3-31-2011

Physician Hospitals v. Sebelius - District Court Opinion

United States District Court for the Eastern District of Texas

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

PHYSICIAN HOSPITALS OF AMERICA and TEXAS SPINE & JOINT HOSPITAL, LTD.	§	
v.	§	No. 6:10-cv-277
KATHLEEN SEBELIUS, in her official capacity as Secretary of the United States Department of Health and Human Services	§	

MEMORANDUM OPINION & ORDER

In this suit, physician-owned hospitals (POHs) challenge a recent amendment to the Medicare Act[1] that limits their ability to bill for services to Medicare patients who were referred by a physician owner. According to the hospitals, the law—Section 6001 of the Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119, 684–89 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1106, 124 Stat. 1029, 1049–50 (2010) codified at 42 U.S.C. § 1395nn—violates a number of their constitutional rights.

Plaintiffs request a declaration that Section 6001 is unconstitutional and ask the Court to enjoin the Secretary of the United States Department of Health and Human Services (the Secretary) from enforcing the amended law. The Secretary challenges the Court's subject matter jurisdiction and alternatively moves for summary judgment on all grounds.

The Court concludes that Congress did not act unconstitutionally and that it is not the function of the Court to determine the wisdom of this congressional action. Having considered

[1] Since 1993, the section of the Medicare Act at issue in this suit has also applied to claims under the Medicaid program. See Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562, § 13624, 107 Stat. 312, 636 (1993). For simplicity, this opinion will refer to both programs collectively as "Medicare."

the parties' briefs, oral arguments, and the applicable law, the Court finds the Secretary is entitled to judgment as a matter of law.

I. BACKGROUND

A. PHA and TSJH Growth, Expansion, and Halting of Development Plans

Plaintiff Physician Hospitals of America (PHA) is a trade association representing the interests of more than one hundred POHs in over thirty states. PHA's members, including Plaintiff Texas Spine and Joint Hospital (TSJH), a twenty-bed hospital in Tyler, Texas, are POHs. PHA's members and TSJH serve Medicare and Medicaid patients along with other private insurance and indigent patients.

Plaintiff TSJH and many of PHA's members are specialty hospitals. Specialty hospitals, as opposed to general or full-service hospitals, are health care facilities that focus on performing certain procedures or on treating patients with particular diseases or conditions. They tailor their care and facilities to fit the chosen type of condition, patient, or procedure on which they focus.[2] *See, e.g.*, U.S. Gov't Accounting Office, GAO-03-683R, Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served 1 (2003) [hereinafter GAO-03-683R]. Specialty hospitals are not new to the hospital industry. They have existed for decades. Specialty hospitals, particularly physician-owned specialty hospitals (specialty POHs), experienced phenomenal growth in recent years. *Id.* at 6.

In March 2008, TSJH's physician owners commissioned plans for an expansion to meet its current and expected patient demand. The estimated cost of the TSJH expansion exceeded $30 million. By March 2010, TSJH had spent more than $3 million on its project by purchasing

[2] Congress's definition is more specific and focuses on facilities that "primarily or exclusively" treat patients with a cardiac or orthopedic condition or who are receiving a surgical procedure. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295–97 (2003). It should be noted that the definition excludes several types of hospitals traditionally considered "specialty hospitals," such as psychiatric hospitals, rehabilitation hospitals, and children's hospitals. *Id.*; 42 U.S.C. § 1395ww(d)(1)(B).

land, obtaining zoning approvals, and other transaction costs. Like TSJH, many other PHA member hospitals around the country also were expanding or developing new facilities or were planning those projects as of March 2010. The financing model used by TSJH and PHA's members to support expansion projects typically was anchored in expected Medicare reimbursements from patient care in those expanded or new facilities.

In March 2010, Congress passed legislation that unquestionably impacts POHs located throughout the country, including Tyler, Texas. On March 23, 2010, President Barack Obama signed the PPACA, which included Section 6001, subtitled "Limitation on Medicare Exception to the Prohibition on Certain Physician Referrals for Hospitals." Pub. L. 111-148, § 6001, 124 Stat. at 684–89 (hereinafter referred to as "Section 6001"). Section 6001, an amendment to the Medicare Act, prohibits new or expanded POHs from filing claims for health services covered by Medicare if there is a financial relationship between the referring physician and the hospital receiving payment.

B. Physician Self-Referral: History of Congressional Action

An understanding of the historical context that gave rise to limiting Medicare payments for physician self-referrals[3] requires a review of congressional activity leading up to the adoption of Section 6001. It is also helpful to trace the growth of specialty POHs in conjunction with Congress's attempt to regulate Medicare payments involving self-referrals.

1. The Enactment of the Stark Law and Whole Hospital Exception

As early as 1989, some members of Congress began taking notice of the increasing numbers of physicians who were referring patients to medical facilities in which the physician

[3] As used herein, "self-referrals" describes the practice of physician referrals of patients to a hospital in which the referring physician has a financial interest.

maintained a financial interest. Congress directed the Office of the Inspector General (OIG) to study

> referring-physician ownership of, or compensation by, entities providing items or services for which Medicare may make payment; the range of such arrangements and the means by which they are marketed to physicians; the potential of such ownership or compensation to influence a physician's decision about referrals and to lead to inappropriate use; and the practical difficulties involved in enforcing actions against such arrangements that violate current anti-kickback provisions.

Office of Inspector Gen., U.S. Dep't of Health and Human Servs., OAI-12-88-01410, Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress ii (1989). The OIG's report, published in May 1989, was followed by the eventual passage of legislation previously proposed by United States Congressman Pete Stark. Ethics in Patient Referrals Act of 1989, H.R. 939, 101st Cong. (1989).

The "Stark Law," as it came to be called, generally prohibited hospitals from billing Medicare for patients referred to facilities in which the referring physician (or immediate family members) had an ownership or other investment interest. *See* Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236–43 (1989) codified at 42 U.S.C. § 1395nn. This first version of the Stark Law, enacted in December 1989, did not affect hospitals. Rather, it affected only self-referrals to facilities furnishing clinical laboratory services. 103 Stat. at 2236. But, in 1993, the law was expanded to encompass self-referrals for additional health services, including hospital treatment. Omnibus Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562, 107 Stat. 312, 596–605 (1993).

Of particular relevance in this dispute is the fact that the Stark Law included a provision that would become known as the "whole hospital exception." It permitted Medicare payment for services when the referring physician had an ownership or investment interest in the *entire*

hospital, rather than merely a subdivision or department of the hospital. 42 U.S.C. § 1395nn(d)(3). According to the legislative history accompanying Section 6001's enactment, the exception was included because, at the time of the Stark Law's enactment, there were a number of rural hospitals where such ownership arrangements were in place. H.R. Rep. No. 111-443, pt. 1, at 355 (2010). Ownership in a "whole hospital" was also acceptable to Congress under the assumption that a physician's potential for economic gain through patient referrals was more likely diluted in a general hospital providing diverse services. *Id.* Given that scenario, the risk that economic self-interest might compromise the physician's judgment was of less concern. GAO-03-683R at 2.

But the Stark Law clearly prohibited physicians with an ownership interest in a distinct hospital subdivision from being able to refer Medicare patients to that subdivision. 42 U.S.C. § 1395nn(d)(3)(c). This provision of the Stark Law reflected congressional concern that ownership in a specific subdivision would create an incentive for self-referrals. H.R. Rep. No. 111-443, pt. 1, at 355.

2. Congress Enacts Specialty POH Moratorium

By 2003, Congress apparently noticed the increase in the number of POHs, in general, and the growth of specialty POHs, in particular. According to a study requested by Congress, the number of specialty POHs tripled between 1990 and 2003. GAO-03-683R at 6. The same report observed that specialty POHs were often similar in size and scope to hospital departments. *Id.* at 2.

In response to this rapid growth, Congress authorized in-depth studies of specialty POHs. Congress directed the Medicare Payment Advisory Commission (MedPAC)[4] and the Department

[4] The Medicare Payment Advisory Commission (MedPAC) is an independent Congressional agency established by the Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4022, 111 Stat. 251, 350–55 (1997), to advise Congress on

of Health and Human Services (HHS) to study and report on the cost and quality of care at specialty POHs as compared with local, full-service community hospitals. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295–97 (2003). Congress also enacted an eighteen-month moratorium on Medicare payments for self-referrals to specialty POHs while agencies conducted the studies. *Id.* As noted below, the moratorium included a provision grandfathering in specialty POHs already in existence or under development, thus allowing those hospitals to continue billing for self-referrals. *Id.*

3. The MedPAC and HHS Study Results

MedPAC reported the results of its study in March 2005. MedPAC, Report to the Congress: Physician-Owned Specialty Hospitals (2005). It found that patients in specialty POHs have shorter stays, but not necessarily lower costs. *Id.* at vii. It also found that such hospitals generally treat less severe cases, but that full-service community hospitals were not suffering financially as a result. *Id.* MedPAC issued five recommendations, three of which called for refinements to the Medicare payment system. *Id.* at viii–xi. In addition to these refinements, MedPAC recommended allowing gainsharing arrangements[5] between physicians and community

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issues affecting the Medicare program. The MedPAC's statutory mandate is quite broad: In addition to advising Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

Two reports issued in March and June each year are the primary outlet for MedPAC recommendations. In addition to these reports and others on subjects requested by Congress, MedPAC advises Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary, testimony, and briefings for congressional staff. MedPAC, http:// www.medpac.gov/about.cfm (last visited March 31, 2011).

[5] In a gainsharing arrangement, hospitals and physicians agree to share savings from measures such as more efficient scheduling of operating rooms. Gainsharing has the potential to encourage physicians and hospitals to cooperate in "developing more efficient ways to deliver care" and "could eventually lead to savings for Medicare." MedPAC 2005 at 44; *see also* OIG Special Advisory Bulletin, Gainsharing Agreements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999) ("While there is no fixed definition of a 'gainsharing' arrangement, the term typically refers to an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts.").

hospitals because it would "provide an alternative to starting physician-owned specialty hospitals" while "maintain[ing] incentives for improved hospital performance." *Id.* at ix, 44–46.

MedPAC explicitly considered removing the whole hospital exception and found it to be "too severe a remedy at this time, although we may wish to consider it in the future." *Id.* at ix. MedPAC observed that:

> specialty hospitals may be an important competitive force that promotes innovation and may be an appropriate response to physician frustration with community hospitals' lack of responsiveness and physicians' desire for control. Therefore, the Commission does not want to preclude their development before gaining a fuller understanding of their quality and efficiency.

Id. at 43.

HHS also found specialty POHs tended to treat less severe cases, but cautioned that its "findings may not be representative of, or generalizable to, all specialty hospitals." HHS, Study of Physician-owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 60–61 (2005). HHS noted that, although some could interpret the treatment of less severe cases as "cherry picking," it could "also be an indicator of quality." *Id.* at 61. HHS also examined referral patterns at specialty POHs and found them "consistent with the likely referral patterns elsewhere." *Id.* Finally, HHS reported that specialty POHs "provide a high level of quality of care" and "patients responded very favorably" to them. *Id.* at 62.

4. CMS Temporary Suspension and HHS Study Reviewed

Following these studies, the Centers for Medicare & Medicaid Services (CMS), which administers Medicare and Medicaid on behalf of the Secretary, temporarily suspended processing enrollment applications for specialty POHs while it reviewed its procedures for qualifying such hospitals for participation in the Medicare program. CMS memorandum to State

Survey Agency Directors, "Hospitals – Suspension of Processing New Provider Enrollment Applications (CMS-855A) for Specialty Hospitals," S&C-05-35, June 9, 2005. In February 2006, Congress extended that suspension for six months while it awaited an additional report from HHS on physician investment in specialty hospitals. *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5006, 120 Stat. 4, 33–34 (2006).

HHS reviewed its earlier study on specialty POHs, as well as MedPAC's 2005 report and survey data from specialty POHs and competitor acute care hospitals. HHS, Final Report to Congress and Strategic Implementation Plan Required Under Section 5006 of the Deficit Reduction Act of 2005 i (2006). The report stated "that the most effective way to deal with perceived unfair competition" is to continue making refinements to the Medicare payment system. *Id.* at vi–vii. HHS specifically noted that it was "not recommending at this time that Congress amend the whole hospital exception to prohibit physician ownership of specialty hospitals." *Id.* at 78. HHS also stated that it did "not believe that a continuation of the suspension [of processing new provider enrollment applications for specialty POHs] is warranted." *Id.* at 79.

5. End of the Moratorium and Subsequent Congressional Action

Following the 2006 HHS report, Congress allowed the moratorium to expire. But Congress continued attempts to prohibit new POHs from billing Medicare for self-referrals. For example, in 2007, the House passed a bill that would have eliminated the whole hospital exception for new or expanded POHs. *See* Children's Health and Medicare Protection Act of 2007, H.R. 3162, § 651, 110th Cong. (1st Sess. 2007) (as passed by House, Aug. 1, 2007). Under the terms of that bill, exceptions could not be granted. *Id.*

In 2008, the House passed a measure with language nearly identical to the 2007 bill that also would have narrowed the whole hospital exception. But this version allowed the Secretary

to grant exceptions for POHs to expand their capacity by 50%. *See* Paul Wellstone Mental Health and Addiction Equity Act, H.R. 1424, § 106, 110th Cong. (2d Sess. 2008) (as passed by House, Mar. 5, 2008). That same year, the Senate proposed a version that would have increased the expansion exception to 200% of a hospital's original capacity. *See* S. Amdt. 4803 to H.R. 2642, § 6002, 110th Cong. (2d Sess. 2008) (as passed by Senate, May 22, 2008); *see also* Children's Health Insurance Program Reauthorization Act of 2009, H.R. 2, § 623, 111th Cong. (1st Sess. 2009) (as passed by House, Jan. 14, 2009) (proposing nearly identical terms); Affordable Health Care for America Act, H.R. 3962, § 1156, 111th Cong. (1st Sess. 2009) (as passed by House, Nov. 7, 2009) (proposing nearly identical terms). None of these bills were successfully enacted, but they demonstrate a prolonged effort by some in Congress to eliminate or narrow the whole hospital exception.

6. Section 6001 Enacted as Part of the PPACA

In March 2010, Congress dramatically limited the availability of the whole hospital exception by enacting Section 6001, purportedly designed to prevent conflicts of interest, to ensure bona fide investment, and to provide patients with disclosures that would facilitate informed consumer choices. Among the new requirements added by Section 6001 was a prohibition on Medicare reimbursements for existing POHs that expand after March 23, 2010. 42 U.S.C. § 1395nn(i)(1)(B). Another new requirement was that new POHs were to have their Medicare provider agreements in place, i.e. have their construction completed by December 31, 2010, less than ten months after the law was enacted. 42 U.S.C. 1395nn(i)(1)(A). Hospitals that fail to meet either of these criteria no longer qualify under the Stark Law's whole hospital exception.

Section 6001 also created categorical exceptions for some POHs. 42 U.S.C. § 1395nn(i)(3). But even these hospitals cannot expand beyond double the number of operating rooms, procedure rooms, and beds it had on March 23, 2010. 42 U.S.C. § 1395nn(i)(3)(C)(ii). The law directs the Secretary to implement an application process for these exceptions by February 1, 2012. 42 U.S.C. § 1395nn(i)(3)(A).

C. Physicians Challenge Constitutionality of Section 6001

When the law was enacted on March 23, 2010, TSJH and many of PHAs members terminated their expansion and development plans. As noted below, all new projects had to be completed by December 31, 2010, and the law's other conditions met by September 23, 2011, for a POH to continue billing for Medicare service. As expansions and new hospital construction take years to complete, many of the projects could not meet the deadlines imposed by Section 6001**,** and thus came to an abrupt halt.

Plaintiffs filed this suit requesting declaratory and injunctive relief. They contend Section 6001 violates their due process and equal protections rights under the Fifth Amendment because it is not rationally related to a legitimate purpose and improperly singles out POHs. Specifically, they claim that Section 6001 was part of a deal with lobbyists for non-physician-owned hospitals to garner support for other health care reform measures. They further contend that Section 6001 effects an unconstitutional and retroactive taking of their real and personal property. Finally, Plaintiffs argue Section 6001 is void for vagueness. For these reasons, Plaintiffs ask the Court to find Section 6001 unconstitutional and to prohibit the Secretary from enforcing the amended law.

In response, the Secretary filed dispositive motions, including a motion to dismiss and this motion for summary judgment. In her motions, the Secretary challenges subject matter

jurisdiction, as well as the substantive merits of Plaintiffs' claims.[6] On the merits, the Secretary argues that there are no constitutional violations, nor are there material facts in dispute.[7]

In reply, Plaintiffs argue that the Court has subject matter jurisdiction and that various factual disputes exist concerning, *inter alia*, the reliability, foundation, and accuracy of the legislative history underlying Section 6001.[8]

Oral arguments were heard on the Secretary's motions, and all responses and replies were considered. Following the hearing, the Court issued a preliminary ruling (Doc No. 90) indicating its intention to grant the Secretary's motion for summary judgment on all grounds except jurisdiction. Accordingly, the Court hereby issues its formal ruling.

After due consideration, the Court finds that it has subject matter jurisdiction, there are no material facts in dispute, and the Secretary is entitled to judgment on the merits as a matter of law.

II. SUMMARY JUDGMENT STANDARD

The Court should grant a motion for summary judgment if no genuine issue as to any material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986); *Norwegian Bulk Transp. A/S v. Int'l Marine Terminals P'ship*, 520 F.3d 409, 411 (5th Cir. 2008). A fact is material if it might

[6] The Secretary raised the same issues in a contemporaneously filed motion to dismiss (Doc. No. 28). The Court denied the Secretary's motion to dismiss on February 18, 2011. (Doc. No. 105).

[7] The Secretary argues that a trial would be inappropriate because the Court should not engage in fact finding to weigh the credibility of legislative history against Plaintiffs' factual contentions. But, the Court allowed limited discovery and reviews the Secretary's motion under the traditional summary judgment standard.

[8] The parties spend considerable effort disputing whether Plaintiffs' challenge is facial or as applied, which would affect whether the Court considers the facts specific to the Plaintiffs. The Court sees this as a distinction without substance in this case. *Cf. Citizens United v. Fed. Election Comm'n*, 130 S. Ct. 876, 893 (2010) ("[T]he distinction between facial and as-applied challenges is not so well defined that it has some automatic effect or that it must always control the pleadings and disposition in every case involving a constitutional challenge. The distinction is both instructive and necessary, for it goes to the breadth of the remedy employed by the Court, not what must be pleaded in a complaint."). In evaluating the Secretary's motion for summary judgment, the Court gives due consideration to Plaintiffs' evidence related to their specific circumstances.

affect the outcome of the suit under the governing law. *Sossamon v. Lone Star State of Texas*, 560 F.3d 316, 326 (5th Cir. 2009). Issues of material fact are "genuine" only if they require resolution by a trier of fact and if the evidence is such that a reasonable jury could return a verdict in favor of the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Sossamon*, 560 F.3d at 326.

When ruling on a motion for summary judgment, the Court must view all inferences drawn from the factual record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Sossamon*, 560 F.3d at 326.

Under Rule 56, the party moving for summary judgment must "demonstrate the absence of a genuine issue of material fact." *Duffie v. United States*, 600 F.3d 362, 371 (5th Cir. 2010) (internal quotations omitted). If the moving party fails to meet this initial burden, the motion must be denied regardless of the nonmovant's response. *Id.* If the movant meets the burden, however, Rule 56 requires the opposing party to go beyond the pleadings and show by affidavits, depositions, answers to interrogatories, admissions on file, or other admissible evidence that specific facts exist over which there is a genuine issue for trial. *Anderson*, 477 U.S. at 256; *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 337 (5th Cir. 2008); *EEOC v. Texas Instruments, Inc.*, 100 F.3d 1173, 1180 (5th Cir. 1996). The nonmovant's burden may not be satisfied by argument, conclusory allegations, unsubstantiated assertions, metaphysical doubt as to the facts, or a mere scintilla of evidence. *Matsushita*, 475 U.S. at 585–86; *United States ex rel. Farmer*, 523 F.3d at 337; *Duffie*, 600 F.3d at 371.

III. PERMANENT INJUNCTION STANDARD

In their Complaint, Plaintiffs ask the Court to permanently enjoin the Secretary from enforcing Section 6001. In addition to demonstrating success on the merits, Plaintiffs must

demonstrate the following elements to achieve the requested equitable relief: (1) Plaintiffs have suffered irreparable injury, (2) remedies available at law (i.e. money damages) are inadequate, (3) the balance of hardship between the parties weighs in favor of injunctive relief, and (4) the public interest would not be disserved by the injunction. *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (setting forth the elements for equitable relief); *see also Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 546 n.12 (1987) (recognizing the similarities between preliminary injunctive relief and permanent injunctive relief).

IV. ANALYSIS

Plaintiffs challenge Section 6001 under several constitutional theories. As discussed in more detail below, the Court finds that it has jurisdiction over the claims in this action. Furthermore, there are no genuine issues of material fact as to whether Section 6001 is rationally based. Also, the challenged law does not result in an unconstitutional, retroactive taking. Finally, Section 6001 is not unconstitutionally vague. Because Plaintiffs' constitutional claims are without merit, injunctive relief is not warranted.

A. Federal Question Jurisdiction

In its motion for summary judgment, the Secretary challenges the Court's subject matter jurisdiction over Plaintiffs' claims because Plaintiffs did not first exhaust their administrative remedies. It is true that Plaintiffs did not channel their claims through the Secretary. However, the Court previously ruled that jurisdiction exists under the exception to the exhaustion requirement set forth in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 15, 20 (2000). For the reasons discussed more fully in the Court's Order Denying the Government's Motion to Dismiss (Doc. No. 105), the Court finds it has jurisdiction over Plaintiffs' claims.

B. Substantive Due Process and Equal Protection[9]

Plaintiffs claim that Section 6001 violates their due process and equal protection rights guaranteed by the Fifth Amendment. According to Plaintiffs, Section 6001 is unconstitutional because it lacks a rational basis. The Secretary counters that Plaintiffs have not presented a genuine issue of material fact on their due process and equal protection claims, and therefore the Secretary is entitled to entry of judgment as a matter of law without the need for a trial. For the reasons discussed below, the Court agrees.

1. Background

As previously noted, the Stark Law was originally enacted in 1989 and prohibited hospitals from billing Medicare for clinical laboratory services provided at a facility in which the referring doctor had a financial interest. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236–43 (1989). And since its inception, the Stark Law's whole hospital exception has allowed Medicare claims for self-referrals when the physician's interest is in an entire hospital. 42 U.S.C. § 1395nn(d)(3).

The law has undergone several expansions and transformations and now encompasses a broad range of services for which self-referrals are prohibited. *See* 42 U.S.C. § 1395nn. In March 2010, Congress enacted Section 6001, which, as previously noted, effectively eliminated the whole hospital exception. Pub. L. 111-148, § 6001, 124 Stat. at 684–89. However, Section 6001

[9] Plaintiffs dedicate a separate section to their retroactivity argument, invoking the substantive due process rational basis standard. Although the effective date of Section 6001 is the date of enactment, Plaintiffs argue it is unconstitutionally retroactive under the rational basis standard because it upset their investment backed expectations in the profitability of their expansion. A law that that reaches into the past and "impose[s] a new duty or liability based on past acts" is treated as retroactive and must survive a rational basis inquiry. *See Pension Benefit Guar. Corp. v. R.A. Gray & Co.*, 467 U.S. 717, 730 (1984); *Gen. Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992) (noting that retroactive laws can interfere with "closed" or "settled" transactions). But Plaintiffs have not indicated what new liability or duty they face based on their past acts. Instead, Plaintiffs argue that the value of their investment has been "forfeited" because Section 6001 changed the law. This argument is better addressed under the Court's takings discussion. *See E. Enters. v. Apfel*, 524 U.S. 498, 537 (1998) (plurality) (O'Connor, J.) ("[T]his Court has expressed concerns about using the Due Process Clause to invalidate economic legislation.").

established a limited grandfathering provision applicable to existing POHs and new POHs. 42 U.S.C. § 1395nn(d)(3)(D) & (i)(1). But the scope of Section 6001's grandfathering provision is narrower than the grandfathering language included in the 2003 moratorium. The 2003 act grandfathered all existing POHs as well as those "under development." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295–97 (2003). But Section 6001 cut off expansion projects immediately upon enactment. Pub. L. 111-148, § 6001, 124 Stat. at 684–89. Also, Section 6001 required new POHs to have their Medicare provider certification by the end of 2010, less than ten months after the law was passed. *Id.* The statute does not except new hospitals that are unable to meet the December 2010 deadline. *Id.* Section 6001 also requires the Secretary to establish a procedure under which some POHs can request an exception and be allowed to expand to twice their size. 42 U.S.C. § 1395nn(i)(3).

Plaintiffs contend that the law, including its disparate treatment of physician owners as compared to other hospital owners, is irrational. Plaintiffs also challenge the factual basis supporting the law. Plaintiffs further argue that Section 6001 was enacted to provide a competitive advantage to commercially-owned hospitals.

The Secretary identifies four justifications for Section 6001: (1) physician ownership leads to overutilization of services, (2) physician ownership results in greater healthcare expenditures, (3) referral patterns undermine public and community hospitals, which provide uncompensated care and other services not typically offered by POHs, and (4) POHs provide inadequate emergency care.

2. Legal Standard

The Court applies strict scrutiny when a due process or equal protection challenge implicates a fundamental right or involves a suspect class. *Reno v. Flores*, 507 U.S. 292, 301–02 (1993). Otherwise, the law or classification is reviewed under the more deferential rational basis standard. *See FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313–14 (1993). Because this case does not involve a fundamental right or a suspect class, the rational basis test applies.

At its most fundamental level, the Court's rational basis analysis is no different than any other summary judgment inquiry: the Court must consider whether there exists a genuine issue of material fact when considering the facts in a light most favorable to Plaintiff. *Sossamon*, 560 F.3d at 326.

As in this case, a party challenging the rational basis of a law may present evidence that undermines the legislatures' judgment. *See, e.g.*, *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 463 (1981) (noting that the challenging parties produced "impressive supporting evidence" to prove the probable negative consequences of the law). Accordingly, in most, if not all of these cases, a *genuine* factual dispute exists.

But the factual dispute must also be material. *Sossamon*, 560 F.3d at 326. And the parameters of materiality are defined by substantive law. *Anderson*, 477 U.S. at 248. In a rational basis challenge, it is well established that "[a]cts adjusting the burdens and benefits of economic life come to the Court with a presumption of constitutionality." *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976); *see also Beach Commc'ns*, 508 U.S. at 314 (stating that, under a rational basis review, statutes come before the Court with "a strong presumption of validity"). A statute must meet two criteria to satisfy constitutional requirements. First, it must be predicated on a legitimate governmental purpose. *Clover Leaf*, 449 U.S. at 461–62 (noting purpose and

rational relationship as two distinct elements of the rational basis analysis). Second, the legislative action must be rationally related to that legitimate purpose. *Id.*; *Heller v. Doe*, 509 U.S. 312, 324 (1993) (a law "fails rational-basis review only when it rests on grounds wholly irrelevant to the achievement of the [government's] objective." (internal quotations omitted)).

To prevail on their claim, Plaintiffs must "establish that [Congress] has acted in an arbitrary and irrational way." *Turner Elkhorn*, 428 U.S. at 15; *see also Heller*, 509 U.S. at 320–21 (observing that "[t]he burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it, whether or not the basis has a foundation in the record" (internal quotations and citations omitted)). To do so, Plaintiffs "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). "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). However, "a regulation that fails to serve any legitimate governmental objective may be so arbitrary or irrational that it runs afoul of the Due Process Clause." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 542 (2005).

In its rational basis analysis, the Court can consider the law's legislative history (including information considered by Congress) and the reasons stated by the Secretary, or the Court can even articulate a basis not suggested by the parties or the evidence. *See, e.g.*, *Nguyen v. INS*, 533 U.S. 53, 77 (2001) ("[The rational basis] standard permits a court to hypothesize interests that might support legislative distinctions."); *Beach Commc'ns*, 508 U.S. at 315 ("[I]t is entirely irrelevant for constitutional purposes whether the conceived reason for the challenged distinction actually motivated the legislature. . . . Thus, the absence of 'legislative facts'

explaining the distinction '[o]n the record,' has no significance in rational-basis analysis.") (citations omitted); *Clover Leaf*, 449 U.S. at 465–70 (reviewing the legislative history, including statements made by legislators and evidence considered by the legislature). The Court also can look to extrinsic evidence, such as expert reports on the social ills addressed by the legislation. *Clover Leaf*, 449 U.S. at 464 ("[P]arties challenging legislation under the Equal Protection Clause may introduce evidence supporting their claim that it is irrational."); *Dunagin v. City of Oxford*, 718 F.2d 738, 748 n.8 (5th Cir. 1983) ("The writings and studies of social science experts on legislative facts are often considered and cited by the Supreme Court with or without introduction into the record or even consideration by the trial court.").[10] The ultimate question for the Court is whether the law "is so unrelated to [achieving] any combination of legitimate

[10] Evidence produced to support or challenge the rationale of a law is generally not case-specific and is subject to opinion, thus it falls within the category of legislative—rather than adjudicative—facts and can provide context when considering the rationality of the law. *See*, Fed. R. of Evid. 201 advisory committee notes (noting that "[l]egislative facts . . . are those which have relevance to legal reasoning and the lawmaking process, whether in formulation of a legal principle or ruling by a judge or court, or in the enactment of a legislative body" and the judiciary should have unrestricted access to legislative facts without "any limitation in the form of indisputability, any formal requests of notice other than those already inherent in affording opportunity to hear and be heard and exchanging briefs, and any requirement of formal findings at any level."). This information may be presented by the parties or even judicially noticed by the Court. *Dunagin*, 718 F.2d at 748 n.8. *See also In re Waller Creek, Ltd.*, 867 F.2d 228, 238 n.14 (5th Cir. 1989) (citing *United States v. City of Miami*, 664 F.2d 435, 443 n. 16 (5th Cir.1981)) ("The power of a federal court to take judicial notice of legislative facts is less constrained than its power to take notice of adjudicative facts.").

Although legislative facts may provide some use to the Court, a plaintiff challenging the rational basis of a law does not demonstrate a material fact issue by showing some dispute—however legitimate—in the legislative facts. *Clover Leaf*, 449 U.S. at 464 ("Where there was evidence before the legislature reasonably supporting the classification, litigants may not procure invalidation of the legislation merely by tendering evidence in court that the legislature was mistaken."); *Vance*, 440 U.S. at 111 (1979) (quoting *Rast v. Van Deman & Lewis Co.*, 240 U.S. 342, 357 (1916)) ("It is the very admission that the facts are arguable that immunizes from constitutional attack the congressional judgment represented by this statute: 'It makes no difference that the facts may be disputed or their effect opposed by argument and opinion of serious strength. It is not within the competency of the courts to arbitrate such contrariety.'"); s*ee also Stern v. Tarrant Cnty. Hosp. Dist.*, 778 F.2d 1052, 1060 (5th Cir. 1985) (en banc) ("The general distinction between legislative and adjudicative facts is . . . important because it helps to show why the district court ought to have asked only whether there was any conceivable basis for the . . . legislative judgment. . . . A factual conclusion by the district court, based on conflicting evidence about a historical fact, would be binding in this court. But such a factual conclusion could *not* be used to displace legislative judgment and therefore could not be a sufficient basis for declaring the . . . action unconstitutional."); *Dunagin*, 718 F.2d at 748 n.8 ("There are limits to which important constitutional questions should hinge on the views of social scientists who testify as experts at trial. . . . The social sciences play an important role in many fields, including the law, but other unscientific values, interests and beliefs are transcendent.").

purposes that [the Court] can only conclude that [Congress's] actions were irrational." *Vance*, 440 U.S. at 97.

3. Analysis

As noted above, the Secretary presented four justifications for Section 6001: (1) physician ownership leads to overutilization of services, (2) physician ownership results in greater healthcare expenditures, (3) referral patterns undermine public and community hospitals, which provide uncompensated care and other services not typically offered by POHs, and (4) POHs provide inadequate emergency care. To survive summary judgment, Plaintiffs must present evidence from which the Court could find these justifications—and any other conceivable justifications—are so unfounded as to be arbitrary. *Wood Marine Serv., Inc. v. City of Harahan*, 858 F.2d 1061, 1066 (5th Cir. 1988) (quoting *Shelton v. City of College Station*, 780 F.2d 475, 479 (5th Cir. 1986) (en banc)) ("Harahan was not required to prove the truth of the legislative facts upon which its zoning ordinance is based. Rather, it was Wood Marine's burden to '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 decisionmakers.'"). Although Plaintiffs present considerable evidence that questions the wisdom and judgment of the legislature, all of the evidence, even when viewed in favor of Plaintiffs, cannot support a finding that Congress acted arbitrarily when passing Section 6001.

Plaintiffs devote most of their rational basis challenge to undermining the factual basis or scientific reasoning underlying many of the reports relied on by the Secretary. The Secretary points to an array of information to support its proposed justifications for Section 6001—some referenced in the congressional record and some produced by the Secretary for the first time in this litigation. Plaintiffs challenge the Secretary's evidence for the following reasons.

First, Plaintiffs note that some "facts" relied on by Congress and the Secretary lack support and appear to be "made up." For example, Plaintiffs claim the Secretary presents an unsupported presumption of current market conditions when it assumed that POHs functioned as subdivisions of whole hospitals. Plaintiffs also contend that when passing Section 6001, Congress misconstrued—without any evidence to support its theory—the original purpose of the Stark Law and the whole hospital exception. H.R. Rep. No. 111-443, pt. 1, at 355–56.

Plaintiffs also argue that the Secretary misapplies the findings of certain studies. For example, the Secretary relies on a 2008 article that primarily addressed concerns of physician-owned imaging centers. Lawrence P. Casalino, *Physician Self-Referral and Physician-Owned Specialty Facilities*, Res. Synthesis Rep. No. 15 (June 2008).

Furthermore, Plaintiffs note that some studies presented by the Secretary and considered by Congress contradict the alleged purposes of Section 6001. The studies, commissioned by Congress, recommended no additional restrictions on POHs. MedPAC, Report to Congress: Physician-Owned Specialty Hospitals (2005); CMS memorandum to State Survey Agency Directors, "Hospitals – Suspension of Processing New Provider Enrollment Applications (CMS-855A) for Specialty Hospitals," S&C-05-35, June 9, 2005. In contrast, Section 6001 imposed greater restrictions.

Plaintiffs also insist that the Secretary presents evidence with flawed or, in some cases, no scientific foundation. For example, the House Report relied on by the Secretary cites an article in *The New Yorker* that relies on anecdotal observations rather than scientific research and empirical data. H.R. Rep. No. 111-443, pt. 1, at 356 (citing Atul Gawande, *The Cost Conundrum*, The New Yorker, June 1, 2009). Through their own expert, Plaintiffs also challenge

as flawed the scientific foundation of studies presented by the Secretary. *See, e.g.*, John Schneider Dep., 41:3–25, 42:1–3, July 30, 2010.

Finally, Plaintiffs contend that the Secretary relies on improper and insufficient legislative history. For example, according to Plaintiff, the 2010 House Report of the Budget Committee, relied on by the Secretary, was generated by a committee with no jurisdiction over Medicare and does not reference the Senate's position. *See* H.R. Rep. No. 111-443. Also, Plaintiffs challenge the significance of Congressman Pete Stark's comments in 2005 explaining the purpose of the Stark Law. *Physician-Owned Specialty Hospitals: Hearing Before the H. Comm. on Ways and Means*, 109th Cong. 5 (2005) (statement of Rep. Stark).

In several of these challenges, Plaintiffs rely heavily on their expert Dr. John Schneider. Dr. Schneider's criticisms range from inadequate foundational data to improper methodology to flawed analyses models. John Schneider Dep., 41:3-25, 42:1-3, July 30, 2010; Schneider Report; Schneider Aff. Dr. Schneider's review of the reports offered by the Secretary are thorough and detailed. Furthermore, Plaintiffs are entitled to offer Dr. Schneider's reports and testimony to challenge the rationality of the law. *Clover Leaf*, 449 U.S. at 464.

But Plaintiffs' challenges (including Dr. Schneider's criticism) to the factual foundation suggested by the Secretary simply demonstrate another—perhaps equally or even more rational—approach the legislature could have pursued. But these challenges are not enough, even if assumed to be true, to render arbitrary Congress's decision to enact Section 6001. *Vance*, 440 U.S. at 111 (1979); *Stern*, 778 F.2d at 1060. The Court is not in the business of passing judgment on the wisdom or appropriateness of legislative action, and the Court can only overturn a statute under the rational basis standard when "the legislative facts on which the classification is apparently based could not reasonably be conceived to be true by the government

decisionmakers." *Vance*, 440 U.S. at 111; *Ferguson v. Skrupa*, 372 U.S. 726, 730 (1963) ("The doctrine that . . . due process authorizes courts to hold laws unconstitutional when they believe the legislature has acted unwisely . . . has long been discarded."); *Shelton*, 780 F.2d at 479.

Plaintiffs argue that the Secretary's proposed justifications are pretextual and that Section 6001 was instead the product of a backroom deal brokered for the benefit of the American Hospital Association and its members. *See, e.g.*, Michael D. Shear, *Biden Rolls Out Deal With Hospitals to Cut $155B in Costs*, Wash. Post, July 8, 2009. According to Plaintiffs, this protectionism legislation is not a legitimate public purpose.

Plaintiffs cite to a string of cases to support the proposition that the Court should make a subjective inquiry into Congress's actual purpose in enacting the law. But almost all these cases are either easily distinguished or are not binding precedent on the Court. Most of the cases involve wholly distinct legal rules. *Kelo v. City of New London*, 545 U.S. 469, 478 (2005) (takings); *Energy Reserves Grp., Inc. v. Kansas Power & Light Co.*, 459 U.S. 400, 411 (1983) (contracts 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) (commerce clause).

Two other cases cited by Plaintiffs that struck down laws as arbitrary found no other conceivable rational basis for the law besides the allegedly illegitimate protectionist purpose. *Craigmiles v. Giles*, 312 F.3d 220, 228 (6th Cir. 2002) ("Finding no rational relationship to any of the articulated purposes of the state, we are left with the more obvious illegitimate purpose to which licensure provision is very well tailored."); *Santos v. City of Houston*, 852 F. Supp. 601, 608 (S.D. Tex 1994) (assuming that the government's proffered justifications were legitimate and finding that none would support the law). In this case, the Secretary has offered several

conceivable purposes other than protecting or currying favor with corporate- or community-owned hospitals. Furthermore, neither *Craigmiles* nor *Santos* is binding on this Court.

In the last case cited by Plaintiffs in their pretextual argument, *Vondy v. White*, the Fifth Circuit noted that unless the challenging party could establish that the government's stated reason was pretextual, then his due process challenged would fail. 719 F.2d 1265, 1266 (5th Cir. 1983). But the Fifth Circuit remanded on other grounds. This statement does not counter the clear mandate from the Supreme Court: A statute survives rational basis scrutiny unless the challenging party negates every conceivable rational basis for the law, regardless of the legislature's actual purpose. *Beach Commc'ns*, 508 U.S. at 315. Accordingly, this objective standard governs the Court's analysis. Although Plaintiffs have submitted a potential alternative basis, this does nothing to refute the other conceivable bases alleged by the Secretary.

Finally, Plaintiffs challenge the law as irrationally limited to POHs. Plaintiffs present evidence suggesting some of the problems allegedly inherent in self-referrals at POHs exist at any hospital. *See, e.g.*, Robert A. Berenson, et al., *Specialty-Service Lines: Salvos in the New Medical Arms Race*, 25 Health Affairs 5, w337–43, July 25, 2006; *see also*, Schneider Report ¶3.2.4 (concluding that corporate or community hospitals present similar concerns in light of incentives provided to physicians for self-referrals). Yet Congress limited the remedy to POHs. According to Plaintiffs, this renders Section 6001 arbitrary.

This argument is without merit. Congress is not required to address every evil with a single legislative act. "[R]ational distinctions may be made with substantially less than mathematical exactitude[,] . . . [and] [l]egislatures may implement their program step by step . . . adopting regulations that only partially ameliorate a perceived evil and deferring complete elimination of the evil to future regulations." *City of New Orleans v. Dukes*, 427 U.S. 297, 303

(1976); *Clover Leaf*, 449 U.S. at 466. Furthermore, "[e]vils in the same field may be of different dimensions and proportions, requiring different remedies." *Williamson v. Lee Optical Co.*, 348 U.S. 483, 489 (1955).

For the reasons discussed above, each of Plaintiffs' challenges that Section 6001 violates their substantive due process and equal protection rights fails.

4. Conclusion

Plaintiffs insist that Section 6001 will detrimentally impact one of the most efficient and successful components of the national healthcare system: POHs. They may be right. But Congress took a different position, focused particularly on concerns that physician ownership creates an incentive for unnecessary referrals. Plaintiffs' evidence and arguments in support of POHs is persuasive and well-documented. It may even suggest a wiser legislative approach. But even if true, it fails to counter every conceivable rational basis for the law. Thus, the Court finds there is no material issue of fact as to Plaintiffs' substantive due process and equal protection claims.

C. Takings

Plaintiffs allege that Section 6001 amounts to governmental intrusion on its property interests without just compensation in violation of the Fifth Amendment. According to Plaintiffs, the statute results in a regulatory taking of their real property and of their capital investment, including their anticipated revenue source of Medicare claims from patients treated in new or expanded POHs. Plaintiffs note that these projected Medicare claims were critical in financing their projects. The Secretary challenges Plaintiffs' takings claim as unripe. In the alternative, the Secretary argues that Section 6001 only affects physician owners' ability to bill Medicare, and Plaintiffs had no reasonable expectation that the law governing Medicare payments would

remain unchanged. The Court holds that Plaintiffs' takings claim is ripe but fails as a matter of law on the substantive argument.

1. Background

As detailed earlier, TSJH was in the midst of $30 million expansion when the PPACA was enacted. Before Congress passed the law, physician owners at TSJH already had invested $3 million in the planned expansion. These funds were used to purchase real property, negotiate zoning approval from the local government, prepare architectural plans, and otherwise facilitate the expansion. TSJH suspended their expansion plans in response to Section 6001. Similarly, dozens of other POHs around the country halted their expansion and construction projects. These projects were halted because they were not economically viable without the ability to bill Medicare for self-referrals. (A 2005 study found that between 48% and 90% of all referrals to POHs came 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 ii (2005)). Congress was aware of the potential impact on these new or expanding POHs. H.R. Rep. No. 111-443, pt. 1, at 808.

According to Plaintiffs, Section 6001 affected two property interests of physician owners: (1) their real property interests in the land purchased for expansion, and (2) the physicians' capital investment in the expansion project. Plaintiffs clarified at oral argument that their takings claim is premised on interference with both of these interests. Plaintiffs argue that Section 6001 affected their real property rights by prohibiting their intended economic use. Plaintiffs also contend that Section 6001 effectively seized physician-owners' development capital by retroactively and unfairly upsetting their investment expectations. Plaintiffs argue that Congress

could have avoided this retroactive effect with a broader grandfathering provision like the one included during the 2003 moratorium on new specialty POHs.

2. Legal Standard

The Fifth Amendment prohibits the taking of private property without just compensation. U.S. Const. Amend. V. Takings jurisprudence includes two types of takings: (1) per se takings where the government physically invades property or applies regulations that deprives the property of all economically beneficial use; and (2) regulatory takings that upset investment-backed expectations but do not render the property valueless. *Linge*, 544 U.S. at 538–39. Plaintiffs' challenge, based on the latter category, is governed by the standard set forth in *Penn Central Transportation Co. v. New York City*.

The regulatory takings doctrine represents the principle that in some circumstances "'justice and fairness' require that economic injuries caused by public action be compensated." *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978). Some factors the Court considers under the *Penn Central* analysis include: (1) the economic impact of the regulation, (2) its interference with reasonable investment backed expectations, and (3) the character of the governmental action. *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979) (citing *Penn Cent.*, 438 U.S. at 124). Relevant to the consideration of these factors is whether the regulation "imposes severe retroactive liability on a limited class of parties that could not have anticipated the liability, and the extent of that liability is substantially disproportionate to the parties' experience." *E. Enters. v. Apfel*, 524 U.S. 498, 528–29 (1998) (plurality) (O'Connor, J). This analysis requires "ad hoc, factual inquiries into the circumstances of each particular case." *Connolly v. Pension Benefit Guar. Corp.*, 475 U.S. 211, 224 (1986).

3. Analysis

Plaintiffs' takings challenge presents several issues. The Court has considered the evidence presented by Plaintiffs, including the details of the hardship TSJH and other PHA member hospitals may suffer. But ultimately Plaintiffs' claim is without merit. First, the Court holds that Plaintiffs' takings claim is ripe. Second, as a matter of law, the statute does not interfere with Plaintiffs' use of their real property. Finally, Plaintiffs' taking claims based on the loss of their investment fails under the *Penn Central* test.

a. Ripeness

As an initial matter, the Secretary argues that Plaintiffs' takings claim is not ripe because Plaintiffs have not sought compensation in the Federal Court of Claims pursuant to the Tucker Act. Under the Tucker Act, the Court of Federal Claims has exclusive jurisdiction to determine the amount of compensation pursuant to a takings claim. 28 U.S.C. § 1346(a)(2). Claims are premature until a claimant avails itself of this process. *Williamson Cnty. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 195 (1985). However, an exception applies when a plaintiff seeks equitable relief and might otherwise sustain uncompensable damages. *See E. Enterp.*, 524 U.S. at 521. In this case, Plaintiffs are seeking declaratory and injunctive relief so that they may proceed with their planned expansion. Accordingly, Plaintiffs' claim is ripe for resolution before this Court.

b. Interest in Real Property

Plaintiffs claim that Section 6001 is a regulatory taking of their real property because it forbids physician owners from using their real property for its intended use: hospital expansion. But Section 6001 merely limits the availability of the whole hospital exception. It does not

impose *any* restrictions on Plaintiffs' use of their real property, and therefore cannot, as a matter of law, form the basis of their takings claim.

Section 6001 does not prohibit physician owners from building or expanding a hospital on their property. *See* 42 U.S.C. § 1395nn. Plaintiffs could lawfully complete their projects and continue to bill Medicare for health services as long as those services were not the result of a physician-owner's referral. *See id.* Plaintiffs could also lawfully continue to self-refer when patients or their private insurers will be billed. *See id.* The only value Plaintiffs have lost, under the law, is the ability to bill Medicare for self-referred patients, and as discussed below, that does not constitute an impermissible taking. *See id.*

Accordingly, Section 6001—which does not proscribe, limit, or otherwise interfere with Plaintiffs' use of their real property—does not result in a regulatory taking of Plaintiffs' real property.

c. Interest in Capital Investment

Plaintiffs also claim that Section 6001 retroactively seizes expected returns on their capital investment by eliminating a critical element of their revenue source: Medicare claims. However, as discussed below, the evidence before the Court cannot support a regulatory taking under the *Penn Central* test.

The first factor under the *Penn Central* test is the economic impact of the regulation. Plaintiffs have submitted evidence that they will suffer enormous financial hardship under Section 6001. For example, if Plaintiffs abandon their expansion plans, they will forfeit the capital investment already expended, which would be a multi-million dollar loss. If Plaintiffs continue with their expansion, they would lose the ability to bill Medicare, an essential revenue source for POHs. Extrapolated across other POH expansion and construction projects, Section

6001 has potentially impacted "[o]ver $5 billion of investments [that] have been made toward" these projects. H.R. Rep. No. 111-443, pt. 1, at 808. Such a financial burden is indicative of a regulatory taking. *See E. Enters.*, 524 U.S. at 529–30 (finding a taking where the financial burden was estimated on the order of $50 to $100 million).

Under the second *Penn Central* factor, the Court considers the statute's interference with reasonable investment backed expectations. Plaintiffs argue that Section 6001 retroactively upsets their expectation that they would be able to bill Medicare for patients self-referred to their expanded facility. But under existing law, Plaintiffs could have no *reasonable* expectation that the Medicare program would remain unchanged.

Medicare is a voluntary program which the government may alter at any time. 42 U.S.C. § 1304. In fact, Congress has altered Medicare benefits numerous times since the program was established. *See, e.g.*, *Greater Dallas Home Care Alliance v. United States*, 10 F. Supp. 2d 638, 641 (N.D. Tex. 1998) (discussing "significant changes" in the payment methodology for home healthcare agencies under Medicare). Furthermore, in 2007 and 2008, Congress considered and almost enacted previous versions of Section 6001 that also did not include the broad grandfathering provisions that Plaintiffs claim they expected. *See, e.g.*, Children's Health and Medicare Protection Act of 2007, H.R. 3162, § 651, 110th Cong. (1st Sess. 2007) (as passed by House, Aug. 1, 2007); Paul Wellstone Mental Health and Addiction Equity Act, H.R. 1424, § 106, 110th Cong. (2d Sess. 2008) (as passed by House, Mar. 5, 2008). In light of the legal and factual background of the Medicare statute, Plaintiffs cannot claim to have had a reasonable expectation that the statute would remain unchanged.

Similarly, as to Plaintiffs' claim that the law is retroactive, the Court notes that the effective date of the law was the date of enactment: March 23, 2011. The statute does not reach

back into the past and assign new duties or liabilities for past actions. *See Pension Benefit Guar.*, 467 U.S. at 730. Instead, the act prohibits future Medicare billing for self-referred patients at expanded or new facilities. 42 U.S.C. § 1395nn.

The final *Penn Central* factor is the character of the governmental action. Section 6001 is more analogous to a "public program adjusting the benefits and burdens of economic life to promote the common good" than a physical invasion of Plaintiffs' property rights. *Lingle*, 544 U.S. at 539 (quoting *Penn Cent.*, 438 U.S. at 124). Furthermore, the impacted program is voluntary. "Governmental 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 & Human Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991 (quoting *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986)). *See also Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993) ("economic hardship is not equivalent to legal compulsion for purposes of takings analysis"). Accordingly, the final *Penn Central* factor suggests Section 6001 does not amount to a regulatory taking.

4. Conclusion

Having considered the parties' arguments and the applicable law, the Court finds Plaintiffs' takings claim ripe. However, Section 6001 does not impose restrictions on Plaintiffs' use of real property. Also, Section 6001 does not interfere with reasonable investment backed expectations that Plaintiffs could bill Medicare for services to self-referred patients at their new or expanded facilities. Accordingly, Plaintiffs' takings claim fails as a matter of law.

D. Vagueness

Finally, Plaintiffs challenge Section 6001 as unconstitutionally vague in violation of the Fifth Amendment's due process requirement. Specifically, Plaintiffs challenge that (1) the

effective date of the law is unclear and (2) Section 6001 creates an exception but does not set forth the criteria to qualify for the exception. The Secretary counters that the statute is sufficiently detailed and clear to satisfy the constitutional requirement. The Court finds that Section 6001 is not unconstitutionally vague.

1. Background

The Stark Law includes several exemptions. Among these, the statute grandfathers facilities that meet certain enumerated requirements within eighteen months from the date the statute was passed (i.e., by September 23, 2011). 42 U.S.C. § 1395nn(d)(3)(D). The list of requirements includes that a POH cannot have expanded after March 23, 2010—the date the statute was enacted—to qualify. 42 U.S.C. § 1395nn(i)(1)(B). Plaintiffs claim the eighteen-month deadline (i.e., September 23, 2011) conflicts with the immediate March 23, 2010 deadline, leaving hospitals to guess at the law's effective date.

Plaintiffs also challenge the provision that directs the Secretary to establish a procedure to consider exceptions for POHs wishing to expand. 42 U.S.C. § 1395nn(i)(3). The Secretary's regulations must be in place by January 1, 2012 and the procedure must be in place by February 1, 2012. *Id.* Plaintiffs argue that POHs cannot determine from the statute whether they will qualify for the exception until the Secretary promulgates the rules. In the case of TSJH, for example, this creates a specific dilemma: If the hospital continues with its expansion before the Secretary promulgates the rules in 2012, it risks violating a requirement that the Secretary may later impose. According to Plaintiffs, this undefined exception renders the statute unconstitutionally vague.

2. Legal Standard

Under the Fifth Amendment, a law must provide a "person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Roark & Hardee LP v. City of Austin*, 522 F.3d 533, 551 (5th Cir. 2008) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108–09 (1972)). A statute so vague that it does not provide fair notice of its requirements violates the constitutional guarantee of due process. *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497–98 (1982).

3. Analysis

Plaintiffs identify two different provisions in Section 6001 as unconstitutionally vague: the grandfathering section and the exception provision. The Court finds that both of these sections satisfy the Fifth Amendment's vagueness standard.

a. Grandfathering Provision

As discussed above, the grandfathering provision sets two pertinent dates: March 23, 2010 and September 23, 2011. By September 23, 2011, a POH wishing to be grandfathered under the statute must satisfy a series of requirements. Several of these requirements concern disclosures to patients and to the Secretary. 42 U.S.C. § 1395nn(i)(1)(C)–(E). Another of the listed requirements states only hospitals that have not expanded since March 23, 2010, can qualify under the grandfathering provision. 42 U.S.C. § 1395nn(i)(1)(B).

Plaintiffs complain that Section 6001's inclusion of the two dates makes the statute so vague that hospitals cannot determine what they must do to be grandfathered under the statute. But Plaintiffs' argument is without merit because the two dates complement, rather than contradict one another. Under the clear terms of the statute, the September 23, 2011, date serves as an umbrella deadline. In other words, *all* of the listed requirements must be satisfied by that

date. The more specific requirement that a POH must forgo expansion after March 23, 2010 does not conflict with the umbrella deadline. If a hospital forgoes expansion after the March 23, 2010, deadline, it will have done so prior to September 23, 2011. Accordingly, the grandfathering requirements do not conflict as suggested by Plaintiffs, and the statute provides hospitals fair notice of what is expected and by when. *See Vill. of Hoffman Estates*, 455 U.S. at 497–98. Thus, the grandfathering provision is not unconstitutionally vague.

b. Exceptions

Section 6001 also establishes exceptions for some POHs to expand. The statute sets forth general categories that define which facilities qualify for the exceptions. 42 U.S.C. § 1395nn(i)(3)(E)&(F). The statute also requires the Secretary to implement an application process by 2012. 42 U.S.C. § 1395nn(i)(3)(A). Plaintiffs argue that the nearly two-year delay between enactment of the statute and the deadline for the Secretary to establish the application process prevents hospitals with expansions already under development—such as TSJH—from knowing what is expected of them. According to Plaintiffs, this lack of information renders Section 6001's exception provision unconstitutionally vague.

The Court finds that the section creating the exception and delegating administration of the application process to the Secretary provides sufficient detail to guide the Secretary in the rule-making process. *See United States v. Whaley*, 577 F.3d 254, 263–64 (5th Cir. 2009) (stating that Congress can delegate rulemaking authority if "Congress has provided an intelligible principle to guide the agency's regulations" (quotations and citations omitted)). The statute also states that no hospital falls within the exception until its application is approved by the Secretary. 42 U.S.C. § 1395nn(i)(3). Plaintiffs have no valid constitutional complaint simply because a hospital such as TSJH must wait until its application is approved—after the Secretary

implements the application period. *See, e.g.*, *Faulk v. Union Pacific R.R. Co.*, No. 07-0554, 2011 WL 777905, at *12 (W.D. La. Mar. 1, 2011) ("[A] law delegating authority to an administrative agency is not void for vagueness because affected parties believe they will not be able to make successful predictions about agency decisions."). This delay may be frustrating for Plaintiffs, but it is not vague or ambiguous under the statute.

V. CONCLUSION

Plaintiffs allege that Section 6001 violates their constitutionally protected rights to due process and equal protection. They also challenge the law as unconstitutionally and retroactively confiscatory. Finally, Plaintiffs claim the law is void for vagueness. Through this action, Plaintiffs ask the Court to declare Section 6001 unconstitutional and enjoin the Secretary from enforcing the amended Stark Law.

In support of their claims, Plaintiffs present a wealth of evidence that demonstrates the hardship they face as a result of the amendment. Plaintiffs also offer testimony and evidence that questions the wisdom and fairness of the legislation. Plaintiffs' evidence appears to sound in logic and reason. But it is not enough for Plaintiffs to convince the Court that their studies and reports are more likely correct. In a case like this, Plaintiffs have a particularly heavy burden to show that the justifications for enacting Section 6001 could not reasonably be conceived to be true. Short of that, the Court does not have the authority to judge the wisdom or fairness of Congress's decision. Rather, as the Supreme Court has said, "[t]he Constitution presumes that . . . even improvident decisions will eventually be rectified by the democratic process and that judicial intervention is generally unwarranted no matter how unwisely . . . a political branch has acted."

At the summary judgment stage, the Court is charged with a single task: determine whether the evidence presents a genuine issue of *material* fact. For the reasons discussed more fully above, the Court finds that although genuine factual disputes exist, none of them are material to Plaintiffs' claims. Accordingly, the Secretary is entitled to judgment as a matter of law. Because Plaintiffs cannot succeed on the merits of their claims, the Court need not consider the equitable factors relevant to Plaintiffs' request for a permanent injunction. For the foregoing reasons, the Secretary's Motion for Summary Judgment is hereby GRANTED.

It is SO ORDERED.

SIGNED this 31st day of March, 2011.

MICHAEL H. SCHNEIDER
UNITED STATES DISTRICT JUDGE