IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

GAMMA HEALTHCARE, INC., Plaintiff, v. ALEX AZAR, in his official capacity as Secretary, United States Department of Health and Human Services, SEEMA VERMA, in her official capacity as Acting Administrator for the Center of Medicare and Medicaid Services, AND JEFF KAHRS, Deputy Regional Administrator for (Region 7) the Center for Medicare and Medicaid Services. Defendants.	)	Case No. 6:20-CV-033337-MDH

ORDER ON EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

Before the Court is Plaintiff Gamma Healthcare, Inc.'s Emergency Motion for Temporary Restraining Order. (Doc. 3). Plaintiff requests the Court issue a TRO pursuant to Rule 65(c) prohibiting Defendants from suspending and revoking GHC's CLIA Certificate until such time as the Court is able to determine whether the preliminary injunction should remain in effect as a permanent injunction pending Plaintiff's opportunity to exhaust its administrative appeal remedies. On October 26, 2020, the Court held a hearing regarding the pending motions. The Court then granted the parties additional time to submit supplemental briefing on the issues presented at the hearing. The parties have now fully briefed the issues and the matter is ripe for review. For the reasons set forth herein, Plaintiff's Motion is **DENIED**.

BACKGROUND

Plaintiff operates clinical laboratories located in Springfield, Missouri and Poplar Bluff, Missouri, which provide a variety of medical testing services. (Doc. 1). Until the events giving rise to this lawsuit, both labs operated under Clinical Laboratory Improvement Amendments ("CLIA") certificates. (Doc. 12, 5). Defendants suspended Plaintiff's federal authority to operate as clinical labs, effective October 26, 2020, pursuant to the Defendants' authority to suspend Plaintiff's lab certificates in advance of an administrative hearing. 42 U.S.C. § 263a(i) (Doc. 12, 1). Plaintiff's Complaint raises the following claims: Injunctive Relief based on allegations of due process violations; Violation of Equal Protection Guarantees of the Fourteenth Amendment; and Violation of Due Process Guarantees of the Fourteenth Amendment.

"Labs like [Plaintiff] must meet certain federal standards in order to be certified to conduct diagnostic tests on human specimens (blood, tissue, and the like), and to receive Medicare or Medicaid reimbursement for their services. These standards are embodied in the Clinical Laboratory Improvement Amendments of 1988 ('CLIA' or 'the Act') and its implementing regulations. *See* 42 U.S.C. § [263a]; 42 C.F.R. Part 493." *Wade Pediatrics v. Dep't of Health & Human Servs.*, 567 F.3d 1202, 1203 (10th Cir. 2009). A lab's compliance with these standards is memorialized in a "CLIA certificate," which is subject to periodic reconsideration. Additionally, the Secretary of Health and Human Services' designee may, on an announced or unannounced basis, enter and inspect any certified lab to determine whether the lab is, in fact, compliance with federal standards. 42 U.S.C. § 263a(g). If the Secretary determines the lab is out of compliance, the Secretary may impose sanctions. 42 U.S.C. §§ 263a(h)–(i). Sanctions may be mild or severe, including suspension or revocation of a lab's federal certification. *Id.* Generally, the Secretary cannot suspend a lab's federal certification before an administrative hearing, assuming the lab

wishes to contest the suspension. 42 U.S.C. § 263a(i). However, if the Secretary determines that a lab's failure to comply with federal standards presents an imminent and serious risk to human health, the Secretary may suspend the lab's certification prior to a hearing. 42 U.S.C. § 263a(i)(2).

Federal regulations govern how the Secretary's designees go about the important work of assessing which labs meet federal standards and which labs need to be pulled into compliance. 42 C.F.R. Part 493. Inevitably, most labs will fail to comply in some material way, but not all failures merit the same response. Federal regulations generally permit two categories of civil sanctions: (1) "principal sanctions," which are suspension, limitation, or revocation of the lab's certification; or (2) "alternative sanctions," which are government-directed plans of correction, state onsite monitoring, or civil money penalties. 42 C.F.R. § 493.1806. The two categories of sanctions get meted out against varying levels and patterns of noncompliance, and federal regulations generally guide the considerations in determining appropriate sanctions. 42 C.F.R. § 493.1804.

In cases of extreme and repetitive noncompliance, the regulations permit the Secretary to suspend a lab's certification prior to a hearing, on a mere five days' notice. 42 C.F.R. §§ 493.1812(b); 493.1840(d)(2). *Cf.* 42 U.S.C. § 263a(i)(2). If a lab's deficiencies pose "immediate jeopardy"—imminent and serious risk to human health and significant hazard to the public health—the lab must take immediate action. 42 C.F.R. § 493.1812(a). If the findings of a revisit to the lab indicate that the lab has not eliminated the imminent and serious risk to human health, the Centers for Medicare & Medicaid Services (CMS) suspends or limits the lab's federal certification. 42 C.F.R. § 493.1812(b). CMS must provide at least five days' notice, but it need not suspend a lab's federal certification in advance of a hearing. 42 C.F.R. §§ 493.1812(b), 493.1840(d)(2).

STANDARD

Before the Court can analyze the issues raised in Plaintiff's Motion for a Preliminary Injunction, the Court must first analyze whether it has jurisdiction over the claims raised in the Complaint. "The burden of establishing that federal jurisdiction exists 'rests upon the party asserting jurisdiction.'" *Midland Psychiatric Assocs., Inc. v. United States,* 145 F.3d 1000, 1003 (8th Cir. 1998) (internal citations omitted). A court must dismiss an action over which it lacks subject-matter jurisdiction. *Degnan v. Sebelius*, 959 F. Supp. 2d 1190, 1192 - 93 (D. Minn. 2013), aff'd sub nom. *Degnan v. Burwell*, 765 F.3d 805 (8th Cir. 2014).

DISCUSSION

The Court generally does not have federal question jurisdiction over any claim for Medicare or Medicaid payment (or nonpayment). *Cf.* 42 U.S.C. §§ 405(h), 1395ii (making § 405(h) applicable). This preclusion also extends beyond Medicare Act. "[C]laims arising under other statutes may be barred by section 405(h) if they are 'inextricably intertwined' with benefit determinations under the Medicare Act." *Clarinda Home Health v. Shalala*, 100 F.3d 526, 529 (8th Cir. 1996) (quoting *Heckler v. Ringer*, 466 U.S. 602 (1984)).

Federal question jurisdiction is barred unless the refusal to exercise such jurisdiction "would mean no review at all." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 10–20 (2000) (explaining broad preclusion of federal jurisdiction over issues related to payments under the Medicare Act). In the Eighth Circuit, "[t]his exception applies where the litigant: (1) raises a colorable constitutional claim collateral to his substantive claim of entitlement; (2) shows that irreparable harm would result from exhaustion; and (3) shows that the purposes of exhaustion would not be served by requiring further administrative procedures." *Clarinda Home Health*, 100 F.3d at 530–31.

With respect to the second and third elements, Plaintiff argues that irreparable harm would result to it from the exhaustion of administrative remedies here, and the purposes of exhaustion would not be served here by requiring further administrative procedures. Specifically, the suspension would allegedly force Plaintiff's labs to close, as 65% of Plaintiff's revenue is dependent upon Medicare certification. (Doc. 17, 5). For their part, Defendants argue that the potential harm to Plaintiff is outweighed by public safety concerns. (Doc. 12, 32). Even if the Court assumes that irreparable harm and purposes of exhaustion elements are met in this case, the Court does not find that Plaintiff has raised a colorable constitutional claim collateral to its substantive claim of entitlement.

With respect to whether Plaintiff presents a colorable claim, Plaintiff suggests that its due process rights were violated due to the suspension. The key procedural due process question is the balance of Plaintiff's private interest, if any, against the process employed and the Government's interest. There is case law that suggests that procedural due process challenges to the pre-hearing suspension of CLIA certificates are not valid. *See*, *e.g.*, *Collum v. Arkansas Dep't of Health & Human Servs.*, No. 4:06CV01496-WRW, 2007 WL 1238726, at *3 (E.D. Ark. Apr. 27, 2007); *D & G Holdings, LLC v. Leavitt*, No. CIV.A. 08-0373, 2008 WL 782446, at *1 (W.D. La. Mar. 20, 2008). Both cases declined to enjoin federal defendants suspending CLIA certificates in advance of a formal, adversarial administrative hearing. Both cases suggested that CLIA certificate holders lack a constitutionally protected property interest in a CLIA certificate, and, in any event, a pre-suspension, adversarial administrative hearing was not required in light of the regulatory notice and "some kind of hearing" procedures provided—referred to in the Supreme Court's seminal *Loudermill* decision as merely "an opportunity to respond" prior to deprivation of a protected property interest. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985).

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