UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DAVID L. SMALLEY, Ph.D.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 4:22CV399 HEA**
	)	
XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
	)	
	)	
Defendant.	)	

OPINION, MEMORANDUM AND ORDER

This matter is before the Court on Defendant's Motion to Dismiss for Lack of Jurisdiction Pursuant to Fed.R.Civ. P. 12(b)(1), [Doc. No. 13], and Plaintiff's Motion for Preliminary Injunction, [Doc. No. 4]. The parties oppose the respective Motions. For the reasons set forth below, Defendant's Motion will be granted.

Facts and Background

Plaintiff's First Amended Complaint alleges the following:

Plaintiff challenges the imposition of a minimum two-year disqualification by the Centers for Medicare & Medicaid Services ("CMS") from acting as the laboratory director of any clinical laboratory in the United States, pursuant to 42 U.S.C. § 263a(k). The disqualification is a result of sanctions imposed by CMS against Gamma Healthcare, LLC ("Gamma"), a former clinical laboratory located

in Poplar Bluff, Missouri, where Plaintiff served as the laboratory director, and the revocation of Gamma's certificate to operate the laboratory pursuant to a settlement agreement between CMS and Gamma. Plaintiff seeks (i) a declaration that the imposition of the sanction without an individual right to appeal is a deprivation of substantive and procedural due process in violation of the Fifth Amendment to the U.S. Constitution; (ii) a declaration that the imposition of the sanction without an individual right to appeal is an unlawful and invalid deprivation of procedural due process under the Administrative Procedure Act ("APA"); (iii) an order vacating the sanction imposed against Plaintiff or, if necessary, an order enjoining the sanction imposed against him and the opportunity to appeal; and (iv) an award of reasonable attorneys' fees and costs.

Plaintiff is a licensed laboratory director residing in the State of Tennessee. Defendant is the Secretary of the United States Department of Health and Human Services ("HHS"). Plaintiff is suing the Secretary in his official capacity only. CMS is a federal agency within HHS, which is responsible for licensing clinical laboratories and enforcing the federal standards for operating clinical laboratories as promulgated under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §§ 263a–263a-7 (1988) ("CLIA").

Plaintiff alleges that his education and experience qualify him to serve as the laboratory director of a high-complexity laboratory in accordance with CLIA and its implementing regulations. See 42 C.F.R. § 493.1443. He has been approved by CMS to serve as the laboratory director of numerous high-complexity laboratories over the years and held licensure as a laboratory director in the States of Tennessee and New York. Plaintiff holds a bachelor's degree in Medical Laboratory Sciences, a master's degree in Biology (Microbiology), a Ph.D. in Biology (emphasizing in Microbiology/Immunology), a master's degree in Strategic Studies, and a master's degree in Healthcare Administration. He completed an internship in Medical Laboratory Sciences with St. Bernards Medical Center, Jonesboro, Arkansas, and through the military is a graduate of the Command and General Staff College and the Army War College. He is board-certified by the American Society for Clinical Pathology as a Medical Technologist and Hematologist and listed on the American Society of Microbiology's National Registry of Certified Microbiologists. He has received CLIA-approved, Director-level certification from the American Board of Bioanalysis ("AAB"), as both a Bioanalyst Clinical Laboratory Director and Public Health Laboratory Director.

Over the past thirty years, Plaintiff has acted as the laboratory director for ten different laboratories in three U.S. States; he was appointed as the Director of Laboratory Services for the Tennessee Department of Health; and he was the

Assistant Surgeon General for the U.S. Army Reserves. In 2005, the U.S. Centers for Disease Control and Prevention ("CDC") appointed Plaintiff to its Clinical Laboratory Improvement Advisory Committee ("CLIAC"), which is responsible for advising CMS on how to improve standards for clinical laboratories across the country. See 42 C.F.R. § 493.2001. While serving on CLIAC, Plaintiff served on its Personnel Committee and was asked to assess and make recommendations on improving CLIA regulations governing laboratory director and personnel standards for clinical laboratories. Plaintiff's service in the laboratory industry has been recognized by the AAB, which in 2010 awarded him the Lucien Dean Hertert Award, the association's highest award for lifetime achievement in the field of Clinical Laboratory Sciences.

During the current COVID-19 public health emergency, Plaintiff was nominated by the AAB, and invited by the CDC, to participate in CLIAC's CLIA Regulations Assessment Workgroup because of his "expertise and experience" in laboratory testing.

In October 2012, Plaintiff was hired as the President and Chief Executive Officer of American Esoteric Laboratories ("AEL"), also known as the "MidSouth Division" of Sonic Healthcare USA, where he had previously served as medical director. In 2016, AEL contracted with Gamma, a clinical laboratory company with testing locations across the southeastern United States servicing over 2,500

skilled nursing homes in eleven States, to provide consultative services to Gamma. As part of the services arrangement between AEL and Gamma, AEL subcontracted the professional services of Plaintiff to serve as a laboratory director for two of Gamma's locations, one in Poplar Bluff, Missouri, and the other in Tyler, Texas.

On June 23, 2020, representatives from the Missouri Department of Health and Senior Services ("MDHSS") arrived at Gamma's Poplar Bluff location to conduct a complaint survey ("June Survey"). On June 25, 2020, Gamma received a Notice and Statement of Deficiencies ("First Notice") from MDHSS, dated the day prior, stating that the MDHSS surveyors had identified "deficiencies in Conditions of Participation that are preventing your laboratory from being in compliance with" CLIA standards. The First Notice identified one condition level deficiency and other standard deficiencies. However, before the ten-day period to submit a response and corrective actions elapsed, MDHSS conducted another on-site survey at the Poplar Bluff location, on July 1, 2020 ("July Survey").

On July 6, 2020, with the assistance and approval of Plaintiff, Gamma submitted to MDHSS a Plan of Correction, along with documentation supporting how certain actions had corrected, or would correct, the alleged deficiencies in the First Notice.

On July 7, 2020, Gamma received another Notice and Statement of Deficiencies ("Second Notice") from MDHSS related to the July Survey,

identifying the exact same condition level deficiency identified in the First Notice. This time MDHSS alleged that the same condition level deficiency posed an "immediate jeopardy" to the community.

On July 17, 2020, with Plaintiff's assistance and approval, Gamma submitted to MDHSS a Plan of Correction, along with documentation supporting how certain actions had corrected, or would correct, the alleged deficiencies in the Second Notice, as well as revisions to the First POC. The Second POC contested the existence of an immediate jeopardy to the community and certain alleged deficiencies.

On or around September 1, 2020, MDHSS notified Gamma that the corrective actions submitted by Gamma were not acceptable and proposed principal sanctions against the laboratory. On or around September 25, 2020, CMS sent Gamma a notice of final sanctions against Gamma, which included immediate suspension and revocation of the laboratory's CLIA certificate. The Notice stated that the suspension would go into effect on October 6, 2020, and that the laboratory had sixty (60) days to appeal the sanctions at a hearing before an ALJ. Gamma's owners, without Plaintiff's knowledge, retained Polsinelli LLP, to represent Gamma and the owner's interests to seek resolution with CMS concerning the sanctions imposed against the laboratory and, subsequently, to file a complaint in federal court and request an ALJ hearing to appeal the sanctions.

Defendant's counsel began communicating exclusively with Gamma's attorneys. Plaintiff was not involved in, or made aware of, any of the discussions with Defendant's counsel or the legal actions taken by Gamma and its owners.

On or around October 23, 2020, Gamma filed its request for an ALJ hearing to challenge the imposition of sanctions. Plaintiff was not made aware of this filing, nor did Gamma or CMS contact him at that time.

On June 11, 2021, Gamma's attorneys informed Plaintiff via email that Gamma had agreed to a settlement with CMS concerning the sanctions against the laboratory, which included revocation of its CLIA certificate, effective May 25, 2021, and waiver of any appeal rights. CMS never contacted Plaintiff and, instead, requested that Gamma's attorney obtain his signature on an attestation acknowledging the settlement terms, which, due to the revocation of the laboratory's CLIA certificate, included a two-year disqualification from him serving as a laboratory director in for any CLIA-certified laboratory in the United States. Plaintiff refused to sign the attestation.

Laboratory Standards under CLIA and its implementing regulations establish the standards and requirements that govern all non-research clinical laboratories located in the United States that perform testing on human specimens. See 42 C.F.R. § 493.1 et seq. (implementing Public Law 100-578, Oct. 31, 1988). A clinical laboratory must obtain and maintain a CLIA certificate to operate

anywhere in the United States (except in CLIA-exempt States). A threshold requirement for any clinical laboratory to operate is the engagement of a laboratory director who meets the qualification requirements set forth in CLIA regulations. See 42 C.F.R. § 493.1405-06, 1443. The laboratory director is responsible for the overall management and direction of the entire laboratory and personnel. See 42 C.F.R. § 493.1403, 1441. The name of the laboratory director is listed on the CLIA-certification and any change to the laboratory director requires notification to CMS. See 42 C.F.R. § 493.51, 63.

CMS is tasked with regulating clinical laboratories through its survey and certification process. More specifically, the Division of Laboratory Services, within the CMS Survey and Certification Group, under the Center for Clinical Standards and Quality, is responsible for implementing the CLIA program. CMS uses state agencies to assist with certifying and monitoring compliance with applicable standards and to report back to CMS when violations are identified. See 42 C.F.R. § 488.1. The State of Missouri, where the Gamma facility at issue was located, has adopted CLIA's standards.

CLIA establishes procedures for laboratories that fail to comply with applicable certification standards, including investigatory, notification, and response requirements. Specifically, the State Operations Manual (the "SOM") is a procedural framework created by CMS to ensure that state agencies are

consistently implementing and enforcing federal standards. Appendix C to the SOM, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services ("Appendix C"), contains instructions to state agencies on how to implement and enforce the CLIA regulations (42 C.F.R. § 493.1 et seq.). The highest-level violations are known as "condition level" deficiencies that pose "immediate jeopardy," meaning the state agency has concluded the noncompliance requires immediate corrective actions because it has caused, is causing, or is likely to cause serious injury or harm, or death, to individuals the laboratory serves or to the general public. See 42 C.F.R. §§ 493.2, 493.1812.

When condition level deficiencies that pose immediate jeopardy are identified during an on-site survey, CMS may impose "principal sanctions" (i.e., suspension, limitation, or revocation of a laboratory's CLIA certificate) prior to the laboratory and its owners and operators having a chance to respond to or correct the deficiencies. See 42 U.S.C. § 263a(i)(2), 42 C.F.R. §§ 493.2 & 493.1812(a).

16. The CLIA statute and regulations permit the laboratory to appeal the imposition of any principal or alternative sanction by requesting a hearing before an Administrative Law Judge ("ALJ"). See 42 U.S.C. § 263a(k); 42 C.F.R. § 493.1844.

Individuals who own or operate a laboratory that has had its CLIA certificate revoked are prohibited from owning or operating any other CLIA-certified (or -

waived) laboratory in the United States for two (2) years (or for as long as the laboratory's certificate remains revoked), whichever is longer. See 42 U.S.C. § 263a(i)(3). The regulations include the laboratory director in the definition of an "operator" of the laboratory if specified criteria are met. 42 C.F.R. § 493.2.

Even after the revocation period lapses, CMS must specifically approve the individual's prospective ownership or operation of any laboratory, which it will only grant after obtaining reasonable assurance from the individual and making a subjective determination that the practices that led to the revocation of the laboratory's CLIA certificate (or waiver) will not recur at the same or new laboratory the individual seeks to own or operate. See 42 C.F.R. § 1001.3001(a). Prior to revocation, however, the owner or operator of a laboratory must be given a reasonable notice and opportunity for hearing. "Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory" has committed certain enumerated actions or had failed to comply with certain requirements. 42 U.S.C.A. § 263a(1)(i).

Defendant moves to dismiss this action for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

Discussion

Under Federal Rule of Civil Procedure 12(b)(1), a party may move to dismiss an action based on lack of subject matter jurisdiction. The Eighth Circuit has held that "[i]n deciding a motion under Rule 12(b)(1), the district court must distinguish between a facial attack—where it looks only to the face of the pleadings—and a factual attack—where it may consider matters outside the pleadings." *Croyle v. United States*, 908 F.3d 377, 380 (8th Cir. 2018). Under a facial challenge, the reviewing court examines the complaint to determine if the plaintiff has satisfactorily alleged grounds for subject matter jurisdiction. The nonmoving party is afforded the same protections he would receive were he defending against a Rule 12(b)(6) motion. A factual challenge, on the other hand, tests the factual basis the nonmoving party has asserted for subject matter jurisdiction. Matters outside of the pleadings may be considered by the reviewing court and the nonmoving party is afforded no Rule 12(b)(6)-type protections.

To survive a motion to dismiss for lack of subject matter jurisdiction, the party asserting jurisdiction has the burden of establishing that subject matter jurisdiction exists. *V S Ltd. P'ship v. Dep't of Hous. & Urban Dev.*, 235 F.3d 1109, 1112 (8th Cir. 2000).

The presence of subject matter jurisdiction is a threshold requirement that must be assured in every federal case. *Kronholm v. Fed. Deposit Ins. Corp.*, 915 F.2d 1171, 1174 (8th Cir. 1990). *See also Sanders v. Clemco Indus.*, 823 F.2d 214,

216 (8th Cir. 1987) ("The threshold requirement in every federal case is jurisdiction and we have admonished the district court to be attentive to a satisfaction of jurisdictional requirements in all cases"). To that end, the issue of subject matter jurisdiction may be raised at any time, by any party or the court. *Gray v. City of Valley Park, Mo.*, 567 F.3d 976, 982 (8th Cir. 2009). If at any time the Court determines that it lacks subject matter jurisdiction, the action must be dismissed. *See* Fed. R. Civ. P. 12(h)(3); *Williams v. United States Postal Serv.*, No. 4:22-CV-00214-JAR, 2022 WL 2315491, at *2 (E.D. Mo. June 28, 2022).

Generally, "sovereign immunity prevents the United States from being sued without its consent." *Iverson v. United States*, 973 F.3d 843, 846 (8th Cir. 2020). *See also Hinsley v. Standing Rock Child Protective Services*, 516 F.3d 668, 671 (8th Cir. 2008) (stating that "[i]t is well settled that the United States may not be sued without its consent"). "Sovereign immunity is jurisdictional in nature." *F.D.I.C. v. Meyer*, 510 U.S. 471, 475 (1994). That is, "[i]t is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction." *United States v. Mitchell*, 463 U.S. 206, 212 (1983). Thus, in order to sue the United States, a plaintiff must show a waiver of sovereign immunity. *See V S Ltd. Partnership v. Dep't of Housing and Urban Development*, 235 F.3d 1109, 1112 (8th Cir. 2000); *Williams* at *2.

Sovereign immunity bars claims against the United States and federal officials in their official capacities unless Congress unequivocally expresses a waiver of sovereign immunity. *Coleman v. Espy*, 986 F.2d 1184, 1189 (8th Cir. 1993); *Kaminski v. United States*, No. 21-MC-0043 (WMW/TNL), 2022 WL 1050051, at *2 (D. Minn. Apr. 7, 2022).

Plaintiff argues that he was denied his constitutional right to due process because he was not given the opportunity to participate in the appeal of CMS's decision to sanction the lab and himself. The record before the Court, however, belies Plaintiff's position.

Plaintiff acknowledges that he was the director of the laboratory. Under the applicable law and regulations, "operator" includes a director. 42 C.F.R. § 439.2. *In the Case of: Sentinel Med. Lab. Inc. v. Health Care Financing Administration*, 2001 WL 227924, at *8 n. 6 ("CLIA requires that [CMS], prior to taking action to revoke a laboratory's CLIA certificate, must offer the opportunity for a hearing to the laboratory's owner or operator, which includes the laboratory director. 42 U.S.C. § 263a(i)(1); 42 C.F.R. § 493.2.")

ALJs interpret the regulations' term "laboratory" "to include any individual who CMS is treating as an owner or operator." *Roy Hollins/Western Reference Lab.*, 2003 WL 21801705, at *3 n. 6. Plaintiff was such a director.

Indeed, Plaintiff's responses to the notices received establish his position as an operator/director. Upon receiving the notices, Plaintiff responded on behalf of the laboratory in an effort to resolve the issues presented after the inspections. On September 25, 2020, CMS faxed its proposed sanctions to Plaintiff and Gamma. On October 2, 2020, Plaintiff acknowledged receipt of the September 25, 2020, letter. On October 15, 2020, CMS served its second proposed sanctions. On October 20, 2020, Plaintiff responded by asking CMS to abate or remove the "immediate jeopardy" finding. On October 21, 2020, CMS notified Plaintiff that revoking Gamma's CLIA certificate would result in his two-year suspension. Plaintiff specifically responded to the October 21, 2020, letter on October 22, 2020, and referenced the fact that CMS proposed to suspend Gamma's CLIA certificate on October 26, 2020. Plaintiff's timely responses to CMS's proposed and actual sanction notices demonstrate that he received CMS's notices and reveal his efforts to cure the defects CMS found.

CMS's September 25, 2020, letter notified Plaintiff of "the laboratory's appeal rights," CMS's October 21, 2020 Notice referred Plaintiff to CMS's "October 15, 2020 letter for the laboratory's appeal rights and instructions on how to file an appeal." The October 15, 2020, letter provides that "[t]he laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R.

§ 498.40 through 498.78." Exhibit 6 at p. 4.4 "[T]he term 'laboratory' in the regulation should be construed to include an individual who CMS is treating as an owner or operator." *Roy Hollins/Western Reference Lab.*, 2003 WL 21801705, at *3 n. 6 (emphasis added). The regulation defines "operator" to include a director. 42 C.F.R. § 493.2. CMS's multiple Notices advised him of his individual right to appeal. *Sentinel Med. Lab. Inc*., 2001 WL 227924, at *8 n. 6 ("CLIA requires that [CMS], prior to taking action to revoke a laboratory's CLIA certificate, must offer the opportunity for a hearing to the laboratory's owner or operator, which includes the laboratory director. 42 U.S.C. § 263a(i)(1); 42 C.F.R. § 493.2.").

Indeed, Plaintiff's extensive history of operating laboratories gives rise to the inference that Plaintiff is familiar with the procedures through which an operator would challenge the two-year suspension. The notices informing Plaintiff of the potential suspension is clearly indicative of the need to pursue the appeal remedies available to Plaintiff.

Curiously, Plaintiff fails to inform the Court of any interaction he had with the owner of the laboratory during the notification process. Plaintiff jumps from receiving the notices and demonstrating what steps he took to remedy the problems to claiming he was unaware of the actions Gamma took after the revocation of the certification, *i.e.*¸ Gamma's request for appeal.

The APA contains an explicit waiver of the government's sovereign immunity for declaratory judgment actions. *See Enyeart v. Minnesota*, 408 F. Supp. 2d 797, 805 (D. Minn. 2006), *aff'd*, 218 F. App'x 560 (8th Cir. 2007)("A well-established exception to the principle of sovereign immunity is that suits for injunctive or declaratory relief against the United States government or federal officers are permitted under the [APA]....

The APA is an express waiver of sovereign immunity in suits requesting non-monetary relief."); *Rothe Dev. Corp. v. United States Dep't of Defense,* 194 F.3d 622, 624 (5th Cir. 1999) (recognizing that the APA waives sovereign immunity from non-monetary claims against government agencies); *Gate Guard Servs. L.P. v. Solis*, No. CIV.A. V-10-91, 2011 WL 2784447, at *3 (S.D. Tex. July 12, 2011). Under the APA, an individual is entitled to judicial review of an agency decision if he "suffer[s] [a] legal wrong because of agency action, or [is] adversely affected or aggrieved by agency action within the meaning of a relevant statute...." 5 U.S.C. § 702. *Gate Guard*, 2011 WL 2784447, at *3. "When ... the relevant administrative agency statutory provisions do not directly provide for judicial review, the APA authorizes judicial review only of 'final agency action.' " *Am. Airlines, Inc. v. Herman,* 176 F.3d 283, 287 (5th Cir. 1999) (citing 5 U.S.C. § 704; *Lujan v. Nat'l Wildlife Federation,* 497 U.S. 871, 882 (1990)). "If there is no 'final agency action,' as required by the controlling statute, a court lacks subject matter

jurisdiction." *Id.* (citing *Veldhoen v. United States Coast Guard,* 35 F.3d 222, 225 (5th Cir.1994 agency action." *Gate Guard*, 2011 WL 2784447, at *3; *Walsh v. Massonti Homecare LLC*, No. 4:20-CV-988 RLW, 2021 WL 4459735, at *2 (E.D. Mo. Sept. 29, 2021). With respect to Constitution-based claims for damages, suits brought against federal public officials in their official capacity are treated as suits against the United States. *See Buford v. Runyon*, 160 F.3d 1199, 1203 (8th Cir. 1998).

"Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit." *F.D.I.C. v. Meyer*, 510 U.S. 471, 475 (1994). "Sovereign immunity is jurisdictional in nature." *Id.* "A waiver of the Federal Government's sovereign immunity must be unequivocally expressed in statutory text ... and will not be implied." *Lane v. Pena*, 518 U.S. 187, 192 (1996). Congress has not waived sovereign immunity for constitutional claims against the United States. *See Laswell v. Brown*, 683 F.2d 261, 268 (8th Cir. 1982); *Camacho-Corona v. Douglas Cty. Dep't of Corr.*, No. 8:12-cv-132, 2012 WL 3112020, at *2 (D. Neb. July 31, 2012) ("It is well settled that the United States has not waived its sovereign immunity for suits seeking damages based on alleged constitutional violations."). *Manos v. Fed. Bureau of Prisons*, No. 18-CV-0427 (PJS/HB), 2020 WL 589441, at *3 (D. Minn. Jan. 14, 2020), report and recommendation adopted, No. 18-CV-0427 (PJS/HB), 2020 WL 586769 (D. Minn. Feb. 6, 2020).

Plaintiff cannot establish a waiver of sovereign immunity because there has been no final agency action *vis a vis* Plaintiff. Despite Plaintiff's participation in the process preceding the appeal, Plaintiff did nothing to protect his interest at the appeal level, even though he was continuously notified of the revocation of the CLIA certification and two-year suspension of him acting as a director of any CLIA laboratories. Accordingly, there has been no final agency action from which Plaintiff can claim a waiver of sovereign immunity.

Conclusion

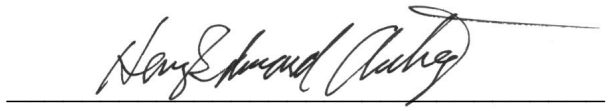
Based upon the foregoing analysis, Defendant's Motion to Dismiss for Lack of Subject Matter Jurisdiction is well taken. Plaintiff has failed to establish a waiver of sovereign immunity which would entitle him to pursue this action against Defendant Secretary in his official capacity. Since the Court lacks subject matter jurisdiction over this action, the Court cannot consider Plaintiff's Motion for Preliminary Injunction/

Accordingly,

IT IS HEREBY ORDERED that Defendant's Motion to Dismiss for Lack of Jurisdiction Pursuant to Fed.R.Civ. P. 12(b)(1), [Doc. No. 13, is **granted**.

An appropriate Order of Dismissal is entered this same date.

Dated this 6th day of July 2022.



HENRY EDWARD AUTREY
UNITED STATES DISTRICT JUDGE