UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SHARP HEALTHCARE, INTERNIST LABORATORY, AND SCRIPPS HEALTH,

Plaintiffs,

vs.

MICHAEL LEAVITT, Secretary of the Department of Health and Human Services,

Defendant.

CASE NO. 08-CV-0170 W (POR)

ORDER GRANTING MOTION FOR A PRELIMINARY INJUNCTION (Doc. No. 15)

Plaintiffs Sharp Healthcare, Scripps Health, and Internist Laboratory have filed a motion for a preliminary injunction. Plaintiffs seek to enjoin Defendant Michael Leavitt, Secretary of Health and Human Services (the "Secretary"), from selecting winners in the Medicare demonstration project for clinical laboratory tests. For the following reasons, the Court **GRANTS** Plaintiffs' motion (Doc. No. 15).

I. BACKGROUND

A. Factual Background

This litigation involves Part B of the Medicare program. Medicare Part B is a voluntary insurance program that covers a portion of the costs for, among other things, clinical diagnostic laboratory services for Medicare beneficiaries. Typically, Medicare

pays for clinical laboratory services on a fee-for-service basis according to the Medicare Part B Clinical Laboratory Fee Schedule established in 1984. See 42 U.S.C. § 13951(h).

In 2003, Congress passed the Medicare Prescription Drug Improvement and Modernization Act of 2003, 42 U.S.C. § 1395w-3. The statute requires the Secretary, through the Center for Medicare and Medicaid Services ("CMS"), to conduct a demonstration project on the application of competitive acquisition for payment of clinical diagnostic laboratory tests that would otherwise be covered by the Medicare Part B Fee Schedule. 42 U.S.C. § 1395w-3(e). Pap smear and colorectal cancer screening tests are excluded from the demonstration project, as well as tests performed by entities that have a "face-to-face encounter with the individual" being tested. 42 U.S.C. § 1395w-3(e)(1)(A)-(B). The statute also requires the Secretary to designate competitive acquisition areas where the project will be implemented. 42 U.S.C. § 1395w-3(a)(1)(A).

On October 17, 2007, the Secretary announced the San Diego-Carlsbad-San Marcos area as the first competitive acquisition demonstration site. See 72 Fed.Reg. 58856-01. Under the bidding process, laboratories must submit bids for 303 laboratory tests, and for the collection and handling of laboratory specimens. Laboratories are required to bid for each of the 303 tests, even if the laboratory does not provide the specific test. Bids will be evaluated based on CMS's determination of the "best value for the Medicare program," using price and non-price criteria. The deadline for submitting bids was February 15, 2008. The winning bidders will be announced on April 11, 2008.

In November 2007, CMS issued a list of Frequently Asked Questions ("FAQ") as part of the final Bidders' Package. In the FAQ, CMS stated that the Secretary had interpreted the face-to-face exception in 42 U.S.C. § 1395w-3(e)(1)(B) as excluding only "testing performed by physician office laboratories or by hospital laboratories for their own patients."

B. Procedural Background

On January 29, 2008, Plaintiffs filed this lawsuit seeking to enjoin the Secretary from implementing the demonstration project. The Complaint includes four counts. Count I alleges the Secretary violated notice and comment requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(b), in developing certain demonstration project rules. In Count II, Plaintiffs allege that three of the Secretary's rules (including the limitation on the face-to-face exception) violate sections 701–706 of the APA because the rules are arbitrary, capricious, an abuse of discretion or not otherwise in accordance with the law. Count III alleges that the Secretary's rules will cause a taking in violation of the Fifth Amendment to the United States Constitution. In Count IV, Plaintiffs contend that the Secretary violated 42 U.S.C. § 1395w-3(e) by increasing the scope of the demonstration project to include collecting and handling laboratory specimens.

On February 4, 2008, Plaintiffs filed a motion for a TRO to enjoin the demonstration project before the February 15, 2008 application deadline. On February 14, 2008, the Court denied the motion because the Secretary had raised serious issues regarding the Court's jurisdiction–thereby preventing a finding that Plaintiffs had a likelihood of success on the merits– and because Plaintiffs had failed to establish that they would suffer irreparable harm by having to comply with the application deadline. In light of the serious jurisdictional issues raised by the Secretary, the Court also issued an order to show cause ("OSC") requiring the parties to provide briefing regarding whether jurisdiction exists, and whether Plaintiffs have standing.

On March 10, 2008, Plaintiffs filed the preliminary injunction motion seeking to enjoin the demonstration project before April 11, 2008, the date the Secretary will announce winning bidders. After Plaintiffs' motion was filed, the parties filed their briefs on the OSC. On April 4, 2008, the Court issued an Order Finding The Court Has Jurisdiction And Plaintiffs' Claims Are Ripe For Review ("OSC Order"). (Doc. No. 23.) The Court now decides Plaintiffs' preliminary injunction motion.

II. LEGAL STANDARD

Rule 65 of the Federal Rules of Civil Procedure authorizes a district court to issue a preliminary injunction in the exercise of its equitable powers. Fed. R. Civ. P. 65. "The standard for granting a preliminary injunction balances the plaintiff's likelihood of success against the relative hardship to the parties." Clear Channel Outdoor, Inc. v. City of Los Angeles, 340 F.3d 810, 813 (9th Cir. 2003). The Ninth Circuit recognizes two tests for granting preliminary injunctive relief. Save Our Sonoran, Inc. v. Flowers, 408 F.3d 1113, 1120 (9th Cir. 2005).

To obtain a preliminary injunction under the "traditional" test, a plaintiff must show "'(1) a strong likelihood of success on the merits, (2) the possibility of irreparable injury to plaintiff if preliminary relief is not granted, (3) a balance of hardships favoring the plaintiff, and (4) advancement of the public interest (in certain cases).'" Save Our Sonoran, 408 F.3d at 1120 (quoting Johnson v. Cal. State Bd. of Accountancy, 72 F.3d 1427, 1430 (9th Cir. 1995)).

To obtain a preliminary injunction under the "alternative" test, a plaintiff must demonstrate *either* (1) a combination of probable success on the merits and the possibility of irreparable injury *or* (2) that serious questions are raised and the balance of hardships tips sharply in his favor. Save Our Sonoran, 408 F.3d at 1120 (citing Johnson, 72 F.3d 1430); Immigrant Assistance Project of the L.A. County of Fed'n of Labor v. INS, 306 F.3d 842, 873 (9th Cir. 2002). "These two formulations represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases. They are not separate tests but rather outer reaches of a single continuum." Baby Tam & Co. v. City of Las Vegas, 154 F.3d 1097, 1100 (9th Cir. 1998). Thus, "the greater the relative hardship to the moving party, the less probability of success must be shown." Immigrant Assistant Project, 306 F.3d at 873 (citations). "Conversely, it has been held that a preliminary injunction may be granted even though the harm factor favors defendant if plaintiff demonstrates a substantial likelihood that he will ultimately prevail." Id. (citations).

"In cases where the public interest is involved, the district court must also examine whether the public interest favors the plaintiff." Fund for Animals, Inc. v. Lujan, 962 F.2d 1391, 1400 (9th Cir. 1992); see also Caribbean Marine Services Co., Inc. v. Baldrige, 844 F.2d 668, 674 (9th Cir. 1988) ("Under either test, however, the district court must consider the public interest as a factor in balancing the hardships when the public interest may be affected.").

III. IRREPARABLE HARM

There are numerous issues raised by the parties related to the irreparable-harm element: (1) can an award of damages compensate Plaintiffs; (2) are injuries to third parties, such as patients relevant; (3) are the damages alleged too speculative; and (4) have Plaintiffs provided sufficient evidence to support their damage claims.

Plaintiffs allege that the demonstration project, as currently being implemented, will result in substantial economic harm. Sharp operates clinical laboratories for the benefit of hospital inpatients and outpatients, and for non-hospital patients and non-hospital ambulatory clinic patients. (Thompson Decl.[1],¶5.) The laboratories also provide phlebotomy, or blood drawing services, to non-hospital and hospital patients directly. (Id., ¶6.) In total, Sharp operates 13 laboratories that provide "outreach" services throughout San Diego,[2]and service thousands of patients and employ hundreds of people. (Id.) Sharp contends that a significant portion of the patients to whom its laboratories furnish services are Medicare beneficiaries (Id.), but it does not provide an

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[1]Donna Thompson has been the Vice President of Business Development for Sharp since 2003. (Thompson Decl., ¶1.) She is responsible for analyzing key operational and financial issues facing Sharp, and has been involved in major operational matters related to clinical laboratories owned and operated by Sharp. (Id., ¶2.) Before becoming a vice president, Thompson was the Service Line Direct for Laboratory, Emergency and Radiology services for Sharp. (Id., ¶3.) In that position, she had general oversight authority over Sharp's laboratory services. Among her responsibilities was quality initiatives and standardization of services. (Id.)

[2]According to Thompson, "outreach" services within the Sharp system describes "all laboratory testing performed by independent, non-hospital laboratories and hospital laboratories for non-hospital patients." (Thompson Decl., ¶5.)

estimate regarding that portion. If it does not win, Sharp alleges that it will "certainly close some drawing sites and, in fact, likely will shut down a significant segment of its outreach laboratory." (Id., ¶17.) Other significant operational changes will be required, including costly changes to Sharp's medical record-keeping system and shifting staff from revenue generating laboratory functions to non-revenue generating administrative functions. (Id., ¶18.) Sharp contends that the economic impact will be significant.

In addition to the direct economic injury, Sharp alleges that patient care will be adversely effected. Sharp's integrated patient care network would be disrupted, thereby delaying the receipt of laboratory test results (including for "stat" or emergency tests), compromising the consistency in laboratory testing that currently exists, and increasing the probability of medical errors and miscommunications. (Thompson Decl., ¶19.) And because the changes would effect Sharp's integrated network, the impact would not only be felt by Medicare beneficiaries, but would adversely effect the overall level of care within the Sharp system. (Id., ¶20.)

Scripps Clinic Medical Laboratories ("SCML") includes three testing laboratories and seven patient centers, located at or near different Scripps clinics throughout San Diego. (Wiesner Decl.,[3] ¶5.) The laboratories service thousands of clinic patients and employ hundreds of employees. (Id.) Similar to Sharp, Scripps is an integrated healthcare system. A significant portion of the patients that SCML services are Medicare beneficiaries. (Id., ¶7.) Scripps contends that its inability to continue to participate in the Medicare program will have wide-ranging, adverse consequences for the entire Scripps health system, and its patients. (Id., ¶11.) Scripps estimates that it will lose a minimum of $1.9 million in revenue, which would lead to a reduction in services and laying off numerous employees. (Id., ¶12.) Additionally, because Scripps would continue to treat Medicare patients, it would be required to set-up costly and

[3]Cindy Wiesner has been the Administrative Director of Scripps Clinic Medical Laboratories for the past 22 years. (Wiesner Decl., ¶1.) She has complete responsibility for the Scripps Clinic clinical laboratory system, including issues related to quality, payment and administration. (Id., ¶2.)

time-consuming procedures to determine which patients' laboratory tests must be conducted by a different (winning) laboratory, and to deal with those tests . (Id., ¶¶16, 17.)

Scripps' patients would also be significantly impacted. Like Sharps, Scripps has an integrated medical network, which includes an integrated medical record system. The record system allows physicians a more complete, comprehensive view of a patient's condition. (Wiesner Decl., ¶15.) The system is particularly important in treating patients with certain diseases because the integrated network allows laboratory results to be consolidated with those of other disciplines, such as imaging and clinical studies. (Id.) Losing the ability to perform laboratory tests for Medicare patients would delay care and could lead to data input errors. (Id., ¶15.) Treatment for cancer patients who are Medicare Part B beneficiaries, particularly those undergoing chemotherapy where laboratory testing is essential to the treatment protocol, would also be adversely impacted. (Id., ¶18.) Additionally, Scripps asserts that disrupting its integrated medical network would mean a slower turn around for laboratory tests, including important blood tests for patients suspected of suffering from cardiac arrest, stroke, or gastro-intestinal bleeding who are being treated at urgent care clinics. (Id., ¶¶12, 13.)

Internist is an 18-year old community-based clinical laboratory with ten employees. (Stevens Decl., ¶¶1,2.) Internist draws blood for certain patients, and performs all necessary tests on site. (Id., ¶3.) It is the only independent laboratory that can perform blood draws and testing in the Oceanside, San Marcos, Vista, Carlsbad area, and is regularly referred special need patients whose medical or physical conditions make blood drawing difficult. (Id., ¶5.)

Approximately 65% of Internist's laboratory services are for Medicare program beneficiaries, and thus Internist depends on Medicare to remain in business. (Stevens Decl., ¶7.) Because all of the Medicare patients that Internist services reside in the demonstration project area, Internist contends that it will lose 65% of its business and be forced out of business if it does not prevail in the bidding process. (Id., ¶15.)

The Secretary argues that these factual allegations are insufficient to establish

irreparable injury for several reasons. The Secretary first argues that the alleged injury is too speculative because the possibility remains that Plaintiffs will win.

In Western State University v. American Bar Association, 301 F.Supp.2d 1129 (C.D. Cal. 2004), a law school sought a preliminary injunction to prevent the ABA from taking final steps to withdraw the school's accreditation. An ABA council had determined that the school's accreditation should be withdrawn, but the decision had to be approved by the ABA's House of Delegates. In opposing the preliminary injunction motion, the ABA argued that the law school's damage claims were too speculative because the "House may or may not vote to withdraw Western's accreditation. . . ." Id. at 1137. The court disagreed:

> The harm if the accreditation is withdrawn is real and substantial. Western need not wait for the axe to fall before seeking an injunction. The Court finds sufficient possibility of irreparable harm if the preliminary injunction is not granted.

Id. at 1138.

The Secretary attempts to distinguish Western State on the ground that when the injunction was granted, the initial decision to withdraw the school's accreditation had already been made. This distinction is unavailing.

In Western State, the House of Delegates vote was the critical event because it marked the point at which the school might potentially lose its accreditation and thus suffer irreparable harm. In this sense, the council's vote was largely irrelevant. Similarly, here, the critical event is April 11, 2008, when Plaintiffs will–if not selected as winners–lose their ability to provide laboratory services to Medicare Part B patients and thus suffer irreparable harm.

Moreover, Western State's statement that a plaintiff need not wait for the axe to fall before seeking an injunction is consistent with the preliminary injunction standard, which requires "the *possibility* of irreparable injury to plaintiff. . . ." Save Our Sonoran, 408 F.3d at 1120 (emphasis added); see also Ohio Forestry Assoc., Inc. v. Sierra Club, 523 U.S. 726, 734 (1998) (recognizing plaintiff's right to seek injunctive relief when

harm is "imminent"). For these reasons, the Court finds Plaintiffs' injuries are not too speculative.[4]

The Secretary next argues that Plaintiffs have, in essence, not established that their alleged injuries are irreparable. The Court disagrees.

Internist's contention that it will lose 65% of its business, which is supported by the declaration of Internist's owner and director, constitutes irreparable harm. See Poeng v. United States, 167 F.Supp.2d 1136, 1143 (S.D.Cal. 2001) (recognizing that the "majority of district courts addressing this issue have concluded that a loss of at least thirty percent of a plaintiff's business can constitute irreparable harm."). Additionally, the harm to Sharp's and Scripps' integrated medical networks, with the attendant adverse consequences to patients, also constitutes harm that cannot be adequately compensated by an award of monetary damages.

The Secretary urges, however, that the Court cannot consider the alleged harm to Plaintiffs' patients. This argument is unavailing for two reasons. Assuming the harm to patients is irrelevant, Internist's injury alone is sufficient for injunctive relief. Moreover, although harm to third parties is generally not relevant, in cases involving Medicare and similar health care programs, courts have routinely considered and granted injunctive relief based on the potential harm to patients. See Frontier Health, Inc. v. Shalala, 113 F.Supp.2d 1192, 1193 (E.D.Tenn. 2000) (finding that injunction appropriate based on potential harm to plaintiff hospital, as well as its employees and patients); Int'l Longer Term Care, Inc. v. Shalala, 947 F.Supp. 15, 19 (D.D.C. 1996) (finding that "irreparable harm likely to be suffered by the residents" of plaintiff nursing home operator was sufficient to grant preliminary injunction); Nat'l Ass'n of Psychiatric Treatment Ctrs. v. Weinberger, 661 F.Supp. 76, 81 (D.Colo. 1986) (finding interruption of CHAMPUS patient care favors granting of preliminary injunction).

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[4]In oral argument, counsel for the Secretary suggested that Western State was at odds with a Tenth Circuit case cited in the Secretary's brief. The Court has again reviewed the section concerning irreparable harm in the Secretary's opposition, and notes that there is no citation to a Tenth Circuit case. (See Def.'s Opp., pp.4–11.)

For all of these reasons, the Court finds Plaintiffs have established irreparable injury.

IV. BALANCE OF HARDSHIPS

Assuming that the Plaintiffs could not establish irreparable injury, injunctive relief would be appropriate if the balance of hardships tips sharply in Plaintiffs' favor and serious issues are raised. Save Our Sonoran, 408 F.3d at 1120; Immigrant Assistance Project, 306 F.3d at 873 ("Conversely, it has been held that a preliminary injunction may be granted even though the harm factor favors defendant if plaintiff demonstrates a substantial likelihood that he will ultimately prevail.").

Plaintiffs identify significant hardships that would flow from losing the bidding competition. Aside from the economic injuries, Sharp and Scripps have identified severe challenges to their integrated medical networks. Internists' employees will be required to find other employment, and its owners would lose their livelihood. And the quality of patient health care (for Medicare beneficiaries and others) will diminish.

The Secretary cannot identify hardships that even remotely rival those identified by Plaintiffs. At most, implementation of the demonstration project will be delayed for a period of months.[5] Given that roughly five years have passed since Congress authorized the project, it is doubtful that a short delay will have a significant impact in the ultimate long term goal of reducing Medicare costs.

For these reasons, the Court finds the hardship tips sharply in Plaintiffs' favor.

[5]In his opposition, the Secretary suggests that issuance of a preliminary injunction would result in an increase in the costs for implementing the demonstration project. (Def.'s Opp., p.12.) However, the Secretary has provided no evidence to support this claim.

V. LIKELIHOOD OF PREVAILING ON THE MERITS

A. The Secretary's rules are final.

The Secretary argues that the rules Plaintiffs challenge are not final and thus not subject to judicial review. The Court addressed this issue in the OSC Order. (See Doc. No. 23, pp.6–7.) For the reasons stated therein, the Court finds that the Secretary's rules are sufficiently final.

B. Plaintiffs are likely to succeed on Count I because the Secretary's failure to comply with the APA was not harmless.

In Count I of the Complaint, Plaintiffs allege that the Secretary violated section 553(b) of the APA. This section provides that "[g]eneral notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law." 5 U.S.C. § 553(b). Subsection (b) further identifies the contents of the notice required:

> (1) a statement of the time, place, and nature of the public rule making proceedings;
> (2) reference to the legal authority under which the rule is proposed; and
> (3) either the terms of substance of the proposed rule or a description of the subjects and issues involved.

Id.

The Secretary does not contend that the APA's notice and comment requirements do not apply to some or all of the rules that Plaintiffs challenge. Accordingly, the Secretary appears to concede that all of the challenged rules–to the extent the Court finds they are final–are subject to the APA. Nor does the Secretary allege that he complied with the APA's notice requirement. In fact, in opposing Plaintiffs' motion for a TRO, the Secretary conceded that "CMS did not publish a notice of rulemaking. . . ." (Def.'s Opp. to TRO, p.19.)

The Secretary contends, however, that Plaintiffs do not have a likelihood of prevailing on Count I because the "notice and comment activities in which CMS did

engage, during the three years when the project was being developed, were sufficient, and rendered any rulemaking violation harmless." (Def.'s Opp., p.15.) The Court is not persuaded.

One of the two cases the Secretary cites (without discussion) for support is Riverbend Farms, Inc. v. Madigan, 958 F.2d 1479, 1488 (9th Cir. 1992). In Riverbend, a group of domestic handlers of navel oranges challenged the Secretary of Agriculture's procedure to regulate the naval orange market. The court found that the Secretary violated the APA by not providing sufficient notice in the Federal Register of weekly Naval Orange Administrative Committee meetings, during which decisions were made concerning the recommendations to give to the Secretary for the following week's restriction on the volume of oranges. Additionally, there was no dispute that the Secretary violated the APA by failing to allow public comment by means other than personal participation in the meetings.

Nevertheless, the Ninth Circuit found the Secretary's failure to follow the APA was harmless because the procedure had been in place for 35 years without challenge. Because plaintiffs clearly knew about the meeting, the court found that plaintiffs were not prejudiced by the Secretary's failure to follow the APA's notice requirements:

> While [plaintiffs] are right that the Secretary must comply with some of the APA's technical requirements, their belated challenge is evidence of the lack of prejudice resulting from the Secretary's failure to do so in the past thirty-five years.

Id. at 1488.

Unlike the situation in Riverbend, the Secretary does not contend that public meetings to discuss the demonstration project occurred an a fairly routines basis, such that Plaintiffs and other members of the public should have known about the meetings. Instead, the Secretary's argument relies on a number of random presentations at industry and professional meetings that occurred between the fall of 2004 and 2007. (Wynn Decl., ¶¶12–23.) The Secretary does not contend that notice of these meetings was published in the Federal Register. Nor is there any other evidence regarding who

received notice of the meetings, and certainly nothing that suggests Plaintiffs either knew or should have known about those presentations.

Moreover, in Riverbend, the Ninth Circuit cautioned courts in applying the harmless error rule:

> we must exercise great caution in applying the harmless error rule in the administrative context. The reason is apparent: Harmless error is more readily abused there than in the civil or criminal trial context. An agency is not required to adopt a rule that conforms in any way to the comments presented to it. So long as it explains its reasons, it may adopt a rule that all commentators think is stupid or unnecessary. Thus, if the harmless error rule were to look solely to result, an agency could always claim that it would have adopted the same rule even if it had complied with the APA procedures. To avoid gutting the APA's procedural requirements, harmless error analysis in administrative rulemaking must therefore focus on the process as well as the result. We have held that the failure to provide notice and comment is harmless only where the agency's mistake "clearly had no bearing on the procedure used or the substance of decision reached."

Riverbend, 958 F.2d at 1487 (citations omitted); see also Paulsen v. Daniels, 413 F.3d 999, 1006 (9th Cir. 2005) (finding harmless error not applicable under the facts of case).

Plaintiffs argue that here, the harmless error rule does not apply because the evidence demonstrates that the failure to provide notice has had a bearing on the substance of the Secretary's decisions. The Court agrees.

For example, as of the November 5, 2007 bidders conference, the Secretary's position was that non-winning laboratories, despite not being able to bill Medicare directly, could not "legally refuse to provide services to a beneficiary based on payment." (Compl., ¶29, Ex. D at p.3.) After this lawsuit was filed, the Secretary changed this rule so that non-winning laboratories do not have to provide services to the beneficiaries. (Def.'s Opp., p. 18.) Thus, the evidence suggests that the Secretary's failure to abide by the APA notice requirements was not harmless. For these reasons, the Court finds that Plaintiffs have established a likelihood of success on Count I.

C. Plaintiffs are likely to succeed on certain aspects of Count II.

Count II to the Complaint charges the Secretary with violating sections 701–706 of the APA. Section 706(2)(A) allows a court to set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

The Secretary argues that Plaintiffs do not have a likelihood of succeeding on this count because: (1) 42 U.S.C. § 1395w-3(b)(10) precludes judicial review of his decisions relating to the critical aspects of the demonstration project; (2) the Secretary's action or rules are not final; and (3) the Secretary's rules do not violate section 706(2)(A). (Def.'s Opp., pp. 16–17, also referring Court to Def.'s Opp. to TRO, pp. 21–23.) Although the Court agrees with the Secretary's argument with respect to certain claims, Plaintiffs have a likelihood of success on others.

1. The face-to-face exception.

The Court has already concluded in the OSC Order that 42 U.S.C. § 1365w-3(b)(10)'s bar on judicial review does not apply to the Secretary's rule regarding the face-to-face exception, and that the rule is final for purposes of this case. (See Doc. No. 23, pp.4–7.) For the reasons expressed in that order, the Court rejects the Secretary's first two arguments.

The third and final issue is whether the Secretary's interpretation of the face-to-face exception is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

"When a court reviews an agency's construction of a statute which it administers, it is confronted with two questions." Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842 (1984). The first is whether Congress has "directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. at 842–843. If not clear, however, and "the agency's statutory interpretation fills a gap or defines a term in a way that is reasonable in light

of the legislature's revealed design, we give that judgment controlling weight." Ariz. Health Care Cost Containment Sys. v. McClellan, 508 F.3d 1243, 1249 (9th Cir. 2007) (citing United States v. Haggar Apparel Co., 526 U.S. 380, 392 (1999).

In evaluating these issues, the Court begins with the plain language of the statute. Ariz. Health, 508 F.3d at 1249 (citing Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc., 484 U.S. 49, 56 (1987). The relevant portion of the statute at issue here provides:

> The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests–
>
> > (A) for which payment would otherwise be made under section 1395l(h) of this title (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1395m(d)(1) of this title (relating to colorectal cancer screening tests); and
> >
> > (B) which are furnished by entities that *did not have a face-to-face encounter with the individual.*

42 U.S.C. § 1395w-3(e)(1) (emphasis added).

The Secretary has interpreted (and limited) the "face-to-face" exception as applying only to laboratories located in a physician's office or hospital laboratories for their own patients. Thus, for example, although Internist allegedly has face-to-face encounters with patients, under the Secretary's interpretation, Internist was required to submit a bid.

Before the Court reaches the question of whether the Secretary's interpretation is reasonable, under Chevron, the Court must first determine whether the face-to-face exception is ambiguous, thereby warranting the Secretary's interpretation. Based on the plain language of the statute, the Court finds that the term is not ambiguous.

The statute is clear and unambiguous that the demonstration project applies to "entities that did not have a face-to-face encounter with the individual." 42 U.S.C. § 1395w-3(e)(1)(B). Indeed, in his opposition to the TRO and the preliminary injunction, the Secretary never once asserts that the statute, or more precisely the term

"face-to-face encounter," is in any way ambiguous; nor does the Secretary point to any legislative history suggesting that Congress did not mean what it said with regard to the face-to-face exception.

Nevertheless, the Secretary seeks to justify his interpretation on the grounds that he has been accorded "considerable discretion" in developing the demonstration project, and his interpretation is reasonable. But neither of these considerations is relevant if Congress's intent is clear. Based on the current record, the Court finds that it is. Accordingly, the Secretary's decision to alter the unambiguous language of the statute violates the APA. For these reasons, the Court finds that Plaintiffs have established a likelihood of success on the merits of this claim.[6]

2. The Secretary's determination of reimbursement amounts for laboratories focusing on SNF and ESRD, and his use of claims paid data.

Plaintiffs challenge the Secretary's decision to require laboratories that service exclusively nursing facility patients and ESRD beneficiaries to accept prices set by the demonstration project. Additionally, Plaintiffs contend that the Secretary's use of Medicare claims paid data to determine and project test volume demand in the demonstration project violates the APA.

Based on the present record, both claims appears to involve the Secretary's discretion in establishing payment amounts and the bidding structure for the demonstration project. These two areas are not subject to judicial review. See 42 U.S.C. § 1395w-3(b)(1)(A), (F). Accordingly, with respect to these claims, Plaintiffs have not established a likelihood of success.

[6]In reaching this conclusion, the Court is in no way deciding whether Plaintiffs laboratories are covered by the face-to-face exception.

D. Plaintiffs have not established a likelihood of success on Count III.

In Count III, Plaintiffs allege that certain rules announced by the Secretary will cause a taking in violation of the Fifth Amendment to the United States Constitution. Specifically, Plaintiffs contend that "one of the Secretary's Demonstration Act policies requires losing bidders to provide laboratory services to Medicare beneficiaries even though they will not be paid for such services." (Pls.' P & A, p.16.)

After this lawsuit was filed, the Secretary issued a statement clarifying that non-winning laboratories do not have to provide services to the beneficiaries. (Def.'s Opp., p. 18.) Based on this statement, the factual premise underlying Plaintiffs' takings claim no longer exists. For this reason, Plaintiffs have not established a likelihood of success on Count III.

E. Plaintiffs have established a likelihood of success on Count IV.

Count IV alleges that the Secretary has violated the controlling statute by expanding the scope of the demonstration project. According to Plaintiffs, the statute authorizes the Secretary to conduct a demonstration project only with respect to clinical diagnostic laboratory *tests*. The Secretary, however, is also requiring laboratories to bid on the price charged for collecting and handling laboratory specimens.

The relevant section of the statute provides,

> The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests–
>
> > (A) for which payment would otherwise be made under section 1395l(h) of this title (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1395m(d)(1) of this title (relating to colorectal cancer screening tests); and

42 U.S.C. § 1395w-3(e)(1).

The Secretary argues that under statute, he has broad authority to conduct the demonstration project, and that the "statute does not set forth a defined list of laboratory tests that would otherwise be paid under the Medicare fee schedule. . . ."

(Def.'s Opp., p.19.) Based on these undisputed facts, the Secretary asserts that he is well within his authority to find that "specimen collection is part and parcel of laboratory testing." (Id., p.20.)

Under Chevron, the threshold issue is whether the statutory language is vague so that the Secretary's interpretation fills a gap or resolves an issue left open by Congress. Chevron, 467 U.S. at 842; Arizona Health, 508 F.3d at 1249. Thus, the first question is whether there is any ambiguity regarding the types of services covered by the demonstration project.

Once again, the analysis begins with the plain language of the statute, which authorizes "a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory *tests*–(A) for which payment would otherwise be made under section 1395l(h) of this title. . . ." 42 U.S.C. § 1395w-3(e)(1) (emphasis added). There does not appear to be any ambiguity in this provision. The project covers *tests*. Specimen collection does not appear to be a test, but is instead the act of collecting the patient's specimen in order to then run the test.

This conclusion is further bolstered by section 1395l(h), which distinguishes between laboratory tests and specimen collection. Under subsection (h)(1)(A), "the Secretary shall establish fee schedules for clinical laboratory tests. . . ." Subsection (h)(3) then mandates the Secretary to "provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory tests was performed. . . ." The fact that the two services are addressed separately, demonstrates that Congress did not intend the term "laboratory test" to include specimen collection.

Because the statute appears to authorize the Secretary to conduct a demonstration project on laboratory *tests*, not specimen collection, the Court finds that Plaintiffs have established a likelihood of success on this claim.

VI. CONCLUSION & ORDER

For the foregoing reasons, the Court **GRANTS** Plaintiffs' motion for a preliminary injunction (Doc. No. 15) and **ORDERS** that Defendant Michael Leavitt, Secretary of the United States Department of Health and Human Services, his employees, his agents and other acting in concert with them, are enjoined from:

1. Announcing winners in the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project for the San Diego-Carlsbad-San Marcos Metropolitan Area;
2. Otherwise implementing and carrying out the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project for the San Diego-Carlsbad-San Marcos Metropolitan Area; and
3. Further disclosing any information included in the bid applications submitted in connection with the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project for the San Diego-Carlsbad-San Marcos Metropolitan Area.

The injunction shall remain in place until further order of the Court.

IT IS SO ORDERED.

DATED: April 8, 2008

Hon. Thomas J. Whelan
United States District Judge