone violated the Title 42 regulations. I conclude that, as a result, CAP has violated 21 U.S.C. § 829 and is subject to civil penalties under 21 U.S.C. § 842. Because there appear to be no reported cases on the availability of Controlled Substances Act civil penalties for a violation of a Title 42 regulation (as the government admitted at oral argument), some elaboration is appropriate.

Section 829 of the Controlled Substances Act permits a Schedule II controlled substance such as methadone to be "dispensed directly by a practitioner . . . to an ultimate user." 21 U.S.C. § 829. It defines "dispense" as "deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance" 21 U.S.C. § 802(10).⁴ It defines "practitioner" as "a physician licensed, registered or otherwise permitted . . . to distribute, dispense, . . . [or] administer . . . a controlled substance *in the course of professional practice*" *Id.* § 802(21) (emphasis added). According to the

⁴ It is immaterial to my analysis whether the methadone is delivered directly or pursuant to an order because, in either event, a "practitioner" must be the source. The text explains how that
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Supreme Court, “the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician’s dispensing authority *to the course of his ‘professional practice.’*” United States v. Moore, 423 U.S. 122, 140 (1975) (emphasis added). Defining the scope of the limitation, therefore, is critical. The Supreme Court said that in the Controlled Substances Act, Congress “understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories.” Id. at 143. According to the Court, Congress’s solution to that concern is found in 42 U.S.C. § 290bb-2a:⁵

That section requires the Secretary of [Health and Human Services], after consultation with the Attorney General and national addict treatment organizations, to “determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction” It was designed “to clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients. . . . Under the new Act, “(t)hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers. . . .” *The negative implication is that physicians who go beyond approved practice remain subject to serious criminal penalties. In the case of methadone treatment the limits of approved practice are particularly clear.*

Moore, 423 U.S. at 144 (1975) (emphasis added). Accord United States v. Badia, 490 F.2d 296, 298 (1st Cir. 1973) (“[t]he combined effect of these statutory definitions in the present context is to limit the meaning of ‘dispense’ to delivery

term imposes the limits that govern here.

⁵ The Court referred to section 257a, which now is section 290bb-2a.

of controlled substances by a physician *who is acting in the course of professional practice or research*) (emphasis added). Moore was a criminal case, but that distinction was immaterial to the Supreme Court’s analysis:

[W]e think it immaterial whether Dr. Moore also could have been prosecuted for his violation of statutory provisions relating to dispensing procedures. There is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for the relatively minor offense of violating § 829 [the violation the government has charged in the current proceeding against CAP] is thereby exempted from prosecution under § 841

Id. at 138.⁶

In fact, the Secretary of Health and Human Services has—after the necessary consultations and in compliance with section 290bb-2a—established the standards for appropriate professional practice for methadone treatment. They appear in the federal opioid treatment regulations of Title 42. There is a specific subsection for “unsupervised or ‘take-home’ use” of methadone. 42 C.F.R. § 8.12(i).⁷ I agree with Magistrate Judge Cohen’s reasoning that the

⁶ The Supreme Court recently confirmed this understanding:

Even though regulation of health and safety is “primarily, and historically, a matter of local concern,” there is no question that the Federal Government can set uniform national standards in these areas. In connection to the [Controlled Substances Act], . . . we find only one area in which Congress set general, uniform standards of medical practice[: 42 U.S.C. §290bb-2a’s provision for “medical treatment of the narcotic addiction of various classes of narcotic addicts”].

Gonzales v. Oregon, 126 S. Ct. 904, 923-24 (2006).

⁷ CAP objects that the Recommended Decision failed to address its constitutional vagueness challenge regarding the word “unsupervised” in this regulation. CAP argues that “supervised” (continued on next page)

second half of CAP's daily split-dose regimen is subject to that subsection, which is designed in part "[t]o limit the potential for diversion of opioid agonist treatment medications to the illicit market." Id.⁸ CAP did not follow the

does not necessarily require that an act be directly observed. Therefore, according to CAP, reasonable minds could come to opposite conclusions about whether CAP's split-dose method constituted "unsupervised use." CAP argues that because the regulation fails to give intelligible standards to guide the conduct of methadone clinics, the regulation violates due process. Def.'s Obj. at 11. I disagree. Magistrate Judge Cohen implicitly rejected this argument when he ruled that the regulation "equates 'take-home use' with 'unsupervised use'" and "may not reasonably be read to distinguish between the two terms," and that this reading was supported by the regulation's statement of purpose (limiting "the potential for diversion of methadone to the illicit market"). Recommended Dec. at 39-40. I agree with the Magistrate Judge and I reject CAP's constitutional argument, following the standard that "[a] civil statute is generally deemed unconstitutionally vague only if it commands compliance in terms 'so vague and indefinite as really to be no rule or standard at all.'" Advance Pharm., Inc. v. United States, 391 F.3d 377, 396 (2d Cir. 2004). The term "unsupervised" does not make 21 C.F.R. § 8.12(i) unduly vague. I reach the same conclusion even if I treat the penalty here as quasi-criminal. See Village of Hoffman Estates v. Flipside, Hoffman Estates, 455 U.S. 489, 499-500 (1982). I do note that one of the considerations in determining the amount of fines to impose under 21 U.S.C. § 842(c)(1) is the willfulness of the violation. United States v. Poulin, 926 F. Supp. 246, 253 (D. Mass 1996). Therefore, if CAP establishes lack of willfulness, that may (I do not yet decide) militate in favor of a less severe fine. (On the summary judgment motion, CAP did not argue that willfulness is an element of the violation. See Def.'s Opp'n to Pl.'s Mot. for Partial Summ. J. (Docket Item 142) at 9-12; Reply to Def.'s Opp'n to Pl.'s Mot. for Partial Summ. J. (Docket Item 150) at 3 ("CAP [does not] dispute that this is a strict liability civil offense").)

⁸ See Luna v. Harris, 888 F.2d 949, 954 (2d Cir. 1989) (citations omitted):

The passage of the 1970 Act resulted in a substantial increase in the number of methadone treatment clinics nationwide. As a result, the risk of illegal diversion of methadone increased. The 1974 Act was passed primarily to respond to this problem. Its chief purpose was "to curb the diversion and abuse of narcotic drugs used in the treatment of narcotic addicts." Congress found that "the use of methadone in the treatment of heroin addiction involves unique and unusually great risks of diversion and criminal profiteering, and noted that a frequent source of illicit methadone was diversion by addicts abusing take-home privileges. The 1974 Act was accordingly designed to "permit flexibility in treatment, while requiring adequate accountability for narcotic drugs administered in that treatment. It . . . provide[s] a statutory complement to the FDA regulation, and provide[s] more specific controls over

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requirements of the subsection (the “time-in-treatment regulations”) for its split-dose regimen.⁹

In light of the clear statements from the Supreme Court in Moore that the Title 21 standards for professional practice in methadone treatment are to be found in the regulations promulgated under Title 42, I reject CAP’s argument that only the Title 42 penalty of certification revocation, 42 C.F.R. § 8.14, is available for violating the Title 42 regulation.¹⁰ The Title 21 civil penalties are available as well.

I also reject CAP’s argument that, because Maine’s Division of Licensing and Certification failed to sign the provider agreement that CAP signed and delivered to it, CAP never became a Medicaid “provider” subject to these regulations. I do not determine whether the document’s written signature provision applied to CAP (the Magistrate Judge found that it did not) because even if it did, ordinary contract principles make the agreement enforceable without the agency’s signature. Both parties have acted consistently as if there were an enforceable contract. CAP has presented thousands of claims to MaineCare, using its MaineCare provider number and attaching a “Provider

diversion.”

⁹ See, supra, footnote 1.

¹⁰ CAP agrees that “the Controlled Substances Act regulates medical practice to the extent that it prohibits a doctor from acting as a drug dealer,” Tr. at 30, but it claims that any misconduct of a narcotic treatment center short of criminal drug dealing for recreational use is subject only to the remedies found in Title 42.

Certification” to each claim, and MaineCare has reimbursed CAP over \$6.8 million for these claims. Plaintiff’s Additional Statement of Facts (included in Pl.’s Response to Def.’s Statement of Material Fact) (Docket Item 140) ¶¶ 74-76; Cap Quality Care’s Reply to the Gov’t’s Additional Facts (Docket Item 153) ¶¶ 74-76.¹¹

After enjoying the benefits of the provider arrangement for years, CAP cannot now deny its validity. See Contship Containerlines, Inc. v. Howard Indus., Inc., 309 F.3d 910, 912 (6th Cir. 2002) (“It is a fundamental tenet of contract law that a legally binding contract can be implied ‘from the circumstances and conduct of the parties.’”); Nightingale v. Leach, 842 A.2d 1277, 1279 (Me. 2004) (“the facts and circumstances surrounding the conduct between the parties can form a binding, implied-in-fact contract”).

Finally, while acknowledging that experts’ opinions about the law generally are inadmissible, CAP claims that the Recommended Decision fails to apply this rule consistently. Def.’s Obj. at 13. I disagree. The Magistrate Judge appropriately rejected CAP’s expert testimony regarding the application of the “take-home” regulations to CAP’s “split-dose” policy because interpretation of the regulations is for the court.¹² The government’s experts’ testimony, which he did

¹¹ CAP requested that the court strike ¶ 74 because it does not state a “fact” as the word is defined in Local Rule 56(b). The Magistrate Judge denied this request. Recommended Dec. at 27 n.19. I affirm his ruling.

¹² I reject CAP’s claim that “determining whether CAP’s ‘split-dose’ practices qualify as unsupervised use is a question properly left to the fact-finder.” Def.’s Obj. at 6. The case CAP cites for support, United States v. Rule Industries, is a “rare . . . exception” to “the well established (continued on next page)

permit, was generally of a different nature, concerning professional standards of practice, see Recommended Decision 4-6, and, in any event, is not pertinent to the rationale for my decision.¹³

CONCLUSION

Congress asked the Secretary of Health and Human Services to establish clear standards for what is and what is not in the course of professional practice for narcotic treatment centers. 42 U.S.C. § 290bb-2a. The Secretary did so. Those standards are the Title 42 federal opioid treatment regulations. The Supreme Court has interpreted the Controlled Substances Act, Title 21, to require that, in narcotic treatment centers, the Schedule II prescription drug methadone only be dispensed in the course of professional practice as established by the Secretary under Title 42. Therefore, the clinic's violation of the Title 42 time-in-treatment regulations for take-home methadone treatment constitutes a violation of 21 U.S.C. § 829(a). As a result, the clinic is subject to monetary penalties under 21 U.S.C. § 842.

principle that application of standards set by statutes, regulations and precedent to undisputed facts will normally give rise to a 'question of law' for the court." United States v. Rule Indus., 878 F.2d 535, 542 (1st Cir. 1989). The regulation and facts at issue in this case do not call for such an exception.

¹³ CAP's objection that the Magistrate Judge permitted characterizations and interpretations of federal regulations by the government's experts cites footnotes 4-6 of the Recommended Decision, which deal with 42 C.F.R. § 8.11(h), the exemption provision for take-home use, as well as 42 C.F.R. § 8.12(i)(2), the 8-point criteria section of take-home regulations. Neither regulation is pertinent to the rationale for my decision. Dr. Reuter's declaration, part of which CAP objects to as "skewed and imbalanced," see Def.'s Obj. at 13, is also immaterial to my analysis in this opinion.

It is hereby **ORDERED** that the plaintiff's motion for partial summary judgment is **GRANTED** as to Count 4.¹⁴ I **AFFIRM** all other findings in the Recommended Decision and **ORDER** that the defendant's motion for summary judgment be **GRANTED** as to any claims arising from paragraphs 313, 316-18, 322-23, 325, and 356-67 of the Second Amended Complaint and otherwise **DENIED**.

SO ORDERED.

DATED THIS 2ND DAY OF MAY, 2007

/s/D. BROCK HORNBY
D. BROCK HORNBY
UNITED STATES DISTRICT JUDGE

¹⁴ The Government's Motion for Entry of a Rule 56(d) Order (Docket Item 166) is now **Moot**.

**U.S. DISTRICT COURT
DISTRICT OF MAINE (PORTLAND)
CIVIL DOCKET FOR CASE #: 2:05cv163 (DBH)**

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