IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

PHYSICIAN HOSPITALS OF AMERICA and TEXAS SPINE & JOINT HOSPITAL, LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 6:10-00277-MHS
KATHLEEN SEBELIUS, in her official capacity as Secretary of the United States Department of Health and Human Services,	)	
Defendant.	)	

DEFENDANT'S MOTION TO DISMISS AND MEMORANDUM IN SUPPORT THEREOF

TO THE HONORABLE JUDGE OF SAID COURT:

Defendant Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services, through undersigned counsel, moves the Court to dismiss Plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6). In support of this motion, the Secretary respectfully refers the Court to the attached memorandum.

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Introduction

Plaintiffs in this action challenge recent amendments to a portion of the Medicare Act known as the Stark Law, which generally prohibits Medicare payments for hospital services resulting from a referral by a physician who has a financial interest in the hospital. *See* 42 U.S.C. § 1395nn. Because of its continuing concern about the conflicts of interest and potential for self-dealing inherent in such referrals, Congress amended the Stark Law to further restrict Medicare payment for self-referred claims. Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), §§ 6001, 10601.[1] Plaintiffs seek to overturn the restrictions based on some notion that Congress cannot change the Stark Law, that Plaintiffs have a constitutional right to lock in the prior terms of the Stark Law *ad infinitum*, and the Plaintiffs, rather than Congress, should be able to dictate the statutory conditions for Medicare payment to hospitals. Further, in the face of a statutory moratorium on payment for certain physician self-referrals from 2003 to 2005, regulatory restrictions imposed by the Secretary of Health and Human Services ("HHS") during the Bush Administration in 2005, government studies in 2005 and 2006 advocating additional limitations, and approval by both chambers of Congress in 2007 through 2009 of restrictions similar to those at issue here, Plaintiffs claim to have suffered harm because they spent money in reliance on the continued availability of the pre-existing statutory exception to the prohibition on payment for self referrals. Plaintiffs' claims are baseless.

As a threshold matter, the Court lacks jurisdiction because Plaintiffs have not presented their claims to the appropriate federal agency, HHS, much less exhausted their administrative

[1] The ACA was amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (Mar. 30, 2010), § 1106. The text of 42 U.S.C. § 1395nn, as amended by the ACA and the Reconciliation Act, is attached as Exhibit 1.

remedies. The Supreme Court and this Circuit have made it abundantly clear that the Medicare statute makes exhaustion a prerequisite of subject matter jurisdiction over claims like those at issue here. *Shalala v. Ill. Council on Long Term Care, Inc.,* 529 U.S. 1, 15 (2000); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *Nat'l Athletic Trainers Ass'n v. U.S. Dep't of Health and Human Servs.*, 455 F.3d 500, 503 (5th Cir. 2006).

Nor could Plaintiffs succeed even if the Court had jurisdiction. As the Supreme Court has recognized, individuals have no constitutional right to continued participation in programs under the Social Security Act, including Medicare, as originally enacted. *See Bowen v. Pub. Agencies Opposed to Soc. Sec. Entrapment*, 477 U.S. 41, 52 (1986); *Flemming v. Nestor*, 363 U.S. 603, 611 (1960). Nor could Plaintiffs reasonably rely on such entrenchment, given the active, bipartisan studies, debates, and regulations since 2003 addressing and questioning the growth of physician-owned hospitals participating in the Medicare and Medicaid programs. The issue before the Court is whether the most recent Stark limitations in Section 6001 of the ACA are rationally related to a legitimate government objective. The numerous studies and reports by governmental agencies and outside researchers alike – as well as conclusions that Congress or, for that matter anyone else, could reasonably draw – give rise to very legitimate concerns about the financial incentives and conflicts of interest associated with self-referrals to physician-owned hospitals, and their demonstrated ability to generate unnecessary and expensive medical procedures, undermine community hospitals that serve important objectives, and raise the expenditures for Medicare and Medicaid. Although Plaintiffs may disagree with Congress and the authors of the many governmental and independent academic studies documenting these problems, that disagreement in no way undermines the more than rational basis for Section 6001.

For these reasons, as elaborated and supplemented below, the Court should reject Plaintiffs' claims in their entirety and enter judgment for Defendant.[2]

Issues Presented

1. Whether the Court has jurisdiction over claims that arise under the Medicare Act but have not been presented to the Secretary for the exhaustion of administrative remedies.

2. Whether Plaintiffs have a legitimate expectation Congress will never change the requirements for Medicare payment, or to expect that Congress will do so only in ways that accommodate Plaintiffs' pecuniary interests.

3. Whether Plaintiffs can show that there is no conceivable basis upon which Congress could rationally determine that physician-owned hospitals increase the utilization of services, result in greater Medicare expenditures, distort the provision of health care services in a community by treating fewer sick and poor patients, or are not responding appropriately to medical emergencies.

4. Whether Plaintiffs can show that Section 6001 constitutes an uncompensated taking of Plaintiffs' property under the Fifth Amendment.

5. Whether Plaintiffs can show that Section 6001 is so vague as to be unconstitutional.

Background

The Medicare program, established by Title XVII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh, is the federal health insurance program for the elderly and disabled. Medicaid, established by Title XIX of the Act, 42 U.S.C. §§ 1396 *et seq.*, is a cooperative Federal-state program that provides health care coverage to specified categories of very low-income persons. The programs are administered by the Centers for Medicare & Medicaid Services ("CMS") on behalf of the Secretary of the HHS.

A. Early Regulation: Concerns about Physician Self-Referral Utilization Rates in Medicare Prompt the Stark Law

In the late 1980s, Congress expressed concern about a practice commonly known as physician self-referral, where a physician refers patients to medical facilities in which that

[2] In the alternative, the Secretary is filing a Motion for Summary Judgment.

physician has an ownership or investment interest. Academic studies suggested that such financial relationships could influence a doctor's decision to refer a patient to a facility for medical services, many of which were unnecessary. *See* 63 Fed. Reg. 1659, 1661; 66 Fed. Reg. 856, 859. Congress directed the HHS Office of the Inspector General to investigate this issue in 1988. The resulting report confirmed that patients referred to a clinical laboratory by a physician-owner received 45 percent more services than other patients. *Id.* This prompted Congress to amend the Medicare Act to restrict Medicare claims when certain financial relationships exist between doctors and medical facilities.

Known as the "Stark Law," 42 U.S.C. § 1395nn was designed to prevent financial conflicts of interest from influencing medical decision-making. The statute generally prevents physicians from referring patients for Medicare services to facilities in which the physician (or an immediate family member) has a financial investment, and it prevents the facility from billing Medicare for those referred services, absent a specific exception.[3] 42 U.S.C. § 1395nn(a).

The law, both as enacted in 1989 and as amended by Section 6001, does not affect self-referrals by physician-owners for patients whose care is paid entirely by private insurance. It also does not restrict hospitals from billing Medicare for services provided to patients who were not referred by physician-owners. Instead, it applies only to claims for Medicare payment for services rendered pursuant to a physician-owner's self-referral.

[3] As originally enacted in 1989, the law covered Medicare payments for referrals for clinical laboratory services. In 1993, the law was expanded to cover a broad array of "designated health services." Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 596, § 13562 (1993). It was also expanded to apply to Medicaid. *Id.* at § 13624 (codified at 42 U.S.C. § 1396b(s)). Additionally, an entity that knowingly presents or causes to be presented a prohibited self-referred claim is subject to civil monetary penalties and liability under the False Claims Act, 42 U.S.C. § 1395nn(g); 31 U.S.C. §§ 3729-3733, and criminal penalties under the "anti-kickback statute," 42 U.S.C. § 1320a-7b(b).

The Stark Law also provides several exceptions to the ban on payment for a physician-owner's self-referred services. The most notable exception, and the one implicated here, is the "whole hospital" exception, which permits Medicare payment for self-referred hospital services when the physician-owner who made the referral has an interest in the entire hospital, rather than merely a subdivision thereof. *See* 42 U.S.C. § 1395nn(d)(3). As it noted in passing the ACA, Congress enacted this exception based on two then-existing market conditions: first, physician-owned hospitals were primarily rural facilities, where "[o]wnership in a whole hospital was not then viewed as a significant incentive for self-referral because these hospitals were usually the only hospitals in the area and they provided a breadth of services," H.R. Rep. No. 111-443, pt. 1, at 355 (2010); second, Congress did not believe that the same financial conflict of interest was present when a physician invested in a large facility providing a range of services because the physician would likely receive only a marginal benefit from his or her own referrals. *Id.*; U.S. General Accounting Office ("GAO"), GAO-03-683R, *Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served* ("GAO, *Specialty Hospitals: National Market Share*"), at 2 (2003). Nonetheless, Congress imposed an additional measure of protection – it expressly prohibited payment for self-referrals where the physician had an ownership interests only in a particular subdivision of the hospital, such as a cardiac or orthopedic department. 42 U.S.C. § 1395nn(d)(3)(C).

B. An Uncertain Regulatory Market: As the Number of Physician-Owned Hospitals Increases, Congress Continues to Question Self-Referral, Particularly as it Applies Under the "Whole Hospital" Exception

The American health care landscape has long included specialty hospitals that predominantly provide particular types of care or serve particular types of patient, although those hospitals historically provided services focused on children's, women's, or psychiatric health

care. GAO, *Specialty Hospitals: National Market Share* at 1. Beginning in the early 1990s, following the enactment of the Stark Law and its "whole hospital" exception, that landscape began to change. The number of specialty hospitals tripled between 1990 and 2003, and those hospitals began to specialize in more profitable areas of care such as cardiac care, orthopedics, and surgery. *Id.* at 6; Medicare Payment Advisory Commission, *Physician-Owned Specialty Hospitals* 3 (2005). Physicians owned, on average, more than 50 percent of these new types of facilities. GAO, *Specialty Hospitals: National Market Share* at 4.

The increase in the number of physician-owned hospitals raised concerns about whether such hospitals were using the "whole hospital" exception to circumvent the Stark Law. H.R. Rep. 111-443, pt. 1, at 355 (2010). Public and private entities collected data from existing hospitals which demonstrated the legitimacy of these concerns. Their reports identified a number of distortions in the health care market as a result of physician-ownership in hospitals – including altered referral patterns, higher per-patient costs, reduced charity care, and inadequate emergency services at physician-owned facilities. The reports found that these distortions ultimately could culminate in, *inter alia*, (1) unnecessary procedures, (2) increased federal health care spending, (3) reduced access to a broad-range of vital health care services in full-service community hospitals, and (4) inadequate emergency care which imperils patient safety. *See infra* Part I.B.1.b (discussing study results).

To examine these concerns more fully, Congress in 2003 enacted an 18-month moratorium on physician self-referral for new and existing specialty hospitals. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, § 507 (2003) (codified as amended in 42 U.S.C. § 1395nn). Specifically, the 2003 Act prohibited Medicare and federal Medicaid payment for self-referred services at new specialty

hospitals providing surgery, cardiac care, and orthopedic services, and imposed restrictions on the expansion of existing hospitals that billed for such services to allow the Medicare Payment Advisory Commission ("MedPAC")[4] to study the impact of specialty hospitals. 117 Stat. 2296-97; 42 U.S.C. § 1395nn(d)(3)(B), (h)(7)(B). The day after the moratorium expired in June 2005, CMS imposed further restrictions by ceasing to enter into Medicare provider agreements with new specialty hospitals until February 2006. *See* CMS Memorandum, "Hospitals – Suspension of Processing New Provider Enrollment Applications (CMS-855A) for Specialty Hospitals," S&C-05-35, Medicare & Medicaid Guide (CCH) ¶ 51,296 (June 9, 2005). With the Deficit Reduction Act of 2005, Congress extended by statute the regulatory suspension on new Medicare enrollments of specialty hospitals for an additional six months and directed CMS to develop a strategic plan concerning specialty hospitals. Pub. L. No. 109-171, 120 Stat. 4, § 5006(c) (2006).

In the wake of the statutory and regulatory moratoria and restrictions, MedPAC and CMS undertook substantial investigations of specialty hospitals. Among MedPAC's findings was that physician-owned specialty hospitals treated "less severe cases (and hence [cases] expected to be relatively more profitable than the average)" and fewer Medicaid patients than community hospitals. MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* vii (2005). It also concluded that the average per-patient cost of providing inpatient care was twenty percent higher at physician-owned orthopedic and surgical hospitals than community hospitals, despite the fact that patients had shorter stays in the physician-owned hospitals. MedPAC, *Physician-Owned Specialty Hospitals Revisited*, at vi–vii (2006). CMS found that "Medicare referrals to physician-owned hospitals came primarily from physician owners," with between forty-eight and

[4] MedPAC "is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program." http://www.medpac.gov/about.cfm.

ninety percent of all referrals to the hospital coming from physician-owners. HHS, *Study of Physician-owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* at ii (2005). CMS also confirmed that physician-owned specialty hospitals treat fewer Medicaid patients and provide less charity care than community hospitals. HHS, *Final Report to the Congress and Strategic and Implementing Plan Required under Section 5006 of the Deficit Reduction Act of 2005*, at vi (2006).

Following the publication of these studies, Congress continued to debate and pass legislation to enhance Medicare and Medicaid's longstanding restrictions on physician-owner self-referrals. In August 2007, the House of Representatives passed the Children's Health and Medicare Protection Act, H.R. 3162, § 651, 110th Cong. (1st Sess. 2007), which would have eliminated the "whole hospital" exception, barring new physician-owned hospitals from billing Medicare for self-referred services, and allowing existing hospitals to do so only if they complied with new restrictions on their size and extent of physician ownership. Both the House and the Senate passed similar provisions in 2008 and 2009. *See* Paul Wellstone Mental Health and Addiction Equity Act, H.R. 1424, § 106, 110th Cong. (2nd Sess. 2008) (passed by U.S. House on Mar. 5, 2008); S. Amdt. 4803 to H.R. 2642, § 6002, 110th Cong. (2d Sess. 2008) (passed by U.S. Senate on May 22, 2008); Children's Health Insurance Program Reauthorization Act of 2009, H.R. 2, § 623, 111th Cong. (1st Sess. 2009) (passed by U.S. House on Jan. 14, 2009); Affordable Health Care for America Act, H.R. 3962, § 1156, 111th Cong. (1st Sess. 2009) (passed by U.S. House on Nov. 7, 2009).

C. Section 6001 of the Patient Protection and Affordable Care Act of 2010: Congress Acts on Concerns About Overutilization, Cherry-Picking, and Inadequate Emergency Care at Physician-Owned Hospitals

Years of studies, statutory and regulatory moratoria, and legislative proposals culminated in the amendment of the Medicare statute by the enactment of Section 6001 of the Patient Protection and Affordable Care Act ("ACA").[5] Congress explained that physician-owned hospitals had undermined the Stark Law's "whole hospital" exception by taking "a 'subdivision of a hospital' and [making] it a free-standing hospital in order to circumvent the prohibition in the [Medicare/Medicaid] physician self-referral laws." H.R. Rep. 111-443, pt. 1, at 355 (2010). Congress noted studies finding that physician self-referral led to increased utilization rates, and that physician-owned hospitals "result in unnecessary procedures, increasing health care spending." *Id.* at 356. Congress also acknowledged MedPAC's determination "that these facilities focus on patients with private insurance, low-severity cases, and perform many outpatient services . . . where they get reimbursed at a higher rate than would an ambulatory surgical center which can also safely perform these services," and echoed concerns about the ability of physician-owned hospitals to provide adequate emergency care. *Id.*

Accordingly, Congress enacted Section 6001 to limit the growth in Medicare and Medicaid on payment for physician-owner self-referrals. The provision permits existing physician-owned hospitals to continue to avail themselves of the "whole hospital" exception, if they satisfy certain criteria, including requirements that the hospitals disclose physicians' ownership interests to patients and CMS, and restrictions to ensure that physicians make bona

[5] Section 6001 of the ACA was amended by Section 10601 of the ACA, Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), and then further amended by Section 1106 of the Health Care and Education Reconciliation Act, Pub. L. No. 111-152, 124 Stat. 1029 (Mar. 30, 2010). For simplicity, Defendant refers to all the amendments to 42 U.S.C. § 1395nn collectively as "Section 6001."

fide investments not conditioned on referrals or generating business. 42 U.S.C. § 1395nn(i)(1)(C), (D). Section 6001 restricts federal Medicare and Medicaid payment for self-referred services, however, by limiting the "whole hospital" exception to hospitals that are Medicare-certified by December 31, 2010, *see id.* § 1395nn(i)(1)(A), and preventing existing Medicare-certified hospitals that choose to expand the size of their facilities after the statute's enactment from seeking payment for self-referred services, *see id.* § 1395nn(i)(1)(B). Congress did, however, allow hospitals to apply to the Secretary for an exception that would permit continued payment for self-referred services even after expansion. *See id.* § 1395nn(i)(3). If a hospital expands after March 23, 2010, but does not satisfy the established criteria, it may continue to bill private insurers as it did previously, and it may still participate in the Medicare and Medicaid programs. However, it may no longer bill or obtain payment from Medicare or Medicaid for services provided as a result of physician-owner self-referrals. If the hospital decides to expand after the Secretary has promulgated the exceptions process, and the hospital receives an exception, it may continue to bill Medicare for self-referred services.

Standard of Review

The Secretary moves to dismiss the complaint pursuant to Rule 12(b)(1) for lack of subject matter jurisdiction. Plaintiffs have the burden of showing subject matter jurisdiction, and this Court must determine whether it has subject matter jurisdiction before addressing the merits of the complaint. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95, 104 (1998).

The Secretary also moves to dismiss pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted. Under this rule, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not

suffice." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). If Plaintiffs fail to state a claim under the governing law, the Court must dismiss the complaint "without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailing one." *Neitzke v. Williams*, 490 U.S. 319, 327 (1989).[6]

Argument

Plaintiffs cannot succeed on any of the claims in their complaint. To begin with, Plaintiffs failed to present their claims to the Secretary. Presentment and exhaustion of statutorily-mandated administrative remedies is a prerequisite to this Court's jurisdiction over this case. But even if the Court had jurisdiction, settled law gives hospitals no right to demand participation in Medicare and Medicaid on the terms of their choosing. Plaintiffs participate in those programs voluntarily, and on the terms established by Congress, with full knowledge that Congress may at any time modify payment requirements and conditions. Plaintiffs must show that Congress had no rational basis to amend the Medicare Act to adjust prospectively the restrictions on Medicare payment for services resulting from referrals to hospitals in which

[6] The Fifth Circuit has made clear that "a facial challenge to the constitutionality of a statute presents a pure question of law." *Ctr. for Individual Freedom v. Carmouche*, 449 F.3d 655, 662 (5th Cir. 2006). *See also Gable v. Patton*, 142 F.3d 940, 944 (6th Cir. 1998) ("Because the four provisions are challenged with regard to facial constitutionality, thus implicating only issues of law, neither Plaintiff nor Defendants contest the appropriateness of summary judgment."); *Gen. Offshore Corp. v. Farrelly*, 743 F. Supp. 1177, 1188 (D.V.I. 1990) ("By definition, a facial challenge is made in a factual vacuum; the court's job is merely to determine whether the statute, however applied, is constitutional."). Furthermore, as Plaintiffs themselves recognize, a facial constitutional challenge to Section 6001 is governed by rational basis review. *See, e.g.*, *Heller v. Doe*, 509 U.S. 312, 319-20 (1993); *Energy Mgmt. Corp. v. City of Shreveport*, 467 F.3d 471, 481 (5th Cir. 2006); *see, e.g.*, Compl. ¶¶ 47, 54, 57; Pls.' Prelim. Inj. Mot. 3, 6, 9. The Supreme Court has made it abundantly clear that a legislative choice subject to the rational basis test "is not subject to courtroom fact-finding and may be based on rational speculation unsupported by evidence or empirical data," *FCC v. Beach Commc'ns*, 508 U.S. 307, 315 (1993), and that the Government, therefore, has "no obligation to produce evidence to sustain the rationality of a statutory classification," *Heller*, 509 U.S. at 320. Accordingly, there are no issues of fact to be decided, and no need for a trial, in order for the Court to determine whether Congress had a rational basis for enacting Section 6001.

physicians have financial interests. Plaintiffs cannot come close to making such a showing. Congress could, if it chose to, prohibit all Medicare and Medicaid payment for self-referred claims based on its longstanding and clearly articulated concerns, which are more than amply supported by governmental and academic studies, as well as common sense. The lesser restrictions encompassed in Section 6001 clearly pass constitutional muster.

I. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS

It is axiomatic that, because courts are "created by statute, they have no jurisdiction absent jurisdiction conferred by statute." *Peoples Nat'l Bank v. Office of Comptroller of Currency of U.S.*, 362 F.3d 333, 336 (5th Cir. 2004); *see also Steel Co.*, 523 U.S. at 94 ("Without jurisdiction the court cannot proceed at all in any cause."). Plaintiffs' complaint cites to 28 U.S.C. § 1331 and § 1343 as the statutory bases for jurisdiction. *See* Compl. ¶ 4. Neither supplies jurisdiction in this case. First, the Fifth Circuit "has long recognized that suits against the United States brought under" 28 U.S.C. § 1343 "are barred by sovereign immunity." *Allied Prof. Home Health Care Agency v. Shalala*, 164 F.3d 282, 286 (5th Cir. 1999). Second, as explained below, jurisdiction is unavailable under § 1331 because Plaintiffs' claims arise under the Medicare Act and that Act is the only potential source of jurisdiction in this Court. *See Shalala v. Ill. Council on Long Term Care, Inc.,* 529 U.S. 1, 24 (2000). This Court lacks jurisdiction under the Medicare Act because Plaintiffs have not exhausted their administrative remedies. Because jurisdiction does not clearly exist, preliminary as well as all other relief should be denied. *See Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008).

A. The Medicare Act Requires That Providers Exhaust Administrative Remedies Prior to Seeking Judicial Review

"The Medicare Act limits the jurisdiction of federal courts to review claims brought under the Act by requiring that 'virtually all legal attacks' be brought through the agency." *Nat'l Athletic Trainers Ass'n v. U.S. Dep't of Health and Human Servs.*, 455 F.3d 500, 503 (5th Cir. 2006). Section 405(h) of the Social Security Act, made applicable to the Medicare Act by 42 U.S.C. § 1395ii, states:

> No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], 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 [i.e., the Medicare Act].

42 U.S.C. § 405(h). Judicial review of Plaintiffs' claims, therefore, is limited to the review provided under Section 405, which requires the existence of a final decision of the Secretary of HHS after the exhaustion of administrative remedies. 42 U.S.C. § 405(g). *Ill. Council,* 529 U.S. at 24 (holding that provider's challenge to Medicare regulation may not be brought under § 1331); *Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (observing that "[j]udicial review of claims arising under the Medicare Act is available only after the Secretary renders a 'final decision'"); *Your Home Visiting Nurse Servs. v. Shalala*, 525 U.S. 449, 456 (1999) ("[J]udicial review under the federal-question statute, 28 U.S.C. § 1331, is precluded by 42 U.S.C. § 405(h).").

The "claim arising under" language of Section 405(h) has been broadly construed by the Supreme Court to "include any claims in which 'both the standing and the substantive basis for the presentation' of the claims" is the Medicare Act. *Ringer*, 466 U.S. at 615 (quoting *Weinberger v. Salfi*, 422 U.S. 749, 760-61 (1975)). The Supreme Court has held that the bar on federal question jurisdiction contained in the Medicare statute "plainly" applies "irrespective of whether the [plaintiff] challenges the agency's [decision] on evidentiary, rule-related, statutory,

constitutional, or other legal grounds." *Ill. Council*, 529 U.S. at 10 (challenge to regulations); *Salfi*, 422 U.S. at 760-61 (challenge to constitutionality of statute). The Court has also made clear that, if administrative processes are available under the Medicare Act, they must be followed "even if they are time-consuming . . . and even if the agency cannot grant the relief sought." *Ill. Council*, 529 U.S. at 20, 22-23; *see also Salfi*, 422 U.S. at 760-61 (constitutional claims must still be exhausted).

In this case, there can be no dispute that Plaintiffs' claims "aris[e] under" the Medicare Act. By challenging the narrowed scope of the "whole hospital" exception regarding billing of and payment by Medicare for self-referred services, Plaintiffs' claims are ultimately claims for entitlement to Medicare payment. Because such claims arise under the Medicare Act, this Court lacks jurisdiction unless and until Plaintiffs have satisfied Medicare's exhaustion requirement, which "consists of a nonwaivable requirement that a 'claim for benefits shall have been presented to the Secretary,'" and "a waivable requirement that the administrative remedies prescribed by the Secretary be pursued fully by the claimant." *Ringer*, 466 U.S. at 617 (quoting *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)). Presentment is an "absolute prerequisite," and exhaustion is a "prerequisite that may be excused only under rather limited conditions." *Id.*

B. Plaintiffs Have Not Presented Their Claim to the Secretary, Much Less Exhausted the Available Administrative Remedies

It is clear here that the Medicare Act provides Plaintiffs with an administrative process that they have failed to exhaust. Once a hospital files a claim for a service provided to a particular patient, a Medicare contractor processes the claim and issues a notice of "initial determination" addressing whether the services are covered, and, if so, the amount Medicare pays for such services. 42 U.S.C. § 1395ff(a)(1); 42 C.F.R. § 405.920. If the claim is denied, the hospital may appeal the initial determination pursuant to the administrative review procedure

outlined in 42 C.F.R. Pt. 405, Subpart I. Once these procedures are complied with and the agency issues a final determination, the hospital may then bring an action in district court. 42 U.S.C. § 1395ff(b)(1)-(2). To the extent Plaintiffs believe Section 6001 imposes unlawful restrictions, they may submit a claim for services performed pursuant to a self-referral inconsistent with the statute, identify that the claimant challenges the constitutionality of Section 6001, and seek judicial review if that claim is denied.

Exhaustion generally is required even though administrative remedies may not, standing alone, afford a means of redress for constitutional claims, or for claims that challenge the validity of a statute or agency regulation. *See Ill. Council*, 529 U.S. at 23; *Ringer*, 466 U.S. at 622. In cases involving a facial challenge to the validity of a regulation or statutory provision, where the agency will necessarily lack authority to decide the question of law or regulation at issue, the provider may request expedited judicial review. 42 U.S.C. § 1395ff(b)(2); 42 C.F.R. § 405.990. But a claimant must still present and exhaust administrative remedies before bringing such a facial challenge. *See Salfi*, 422 U.S. at 760-61 (constitutional claims must still be exhausted); *Colo. Heart Inst. v. Johnson*, 609 F. Supp. 2d 30, 36 (D.D.C. 2009) (requiring exhaustion before facial challenge to Medicare regulation implementing the Stark Law).

It is undisputed that Plaintiffs have not exhausted their administrative remedies. Here, there has not even been presentment of a disputed claim to the Secretary – a non-waivable requirement. *Ill. Council*, 529 U.S. at 15; *Ringer*, 466 U.S. at 617, Nor could there have been because Plaintiff Texas Spine and Joint Hospital ("TSJH") has alleged only that it *may* at some point become ineligible for the "whole hospital" exception *if* it expands without receiving authorization from the Secretary. Only after this happens will Plaintiffs be able to present a claim for payment, and then, after the exhaustion of (expedited) administrative remedies, 42

U.S.C. § 1395ff(b)(2), will they be entitled to bring a suit in federal court challenging the statute. Plaintiffs cannot evade these carefully delineated Congressional requirements by filing suit alleging federal question jurisdiction.[7]

For all these reasons, the Court lacks subject matter jurisdiction over Plaintiffs' claims.

II. PLAINTIFFS' CONSTITUTIONAL CHALLENGES LACK MERIT

Even if, contrary to the controlling Supreme Court and Fifth Circuit precedent discussed above, the Court determines that it may review this case despite Plaintiffs' failure to comply with statutorily mandated procedures, Plaintiffs still cannot succeed on any of their constitutional challenges to Section 6001. "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid," *United States v. Salerno*, 481 U.S. 739, 745, (1987), and Plaintiffs cannot come close to meeting that burden.

[7] Because presentment is non-waivable, this Court need not reach the question of whether full exhaustion is required. But even if the Court somehow were to find that Plaintiffs had fulfilled the presentment requirement, there would not be sufficient basis to waive full exhaustion here. While exhaustion may be waived in "special cases," Plaintiffs must show that (1) exhaustion would be futile, (2) their claim is collateral to a substantive claim of entitlement to benefits, and (3) they would suffer irreparably injury absent immediate judicial review. *See, e.g.*, *Mathews*, 424 U.S. at 330-32 & n.11; *Ill. Council*, 529 U.S. at 24. Far from being "collateral" to a claim for benefits, the challenge Plaintiffs raise is precisely that the statute would result in the denial of payment by Medicare for services. Further, a demand for money does not constitute an irreparable injury. *See Sampson v. Murray*, 415 U.S. 61, 90-91 (1974). The cost and delay involved in pursuing administrative remedies are neither an irreparable injury nor an independent basis for waiver of exhaustion. *See Atl. Urological Assocs., P.A. v. Leavitt*, 549 F. Supp. 2d 20, 31-32 (D.D.C. 2008) (exhaustion not waived by cost and delay that "will not terminate the Plaintiffs' participation in Medicare"). Finally, providers are not excused from exhausting claims they know are barred by the statute because, as the Fifth Circuit has recognized, the administrative process allows them to claim reimbursement with a disclosure that the claim is for statutorily-excluded services. *Nat'l Athletic Trainers Ass'n*, 455 F.3d at 505-07 (finding that such procedures protect claimants from sanctions for knowingly submitting false claims).

A. Plaintiffs' Due Process Claim Is Baseless

For over two decades, the Stark Law has limited Medicare payment for services furnished pursuant to physician-owner self-referrals, out of a concern that the financial incentives inherent in such a practice overburden the programs and jeopardize patient safety. Through Section 6001, Congress amended Stark's "whole hospital" exception, and its decision easily withstands rational basis review. Plaintiffs have no entitlement to participate in Medicare or Medicaid absent compliance with the terms set by Congress and the Secretary, *Bowen v. Pub. Agencies Opposed to Soc. Sec. Entrapment*, 477 U.S. 41, 52 (1986); *Flemming v. Nestor*, 363 U.S. 603, 611 (1960), and Congress has great latitude in establishing conditions for the expenditures of funds. Plaintiffs' due process claims are without merit.

1. Plaintiffs Cannot Require or Reasonably Expect that Medicare Program Requirements Will Never Change, or That They Will Change Only in a Manner That Accommodates Plaintiffs' Pecuniary Interests

In *Flemming v. Nestor*, the Supreme Court rejected the notion that Congress' amendment of the eligibility criteria for Social Security benefits violated due process. 363 U.S. at 611. Just as the court found with respect to Social Security benefits, "[t]o engraft upon the [Medicare] system a concept of 'accrued property rights' would deprive it of the flexibility and boldness in adjustment to everchanging conditions which it demands." *Id.* at 610. It was in order to preserve that flexibility that Congress expressly reserved the right in 42 U.S.C. § 1305 to amend or repeal all provisions of the Medicare Act – including 42 U.S.C. § 1395nn. *See id.* at 611. As the Supreme Court made clear in *Public Agencies Opposed to Social Security Entrapment*, "[i]n view of the purpose and structure of the [Social Security] Act, and of Congress' express reservation of authority to alter its provisions, courts should be extremely reluctant to construe [existing program terms] in a manner that forecloses Congress' exercise of that authority." 477

U.S. at 52 (holding that Congress reserved the right to amend a state's agreement with the federal government regarding Social Security benefits for state employees).

The only legitimate expectation Plaintiffs have in their continued participation in Medicare and Medicaid is that they be permitted to do so on the terms set by Congress. Because participation is voluntary, a provider has no constitutionally protected interest in reimbursement in any manner other than that provided by the Medicare Act. *See Smith v. N. La. Med. Rev. Ass'n*, 735 F.2d 168, 172 (5th Cir. 1984); *see also Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) (statute freezing fees physicians could bill to Medicare patients did not violate due process, as physicians are not required to participate in Medicare); *Greater Dallas Home Care Alliance v. United States*, 10 F. Supp. 2d 638, 641, 646 (N.D. Tex. 1998) (upholding a law requiring providers to return overpayments received for services provided prior to the law's enactment, and rejecting contention that the law constitutes retroactive deprivation, because a provider's property interest in Medicare payments is limited to the level of benefits provided by Congress); *see also S.D. v. Hood*, 391 F.3d 581, 586 (5th Cir. 2004) (recognizing that states that voluntarily choose to participate in Medicaid do so subject to federal requirements as to their participation).

It is also clear here that Plaintiffs had no reasonable expectation that Congress and CMS would never change the requirements for Medicare and Medicaid payment by imposing further restrictions on payment for services resulting from physician self-referrals. To the contrary, Congress enacted the Stark Law in 1989, expanded its coverage in 1993, and imposed an 18-month moratorium in 2003 on Medicare and Medicaid payment for self-referred services in new or expanded specialty hospitals. CMS then enacted its own regulatory moratorium on Medicare payment for self-referred services performed at new hospitals in June 2005. On August 1, 2007

– months before Plaintiff TSJH contends it purchased land for its expansion project – the House of Representatives passed a bill that would have eliminated the "whole hospital" exception for new physician-owned hospitals and imposed limitations on the growth of existing physician-owned hospitals. Children's Health and Medicare Protection Act, H.R. 3162, § 651, 110th Cong. The House and the Senate passed similar measures in March 2008, May 2008, January 2009, and November 2009, before ultimately enacting Section 6001. For Plaintiffs to claim that TSJH's purchase and development of land in 2008 and 2009 was taken against the backdrop of "no law restricting or discouraging the expansion of investor-backed health facilities," Pls.' Prelim. Inj. Mot. 5, is disingenuous at best. While Plaintiffs are free to expand their hospitals or open new hospitals as they see fit, neither they nor this Court may dictate to Congress the terms for continued voluntary participation in and payment by Medicare and Medicaid.

Furthermore, Plaintiffs are incorrect in their contention that Section 6001 has impermissible retroactive effects because it inflicts "retroactive financial deprivation" on physician-owners who have "lawfully and responsibly committed significant funds to acquire, build, or expand upon a hospital." Compl. ¶ 54. Section 6001 applies only to services provided after the ACA's enactment. Furthermore, "'[i]t is often the case that a business will undertake a certain course of conduct based on the current law, and will then find its expectations frustrated when the law changes.' Such expectations, however legitimate, cannot furnish a sufficient basis for identifying impermissibly retroactive rules."[8] *Nat'l Cable & Telecomm. Ass'n v. F.C.C.*, 567

[8] Although Section 6001 has no retroactive application, Defendant notes that Plaintiffs' statement of the law on retroactivity is also incorrect. Due process does not require the government to "avoid retroactive action and give maximum respect to investor-backed expectations." Pls.' Prelim. Inj. Mot. 5. Instead, "retroactive aspects of legislation" satisfy due process if "a rational legislative purpose" justifies the retroactivity, *United States v. Sperry Corp.*, 493 U.S. 52, 64 (1989), and "legislation readjusting rights and burdens is not unlawful solely because it upsets otherwise settled expectations," even in cases where, unlike the present

F.3d 659, 670 (D.C. Cir. 2009) (quoting *Chem. Waste Mgmt. v. EPA*, 869 F.2d 1526, 1536 (D.C. Cir. 1989)).

2. Congress' Restrictions on Medicare Payment for Physician-Owner Self-Referred Services Are Supported by a Rational Basis

Plaintiffs also cannot satisfy their extremely heavy burden of showing that Section 6001 violates due process because of an improper purpose. "[L]egislative Acts adjusting the burdens and benefits of economic life come to the Court with a presumption of constitutionality," and in order to show a due process violation, Plaintiffs must "establish that the legislature has acted in an arbitrary and irrational way." *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976). Thus, the relevant inquiry "is only whether a rational relationship exists between [Section 6001] and a *conceivable* legitimate objective. If the question is at least debatable, there is no substantive due process violation." *Energy Mgmt. Corp. v. City of Shreveport*, 467 F.3d 471, 481 (5th Cir. 2006) (internal quotation omitted and emphasis added). While the Government has "no obligation to produce evidence to sustain the rationality of a statutory classification," *Heller v. Doe*, 509 U.S. 312, 320 (1993), "those challenging the legislative judgment must convince the court that the legislative facts on which the classification is apparently based could not reasonably be conceived to be true by the governmental decisionmaker," *Vance v. Bradley*, 440 U.S. 93, 111 (1979). "Only by faithful adherence to this guiding principle of judicial review," the Supreme Court has cautioned, "is it possible to preserve to the legislative branch its rightful independence and its ability to function." *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 365 (1973). Plaintiffs' attack on Section 6001 flies in the face of a long legacy of Supreme

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one, "the effect of the legislation is to impose a new duty or liability based on past acts." *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 16 (1976) (collecting cases). The cases Plaintiffs cite in their preliminary injunction motion analyze takings claims, rather than due process claims.

Court precedent recognizing the courts' limited role in reviewing the reasonableness of Congress' legislative judgment.

Furthermore, "[i]t is, of course, constitutionally irrelevant whether" an identified basis for the law "in fact underlay the legislative decision, because this Court has never insisted that a legislative body articulate its reasons for enacting a statute." *U.S.R.R. Ret. Bd. v. Fritz*, 449 U.S. 166, 179 (1980). *See, e.g.*, *Williamson v. Lee Optical*, 348 U.S. 483, 488 (1955) (sustaining statute based on hypothetical objectives the legislature "might" rationally have pursued). Under this "deferential standard" of review, there is "no need for mathematical precision in the fit between justification and means." *Concrete Pipe & Prods. v. Constr. Laborers Pension Trust*, 508 U.S. 602, 639 (1993); *see also United States v. Comstock*, 130 S. Ct. 1949, 1957 (2010) ("'If it can be seen that the means adopted are really calculated to attain the end, the degree of their necessity, the extent to which they conduce to the end, the closeness of the relationship between the means adopted and the end to be attained, are matters for congressional determination alone.'") (quoting *Burroughs v. United States*, 290 U.S. 534, 547-48 (1934)). Section 6001 easily surpasses this test.

For this Court to invalidate the statute, Plaintiffs must establish that Congress could not rationally have believed that Section 6001 serves to advance any legitimate government objectives. Plaintiffs cannot do so. There is no serious question that Section 6001 is rationally related to the protection of public health and controlling health care costs, each of which has been recognized as a legitimate government objective by the Fifth Circuit. *E.g.*, *Women's Med. Ctr. v. Bell*, 248 F.3d 411, 419 (5th Cir. 2001) (recognizing "protecting the health of Texas women" as a legitimate government purpose); *Montagino v. Canale*, 792 F.2d 554, 557 (5th Cir. 1986) (time limit on medical malpractice claims was justified by legitimate interest in reducing

malpractice claims and insurance rates, "resulting in health care being more accessible to patients at reasonable costs").

For more than two decades, the Stark Law has limited the terms under which Medicare will allow payment for services generated by physician-owner self-referrals. As another court has recognized, the long-standing restrictions on physician-owned hospitals were first enacted in 1989, not to confer competitive advantage upon competitor hospitals, but rather "to address the strain placed on the Medicare Trust fund by the overutilization of certain medical services by physicians who, for their own financial gain rather than their patients' medical need, referred patients to entities in which the physicians held a financial interest." *Am. Lithotripsy Soc'y v. Thompson*, 215 F. Supp. 2d 23, 26 (D.D.C. 2002).

The Stark Law is a plainly rational attempt to address the legitimate objective of limiting overutilization of medical services, which poses a threat to patient health because of unnecessary procedures and imposes undue expense to Medicare and Medicaid. Notably, in the 21 years of Stark's existence, no court has held otherwise. Section 6001 merely limits Stark's "whole hospital" exception to account for post-Stark developments in physician ownership of hospitals, and their implications for patients and the Medicare program.[9] The number of physician-owned hospitals grew rapidly in the 1990s and 2000s, following the enactment of Stark. *See* Compl. ¶

[9] In their attempt to call into question the basis for the law, Plaintiffs frequently misstate the scope of the new law, contending that Section 6001 prohibits physicians and their families "from owning a legal and necessary business . . . that anyone else in Smith County or the country can own." Compl. ¶ 13; *see also* Pls.' Prelim. Inj. Mot. 4 (contending that Section 6001 "disallows the expansion of existing Medicare-certified physician-owned facilities"). Section 6001 does no such thing. The law places no additional restrictions on physicians', or their families', ability to purchase an interest in any hospital or to develop a new hospital. It also does not restrict physician-owned hospitals with a Medicare provider agreement from billing Medicare or Medicaid for services referred by non-owner physicians, or from billing third-party payors (*e.g.*, private insurers) for any services. It merely narrows the Stark Law's previous exception by placing additional limits on Medicare (rather than private) payment for physician-owner self-referred hospital services.

15; GAO, *Specialty Hospitals: National Market Share* at 6. Congress recognized that the growth of such hospitals, which tend to be specialty hospitals, undermined the Stark Law's "whole hospital" exception, given that specialty hospitals are more similar to a subdivision of a hospital (as to which payment for physician-owner self-referrals was already banned) than an entire hospital. H.R. Rep. 111-443, pt. 1, at 355 (2010). Studies and reports conducted in the years leading up to enactment of Section 6001 demonstrate that physician-ownership continued to raise concerns about increased utilization of services, increased health care expenditures, detrimental impacts on non-physician-owned hospitals, and inadequate emergency care.

First, it was more than reasonable for Congress to believe that a physician-owner's financial interest in a facility creates an incentive to steer patients to and recommend procedures at the facility. Studies and reports of numerous governmental agencies, independent organizations, and private researchers provide direct evidence that such incentives can lead to increased utilization of health care procedures and services that are not always in the patients' best interests, as well as a resulting increase in health care expenditures.[10] For example, in a 2005 report, MedPAC stated that "the incentive for a group of physician-investors to increase admissions can be substantially larger than specialty hospital advocates suggest." MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* 20 (2005). In enacting Section 6001, Congress expressly noted its concerns about the effects of financial incentives on referral patterns and the utilization of health services, *see* H.R. Rep. 111-443, pt. 1, at 355 (2010), and cited to MedPAC's report, which found that "[p]hysician-owned heart hospitals were associated

[10] While the rationale underlying Section 6001 is amply supported by the extensive studies discussed herein, even if that were not the case, a statute does not need an extensive factual record to be upheld by this Court because "a legislative choice is not subject to courtroom fact-finding and may be based on rational speculation *unsupported by evidence or empirical data*." *Beach Commc'ns*, 508 U.S. at 315 (emphasis added).

with a statistically significant increase in the rate of cardiac surgeries in the market area," MedPAC, *Physician-Owned Specialty Hospitals Revisited*, at v–vii (2006).

Research by independent experts reinforced these findings about increased utilization: "after physicians established ownership interest in a specialty spine/orthopedic hospital, the frequency of use of surgical, diagnostic, and ancillary services used in the treatment of injured workers with back/spine disorders increased significantly." Jean M. Mitchell, *Do Financial Incentives Linked to Ownership of Specialty Hospitals Affect Physicians' Practice Patterns?*, 47 Med. Care 732, 736 (2008). Similar studies found that the opening of physician-owned cardiac hospitals was also associated with disproportionate increases in utilization rates. Brahmajee K. Nallamothu et al., *Opening of Specialty Cardiac Hospitals and Use of Coronary Revascularization in Medicare Beneficiaries*, 297 J. Am. Med. Ass'n 962, 962 (2007). These concerns about increased utilization rates are further supported by extensive Congressional testimony and additional outside studies. *See, e.g.*, *Physician-Owned Specialty Hospitals: Profits Before Patients?: Hearing before the S. Comm. on Finance*, S. Hrg. 109-905, 109th Cong. 2, 183 (2006); *Physician-Owned Specialty Hospitals*: *Hearing Before the H. Comm. on Ways and Means*, Serial No. 109-37, 109th Cong. 15, 24 (2005); Lawrence P. Casalino, *Physician Self-Referral and Physician-Owned Specialty Facilities*, Res. Synthesis Rep. No. 15 (June 2008), at 12; Jean M. Mitchell, *Utilization Changes Following Market Entry by Physician-owned Specialty Hospitals*, 64 Med. Care Res. & Rev. 395, 401-13 (2007).

Second, Congress determined that the growth of physician-owned specialty hospitals increased health care expenditures associated with the Medicare and Medicaid programs. MedPAC reported that increased utilization leads to increased expenditures; for diagnoses with "high marginal profits, financial incentives to increase utilization can exceed $1,000 per [patient]

admission."[11] MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* 21 (2005); *see also* Casalino, *Physician Self-Referral and Physician-Owned Specialty Facilities* at 12. The increased utilization associated with physician-ownership has especially significant effects on spending due to the fact that physician-owned hospitals provide many procedures that could otherwise be provided by ambulatory surgical centers ("ASCs"), to which Medicare pays lower rates for the services provided. H.R. Rep. 111-443, pt. 1, at 355 (2010); Letter from Peter R. Orszag, Director, Congressional Budget Office, to Sen. Jon Kyl (Dec. 19, 2007). Indeed, the Congressional Budget Office determined that the adjusted restrictions in Section 6001 would result in a net savings of $500 million over a ten-year period. Letter from Douglas W. Elmendorf, Director, Congressional Budget Office, to Nancy Pelosi, Speaker, U.S. House of Representatives, at Table 5 (Mar. 20, 2010) ("CBO Letter").

Third, numerous government reports and academic studies have found that physician-owned hospitals take a smaller percentage of low-income patients and care for patients who are less sick than patients treated by general hospitals, and it was beyond reasonable for Congress to believe that the favorable patient mix at physician-owned hospitals renders other, non-physician-owned hospitals less able to provide a wide-range of less profitable services, such as emergency services and uncompensated or charity care. MedPAC found that physician-owned hospitals

[11] Not only are physician-owned hospitals associated with increased costs due to increased utilization of health services, but some of these hospitals have higher per-patient costs than community hospitals for the same procedures. Data indicate that "both the aggregate mean and median values for costs at physician-owned specialty hospitals are higher than the corresponding values for peer, competitor, and community hospitals." MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* 14 (2005). The same MedPAC report then recounted that patients at specialty hospitals tend to have shorter stays than in community hospitals. *Id.* at 15–17. Because "shorter stays should lead to lower costs," MedPAC questioned "[t]he apparent inconsistency of these results" and indicated that physician-owned hospitals must have factors that were contributing to higher costs despite shorter patient stays. *Id.* at 16; *see also* Kathleen Carey et al., *Specialty and Full-Service Hospitals: A Comparative Cost Analysis*, 43 Health Services Research 1869, 1869 (2008).

"treat patients who are generally less severe cases (and hence expected to be relatively more profitable than the average) and concentrate on particular diagnosis-related groups (DRGs), some of which are relatively more profitable," and recognized that physician-owned hospitals treat disproportionately fewer low-income patients, including Medicaid patients, than community hospitals. MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* vii, 4 (2005); *see also* Lawrence P. Casalino, *Physician Self-Referral and Physician-Owned Specialty Facilities*, at 10, 19; Jean M. Mitchell, *Effects of Physician-Owned Limited-Service Hospitals: Evidence from Arizona*, Health Affairs Online, Oct. 25 2005, at 484-86. The General Accounting Office reported similar results, finding that "inpatient discharge data . . . showed that 21 of the 25 specialty hospitals treated lower proportions of severely ill patients than did area general hospitals." GAO, *Specialty Hospitals: National Market Share*, at 4. "[A] hospital [that] is typically paid a fixed, lump-sum amount for treating someone with a given diagnosis . . . can benefit financially by treating a disproportionate share of less ill patients" who need a less care. *Id.* at 2. Because general hospitals operating in the same communities as physician-owned hospitals have fewer profitable patients, because of both payer mix and severity, it may become more difficult for them to offset operational loses associated with high-cost areas of care, such as emergency services, which are not traditionally provided by physician-owned hospitals. Indeed, Congress heard testimony from representatives of Texas's non-physician-owned hospitals about the detrimental impact that physician-owned hospitals were having on their ability to provide care to uninsured patients and other non-profitable services. *See Physician-Owned Specialty Hospitals: Hearing Before the H. Comm. on Ways and Means*, Serial No. 109-37, 109th Cong. (2005), at 77-84 (statements of Richards A. Bettis, President/CEO, Texas Hospital Association, and D.J Calkins, Valley Hospital Board of Managers, Seguin, Texas).

Finally, in Section 6001, Congress also acted on its serious concerns about the ability of physician-owned hospitals to respond to medical emergencies. *See* H.R. Rep. 111-443, pt. 1, at 356 (2010). Those concerns are supported by Congressional testimony, *Physician-Owned Specialty Hospitals: Profits Before Patients?: Hearing before the S. Comm. on Finance*, S. Hrg. 109-905, 109th Cong. 34, 41 (2006), as well as an HHS study requested by Congress after two patients died at physician-owned hospitals following elective surgery. That study found that seven percent of physician-owned specialty hospitals failed to meet HHS requirements that the hospital have a physician on duty or on call and a registered nurse on duty at all times, and that thirty-four percent of specialty hospitals used 911 to obtain assistance necessary to stabilize a patient, also in contravention of Medicare requirements. HHS Office of Inspector Gen., *Physician-Owned Specialty Hospitals' Ability to Manage Medical Emergencies* at ii-iii (2008).

In light of these well-documented concerns about physician-owned hospitals, it is not only reasonable but logical that Congress considered and imposed numerous restrictions on them. While Plaintiffs may point to studies or reports that they contend contradict the analysis of MedPAC, the General Accounting Office, CMS, and the numerous independent experts who have expressed concerns about physician-ownership and self-referrals, Plaintiffs cannot come close to meeting their burden of showing that Congress acted irrationally. Because there is far more than a rational connection between these legitimate concerns and the limited restrictions on Medicare payment for physician-owner self-referred services, Section 6001 plainly satisfies due process. *See Energy Mgmt. Corp.*, 467 F.3d at 481 ("If the question is at least debatable, there is no substantive due process violation." (internal quotation marks omitted and emphasis added)).

Plaintiffs cannot overcome the existence of a rational basis by casting aspersions on Congress' purpose in enacting Section 6001. While Plaintiffs' complaint fails to offer any

counter to the legitimate concerns identified herein which underlie Section 6001, they instead invoke irrelevant provisions of the ACA in an attempt to create a perception of a supposed "deal" in July 2009 in which non-physician-owned hospitals allegedly made concessions in order to get new restrictions on physician-owned hospitals. Pls.' Prelim. Inj. Mot. 8. What Plaintiffs completely ignore, however, are the numerous bills passed before July 2009, by both the House and the Senate, as well as multiple moratoria imposed by Congress and CMS, that were similar to Section 6001 and limited or would have limited Medicare coverage for physician-owner self-referrals. Plaintiffs' attempts to create a false pretext for the law should be rejected outright.[12]

[12] Given that Section 6001 satisfies rational basis review for the reasons described above, Defendant will not extensively address Plaintiffs' contentions that due process prohibits laws that favor certain commercial interests over others. *See* Pls.' Prelim. Inj. Mot. 6. That said, Defendant notes that most of the cases Plaintiffs rely on do not even address due process. *See Berman v. Parker*, 348 U.S. 26, 28 (1954) (takings claim); *Energy Reserves Group, Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 411 (1983) (contract clause); *City of Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978) (commerce clause); *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 537-38 (1949) (same).

Plaintiffs' reliance on *Craigmiles v. Giles*, 312 F.3d 220, 225 (6th Cir. 2002), and *Santos v. City of Houston*, 852 F. Supp. 601, 608 (S.D. Tex. 1994), is also misplaced. Those courts could identify no legitimate government objective served by the laws at issue and therefore concluded that only economic protectionism could have motivated the legislatures. By contrast, Defendant has explained by reference to legislative history, testimony, and outside numerous studies the legitimate objectives served by Section 6001. Additionally, the courts in these two cases incorrectly focused on their views of the legislatures' subjective motives, rather than whether there was any conceivable legitimate rationale for the laws.

In any event, even if this Court somehow concludes that the only possible purpose of Section 6001 was to promote community hospitals, that would still be rational and consistent with due process. The Supreme Court has consistently recognized that protecting certain industries, "absent a specific federal constitutional or statutory violation," is a legitimate government interest. *Powers v. Harris*, 379 F.3d 1208, 1220 (10th Cir. 2004). *See, e.g.*, *Fitzgerald v. Racing Ass'n of Cent. Iowa*, 539 U.S. 103, 109 (2003) (holding that the objective of promoting intrastate riverboat gambling provided a rational basis for legislation taxing riverboat slot machines more favorably than racetrack competitors); *City of New Orleans v. Dukes*, 427 U.S. 297, 304 n.5 (1976); *Ferguson v. Skrupa*, 372 U.S. 726, 730-31 (1963).

B. Section 6001 Does Not Deny Plaintiffs Equal Protection

Plaintiffs' contention that Section 6001 denies them the equal protection of the laws because it treats physician-owned hospitals differently than non-physician-owned hospitals must fail for reasons similar to the due process analysis above. Plaintiffs concede, as they must, that their equal protection claim is also subject to rational basis review, Compl. ¶ 57; Pls.' Prelim. Inj. Mot. 10, as physician-owners are not a suspect class and their payment by or participation in Medicare and Medicaid is not a fundamental right. Therefore, Section 6001 "is accorded a strong presumption of validity" and "must be upheld against equal protection challenge if there is *any reasonably conceivable state of facts* that could provide a rational basis for the classification." *Heller*, 509 U.S. at 319-20 (internal quotation marks omitted) (emphasis added). As with due process, "equal protection [analysis] is not a license for courts to judge the wisdom, fairness, or logic of legislative choices," *Beach Commc'ns*, 508 U.S. at 313, and the government need not prove that the factual basis for the classification is correct, *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 812 (1976) ("The State is not compelled to verify logical assumptions with statistical evidence.").

The Stark Law has, since its enactment in 1989, required different treatment for Medicare billing and payment of claims resulting from physician-owner self-referrals and those claims that do not. That is, indeed, the essential purpose of Stark – to prevent potential and actual abuse resulting from the practice of self-referral. Plaintiffs do not (and could not reasonably) contend that Congress acted irrationally in imposing these restrictions. Instead, they contend only that the ACA's strengthening of Stark's restrictions (or, more precisely, narrowing of the relevant exceptions to Stark) has no rational basis because it constitutes "clear economic favoritism" of non-physician-owned over physician-owned hospitals. Pls.' Prelim. Inj. Mot. 11. But Congress'

distinction in treatment plainly survives rational basis review. As discussed above, it is conceivable – and indeed supported by Congressional testimony, government reports, outside studies, and common sense – that physicians with a financial interest in a facility are or may be more likely to refer patients to those facilities, and to order more expensive and more extensive tests and procedures to be performed at those facilities. *See supra* Part I.B.1.b. And imposing further restrictions on Medicare payment for those services is rationally related to the legitimate objectives of preventing unnecessary use of hospital services and reducing Medicare and Medicaid program costs. *See id.*; CBO Letter, at Table 5 (estimating that Section 6001 would result in a net savings of $500 million over ten years).[13]

A rational basis exists for Congress' longstanding distinction between billing and payment for Medicare services based on whether they result from referrals by physician-owners or non-physician owners, and for Congress' narrowing of the Stark Law's "whole hospital" exception in Section 6001. Plaintiffs' equal protection claim therefore must fail.

C. Plaintiffs' Takings Claim Is Unripe and Meritless

The Takings Clause "is designed not to limit the governmental interference with property rights per se, but rather to secure compensation in the event of otherwise proper interference amounting to a taking." *First English Evangelical Lutheran Church of Glendale v. Cnty. of Los Angeles*, 482 U.S. 304, 314-15 (1987). Plaintiffs allege that "physicians' investments" in hospitals "are severely diminished" by Section 6001 and "the Law does not

[13] In any event, as with due process, equal protection is not violated by the fact that legislation rationally favors one set of commercial actors over another. *See, e.g.*, *Nordlinger v. Hahn*, 505 U.S. 1, 12 (1992) ("The State . . . legitimately can decide to [favor] established, 'mom-and-pop' businesses [over] newer chain operations."); *Powers*, 379 F.3d at 1220; *Schafer v. Aspen Skiing Corp.*, 742 F.2d 580, 583 (10th Cir. 1984) (granting special benefits only to one set of commercial actors, absent a specific federal constitutional or statutory violation, does not violate equal protection.).

provide for compensation for these affected physicians," *id.* ¶ 68, apparently because Medicare will no longer pay physician-owned hospitals for services that are rendered based on their owners' referrals if the hospitals do not comply with Section 6001. This claim, however, fails for two independent reasons. First, the claim is not ripe because Plaintiffs have not sought compensation in the Court of Federal Claims under the Tucker Act, 28 U.S.C. § 1491, for any damages resulting from Section 6001. Second, even if the claim were ripe, any effects of Section 6001 would not constitute a taking as a matter of law.

1. Plaintiffs' Takings Claim Is Unripe

Though regulatory actions can result in compensable takings, *see, e.g.*, *Lingle v. Chevron U.S.A., Inc.*, 544 U.S. 528, 537-40 (2005), the government need not provide compensation in advance of or simultaneously with the taking. Instead, the government need only provide a "reasonable, certain and adequate provision for obtaining compensation." *Preseault v. Interstate Commerce Comm'n*, 494 U.S. 1, 11-12 (1990) (quotation marks omitted). Congress has, in fact, provided such a provision in this case—the Tucker Act vests the United States Court of Federal Claims with exclusive jurisdiction over claims exceeding $10,000 founded "either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the United States."[14] 28 U.S.C. § 1346(a)(2); *see also United States v. Causby*, 328 U.S. 256, 267 (1946) ("[I]f there is a taking, the claim is founded upon the Constitution and within the jurisdiction of the Court of Claims to hear and determine." (internal quotation marks omitted)). Given the existence of Tucker Act relief, "taking claims against the Federal Government are premature until the property owner has availed itself of the process

[14] Federal district courts have concurrent jurisdiction to hear cases involving damages claims under $10,000. 28 U.S.C. § 1346(a)(2). Given the nature of Plaintiffs' claims, Defendant presumes that Plaintiffs contend that more than $10,000 is at stake. *See* Compl. ¶ 3.

provided by the Tucker Act." *Williamson Cnty. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 195 (1985); *see also Paradissiotis v. Rubin*, 171 F.3d 983, 989 (5th Cir. 1999) ("[T]he Court of Federal Claims has exclusive jurisdiction for all claims for monetary relief against the United States greater than $10,000."); *Wilkerson v. United States*, 67 F.3d 112, 118 (5th Cir. 1995) (stating that the Firth Circuit has "consistently refused to allow district courts to adjudicate issues which belong solely to the Court of Claims").

Plaintiffs' takings claim is thus not ripe because they have not sought compensation in the Court of Federal Claims pursuant to the Tucker Act. Parties challenging changes to Medicare reimbursement, including parties "threatened with severe financial injury," may seek damages if in fact their claims are valid. *See Greater Dallas Home Care Alliance*, 10 F. Supp. 2d at 650. Despite this fact, Plaintiffs have neither alleged nor otherwise indicated that they have pursued a suit for damages pursuant to the Tucker Act.[15] As such, Plaintiffs are required to present their takings claim to the Court of Federal Claims.

2. Plaintiffs' Takings Claim Is Meritless

Plaintiffs' takings claim would fail even if the Court were to find it ripe for consideration because Plaintiffs have the choice of whether to participate in the Medicare program. The Fifth Circuit has held, in the context of a statute imposing requirements on Medicare providers, that "[g]overnmental regulation that affects a group's property interests 'does not constitute a taking of property where the regulated group is not required to participate in the regulated industry.'" *Burditt v. U.S. Dep't of Health and Human Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991) (quoting

[15] Nor would either of the two limited exceptions to the Tucker Act apply here. The ACA has not unambiguously withdrawn Tucker Act jurisdiction to hear a suit involving the statute that is alleged to have effected the taking. *Preseault*, 494 U.S. at 12. Additionally, Plaintiffs' claim does not involve "a direct transfer of funds mandated by the Government." *E. Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (quotation marks and citation omitted); *see also Student Loan Mktg. Ass'n v. Riley*, 104 F.3d 397, 402 (D.C. Cir. 1997).

Whitney v. Heckler, 780 F.2d 963, 972 (11th Cir. 1986)). Other courts have consistently held that statutes and regulations affecting Medicare payment rates and criteria do not constitute uncompensated takings. *See, e.g.*, *Painter v. Shalala*, 97 F.3d 1351, 1357–58 (10th Cir. 1996) (holding that a physician did not have property interest in Medicare reimbursement because he was aware of reimbursement rate and could have refused to provide services); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (holding that a statute limiting physician charges under Medicare was not a "taking" because, "where a service provider voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no taking"); *Whitney*, 780 F.2d at 972 (holding that a temporary freeze on nonparticipating physicians' fee charges to Medicare patients does not constitute a taking because the physicians "are not required to treat Medicare patients"); *Minn. Ass'n of Health Care Facilities, Inc. v. Minnesota*, 742 F.2d 442, 446 (8th Cir. 1984) (state statute limiting the fees nursing homes participating in Medicaid charge non-Medicaid patients is not a Fifth Amendment taking because "the state does not require that nursing homes admit medical assistance residents and participate in the Medicaid Program").

Even if the Court were to discount the categorical holding that a taking cannot arise out of participation in a voluntary government program, Plaintiffs cannot demonstrate a taking in this case. Courts employ several factors in determining whether a legislative scheme results in a regulatory taking, including (1) the economic impact of the regulation, "'particularly, the extent to which the regulation has interfered with distinct investment-backed expectations,'" and (2) "the 'character of the governmental action' – for instance whether it amounts to a physical invasion or instead merely affects property interests through 'some public program adjusting the benefits and burdens of economic life to promote the common good.'" *Lingle*, 544 U.S. at 538-

39 (quoting *Penn Cent. Transp. Co. v. City of N.Y.*, 438 U.S. 104, 130 (1978)). In this case, consideration of each factor shows that Section 6001 does not give rise to a takings claim.

First, Plaintiffs' claim is predicated on the loss of physicians' investments to "acquire, build, or expand upon a hospital," Compl. ¶ 68, such as TSJH's alleged expenditure of $2.1 million to acquire land, *id.* ¶ 3. To the degree that such investments were in actual property, the loss of such an investment is not cognizable as a taking so long as the property owner can maintain some use of the land. The Supreme Court has dismissed takings claims as meritless where the challenged government action merely prohibited the use of the land for a particular purpose. *See Penn Cent. Transp. Co.*, 438 U.S. at 126 (collecting cases). This was true even in a case where the challenged regulation prevented the "most beneficial use of the property" and resulted in the termination of a thirty-year-old business. *Id.* at 127; *see also Goldblatt v. Town of Hempstead, N.Y.*, 369 U.S. 590, 594 (1962) (noting the Supreme Court's holding that a regulation did not constitute a taking despite causing a decrease in land value from $800,000 to $60,000). Even if Section 6001 somehow prohibited TSJH or other physician-owned hospitals from using certain land to build or expand a physician-owned hospital – which it plainly does not – Plaintiffs cannot contend that the law prohibits all use of the land at issue; the statute does not even prohibit use of the land for hospital expansion. What the statute prohibits is further submission by physician-owned hospitals of Medicare claims for services referred by physician-owners if the hospitals expanded without obtaining an exemption from the Secretary.

Furthermore, to the degree that their claims are not based on real property, Plaintiffs cannot establish that Section 6001 interfered with reasonable investment-backed expectations. "Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end." *Concrete Pipe and Prods.*

of Cal., Inc., 508 U.S. at 645. This is particularly true in the context of Medicare, where Plaintiffs are "not required to participate in the regulated industry." *Burditt*, 934 F.2d at 1376. As discussed above, Congress has regulated physician-ownership of medical facilities for more than twenty years with regard to Medicare payment for self-referred services, and has devoted additional attention to the problems specifically associated with physician-owned hospitals since at least 2003. In such instances, a party's reliance on existing law would be misplaced where there was "no reasonable basis to expect that the legislative ceiling would never be" adjusted, *Concrete Pipe and Prods. of Cal., Inc.*, 508 U.S. at 646, and Plaintiffs could have had no reasonable "settled expectations" of Congressional inaction here. *See also Penn Cent. Transp. Co.*, 438 U.S. at 130 ("[T]he submission that [a party] may establish a 'taking' simply by showing that they have been denied the ability to exploit a property interest that they heretofore had believed was available for development is quite simply untenable.").

Second, Section 6001 is a classic example of Congressional action designed to "adjust[] the benefits and burdens of economic life to promote the common good." *Lingle*, 544 U.S. at 539 (internal citation and quotation omitted). As discussed in more detail above, it arose out of congressional concerns about the overutilization of medical services at physician-owned hospitals and whether such facilities distort the provision of health care in communities by treating fewer low-income and sick patients, as well as concerns about the quality of emergency services at physician-owned hospitals. In cases like this one, the Supreme Court has dismissed a wide variety of takings claims against new regulations "in which a state tribunal reasonably concluded that 'the health, safety, morals, or general welfare' would be promoted by prohibiting particular contemplated uses of land." *Penn Cent. Transp. Co.*, 438 U.S. at 125 (quoting *Nectow v. City of Cambridge*, 277 U.S. 183, 188 (1928)).

Plaintiffs' contentions would stretch the takings doctrine beyond all recognition, expanding it to create an uncompensated taking every time Congress prospectively changes the terms for Medicare payment simply because voluntary participants in the program have a financial interest in maintaining the existing terms. The Fifth Amendment imposes no such limitations on Congress' ability to modify the criteria for voluntary participation in government programs, and the Supreme Court has held that they do not exist. *Bowen*, 477 U.S. at 52; *Flemming*, 363 U.S. at 611. Plaintiffs' right to invest in physician-owned hospitals and to bill Medicare for self-referred (or any other) services, to the extent such a right exists, is constrained by the terms and conditions set by Congress.

D. Plaintiffs Cannot Show That Section 6001 Is Void for Vagueness

Finally, Plaintiffs contend that Section 6001 is unconstitutionally vague. "Due process prohibits laws so vague that persons 'of common intelligence must necessarily guess at [their] meaning and differ as to [their] application.'" *Okpalobi v. Foster*, 190 F.3d 337, 357 (5th Cir. 1999) (quoting *Smith v. Goguen*, 415 U.S. 566, 572 n.8 (1974)). The standard for evaluating vagueness is not mechanically applied, but "depends in part on the nature of the enactment." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). "In the civil context, the statute must be so vague and indefinite as really to be no rule at all." *Groome Res. Ltd. v. Parish of Jefferson*, 234 F.3d 192, 217 (5th Cir. 2000) (quotation omitted). A party seeking to challenge the facial validity of a statute "confront[s] a heavy burden" of demonstrating that the law cannot be applied in *any* circumstance. *Roark & Hardee LP v. City of Austin*, 522 F.3d 533, 548 (5th Cir. 2008) (emphasis added). Plaintiffs argue that Section 6001 is impermissibly vague because the provision is unclear as to: (1) when the restriction on facility expansion takes effect and (2) the criteria for receiving an exception to the ban on expansion.

First, Plaintiffs contend that it is unclear whether physician-owned hospitals may expand at all after March 23, 2010. As noted above, Section 6001 contains no ban on the expansion of physician-owned hospitals; it only prohibits Medicare and Medicaid payment for services that are the result of physician-owner self-referrals if certain conditions are not met. Section 1395nn(i)(1)(B) provides that those hospitals that seek to rely on the "whole hospital" exception may not increase the "number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after the date of the enactment of this subsection" (*i.e.*, after March 23, 2010).[16] This provision is clear that a hospital that increases its number of licensed beds after enactment of the statute does not satisfy the criteria of the Stark Law, and therefore may not bill *Medicare* for *prohibited self-referred services*. To the extent Plaintiffs claim that the effective date of that provision is unclear, they themselves state that "the plain language" of this provision "demands that hospitals cease all expansion and aggregate physician ownership increases after March 23, 2010 if they wish to qualify for expansion." Pls.' Prelim. Inj. Mot. 13.

Despite recognizing the "plain language" of Section 6001, Plaintiffs nonetheless claim that the interplay between 42 U.S.C. § 1395nn(i)(1)(B) and (d)(3)(D) creates unconstitutional ambiguity. Subsection (d)(3)(D) provides that an existing physician-owned hospital remains eligible for the "whole hospital" exception only if the hospital meets six independent requirements described in subsection (i)(1) "not later than 18 months after" the ACA's March 23, 2010 enactment. 42 U.S.C. § 1395nn(d)(3)(D). Certain criteria in subsection (i)(1) do not separately provide an effective date, and accordingly need only be satisfied within 18 months of enactment. *See, e.g.*, 42 U.S.C. § 1395nn(i)(1)(C)(ii) (requiring hospitals to have procedures for

[16] For hospitals that did not have a provider agreement in effect on the date of enactment of the ACA, but will have such an agreement in effect on December 31, 2010, the baseline number of operating rooms, procedure rooms, and beds is the number of such rooms and beds as of the effective date of their provider agreement. 42 U.S.C. § 1395nn(i)(3)(C)(iii).

the disclosure of referring physician's ownership interest to patients). But others, including the limitation on facility expansion, plainly indicate an earlier effective date of March 23, 2010.

Plaintiffs' contention that subsection (d)(3)(D) creates ambiguity over the effective date of the limitation on facility expansion is not only inconsistent with Plaintiffs' own concession, it also robs the statute of its ordinary meaning. On its face, the subsection's "not later than" language indicates that each of the criteria must be met no later than eighteen months after enactment, but the individual criteria may separately require compliance before that date. *See Occidental Chem. Corp. v. Power Auth. of N.Y.,* 990 F.2d 726, 727 (2d Cir. 1993) (finding that a statute requiring action "ending not later than" a specified date meant that the statute contemplated the completion of the action in a "shorter time"); *see also Fernandes v. Limmer*, 663 F.2d 619, 636 (5th Cir. 1981) ("'We can never expect mathematical certainty from our language.' The minimal ambiguity presented in [the challenged statute] is well within constitutional limits.") (quoting *ISKCON v. Eaves*, 601 F.2d 809, 830 (5th Cir. 1979)).

Second, Plaintiffs raise no viable constitutional challenge to 42 U.S.C. § 1395nn(i)(3). That section provides that hospitals may (but are not required to) apply for an exception to the limitation on continued Medicare billing for self-referred services at an expanded physician-owned hospital, and Plaintiffs contend that the statute is unconstitutionally vague because it does not clearly define which hospitals are eligible for an exception. Congress deliberately described general categories of hospitals that can qualify for exceptions but left further development of that matter to the Secretary by requiring the Secretary to promulgate regulations by January 1, 2012 to "establish and implement a process under which" hospitals may apply for an exception, and to implement the process on February 1, 2012. 42 U.S.C. § 1395nn(i)(3)(A)(i), (iii)-(iv). Congress was not obligated to specify by chapter and verse the parameters of the exception-granting

process (or to require the Secretary to do so immediately after the enactment of the challenged provision on March 23, 2010), particularly because, by statute, hospitals cannot even apply for an exception until 2012. Congress' decision to provide the Secretary with authority to develop the exceptions process, rather than to undertake that task itself, does not make the statute unconstitutionally vague.[17] *See Godinez-Arroyo v. Mukasey*, 540 F.3d 848, 850 (8th Cir. 2008) (finding that statutory "[g]aps indicate Congress delegated policymaking to administrative agencies, who have 'great expertise' and who are 'charged with responsibility for administering' the laws") (internal citation omitted). And Plaintiffs are not constitutionally entitled to immediate access to the exceptions-granting process.

Furthermore, it is worth noting that, outside of the First Amendment context, the purpose of the void for vagueness doctrine is to protect individuals from statutes that fail to warn of prohibited conduct or are subject to arbitrary enforcement. *Freedom to Travel Campaign v. Newcomb*, 82 F.3d 1431, 1440 n.11 (9th Cir. 1996). Neither situation exists here. Rather than prohibit conduct, the provision challenged as vague by Plaintiffs creates an opportunity for hospitals to become exempt from a generally applicable prohibition on conduct. Plaintiffs plainly have no entitlement to an exception, and they run no risk of engaging in conduct prohibited by statute unless they choose to blithely disregard its contents and submit self-referred claims from physician-owned hospitals that have chosen to expand before obtaining an exception to the self-referral prohibition. Furthermore, Congress can hardly be said to have encouraged arbitrary or discriminatory enforcement. By requiring the Secretary to promulgate regulations establishing the exception process, Congress has instead ensured the creation of standards that

[17] Congress also made it unmistakably clear that judicial review of the Secretary's establishment of the exception process and her decisions on particular exception requests is unavailable, *see* 42 U.S.C. § 1395nn(i)(3)(I), thereby committing the implementation and interpretation of subsection (i)(1) solely to the Secretary's discretion.

will be in place before any hospital is even eligible to apply for an exception. *See, e.g.*, *Vill. of Hoffman Estates*, 455 U.S. at 498-99 (finding that regulated business activity is subject to a less strict vagueness standard, due in part to enterprise's ability to "resort to an administrative process"); *United States v. Lachman*, 387 F.3d 42, 56 (1st Cir. 2004) ("The mere fact that a statute or regulation requires interpretation does not render it unconstitutionally vague.").

Conclusion

For the reasons stated herein, the Secretary requests that the Court deny Plaintiffs' complaint in its entirety and enter judgment for the Secretary.

Dated: August 17, 2010.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of August, 2010, I caused a true and correct copy of the this document to be filed and served upon counsel of record electronically by means of the Court's ECF system.

/s/ Scott Risner
Scott Risner