IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

BLUE VALLEY HOSPITAL, INC., **Plaintiff,** **v.** **ALEX M. AZAR II,** in his official capacity as Secretary, United States Department of Health and Human Services, **SEEMA VERMA,** Administrator for the Center of Medicare and Medicaid Services, and **JEFF HINSON**, Regional Administrator for (Region 7) the Center for Medicare and Medicaid Services, **Defendants.**	**Case No. 18-2176-JAR-GLR**

MEMORANDUM AND ORDER

Plaintiff Blue Valley Hospital, Inc. ("BVH") seeks injunctive relief to prevent Defendants, the Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS"), from terminating BVH's Medicare certification and provider contracts pending review by an administrative appeals board and any subsequent judicial review. BVH also seeks to enjoin Defendants from publishing, disseminating, or communicating to third parties or the public any notice or communication suggesting that BVH's Medicare participation rights have been or will be decertified or terminated. Before the Court is BVH's Motion for Preliminary Injunction, as supplemented (Docs. 3, 24) and Defendants' response seeking dismissal of the case under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, as supplemented (Docs. 8, 25). BVH has responded to the motion to dismiss (Docs. 15, 24) and the Court is now prepared to rule. As described more fully below, the Court dismisses the case for lack of jurisdiction.

I. Background

The following facts are alleged in the Amended Verified Complaint and/or presented in BVH's Motion for Emergency TRO and Preliminary Injunction and the parties' subsequent briefing.

BVH is an acute care hospital located in Overland Park, Kansas. It is a licensed facility and was recently accredited by the Healthcare Facilities Accreditation Program ("HFAP"). BVH offers a wide variety of services, including bariatric and spine surgery, general hospitalist services, inpatient care, therapy services, and specialty consults. In particular, BVH provides "unique and specialized bariatric and intervention services to the underserved surrounding community and region."[1]

Since 2015, BVH had been certified by CMS as a provider under the Medicare Program. On September 6, 2017, CMS issued S&C Memo 17-44.[2] The memo states the statutory rule that a hospital must be primarily engaged in providing certain care "to inpatients."[3] It then identifies factors that could be used in making that determination:

> CMS considers multiple factors and will make a final determination based on an evaluation of the facility in totality. Such factors include, but are not limited to [average daily census], [average length of stay], the number of off-campus outpatient locations, the number of provider based emergency departments, the number of inpatient beds related to the size of the facility and scope of services offered, volume of outpatient surgical procedures compared to inpatient surgical procedures, staffing patterns, patterns of [average daily census] by day of week, etc. Hospitals are not required to have

[1]Doc. 1 ¶ 31.

[2]Doc. 25, Ex. A. BVH did not attach the S&C Memo to either complaint; Defendants attached the Memo to their supplemental brief on jurisdiction. The Court may consider documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity. *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002).

[3]42 U.S.C. § 1395x(e)(1); Doc. 25, Ex. A at 1–2.

> a specific inpatient to outpatient ratio in order to meet the definition of primarily engaged.[4]

The memo states that, "for surveyors to determine whether or not a hospital is in compliance with the statutory and regulatory requirements of Medicare participation, including the definition of a hospital, they must observe the provision of care;" if there are no inpatients to observe, only then do surveyors turn to census data, and only then so that they can decide how to proceed.[5] If the numbers add up, a second survey is attempted at a later date so that patient care can be observed.[6] A facility is not penalized just because they don't have inpatients at the time of the survey as long as census data suggests that, on average, they are primarily engaged in providing care to inpatients, that is, patients who stay two midnights.[7]

The memo goes on to state that when the facility does not have the inpatient numbers, the surveyors are instructed to determine whether a second survey should be attempted or whether to recommend termination of the provider agreement. Factors that go into that determination are:

- the number of off-campus emergency departments;
- the number of inpatient beds in relation to the size of the facility and services offered;
- the volume of outpatient surgical procedures compared to inpatient surgical procedures;
- if the facility is a "surgical" hospital, are most procedures outpatients, are they routinely scheduled early in the week, and are most patients discharged before the weekend;
- patterns and trends in the average daily census by day of week;
- staffing patterns; and

[44]Doc. 25, Ex. A at 2.

[5]*Id.* at 3.

[6]*Id.*

[7]*Id.* at 2–4.

- how the facility holds itself out to the community[8]

The memo states that the determination of whether a facility meets the definition of a hospital "will not be based on a single factor, such as failing to have two inpatients at the time of the survey."[9]

On November 13 and 14, 2017, the Kansas Department of Health and Environment ("KDHE"), pursuant to direction from CMS, conducted an onsite survey of BVH to validate the findings of BVH's recent accreditation by HFAP.[10] The KDHE survey was conducted unannounced and without prior notice to BVH. On February 2, 2018, CMS informed BVH of the results of the survey and issued a Statement of Deficiencies regarding whether BVH meets the definition of "primarily engaged" in providing inpatient services, and tagging BVH with operating an outpatient surgical center with little to no inpatient census.[11] In support CMS relied on historical data and statistics relating to the average daily census ("ADC") and average length of stay ("ALOS") of admitted patients. CMS found that BVH did not meet the two patient ADC and two-night AKOS requirements.[12] BVH alleges that this new criteria was issued in the S&C Memo and sought to impose new standards for determining compliance without following statutory rule-making procedures, including public notice and opportunity for comment.[13]

These deficiencies were "determined to be of such serious nature as to substantially limit the hospital's capacity to render adequate care and services and prevent it from being in

[8]*Id.* at 3–4.

[9]*Id.* at 4.

[10]*Id.* ¶ 34, Doc. 1-1, Ex. A.

[11]*Id.*, Ex. A.

[12]*Id.*

[13]Doc. 23 ¶ 52.

compliance with all the [Conditions of Participation] for hospitals."[14] Because BVH was found to be out of compliance with one or more of the Conditions of Participation, CMS decided to terminate the Medicare provider agreement for BVH as of May 3, 2018.[15] The Noncompliance Notice indicated that "[t]ermination can only be averted by correction of the enclosed deficiencies," and requested BVH submit a plan of correction within ten days. The Noncompliance Notice further stated that, upon review of the Plan of Correction, CMS would conduct another survey to verify that the necessary corrections had been implemented and would then communicate the findings to BVH in writing.[16]

On February 12, 2018, BVH submitted a Plan of Correction outlining the specific measures it had taken and would be taking to remedy the alleged deficiencies, as well as a Statement of Compliance.[17] On March 27, 2018, CMS sent BVH a final notice that it was terminating its provider agreement effective April 11, 2018.[18] CMS stated that BVH still had not met the definition of a hospital as required by certain regulations, and concluded that the Plan of Correction submitted by BVH lacked any specific dates as to when BVH would come into compliance and was "aspirational only."[19] BVH was told how to claim payments for services through the date of termination and how to appeal the termination decision to an Administrative Law Judge and the Departmental Appeals Board.

Following receipt of the Termination Notice, BVH submitted additional documents and information to CMS and made numerous requests for CMS to reconsider its decision and

[14]Doc. 1-1, Ex. A.

[15]*Id.*

[16]*Id.*

[17]Doc. 1-2, Ex. B.

[18]Doc. 1-3, Ex. C.

[19]*Id.*

conduct a second survey. Over the following weeks, BVH believed CMS would reconsider its termination decision and would be conducting another survey. On April 11, 2018, the effective date of termination, CMS's regional counsel advised BVH that CMS would not be reconsidering or conducting another survey, and that "the termination will take effect today as scheduled."

On April 12, 2018, BVH requested an expedited administrative appeal of the termination decision.[20] That same date, BVH filed this lawsuit seeking a temporary restraining order and injunction enjoining CMS from terminating BVH's Medicare participation rights pending the aforementioned administrative process and any subsequent judicial review. The Verified Complaint alleged one count: injunctive relief pending its administrative appeal and any subsequent judicial review. Citing the "lack of merit to CMS's determination and the lack of due process,"[21] the prayer for relief sought a temporary restraining order/preliminary injunction pending the duration of BVH's administrative appeal and any subsequent judicial review process, prohibiting Defendants from denying BVH's Medicare participation rights, decertifying BVH's Medicare rights and terminating its Medicare provider agreement, and publishing, disseminating, or communicating to third parties any notice or communication suggesting BVH has or will be decertified under Medicare or its provider agreement.[22]

The Court set the matter for hearing on the motion for TRO and ordered expedited briefing from the parties.[23] After CMS agreed to postpone the termination date to the original stated date of termination, May 3, 2018, and to re-evaluate BVH in the interim, counsel for BVH requested continuation of the TRO hearing until the re-evaluation had been completed. The

[20]Doc. 1-4, Ex. D.

[21]Doc. 1 ¶ 76.

[22]Doc. 1 at 17–18.

[23]Doc. 7.

Court notified the parties it would convert the motion for TRO to one for preliminary injunction. At a status conference on April 24, 2018, CMS confirmed that it would postpone the termination date until the Court could conduct a preliminary injunction hearing. The Court then set the matter for hearing on May 11, 2018, and ordered briefing on Defendants' motion to dismiss under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, as raised in its response to the TRO/Preliminary Injunction motion.[24]

At 5:01 p.m. on May 10, 2018, AUSA Christopher Allman sent an email to the Court and counsel for BVH that stated: "CMS has authorized me to inform all of you of the results of its revisit of BVH: BVH is not in compliance with Medicare conditions of participation and will be terminated. Formal notice and the Form CMS-2567 Statement of Deficiencies will be issued by CMS in the near future—but probably not before tomorrow's scheduled hearing."

At the hearing the next morning, Defendants confirmed that CMS's latest formal Notice and Statement of Deficiencies had yet to be issued, but purportedly made additional findings relative to BVH's status as a qualified hospital under Medicare rules and definitions. Defendants also confirmed that the notice would not give BVH the opportunity to present a Plan of Correction, and that the termination date would be the next day, May 12, 2018. BVH, which came prepared to present evidence on the administrative process it had received from CMS with respect to the November 2017 onsite survey and the February 2018 Notice and Statement of

[24]Docs. 8, 12, 14. BVH's suggestion that Defendants cannot challenge subject matter jurisdiction outside a dispositive motion filed under Rule 12 is not well taken. Both of the Complaints and Motion for TRO set out exemptions and/or waiver of the administrative exhaustion requirement as a basis for this Court's subject matter jurisdiction. After BVH contacted chambers about setting this matter for an expedited TRO hearing, Defendants indicated they would challenge the motion for lack of subject matter jurisdiction, and filed their response seeking dismissal under Rule 12(b)(1) within two days of the Court's order. Defendants then sought an extension of time to reply to the jurisdictional issues, which was granted. There were no complaints or questions about this process at the telephone status conference April 24, 2018, and as BVH is aware, a court lacking jurisdiction must dismiss the case, regardless of the stage of the proceedings, when it becomes apparent that jurisdiction is lacking. Fed. R. 12(h)(3).

Deficiencies, claimed surprise over the termination date, and argued for continuance of the hearing until it had the opportunity to review the re-survey Statement of Deficiencies and reasoning behind them. In addition, despite the characterization of its due process claim set out in its Verified Complaint, its Motion for TRO and Preliminary Injunction, and its response to Defendants' motion to dismiss, BVH urged that the relief it seeks includes a due process right to a pre-termination hearing. Accordingly, the Court continued the hearing to June 11, 2018, directed BVH to amend its complaint to identify precisely what constitutional claim it was asserting, and stayed the May 12 termination date in the interim.[25] The Court also directed supplemental briefing on the jurisdictional and preliminary injunction issues.[26]

BVH filed its Amended Verified Complaint on May 25, 2018.[27] Although it suggests at various points it has the constitutional right to a pre-termination hearing, BVH continues to assert arguments challenging the agency's underlying rule-making process and lack of notice-and-comment, and the application of those rules to BVH as the "most noteworthy" grounds for its due process claim.[28]

In its Amended Complaint, BVH also alleges the re-survey conducted from April 22 through 25, 2018 was "orchestrated," a "total sham," and far from "due process."[29] BVH further complains that the re-survey suffers from the same procedural issues and unfairness as the first survey, and continues to use and rely on historical statistical averages to determine BVH's compliance with ADC and ALOS requirements, relying on data from approximately three to four

[25]Doc. 22.

[26]*Id.*

[27]Doc. 23.

[28]Doc. 23 ¶¶ 86–101.

[29]Doc. 23 ¶ 71.

years before the purported new rules went into effect to determine statistical averages.[30]

The re-survey Statement of Deficiencies, which Defendants attach to their supplemental brief, identifies thirty-seven pages of deficiencies, including issues that directly affect patient care.[31] In addition, updated deficiencies in the re-survey listed problems taken directly from medical records, staff comments, and surveyor observations. The revised findings include admissions by BVH's leadership acknowledging that BVH knew it was not in compliance, and that to get its numbers up, a discount was offered to employees and their friends and families to incentivize them to have surgery so BVH could increase its census numbers.[32] Interviews with former employees suggest they quit working at BVH because they were told to falsify medical records to make it appear that the patient needed to stay two nights, so BVH could justify keeping patients longer to inflate their inpatient numbers.[33] The re-survey found that BVH "failed to use safe practices for medication administration," and cited examples of failing to document or properly monitor medication administration, including medications that BVH routinely allowed patients to bring from home, leading to "the potential for medication errors, drug overdose, adverse drug reactions, and ineffective medication management."[34] The re-survey noted inconsistencies in one patient's record,[35] and found that BVH contracts with a grocery store to provide food for patients, but does not verify nutritional value or ensure safe food handling.[36] CMS did not accept a Plan of Correction or any other attempt by BVH to

[30] *Id.*

[31] Doc. 25, Ex. B.

[32] *Id.* at 9–10.

[33] *Id.* at 10–11.

[34] *Id.* at 16–19.

[35] *Id.* at 33–35.

[36] *Id.* at 36–37.

respond or comply with the findings.

In response, Defendants renew their request for dismissal of the case for lack of subject matter jurisdiction.[37]

II. Subject Matter Jurisdiction

Before the Court can address the issue of whether BVH meets the requirements for issuance of a preliminary injunction, it must determine that it has subject matter jurisdiction to grant its request. BVH argues that jurisdiction lies under 42 U.S.C. § 1331 or alternatively, because its claim meets the "total denial of review" exception to administrative exhaustion and/or is "entirely collateral" to the administrative claim presented to the Secretary. The Court addresses each issue in turn.

A. Channeling/Exhaustion Requirement

Federal courts are courts of limited jurisdiction and, as such, must have a statutory or constitutional basis to exercise jurisdiction.[38] When the United States, one of its agencies, or its employees named in their official capacities are named as defendants, a waiver of sovereign immunity is required before the court can assume subject matter jurisdiction.[39] A court lacking jurisdiction must dismiss the case, regardless of the stage of the proceeding, when it becomes apparent that jurisdiction is lacking.[40] The party who seeks to invoke federal jurisdiction bears the burden of establishing that such jurisdiction is proper.[41] "Thus, plaintiff bears the burden of

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[37]Doc. 25.

[38]*Montoya v. Chao*, 296 F.3d 952, 955 (10th Cir. 2002).

[39]*See United States v. Sherwood*, 312 U.S. 584, 586 (1941); *High Country Citizens All. v. Clarke*, 445 F.3d 1177, 1181 (10th Cir. 2006).

[40]*Laughlin v. Kmart Corp.*, 50 F.3d 871, 873 (10th Cir. 1995); Fed. R. Civ. P. 12(h)(3).

[41]*Montoya*, 296 F.3d at 955.

showing why the case should not be dismissed."[42] Mere conclusory allegations of jurisdiction are not enough.[43]

The Medicare Act incorporates two key provisions of the Social Security Act dealing with judicial review of agency actions. 42 U.S.C. § 1395cc(b)(2) provides that, after the Secretary has determined that a Medicare provider fails to comply substantially with provisions of its provider agreement, or with certain provisions of the Medicare Act or its regulations, the Secretary may terminate the provider agreement. 42 U.S.C. § 1395cc(h)(1)(a), in turn, provides that an institution dissatisfied with a determination by the Secretary under § 1395cc(b)(2) is entitled to a hearing to the same extent as provided in 42 U.S.C. § 405(b), "and to judicial review of the Secretary's final decision after such hearing as provided in 42 U.S.C. § 405(g)."

Section 405(g) provides for a strict administrative exhaustion requirement as a prerequisite to judicial review:

> Any individual, after any final decision of [the Secretary] made after a hearing to which he was a party . . . may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of a notice of such decision. . . . The findings of [the Secretary] as to any fact, if supported by substantial evidence, shall be conclusive. . . . The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions.

Congress expressly incorporated this provision to govern various Medicare matters, including enrollment-related and provider-termination decisions.[44]

The second key judicial review provision of the Social Security Act incorporated in the Medicare Act is 42 U.S.C. § 405(h), which provides that judicial review under § 405(g) is the

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[42]*Harms v. IRS*, 146 F. Supp. 2d 1128, 1130 (D. Kan. 2001).

[43]*United States ex rel. Hafter, D.O. v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1160 (10th Cir. 1999).

[44]*See* 42 U.S.C. § 1395cc(j)(8), (h)(1)(A).

sole and exclusive basis for any court's jurisdiction:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

"The second sentence of § 405(h) thus precludes judicial review of the Secretary's determinations under the Medicare Act pursuant to § 405(g) unless its exhaustion requirements are met. The third sentence forecloses alternative routes of review under federal question jurisdiction or jurisdiction based on the United States' status as a defendant."[45]

Despite this statutory scheme, BVH contends that the exhaustion requirement does not apply because it is not challenging the merits of a final agency termination decision, but merely seeking injunctive relief, and thus the Court has jurisdiction under 28 U.S.C. § 1331.[46] In other words, BVH argues, "administrative channeling and exhaustion only apply to actions where plaintiff seeks judicial review of the merits of a Medicare termination decision *itself*, i.e., where the plaintiff is asking the Court to review and reverse the merits of the termination decision (the factual findings of noncompliance.")[47] This argument is misplaced.

BVH focuses on the nature of the interim injunction relief it seeks, and characterizes its action as merely seeking a stay to preserve the status quo pending the administrative review process. But the Supreme Court has repeatedly upheld the jurisdictional bar in Medicare-related

[45]*THI of Kan. at Highland Park, LLC v. Sebelius*, No. 13-2360-JAR-JPO, 2013 WL 4047570, at *5 (D. Kan. Aug. 9, 2013).

[46]Doc. 15 at 3–5.

[47]*Id.* at 4 (emphasis in original).

matters. In *Heckler v. Ringer*, the Court recognized that the Medicare statute provided "the sole avenue of judicial review" for any matter "arising under" the Medicare Act.[48] And in *Shalala v. Illinois Long Term Care, Inc.*, the Court stressed that § 405(h) "demands the 'channeling' of virtually all legal attacks through the agency.[49] Clearly, BVH's constitutional challenge to the Secretary's authority to terminate its provider agreement under the Act during the pendency of an administrative hearing process prescribed by the Act should be deemed to "arise under" the Medicare Act, as that term is applied by the Supreme Court. BVH cannot avoid this requirement by arguing that it only requests the Court's jurisdiction in the form of a preliminary injunction against CMS, and has identified no authorities holding that actions akin to this one do not arise under the Medicare Act for § 405(h) purposes.[50] Indeed, this interpretation would effectively allow any party who wanted to stop proposed agency action to simply seek injunctive relief in federal court, which would render the "strict administrative exhaustion requirement" of § 405 a nullity. Thus, in accordance with federal law, this Court lacks jurisdiction to entertain BVH's request unless BVH can satisfy the so-called *Michigan Academy* or *Eldridge* exceptions to the channeling requirements of § 405(g) recognized by the Supreme Court.

B. "*Michigan Academy*" Exception

In *Shalala v. Illinois Council on Long Term Care, Inc.*, the Supreme Court determined that Congress intended an exception to the administrative channeling requirement in § 405(h), "where it would not simply channel review through the agency, but would mean no review at

[48]466 U.S. 602, 614–15 (1984).

[49]529 U.S. 1, 13 (2000).

[50]*See V.N.A. of Greater Tift Cty., Inc. v. Heckler*, 711 F.2d 1020, 1031–32 (11th Cir. 1983) (rejecting provider's theory that § 405(h) preclusion does not apply to action where provider "is not asking for review on the merits but merely a stay to maintain the status quo," noting the third sentence of § 405(h) precludes any "action," and does not limit its scope to judicial review on the merits).

all."[51] This so called *Michigan Academy* exception is narrowly circumscribed, as the Supreme Court made clear that hardship caused by the practical effects of administrative channeling is not the test, but rather an actual lack of review.[52] The Court cautioned, "we do not hold that an individual party could circumvent § 1395ii's channeling requirement simply because that party shows that postponement would mean added inconvenience or cost in an isolated, particular case."[53] The Court has consistently drawn a distinction between "a total preclusion of review and postponement of review."[54]

BVH argues that if the termination of its Medicare provider agreement was allowed to go forward, it would cause BVH to close due to a lack of Medicare dollars, effectively foreclosing its financial ability to pursue administrative remedies and challenge Defendants' conduct. Although BVH makes the conclusory statement that other small hospitals would be similarly foreclosed from review,[55] it focuses exclusively on the specific financial inconvenience to BVH if it is not granted injunctive relief pending review of termination of its Medicare provider agreement. Because BVH is explicitly entitled to administrative and judicial review of the agency's decision to terminate its provider agreement, and because the harm to BVH is an isolated, delay-related harm, the *Michigan Academy* exception does not apply.[56]

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[51]*Shalala*, 529 U.S. at 19 (construing *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667 (1986)).

[52]*Id.* at 22.

[53]*Id.*

[54]*Id.* at 19–20.

[55]Doc. 23 ¶ 31.

[56]*See THI of Kan.*, 2013 WL 4047570, at *6–7 (rejecting similar argument that plaintiff would be forced to close its doors if termination was allowed to go forward).

C. "Entirely Collateral" Basis for Exercising Jurisdiction

Alternatively, BVH invokes the so-called *Eldridge* "entirely collateral" exception. In *Matthews v. Eldridge*,[57] the Supreme Court explained that the requirement under § 405(g) that there be a final decision by the Secretary after a hearing as a condition to federal jurisdiction consists of a waivable and nonwaivable element:

> The waivable element is the requirement that the administrative remedies prescribed by the Secretary be exhausted. The nonwaivable element is the requirement that a claim . . . shall have been presented to the Secretary. Absent such a claim there can be no "decision" of any type. And some decision by the Secretary is clearly required by the statute.[58]

Here, BVH has fulfilled the nonwaivable element of administrative exhaustion by presenting its appeal of the termination decision to the Secretary. Thus, the Court determines if the remaining steps of administrative exhaustion required in § 405(g) should be waived.

Although Defendants have clearly not waived exhaustion here, "agency waiver may be, in the court's discretion, deemed improperly withheld where the plaintiff's interest in prompt resolution is so great that deference to the agency's judgment on the utility of exhaustion is appropriate."[59] *Eldridge* did not create an exception to the channeling requirements in § 405(g) but instead found that the "final decision" requirement would be deemed satisfied as to a claim where "(1) the plaintiff asserts a colorable constitutional claim that is collateral to the substantive

[57]424 U.S. 319 (1976).

[58]*Id.* at 328.

[59]*Harline v. Drug Enforcement Admin.*, 148 F.3d 1199, 1202–03 (10th Cir. 1998) (citing *Eldridge*, 424 U.S. at 330; *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 (1994)).

issues of the administrative proceedings, (2) exhaustion would result in irreparable harm, and (3) exhaustion would be futile."[60] "The plaintiff bears the burden of establishing these elements."[61]

As to the first element, while Defendants believe there is significant overlap between the relief requested by BVH here and the arguments pending in the administrative appeal, in their supplemental briefing they assume for the sake of argument that BVH's claim is entirely collateral.[62] The Court remains unconvinced that BVH's claim is "entirely collateral" for purposes of the *Eldridge* exception. In *Eldridge*, the Court deemed as collateral the plaintiff's constitutional claim demanding a pre-termination hearing; plaintiff's constitutional claim regarding his procedural rights involved an analysis of Supreme Court jurisprudence on the Due Process Clause, which involved completely separate issues from his challenge to the Secretary's decision to terminate benefits.[63] Since then, due process "claims to a deprivation hearing as a matter of constitutional right" have fit under this narrow exemption; multiple courts, including this Court, have likewise held that the "entirely collateral" requirement applies when a plaintiff is asserting a constitutional challenge demanding that a pre-termination hearing take place.[64]

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[60]*Harline*, 148 F.3d at 1202–03 (citing *Eldridge*, 424 U.S. at 330); *see also Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 364 (6th Cir. 2000); *THI of Kan.*, 2013 WL 4047570, at *8; *cf. Family Rehab., Inc. v. Azar*, 886 F.3d 496, 504 (5th Cir. 2018) (construing the "colorable" requirement as meaning that the claimant's showing of irreparable harm must be colorable); *GOS Operator, LLC v. Sebelius*, 843 F. Supp. 2d 1218, 1231 (S.D. Ala. 2012) (same).

[61]*Harline*, 148 F.3d at 1202–03 (citing *Koerpel v. Heckler*, 797 F.2d 858, 863 (10th Cir. 1986)).

[62]Doc. 25 at 4.

[63]*Eldridge*, 424 U.S. at 330–31.

[64]*See, e.g.*, *Ringer*, 466 U.S. at 618; *Family Rehab., Inc.*, 886 F.3d at 501–03 (holding plaintiff's claim seeking only a hearing before the recoupment of its Medicare revenues is "plainly collateral" under *Eldridge*); *Ram v. Heckler*, 792 F.2d 444, 446 (4th Cir. 1986) (holding a plaintiff's claim "that he is entitled to a pre-suspension hearing is 'entirely collateral' to his substantive claim that the suspension is in error" when the "final decision on [plaintiff's] substantive claim would not answer the constitutional challenge to the validity of a suspension prior to a hearing."); *Blossom South, LLC v. Sebelius*, 987 F. Supp. 2d 289, 297 (W.D.N.Y. 2013) (holding plaintiff's constitutional challenge demanding a pre-termination hearing is entirely collateral to its substantive claim of entitlement to participate in the Medicare program); *GOS Operator, LLC*, 843 F. Supp. 2d at 1229–31 (finding due process claim entirely collateral where plaintiff brought a constitutional challenge demanding a pre-termination hearing); *THI of Kan. at Highland Park v. Sebelius*, No. 13-2360-JAR, 2013 WL 4047570, at *8 (D. Kan. Aug. 9,

The Amended Complaint in this case asserts a broad due process claim that BVH characterizes as:

> the failure to follow statutory-rulemaking procedures, lack of notice and opportunity to be heard, the use and application of erroneous, arbitrary and capricious procedures and rules, the failure to provide BVH review in a meaningful time and manner, failure to allow BVH a reasonable opportunity to comply with new rules imposed without notice or grace period, and general widespread procedural unfairness.[65]

The gravamen of BVH's due process challenge continues to focus on CMS's reliance on newly-issued, arbitrary and invalid agency rules, which BVH contends were improperly issued without following statutory "notice and comment" rule-making requirements.[66] BVH concludes, "[a]ccordingly, the CMS improperly relied upon invalid rules in rendering its decision against BVH. The erroneous application of these invalid rules without affording a pre-termination hearing constituted an abuse of CMS's procedural authority in reviewing BVH and reaching its termination decision. Such an error is inherently unfair and deprived BVH of due process."[67] This claim is nearly identical to the arguments BVH makes in its administrative appeal:

> Furthermore, the Medicare Act does not exempt interpretive rules from the notice-and-comment rulemaking process. . . .
>
> Accordingly, the new criteria set forth in the Letter Guidance constituted improper rule-making and is rendered invalid. As such, CMS's improper reliance on such criteria constituted an abuse of discretion and violation of BVH's due process rights, especially considering CMS's lack of review or consideration of BVH's

2013) (finding plaintiff's due process challenge seeking injunctive relief on the grounds that it is entitled to a pre-termination hearing "entirely collateral" from its substantive challenge to the Secretary's termination decision).

[65]Doc. 23 at 27.

[66]*Id.* at 20–22.

[67]*Id.* at 22–23 (emphasis in original).

> submissions demonstrating its compliance. On this basis alone, BVH is entitled to a reversal of CMS's termination decision.[68]

Although BVH argues it has "in essence" adequately pled a constitutional claim that is entirely collateral to its substantive claim, it appears to remain inextricably intertwined with its substantive challenge to the termination decision.

For a cause of action to be entirely collateral, it must not be "the vehicle by which [the plaintiff] seek[s] to reverse" the agency decision,[69] or seek an ultimate award of the benefits denied by the agency.[70] Such claims must be completely separate from the claim that the plaintiff is entitled to benefits or continued participation in the Medicare program; if they are "inextricably intertwined" with the claim on the merits for benefits or participation, they are not entirely collateral.[71] Even where a plaintiff does not directly challenge the substance of the agency action, "[i]f the court must examine the merits of the underlying dispute, delve into the statute and regulations, or make independent judgments as to plaintiffs' eligibility under a statute, the claim is not collateral."[72]

Under these principles, BVH's claim is plainly not entirely collateral. The crux of BVH's due process claim alleges a violation of its rights via CMS's reliance on new agency rules that it argues were improperly issued without following statutory notice and comment requirements in reaching the termination decision. Indeed, BVH requests the Court to halt

[68]Doc. 1-4 at 6 (BVH's April 12 administrative appeal letter, attached as Ex. D. to BVH's Complaint) (emphasis added). BVH's Complaint specifically states that this document contains the "specifics of BVH's underlying claim(s) for reversal of the CMS's decision." Doc. 1 ¶ 50.

[69]*Elgin v. Dep't of Treasury*, 567 U.S. 1 (2012).

[70]*See Ringer*, 466 U.S. at 614 (rejecting claims that were "at bottom" for benefits).

[71]*Cathedral Rock of North Coll. Hill, Inc. v. Shalala*, 223 F.3d 345, 363 (6th Cir. 2000).

[72]*Family Rehab., Inc. v. Azar*, 886 F.3d 496 (5th Cir. 2018) (citing *Ringer*, 466 U.S. at 614).

termination of its provider agreement during the entire administrative appeal process while it challenges CMS's decision on these same due process grounds. Thus, BVH's due process claim is inextricably intertwined with its substantive challenge to Defendants' termination decision, as it "essentially cloaks a substantive challenge to [CMS's] revocation decision in the form of a procedural due process constitutional challenge."[73] By challenging the agency's rule-making process and the application of those rules to BVH in the termination decision, BVH's due process claim is the vehicle by which it seeks to reverse the agency, and cannot be entirely collateral.

This conclusion is further evidenced by BVH's focus on its underlying administrative appeal in arguing that it is likely to succeed on the merits of its claim in its request for preliminary injunction.[74] BVH emphasizes that it is not asking the Court to rule on the underlying merits of the termination decision and that any such determination is unwarranted and improper because it only seeks a preliminary injunction to maintain the status quo. But this inquiry misses the mark—if BVH's procedural due process claim is "entirely collateral" to the substantive challenge, it follows that its request for a preliminary injunction requires a showing that BVH has a substantial likelihood of success on the merits of that procedural due process claim.[75] In support of its request for preliminary injunction, however, BVH outlines what it argues are the "meritorious arguments in support of its underlying claims," which include the

[73]*Stubbs v. Price*, 281 F. Supp. 3d 1360, 1365 (N.D. Ga. 2017).

[74]Doc. 3 at 11–12; Doc. 23, ¶¶ 82–101.

[75]*See THI of Kan.*, 2013 WL 4047570, at *9 n.31 (explaining analysis would be restricted to likelihood of success on the merits of plaintiff's procedural due process claim, not on the underlying administrative challenge to the Secretary's deficiency findings); *GOS Operator, LLC v. Sebelius*, 843 F. Supp. 2d 1218, 1232 (S.D. Ala. 2012) (analyzing whether the plaintiff was likely to succeed on his procedural due process claim that he should have been entitled to an administrative hearing before his provider agreement could be terminated).

invalidity of the rules that served as a basis for termination of its rights and the arbitrary and capricious nature of Defendants' process and decision. Thus, at the preliminary injunction stage, the Court would be tasked with weighing in on the merits of the same issue presented in the administrative matter before the agency has a chance to issue a final decision, which runs afoul of the administrative exhaustion requirements of § 405.[76]

Even generously reading BVH's due process claim as limited to a collateral demand for a pre-termination hearing, however, it cannot meet its additional burden of stating a colorable constitutional claim. Although BVH argues that the "colorableness" of its procedural due process claim is irrelevant for jurisdictional purposes, the Tenth Circuit has explained,

> The requirement that a constitutional claim be colorable to invoke federal court jurisdiction during pending administrative proceedings is well justified. The exhaustion requirement generally prevents premature interference with agency processes, allowing agencies an opportunity to (1) correct their own errors, (2) afford the parties before them and reviewing courts the benefit of their experience and expertise, and (3) compile a record which is adequate for judicial review. If the mere allegation of a denial of due process could suffice to establish subject-matter jurisdiction, then every act of an agency would be immediately judicially reviewable, undermining a statutory scheme which limits judicial review to further the above policies. Furthermore, encouraging parties to circumvent agency procedures would diminish agency effectiveness by making enforcement efforts far more complicated and expensive.[77]

To determine whether a claim is colorable, it is necessary to examine its merits.[78] A determination that a claims lacks merit, however, does not necessarily mean it is so lacking as to

[76]*See Shalala v. Ill. Council on Long Term Care*, 529 U.S. 1, 13 (2000) (noting the requirements of § 405 "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts").

[77]*Harline v. Drug Enforcment Admin.*, 148 F.3d 1199, 1203 (10th Cir. 1998) (citations omitted) (emphasis added).

[78]*See Koerpel v. Heckler*, 797 F.2d 858, 863 (10th Cir. 1986).

fail the colorable test.[79] In this context, a constitutional claim is not colorable if it is "immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial or frivolous."[80] A plaintiff fails to state a colorable claim if the claim is "so insubstantial, implausible, foreclosed by prior decisions of [the Supreme] Court, or otherwise completely devoid of merit as not to involve a federal controversy."[81]

BVH claims that Defendants failed to provide sufficient due process in reaching and attempting to enforce their termination decision, and thus additional procedural safeguards are necessary to ensure due process. "A claim of denial of procedural due process requires that the plaintiff have a constitutionally protected property interest that was injured or revoked without proper procedural protections."[82] "The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'"[83] The inquiry here centers on what process is due before revocation of BVH's participation rights takes effect. Thus, BVH must show that further pre-deprivation safeguards are justified in light of the "elaborate character of the administrative procedures provided by the Secretary."[84] As this Court noted in *THI of Kansas*, the overwhelming majority of circuit courts of appeals, including the Tenth Circuit, have determined that Medicare providers enjoy no constitutional right to a pre-termination hearing.[85] This case is no exception.

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[79]*See id.* (citation omitted).

[80]*Harline*, 148 F.3d at 1203 (quoting *Koerpel*, 797 F.2d at 863).

[81]*Id*. (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998)).

[82]*Schanzenbach v. Town of La Barge*, 706 F.3d 1277, 1283–84 (10th Cir. 2013).

[83]*Eldridge*, 424 U.S. at 333 (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)).

[84]*Id.* at 339–40.

[85]*THI of Kan.*, 2013 WL 4047570, at *8 n.27 (citing *Geriatrics, Inc. v. Harris*, 640 F.2d 262, 265 (10th Cir. 1981)); *Koerpel v. Heckler*, 797 F.2d 858 (10th Cir. 1986); *see also Arriva Med. LLC v. U.S. Dep't of Health &*

The balancing factors set forth in *Eldridge* govern the Court's analysis of what pre-termination procedural protections are due: (1) "the private interest that will be affected by the official action"; (2) "the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any of additional or substitute procedural safeguards"; and (3) "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail."[86]

Under the first factor, BVH's interest is not particularly compelling because a Medicare provider is not the intended beneficiary of the program; its "financial need to be subsidized for the care of its medical patients is only incidental to the purpose and design of the Medicare program."[87] Because providers also receive full retroactive payments if they prevail, their interest is only in "uninterrupted" reimbursements.[88]

Under the second factor, the Court addresses the process that was given and whether additional safeguards would mitigate the risk of erroneous deprivation. BVH contends that the erroneous procedures and so-called "process" used by Defendants tainted the entire review and decision making processes, creating a near-certain risk of an erroneous termination decision against BVH.[89] BVH claims that CMS refused it an opportunity to respond and correct the noted deficiencies and then failed to meaningfully consider BVH's proposals.[90] But BVH has received

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Human Servs., 239 F. Supp. 3d 266, 287 (D.D.C. 2017) (collecting cases); *GOS Operator, LLC v. Sebelius*, 843 F. Supp. 2d 1218, 1233 (S.D. Ala. 2012) (collecting cases).

[86]*THI of Kan.*, 2013 WL 4047570, at *8 (citing *Eldridge*, 424 U.S. at 335); *Autumn Health Care of Zanesville, Inc. v. U.S. Dep't of Health & Human Servs.*, 959 F. Supp. 2d 1044, 1051–53 (S.D. Ohio 2013) (citing *Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 361–65 (6th Cir. 2000)).

[87]*Id.* at *9 (quoting *Cathedral Rock of N. Coll. Hill, Inc.*, 223 F.3d at 365).

[88]*Eldridge*, 424 U.S. at 340.

[89]Doc. 23 ¶ 120.

[90]*Id.* at 20.

significant process up to this point. CMS conducted an on-site survey by the KDHE in November 2017. BVH was given ninety days to address the deficiencies involving whether BVH meets the definition of "primarily engaged" in providing inpatient services, as outlined after the survey and to avoid termination. BVH had the opportunity to submit a Plan of Correction, which was rejected by CMS after it read it and found it to be lacking as aspirational only, and otherwise faulty because it did not include a specific time frame for BVH to come into compliance. BVH subsequently submitted additional documents and information to CMS, and made "numerous requests for CMS to reconsider" its decision and conduct a second survey.

After the administrative appeal and this lawsuit was filed, CMS agreed to push back the termination date and re-evaluate BVH in the interim, which resulted in additional deficiencies and the same termination conclusion. BVH claims that the re-survey was a "sham" that suffers from more procedural deficiencies than the first survey and CMS's refusal to accept a plan of correction in response.[91] BVH fails, however, to explain beyond this conclusory accusation how or why the re-survey was a "sham" or otherwise deficient. Indeed, despite this Court's continuance of the May 11 hearing to allow BVH to review the re-survey's findings, BVH fails to discuss or offer any analysis of the thirty-seven page deficiency report in support of its claim of jurisdiction. It is unclear how a pre-termination hearing would change the outcome of either survey or what BVH would present at a hearing that it could not have done in its Plan of Correction.

Nor do the remaining procedural violations alleged in the Amended Complaint boost the risk of error. These violations relate to the promulgation and application of S&C Memo 17-44,

[91] *Id.*

which BVH claims was improper because it did not comply with rule-making procedures requiring a notice-and-comment period.[92] As previously discussed, this question is beyond this Court's purview because it mirrors the substantive challenge to the termination decision in the pending administrative appeal. That being said, to the extent BVH argues S&C Memo 17-44 failed to give it adequate notice or opportunity to comply, it does not appear the memo creates a new rule or standard based on historical census data alone as suggested by BVH. As Defendants argued at the May 11 hearing and in their supplemental briefing, S&C Memo 17-44 sets out the non-exhaustive criteria used to evaluate the statutory standard of whether a facility is "primarily engaged" in inpatient care. Because the memo is only interpretive of an existing rule, notice-and-comment procedures were not required.[93] Accordingly, the Court finds that BVH has received sufficient process such that a pre-termination hearing is not required by the due process clause to preserve its relatively weak interest in continuing to receive Medicare provider payments.

Finally, under the third factor, the Court finds that the Government's interest in expeditious provider termination procedures is strong. As the Court in *Eldridge* noted, this factor considers "the administrative burden and other societal costs that would be associated with requiring, as a matter of constitutional right, an evidentiary hearing upon demand in all cases."[94] Although BVH urges that it is not suggesting a pre-termination hearing is warranted in every case where a provider's rights are terminated, if the Court singles BVH out for a hearing, it follows that other similarly situated providers would likely be able to assert similar procedural

[92]*Id.* at 2, 20.

[93]*Trust Under Will of Wills v. Burwell*, ---F. Supp. 3d---, No. 16-6615, 2018 WL 558469, at *5 (E.D. Pa. Jan. 25, 2018), *appeal docketed*, No. 18-1594 (3d Cir. March 22, 2018); 42 U.S.C. § 1395hh(a)(2), (c)(1).

[94]*Eldridge*, 424 U.S. at 347.

due process claims. As Defendants note, this would be an administrative burden in general and would set a difficult precedent to implement. And more specifically, it would be an undue burden in this case given the opportunity to correct that BVH was given. BVH was tagged with numerous deficiencies in both surveys, including compromise of patient care. As such, the government interest in protecting patients through an expeditious provider-termination procedure is quite strong.

In sum, the Court finds that BVH does not assert a colorable constitutional claim that is entirely collateral to its substantive administrative appeal. Because BVH is not entitled to a waiver of the administrative exhaustion requirement under *Eldridge*, the Court lacks jurisdiction to consider the claim presented in the Amended Complaint or in BVH's motion for preliminary injunction.[95] Even if the Court found that BVH presented an entirely collateral colorable constitutional claim and proceeded to consider the motion for preliminary injunction, it could not find that BVH had a likelihood of success on the merits of such a claim under the analysis set forth above.[96]

IT IS THEREFORE ORDERED BY THE COURT that Defendants' Motion to

[95]Although it need not reach the second and third *Eldridge* factors, it appears that BVH has sufficiently claimed that erroneous termination will "damage it in a way not recompensable through retroactive payments." *Eldridge*, 424 U.S. at 331. As BVH argues, if its provider agreement is terminated, it will go out of business and there would be a disruption to Medicare patients scheduled for surgery; these combined threats have been held as sufficient to allege irreparable injury. *See Family Rehab., Inc. v. Azar*, 886 F.3d 496, 504 (5th Cir. 2018). The Court notes that in *Azar*, however, the plaintiff facility sought only a pre-termination hearing before recoupment of its Medicare revenues. *Id.*

[96]*See., e.g.*, *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1258 (10th Cir. 2005) (quoting *SCFC ILC, Inc. v. Visa USA, Inc.*, 936 F.2d 1096, 1098 (10th Cir. 1991) (setting forth the standards for obtaining a preliminary injunction, including likelihood of success on the merits). As the Court previously noted, the likelihood of success on the merits analysis would be restricted to likelihood of success on the merits of BVH's procedural due process claim, not on its likelihood of success on the underlying administrative challenge to the Secretary's termination findings. *See Arriva Med. LLC v. U.S. Dep't of Health & Human Servs.*, 239 F. Supp. 3d 266, 287–92 (D.D.C. 2017) (applying *Eldridge* balancing factors in analysis of whether plaintiff had demonstrated likelihood of success on the merits of procedural due process claim to pre-termination hearing); *GOS Operator, LLC v. Sebelius*, 843 F. Supp. 2d 1218, 1232–35 (S.D. Ala. 2012) (same).

Dismiss pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction as supplemented (Docs. 8, 25) is **granted**. The Court therefore does not reach the Motion for Preliminary Injunction. This case is dismissed without prejudice.

IT IS SO ORDERED.

Dated: June 7, 2018

S/ Julie A. Robinson
JULIE A. ROBINSON
CHIEF UNITED STATES DISTRICT JUDGE