

UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

KEVIN BANKS, et al.,)	
)	
Plaintiffs)	
)	
v.)	Civil No. 96-39-B-DMC
)	
KEVIN CONCANNON,)	
COMMISSIONER, MAINE)	
DEPARTMENT OF)	
HUMAN SERVICES,)	
)	
Defendant)	

**MEMORANDUM DECISION ON CROSS-MOTIONS FOR
JUDGMENT BASED ON A STIPULATED RECORD¹**

The plaintiffs allege that the defendant's refusal to cover methadone and related transportation costs under Maine's Medicaid program violates the federal Medicaid statute. They seek declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201-2202, and reasonable attorney fees and costs pursuant to 42 U.S.C. § 1988(b). The parties have agreed to a consolidation of the plaintiffs' application for preliminary injunction with trial on the merits, and, in lieu of trial, to submit the case for decision on the basis of a stipulated record. Any factual disputes may therefore be resolved by the court. *See Boston Five Cents Sav. Bank v. Secretary of Dep't of Hous. & Urban Dev.*, 768 F.2d 5, 11-12 (1st Cir. 1985). For the reasons set forth below, I conclude that the defendant's refusal violates the federal Medicaid statute, and enter judgment for the plaintiffs.

Factual Background

¹ Pursuant to 28 U.S.C. § 636(c), the parties have consented to have United States Magistrate Judge David M. Cohen conduct all proceedings in this case, including trial, and to order the entry of judgment.

Methadone is a synthetic opiate substitute which, when administered at medically appropriate dosages, removes the withdrawal symptoms associated with detoxification from opiates without creating a “high.” Affidavit of Roger C. Kendrick, D.O. (“Kendrick Aff.”) ¶ 2, Exh. B to Memorandum in Support of Plaintiffs’ Motion for Temporary Restraining Order and Preliminary Injunction (Docket No. 4). To be effective, methadone must be administered on a daily basis. *Id.* ¶ 3. Without regular dosage, patients begin to involuntarily detoxify and experience increasingly severe withdrawal symptoms. *Id.*

The plaintiffs are categorically eligible under the Maine Medicaid program. Stipulations of Fact (Docket No. 9) ¶ 1. They currently receive methadone to treat their drug addiction at the Habit Management Institute (“HMI”), a methadone clinic in South Portland, Maine. *Id.* ¶ 2. HMI dispenses methadone to the plaintiffs on a daily basis and charges each plaintiff \$25 per week. *Id.* The \$25 fee includes both the cost of the drug and a daily fee for dispensing the drug. *Id.* The plaintiffs also receive substance abuse counseling at HMI. *Id.* ¶ 3.

The manufacturer(s) of methadone has entered into and has in effect a rebate agreement as described in 42 U.S.C. § 1396r-8(b). *Id.* ¶ 5. Methadone is not a drug subject to any exclusion or restriction provided in 42 U.S.C. § 1396r-8(d)(1)(B) or (d)(2). *Id.* ¶ 6. Methadone satisfies all the criteria for a “covered outpatient drug” as defined by 42 U.S.C. § 1396r-8(k)(2) and is not subject to any of the limitations provided in 42 U.S.C. § 1396r-8(k)(3). *Id.* ¶ 7.

The Maine Medicaid program provides coverage for prescribed drugs as an optional service pursuant to 42 U.S.C. § 1396d(a)(12). *Id.* ¶ 8. The program currently pays for the plaintiffs’ substance abuse treatment but not their methadone. *Id.* ¶ 4. At all times relevant to this case, the defendant has acted in his official capacity and under color of state law in administering the Maine Medicaid program. *Id.* ¶ 9.

Prior to July 26, 1995 the Maine Medicaid program was providing necessary transportation services for Medicaid eligible persons, seven days per week, to clinics that dispensed methadone. Complaint (Docket No. 2) ¶ 15; Answer (Docket No. 11) ¶ 15. On February 13, 1996 this court entered a temporary restraining order, agreed to by the parties, requiring, inter alia, that the defendant provide “Medicaid coverage for transportation services for the two named Plaintiffs . . . consistent with the terms and conditions set forth in the emergency rules for transportation services for seven day clinic services, which became effective on October 25, 1995 and expired on January 22, 1996.” Agreed Order (Docket No. 7) ¶ 2.

Legal Analysis

“Although participation in the Medicaid program is entirely optional, once a State elects to participate, it must comply with the requirements of [the federal Medicaid statute].” *Harris, Sec’y of Health & Human Servs. v. McRae*, 448 U.S. 297, 301 (1980). Under the federal Medicaid statute, states have the option whether to provide coverage for prescribed drugs. 42 U.S.C. §§ 1396a(a)(10), 1396d(a)(12). Maine has opted to cover prescribed drugs, and methadone is a covered outpatient drug as defined in § 1396r-8(k)(2).

Section 1396r-8(d) permits certain restrictions on covered outpatient drugs:²

(1) Permissible restrictions. (A) A State may subject to prior authorization any covered outpatient drug. . . .

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if --

² Section 1396r-8(a) requires that, for a state to receive federal payment for any manufacturer’s covered outpatient drugs, the manufacturer must have entered into and have in effect a rebate agreement as described in § 1396r-8(b). As noted above, the parties agree that the requisite agreement(s) regarding methadone is in effect.

- (i) the prescribed use is not for a medically accepted indication . . . ;
- (ii) the drug is contained in the list referred to in paragraph (2);
- (iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary . . . ; or
- (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction. The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted

The parties agree that neither subsection (d)(1)(B) nor subsection (d)(2) applies to methadone, and the defendant has not suggested that its refusal to cover the plaintiffs' methadone treatment is part of a prior authorization program authorized by subsection (d)(1)(A). Thus, methadone is not subject to § 1396r-8(d)'s enumerated restrictions on covered outpatient drugs.³

The defendant argues that certain federal regulations permit him to deny coverage for methadone. These regulations state that the service provided "must be sufficient in amount, duration and scope to reasonably achieve its purpose," 42 C.F.R. § 440.230(b), and that states "may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures," *id.* § 440.230(d). In response, the plaintiffs contend that § 1396r-8(d) enumerates the only permissible restrictions on covered outpatient drugs such as methadone, and that regulations of general applicability cannot contravene the express language of § 1396r-8(d).

Congress enacted subsection (d), "Limitations on coverage of drugs," without any suggestion that the limitations therein were non-exclusive. Subsection (d)(1) establishes certain "Permissible restrictions," and subsection (d)(6) establishes "Other permissible restrictions." One can reasonably

³ Additionally, § 1396r-8(d)(6) permits certain limitations on therapeutic drugs and allows states to address individual instances of fraud and abuse. There is no suggestion that subsection (d)(6) applies here.

infer from Congress’s chosen terminology that non-enumerated restrictions are impermissible. However, since Congress did not explicitly state that the *only* permissible restrictions are those enumerated in subsection (d), one might also reasonably infer that other restrictions are permissible. Accordingly, I must look beyond the words of § 1396r-8(d).⁴

Congress requires state Medicaid plans to provide sufficient procedures “relating to the utilization of, and the payment for, care and services available under the plan” as needed to safeguard against unnecessary utilization and to “assure that payments are consistent with efficiency, economy, and quality of care.” 42 U.S.C. § 1396a(a)(30). One might argue that finding section 1396r-8(d)’s restrictions to be exclusive would frustrate mandated efficiency-driven efforts by states to limit covered outpatient drug provision, and thus contravene section 1396a(a)(30).

This argument, however, is unpersuasive. Section 1396r-8(d) offers ample means for states to assure efficient coverage of prescribed drugs. States may institute a prior authorization program for any covered outpatient drug, § 1396r-8(d)(1)(A), or exclude a covered outpatient drug if its

⁴ The Maine Department of Human Services is not the agency charged with implementing the federal Medicaid statute. Accordingly, I need not follow the analytical framework set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See Kenaitze Indian Tribe v. Alaska*, 860 F.2d 312, 315-16 (9th Cir. 1988) (where state legislation interprets federal law, court need not defer to state interpretation because state lacks experience implementing federal law and policy, state is not subject to congressional supervision via advice and consent, appropriation and oversight, and Congress did not delegate to state authority to interpret statute), *cert. denied*, 491 U.S. 905 (1989); *see also New Mexico v. Watkins*, 969 F.2d 1122, 1131 (D.C. Cir. 1992) (court need not defer to federal agency’s interpretation of statute other than its enabling statute).

In any event, I note that the federal regulations at issue do not clarify how the Secretary of the Department of Health and Human Services would interpret § 1396r-8(d). 42 C.F.R. § 440.230(b) merely establishes a floor below which a state’s coverage may not fall, and thus does not speak to whether the subsection (d) limitations are exclusive. 42 C.F.R. § 440.230(d) is a regulation of general applicability, rather than one interpreting § 1396r-8(d). *See* 42 C.F.R. § 440.200(b). Moreover, the regulation allows states to place only “appropriate” limits on a service. 42 C.F.R. § 440.230(d). “Appropriate limits” could mean those limits that do not contravene the Medicaid statute.

prescribed use is not a “medically accepted indication,” § 1396r-8(d)(1)(B)(i). They may establish a formulary and exclude a covered outpatient drug for treatment of a specific condition, provided that the excluded drug has no significant advantage “in terms of safety, effectiveness, or clinical outcome” over other drugs included in the formulary. § 1396r-8(d)(4)(C). Finally, they may limit the minimum or maximum quantities per prescription or the number of refills on therapeutic drugs, if such limitations are necessary to discourage waste, and take any measures authorized under the Social Security Act to “address individual instances of fraud or abuse.” Section 1396r-8(d)(6). Thus, section 1396r-8(d) affords participating states the necessary tools to ensure efficient covered outpatient drug service, and thus comply with section 1396a(a)(30).

In addition, the detailed structure I have just described indicates that Congress carefully considered the appropriate restrictions for covered outpatient drugs. By setting forth this detailed list of permissible restrictions, Congress implied that there are no others. *See Sunshine Dev., Inc. v. FDIC*, 33 F.3d 106, 116 (1st Cir. 1994) (where statute contains enumeration of applicable exceptions, principle of *expressio unius est exclusio alterius* ordinarily applies, under which “a legislature’s affirmative description of certain powers or exemptions implies denial of nondescribed powers or exemptions”). Perhaps most obviously, Congress’s choice of the term *covered* outpatient drugs suggests that coverage is to be the general rule, subject to specifically-enumerated restrictions.

Finally, the legislative history concerning section 1396r-8(d) suggests that Congress intended covered outpatient drugs to be subject only to the restrictions enumerated in section 1396r-8(d). The House Conference Report observed, regarding the relevant provision of the House bill, “States are required to cover a manufacturer’s covered outpatient drugs prescribed for a medically accepted indication when the manufacturer . . . has entered into and complies with a rebate agreement. States are not required to cover any drug for which the manufacturer . . . has imposed certain conditions

of sale.” H.R. Conf. Rep. No. 964, 101st Cong., 2d Sess. 824, *reprinted in* 1990 U.S.C.C.A.N. 2374, 2529. The Senate amendment merely added more detailed restrictions, *see id.* at 828-29, *reprinted in* 1990 U.S.C.C.A.N. 2374, 2533-34, which were ultimately enacted, *see* § 1396r-8(d). Thus, it seems that Congress intended to allow only limited restrictions on covered outpatient drugs, rather than grant states broad discretion to restrict such coverage in the name of medical necessity or efficiency, as the defendant suggests.

The defendant’s reliance on this court’s unpublished decision in *Hines v. Sheehan, Comm’r, Maine Dep’t of Human Servs.*, Civ. No. 94-326-P-H, 1995 WL 463685 (D. Me. July 26, 1995), is misplaced. In *Hines* the plaintiffs argued that the defendant’s restrictions on liquid dietary supplements, an over-the-counter drug, violated the federal Medicaid statute and regulations. *Id.* at *1. The court held that the state’s limited coverage nonetheless satisfied the requirements of 42 C.F.R. § 440.230(b) (optional Medicaid service “must be sufficient in amount, duration and scope to reasonably achieve its purpose”), one of the regulations on which the defendant relies in this case. *Hines*, 1995 WL 463685 at *2. *Hines*, however, did not involve the restrictions enumerated in § 1396r-8(d) because liquid dietary supplements are over-the-counter drugs, not covered outpatient drugs such as methadone. *See id.* at *1. Thus, the *Hines* analysis is inapplicable to methadone.

In summary, I find that the restrictions enumerated in section 1396r-8(d) are the only permissible limitations on covered outpatient drugs. Because the defendant has not demonstrated that its refusal to cover methadone falls within any such restrictions, its refusal violates the federal Medicaid statute. Furthermore, the Maine Medicaid plan must “ensure necessary transportation for recipients to and from providers.” 42 C.F.R. § 431.53(a). The undisputed evidence in the written record establishes that, for most patients undergoing methadone treatment, daily visits to the

methadone clinic are required. *See* Kendrick Aff. ¶¶ 3-4. The defendant, therefore, must provide eligible Medicaid recipients with necessary transportation to and from methadone clinics.

Accordingly, judgment shall enter as follows:

1. The defendant's policy of excluding coverage of methadone, and necessary transportation to methadone clinics, from the Maine Medicaid program violates the federal Medicaid statute;
2. The defendant is ordered to immediately provide coverage for methadone, consistent with applicable provisions of federal law; and
3. The defendant is ordered to ensure necessary transportation for recipients to and from methadone providers, consistent with 42 C.F.R. § 431.53(a); and
4. The defendant is ordered to pay the plaintiffs' reasonable costs and attorney fees, pursuant to 42 U.S.C. § 1988(b).

Dated at Portland, Maine this 19th day of March, 1996.

David M. Cohen
United States Magistrate Judge