

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

SHARP HEALTHCARE, et. al.,  
Plaintiffs,  
vs.  
MICHAEL LEAVITT, Secretary of the  
Department of Health and Human  
Services,  
Defendant.

CASE NO. 08-CV-0170 W (POR)  
**ORDER FINDING THE COURT  
HAS JURISDICTION AND  
PLAINTIFFS' CLAIMS ARE  
RIPE FOR REVIEW**

Plaintiffs Sharp Healthcare, Scripps Health, and Internist Laboratory filed a motion for a temporary restraining order. In denying the motion, the Court ordered Plaintiffs to show cause why this case should not be dismissed for lack of jurisdiction and standing. Having reviewed the parties' responses to the OSC, the Court finds that jurisdiction and standing exist.

**I. PROCEDURAL BACKGROUND**

On February 4, 2008, Plaintiffs filed a motion for a TRO to enjoin the Secretary's deadline to submit bids to provide clinical diagnostic laboratory tests covered by Medicare Part B. On February 14, 2008, the Court denied the TRO finding that the Secretary had raised serious issues regarding the Court's jurisdiction (thereby preventing Plaintiffs from establishing a likelihood of success on the merits) and finding that

1 Plaintiffs would not suffer irreparable harm by having to comply with the application  
2 deadline.

3 In light of the serious jurisdictional issues raised by the Secretary, the Court also  
4 issued an OSC requiring the parties to provide briefing on the following issues:

5 (1) Do Plaintiffs have to exhaust administrative remedies before pursuing their  
6 claims in federal court?

7 (2) Is judicial review of Plaintiffs' claims barred under 42 U.S.C. § 1395w-3(10)?

8 (3) Are ripeness and standing requirements met?

9 The parties have submitted their briefing. For the reasons discussed below, the  
10 Court finds that it has jurisdiction, and that Plaintiffs have standing.

11

12 **II. EXHAUSTION OF ADMINISTRATIVE REMEDIES**

13 In Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000), the  
14 Supreme Court held that 42 U.S.C. § 405(h), which is incorporated into the Medicare  
15 Act by 42 U.S.C. § 1395ii, “demands the ‘channeling’ of virtually all legal attacks  
16 through the agency.” Id. at 13. In so holding, however, the Supreme Court recognized  
17 an exception to the channeling requirement where application of § 405(h) would  
18 amount to “no review at all.” Id. at 19.

19 There is no dispute that Plaintiffs did not pursue administrative remedies before  
20 filing this lawsuit. The issue, therefore, is whether requiring Plaintiffs to first seek  
21 administrative review would amount to “no review at all.”

22 The Secretary argues that administrative review is available for Plaintiffs' claims.  
23 According to the Secretary, after winners are selected, Plaintiffs—whether they win or  
24 lose—will be in a position to submit claims for laboratory tests to Medicare and, if not  
25 satisfied with the reimbursement, may pursue administrative claims.

26 But the controlling statute provides that losing laboratories are not entitled to  
27 payment from Medicare. See 42 U.S.C. §1395w-3(5)(A) (“Payment under this part for  
28 competitively priced items and services . . . shall be based on bids submitted and

1 accepted under this section. . . .”) And the Department of Health and Human Services’  
2 October 17, 2007 Notice specifically states that “[w]e will not directly pay... for services  
3 furnished by a required bidder that . . . did not win.” 72 F.R. 58856-01; see also Def.’s  
4 Opp. to TRO, p.5 (“Required bidders who either lose in the bidding process or fail to  
5 submit bids may not bill Medicare directly for any of the laboratory tests involved in the  
6 project.”) Accordingly, contrary to the Secretary’s contention, if Plaintiffs lose, they  
7 cannot submit claims to Medicare and, therefore, will not be in a position to obtain  
8 administrative review.<sup>1</sup>

9 Furthermore, in a February 1, 2008 letter sent to providers, the Secretary stated  
10 that non-winning laboratories cannot pursue administrative appeals. (See Plts.’ OSC  
11 Brief, Ex. A, p.7 (“non-winner laboratories . . . have no appeal rights when Medicare  
12 denies payment for the test. . . .”).) This statement contradicts the Secretary’s  
13 representation to the Court that administrative review is available to Plaintiffs.

14 The Secretary attempts to explain away this contradiction on two grounds. First,  
15 the Secretary asserts, in essence, that the position in the February letter *could* change  
16 to allow for administrative review in the future. But the Court must rule based on the  
17 present set of facts. And at present, non-winning laboratories have no appeal rights.

18 The Secretary next argues that the February letter reflects his interpretation that  
19 42 U.S.C. § 1395w-3(b)(10) bars both judicial and administrative review of all of  
20 Plaintiffs’ claims. Far from helping the Secretary, this argument seals his fate. Based on  
21 the Secretary’s interpretation of subsection (b)(10), there is no dispute that Plaintiffs  
22 could not have obtained administrative review before filing this lawsuit. Nor could  
23 Plaintiffs have obtained review if they waited until after winning bids were selected.  
24 Accordingly, the Court must find that application of § 405(h)’s administrative  
25

---

26  
27 <sup>1</sup>Moreover, even assuming that Plaintiffs—if not declared winners—can submit claims to  
28 CMS, it appears that the claims would be limited the amount of reimbursement received. (See  
Def.’s Opp. to OSC, p.13 (“If they are dissatisfied with the reimbursement they receive, they  
may then present their claims to CMS and pursue an administrative remedy....”).)

1 channeling requirement would amount to no review at all. Plaintiffs, therefore, were  
2 not required to pursue administrative remedies before filing this lawsuit.

3  
4 **III. AVAILABILITY OF JUDICIAL REVIEW**

5 The statute authorizing the demonstration project, 42 U.S.C. § 1395w-3(e),  
6 includes a limitation on judicial review. Subsection (b)(10) prohibits judicial review of  
7 the following six areas related to the project:

- 8  
9 (A) the establishment of payment amounts under paragraph (5);  
10 (B) the awarding of contracts under this section;  
11 (C) the designation of competitive acquisition areas under subsection  
12 (a)(1)(A) of this section;  
13 (D) the phased-in implementation under subsection (a)(1)(B) of this  
14 section;  
15 (E) the selection of items and services for competitive acquisition under  
16 subsection (a)(2) of this section; or  
17 (F) the bidding structure and number of contractors selected under this  
18 section.

19 In opposing the TRO, the Secretary argued that (b)(10) precludes judicial review  
20 of all of Plaintiffs' claims. Although the Court believes that certain claims are covered  
21 by this provision, judicial review is available for some of Plaintiffs' claims.

22 For example, Plaintiffs contend that the Secretary violated the Administrative  
23 Procedure Act ("APA") by enacting a rule requiring some laboratories that have a face-  
24 to-face encounter with the patients, such as Plaintiffs, to participate in the competitive  
25 bidding process. (Compl., ¶36(a).) Plaintiffs contend that this rule conflicts with the  
26 express language of 42 U.S.C. § 1395w-3(e)(1)(B), which excepts all entities that have  
27 a face-to-face encounter from the bidding requirement.

28 The Secretary responds that judicial review of this claim is foreclosed by  
subsection (b)(10)(F), which precludes review of the "bidding structure." The Secretary  
contends that "application of the face-to-face exception . . . is encompassed within his  
overall effort to create a viable bidding structure. . . ." (Def.'s OSC Brief, p.9.)

1 According to the Secretary, “category (F) . . . necessarily incorporates the determination  
2 of who is and is not required to submit bids in order to participate in the demonstration  
3 project.” (Id.)

4 The analysis of whether judicial review is available begins with the “strong  
5 presumption that Congress intends judicial review of administrative action.” Bowen v.  
6 Michigan Academy of Family Physicians, 476 U.S. 667, 670 (1986). “[O]nly upon a  
7 showing of ‘clear and convincing evidence of a contrary legislative intent should the  
8 courts restrict access to judicial review.” Id. at 671 (citing Abbott Laboratories v.  
9 Gardner, 387 U.S. 136, 141 (1967)).

10 Here, the Secretary’s argument requires the Court to find that the term “bidding  
11 structure” necessarily includes the determination of who is required to bid. But “bidding  
12 structure” may reasonably be interpreted as encompassing only the Secretary’s  
13 establishment of the procedures or process that bidders must follow. In short, the term  
14 is ambiguous, at best, regarding whether it provides the Secretary with unchecked  
15 discretion to determine who must submit bids. In light of this ambiguity, the Court finds  
16 that the Secretary has not provided “clear and convincing evidence” that Congress  
17 intended to preclude judicial review of his interpretation of the face-to-face exception.

18  
19 Moreover, inherent in the Secretary’s argument is the notion that he may  
20 disregard Congress’s express statutory command that only entities that do *not* have a  
21 face-to-face encounter are required to bid. This contradicts the strong presumption that  
22 “Congress intends the executive to obey its statutory commands and, accordingly, that  
23 it expects the courts to grant relief when an executive agency violates such a  
24 command.” Bowen, 476 U.S. at 681.

25 For these reasons, the Court finds jurisdiction exists in this case.<sup>2</sup>

26  
27 <sup>2</sup>The purpose of the OSC was to determine whether the Court has jurisdiction over any  
28 part of this case. The resolution of this issue is made urgent because of the fast approaching  
preliminary injunction hearing. As indicated *supra*, although the Court finds that judicial  
review of the face-to-face exception is not precluded, other claims may be barred. Resolution

1 **IV. STANDING/RIPENESS**

2 The Secretary contends that Plaintiffs lack standing for two reasons: (1) Plaintiffs'  
3 injury is too speculative; and (2) the Secretary's rules are not yet final. The Court  
4 disagrees.

5 The ripeness requirement is designed to "prevent courts, through avoidance of  
6 premature adjudication, from entangling themselves in abstract disagreements over  
7 administrative policies, and also to protect the agencies from judicial interference until  
8 an administrative decision has been formalized and its effects felt in a concrete way by  
9 the challenging parties. Ohio Forestry Association, Inc. v. Sierra Club, 523 U.S. 726,  
10 732–733 (1998) (citing Abbott Laboratories v. Gardner, 387 U.S. 136, 148–149  
11 (1967)). "To satisfy the injury in fact requirement, a plaintiff asserting a procedural  
12 injury must show that the 'procedures in question are designed to protect some  
13 threatened concrete interest of his that is the ultimate basis of his standing.'" Cantrell  
14 v. City of Long Beach, 241 F.3d 674, 679 (9th Cir. 2001).

15 In Paulsen v. Daniels, 413 F.3d 999 (9th Cir. 2005), federal prisoners challenged  
16 a Bureau of Prisons ("Bureau") interim regulation making certain prisoners ineligible  
17 from participation in an early release incentive program. The prisoners argued that the  
18 Bureau violated the APA in adopting the regulation. The Bureau did not dispute  
19 violating the APA, instead arguing that the prisoners lacked standing because they  
20 could not establish injury in fact. The Ninth Circuit disagreed:

21 [The Bureau's] procedural violations of the APA threatened petitioners'  
22 concrete interest to have the public participate in rulemaking that made  
23 them ineligible for a sentence reduction. The effect of the regulation was  
24 to deny them sentence reduction. The petitioners have clearly sustained  
25 an injury in fact affording them standing to file their habeas petitions.

26 Id. at 1005.

27 Similar to Paulsen, the Secretary's alleged procedural violations of the APA  
28 threaten Plaintiffs' interest in having the public participate in rulemaking pertaining to

---

of the other claims is beyond the scope of this order.

1 the demonstration project for laboratory tests. As providers of those laboratory tests,  
2 there is no dispute that the Secretary's rules have impacted Plaintiffs. For example,  
3 Plaintiffs contend that they are face-to-face laboratories and, therefore, should not have  
4 been required to submit bids. The Secretary's rule limiting the face-to-face exception,  
5 however, obligated Plaintiffs to submit bids. This, in turn, required Plaintiffs to devote  
6 "significant time and expense" in preparing the bids (Compl., ¶145), and Plaintiffs—as  
7 required bidders—are now threatened with the prospect of losing the ability to participate  
8 in Medicare. Thus, far from being an "abstract disagreement," Plaintiffs have felt the  
9 effects of the agency's decision in a concrete way.

10 Nor is the Court persuaded by the Secretary's contention that standing is lacking  
11 because the rules are not yet final. Agency action is final if it marks the consummation  
12 of the agency's decision making process, and results in the determination of rights or  
13 obligations. Ecology Ctr., Inc. v. U.S. Forest Serv., 192 F.3d 922, 925 (9th Cir. 1999).  
14 Here, there is no dispute that the Secretary's rule regarding the face-to-face exception  
15 has been implemented, and has imposed obligations upon Plaintiffs. Accordingly, the  
16 rule is final with respect to the current demonstration project.

17

18 **V. CONCLUSION**

19 For the reasons addressed above, the Court finds that it has jurisdiction over this  
20 case, and that Plaintiffs satisfy the standing requirements.

21

22 **IT IS SO ORDERED.**

23

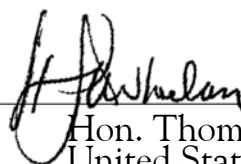
24

25 DATED: April 4, 2008

26

27

28

  
\_\_\_\_\_  
Hon. Thomas J. Whelan  
United States District Judge

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28