UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE, *et al.*, Plaintiffs, v. JUDITH ROGERS, M.H.A., *et al.*, Defendants.	Civil Action No. 12-01229 (TFH) REDACTED

MEMORANDUM OPINION

This lawsuit was commenced by Dr. John Doe and Dr. Doe's limited liability company ("the plaintiffs") to recover damages and secure declaratory and injunctive relief against the Secretary of the Department of Health and Human Services, the National Practitioner Data Bank, and three officials who administer the National Practitioner Data Bank (collectively "the defendants"). The plaintiffs allege that the defendants unlawfully accepted, maintained, and continue to release an inaccurate, fraudulent and untimely Adverse Action Report that was submitted to the National Practitioner Data Bank by Dr. Doe's prior employer, Peconic Bay Medical Center (the "Hospital" or "PBMC"). Pending before the Court are a Motion to Dismiss or, Alternatively, for Summary Judgment [ECF No. 26] that was filed by the defendants and a Cross-Motion for Summary Judgment [ECF No. 45 (Sealed)] that was filed by the plaintiffs. For the reasons that follow, the Court will grant in part and deny in part the defendants' Motion to Dismiss or, Alternatively, for Summary Judgment, and deny the plaintiffs' Cross-Motion for Summary Judgment. The Court will also remand to the Secretary for further proceedings consistent with this Opinion.

BACKGROUND AND PROCEDURAL POSTURE

I. The Health Care Quality Improvement Act

Nearly three decades ago, Congress enacted the Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-11152 (West 2014) (the "Act" or "HCQIA"), to address the nationwide problem of medical malpractice and the "need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance." 42 U.S.C. § 11101(1)-(2). Congress found that professional review conducted by peers could remedy the medical malpractice problem but incentives and protections to encourage effective professional peer review needed to be established. *Id.* § 11101(3)-(5). The Health Care Quality Improvement Act promotes effective professional peer review by prescribing mandatory review and reporting requirements for health care entities, *id.* §§ 11131, 11132, 11133, setting standards to govern a professional review action, *id.* § 11112, and, significantly, providing immunity from damages liability to professional review bodies and designated participants if the professional review action complies with certain standards enumerated in the statute, *id.* § 11111(a)(1).

Relevant to this case, the Health Care Quality Improvement Act compels "[e]ach health care entity which . . . accepts the surrender of clinical privileges of a physician . . . while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct" to report such action or surrender of clinical privileges to the Secretary of

the Department of Health and Human Services.[1] *Id.* §§ 11133(a)(1)(B)(i) (quotation), 11134(b). The Health Care Quality Improvement Act also obligates hospitals to request reported information about a physician who seeks clinical privileges or applies to join a hospital's medical staff, *id.* § 11135(a), and establishes a presumption that a hospital knows information that has been reported about a physician regardless of whether the hospital actually obtains the information as required by the Act, *id.* § 11135(b). The Health Care Quality Improvement Act recognizes, however, that there might be disputes about the accuracy of reported information, so it directs the Secretary of the Department of Health and Human Services to issue regulations that provide procedures to dispute a report's accuracy. *Id.* § 11136(2).

II. The National Practitioner Databank

In accordance with the delegations contained in the Health Care Quality Improvement Act, the Secretary of the Department of Health and Human Services promulgated regulations that established the National Practitioner Data Bank. 45 C.F.R. § 60.1. The National Practitioner Data Bank collects and releases information that the Health Care Quality Improvement Act requires health care entities to report regarding the "professional competence and conduct of physicians, dentists, and other health care practitioners." *Id.*

The Department of Health and Human Services also published an NPDB Guidebook to "inform the United States health care community about the NPDB and what is required to comply with the requirements established by Title IV of Public Law 99-660, the Health Care

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[1] "The sanction against a health care entity that fails to substantially comply with this requirement is significant: the health care entity loses the statutory immunity created in § 11111(a)(1) of the HCQIA." *Straznicky v. Desert Springs Hosp.*, 642 F. Supp. 2d 1238, 1245 (D. Nev. 2009) (citing 42 U.S.C. § 11133(c)(1)).

Quality Improvement Act of 1986, as amended."[2] U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RESOURCES & SERVS. ADMIN., NPDB GUIDEBOOK A-1 (2001).[3] The NPDB Guidebook states that "[t]he establishment of the NPDB represents an important step by the U.S. Government to enhance professional review efforts by making certain information concerning medical malpractice payments and adverse actions available to eligible entities and individuals." *Id.* at A-3. As one federal appellate court explained:

> The Data Bank prevents a physician who applies to become a member of a hospital's medical staff or for clinical privileges from being able to hide disciplinary actions that have been taken against him. Information in the Data Bank is intended "only to alert . . . health care entities that there may be a problem with a particular practitioner's professional competence or conduct" because the practitioner has been the subject of a disciplinary action. The Data Bank contains not only the hospital's side of the story but also the physician's response. What the requesting hospital does with the information it obtains from the Data Bank is entirely up to that hospital. It could completely discount the information, or it could back off from any professional relationship with the physician, or it could make further inquiries to determine what had actually happened.

Leal v. Secretary, U.S. Dep't of Health & Human Servs., 620 F.3d 1280, 1283-84 (11th Cir. 2010).

The review, reporting and disclosure regulations that apply to the National Practitioner Data Bank are codified at 45 C.F.R. §§ 60.1-60.22 and "establish procedures to enable

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[2] The Health Care Quality Improvement Act provides that "[t]he Secretary may establish, after notice and opportunity for comment, such voluntary guidelines as may assist the professional review bodies in meeting the standards" for professional review. 42 U.S.C. § 11114. The Health Care Quality Improvement Act also requires that "the information required to be reported" by the Act "shall be reported to the Secretary, or, in the Secretary's discretion, to an appropriate private or public agency which has made suitable arrangements with the Secretary with respect to receipt, storage, protection of confidentiality, and dissemination of the information under this subchapter." *Id.* § 11134(b).

[3] The 2001 edition of the NPDB Guidebook was in effect at the time of the events at issue in this case. The NPDB Guidebook was updated in April, however, and that edition is available at http://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf.

individuals or entities to obtain information from the NPDB or to dispute the accuracy of NPDB information." 45 C.F.R. § 60.2. The details of the procedures to dispute the accuracy of an Adverse Action Report are discussed *infra* at part B(5). With respect to the relevant requirement for reporting, the National Practitioner Data Bank regulations mirror the Health Care Quality Improvement Act by stating that hospitals must report to the National Practitioner Data Bank the "[a]cceptance of the surrender of clinical privileges or any restriction of such privileges by a physician . . . [w]hile the physician . . . is under investigation by the health care entity relating to possible incompetence or improper professional conduct . . . ." 45 C.F.R. § 60.12(a)(1)(ii).

III. The Surgical Incident and Resulting Adverse Action Report

On Friday, October 2, 2009, Dr. Doe commenced a late-night emergency laparoscopic appendectomy on a 14-year-old girl who had acute appendicitis. First Am. Compl. ¶¶ 48, 49; Administrative Record ("AR") 0153 [ECF No. 19-4 (Sealed)]; Pls.' Statement of Undisputed Material Facts Pursuant to Local R. 7(h) ¶ 4 [ECF No. 45-2 (Sealed)]. During the surgery, Dr. Doe removed what he characterized as an "inflamed band" but the anesthesiologist protested was the patient's Fallopian tube. AR 0101 [ECF No. 19-3 (Sealed)] ("During the procedure it was noted by [the anesthesiologist] that [Dr. Doe] removed segment of ® Fallopian tube." (capitalization formatting omitted)); AR 0143 [ECF No. 19-3 (Sealed)] (stating that the anesthesiologist "shouted loudly" at Dr. Doe); AR 0283 [ECF No. 32-1 (Sealed)] (stating that "the error was immediately detected by the anesthesiologist during the procedure"). A subsequent pathology report confirmed that the "inflamed band" was part of the patient's right Fallopian tube. First Am. Compl. ¶ 51 [ECF No. 23]; AR 0142-0143 at ¶ 85 [ECF No. 19-3

(Sealed)];[4] AR 0181 [ECF No. 19-4 (Sealed)]; AR 0185 [ECF No. 19-4 (Sealed)]; AR 0219 [ECF No. 19-5 (Sealed)]; Pls.' Statement of Undisputed Material Facts Pursuant to Local R. 7(h) ¶ 4 [ECF No. 45-2 (Sealed)]. There is no dispute that Dr. Doe failed to recognize the anatomical identity of the "inflamed band" before he intentionally cut and removed it.[5] Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 3-4 [ECF No. 45 (Sealed)] (stating that "[t]he surgery included the surgeon's considered medical judgment that it was necessary to remove an inflamed band, which was later conclusively identified as a damaged Fallopian tube . . ."); AR 0010 [ECF No. 19-1 (Sealed)] (asserting that the decision to cut and remove the "inflamed band" was an intentional exercise of his medical judgment); AR 0143 [ECF No. 19-3 (Sealed)] ("As it turned out, the pathologist later identified this inflamed band as the right Fallopian tube."); AR 0158 [ECF No.

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[4] AR 0140-46 [ECF No. 19-3 (Sealed)] reproduces several sections of a civil complaint that Dr. Doe filed in 2010 against the National Practitioner Data Bank, Peconic Bay Medical Center, named officials at Peconic Bay Medical Center, and 10 unidentified individuals. *See* [redacted]. The facts alleged in the complaint were verified under oath by Dr. Doe. AR 0146 [ECF No. 19-3 (Sealed)].

[5] Throughout these proceedings Dr. Doe challenged the notion that cutting and removing part of the Fallopian tube was "inadvertent" because the decision to proceed with the surgery was an intentional exercise of his medical judgment. AR 0010 [ECF No. 19-1 (Sealed)]. His position seems to be that it would not have mattered whether he knew he was cutting a Fallopian tube or "an inflamed band" because the procedure was necessary in either case to gain access to the appendix. *Id.* This is whistling past the graveyard. Although it may be the case that Dr. Doe intended to cut and remove whatever was there regardless of what it was, as a matter of anatomy and logic he did not know that what he was cutting was a Fallopian tube so he cannot be said to have intentionally cut and removed a Fallopian tube as a distinct organ. It therefore is accurate to say that his removal of the Fallopian tube was inadvertent in the sense that he did not know he was removing that specific organ. According to the Hospital, "the Hospital committees that reviewed this matter concluded that [Dr. Doe] removed part of the patient's fallopian tube because he did not recognize the anatomy" and "the anesthesiologist's intervention prevented [Dr. Doe] from removing the patient's ovary rather than her appendix." AR 0283 [ECF No. 32-1 (Sealed)].

19-4 (Sealed)] ("Pathological analysis of the inflamed band indicated that it was the right Fallopian tube."); AR 0169 [ECF No. 19-4 (Sealed)] (stating that he cut "an inflamed band"); AR 0180 [ECF No. 19-4 (Sealed)] (referring to the cut organ as an "adherence"); AR 0219 [ECF No. 19-5 (Sealed)] (stating that the "band was later identified as a portion of the Fallopian tube"); Pls.' Statement of Undisputed Material Facts Pursuant to Local R. 7(h) ¶ 4 [ECF No. 45-2 (Sealed)] (stating that an "inflamed band . . . was later conclusively identified as a severely inflamed Fallopian tube").

The following Monday, Dr. Doe met with three Hospital officials to discuss the surgical incident,[6] which the Hospital claims was reported by both the anesthesiologist and a nurse who was present during the surgery.[7] Dr. Doe claims that, during that meeting, the Vice President for Medical Affairs told Dr. Doe that he was being fired. AR 0143 at ¶ 87 [ECF No. 19-3 (Sealed)] (stating that the Vice President of Medical Affairs "told the plaintiff that he was fired"); AR 0203 [ECF No. 19-5 (Sealed)] (stating that Dr. Doe "called me a few hours later on October 5th and told me that he had just met with [the Vice president of Medial Affairs] and he had been fired from his position at the hospital"). The hospital claims that the officials "informed [Dr. Doe] that he could not exercise his surgical privileges pending further investigation of the care he provided to [the] patient." AR 0084 [ECF No. 19-2 (Sealed)]. Regardless of who said what, it is undisputed that, at some point that day, the Vice President of Medical Affairs told Dr. Doe

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6 AR 00143 [ECF No. 19-3 (Sealed)] (stating that Dr. Doe met with the Vice President of Medical Affairs, the Acting Chief of Surgery, and the President of the Medical Staff); AR 0106 [ECF No. 19-3 (Sealed)] (memorializing the meeting's occurrence).

7 AR 0082 [ECF No. 19-2 (Sealed)] (stating that the "surgical error" was "reported on Monday morning, October 5, 2009 . . . by the anesthesiologist who was present during the procedure" and "[t]he operating room nurse also filed an incident report").

that the Hospital was required to report the surgical incident to the New York State Department of Health and that such a report was necessary "whenever an organ other than the organ operated is injured." AR 0161 [ECF No. 19-4 (Sealed)]; AR 0203 [ECF No. 19-5 (Sealed)]. The hospital did, in fact, file a report that day via the New York Patient Occurrence Reporting and Tracking System ("NYPORTS")[8] and stated in the report that "[t]he physician has been placed on suspension pending completion of the investigation and the family notified." AR 0108 [ECF No. 19-3 (Sealed)]. The Hospital also submitted a Sentinel Event Self-Report to The Joint Commission[9] that contained the same statement that "[t]he physician has been placed on suspension pending completion of the investigation and the family notified." AR 0109 [ECF No. 19-3 (Sealed)].

Later that same day, Dr. Doe executed a letter voluntarily suspending his surgical privileges and stating "I will not operate at Peconic Bay Medical Center for the next two weeks effective October 5, 2009 through October 19, 2009, or until mutually agreed upon. I will however, finish the follow-up care on patients that I am currently involved with on the clinical floors without performing any surgery." AR 0110 [ECF No. 19-3 (Sealed)]. Dr. Doe claims that this letter was prompted by his discovery "that he was going to have to return to the University of Tennessee to complete another year of cardiothoracic surgery fellowship in preparation for his Board exam." First Am. Compl. ¶ 53.

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8 AR 0083 [ECF No. 19-2 (Sealed)] (identifying the acronym).

9 The Joint Commission is a not-for-profit organization that is "the nation's oldest and largest standards-setting and accrediting body in health care." *About The Joint Commission*, http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (last visited April 19, 2015).

Two days later, on October 7, 2009, Dr. Doe tendered a short letter of resignation that stated "[e]ffective October 16, 2009, I resign from Peconic Bay Medical Center." AR 0113 [ECF No. 19-3 (Sealed)].

On December 3, 2009, about two months after Dr. Doe resigned, the Hospital submitted an Adverse Action Report to the National Practitioner Data Bank. AR 0132 [ECF No. 19-3 (Sealed)]. The Adverse Action Report stated:

> In June 2009, the physician commenced practice at the Hospital in thoracic and general surgery. On Friday, October 2, 2009, the physician performed a laparoscopic appendectomy on a 14-year-old female. In the course of performing the procedure, the physician inadvertently removed part of one of the patient's fallopian tubes. On or about Monday, October 5, 2009, the physician agreed to refrain from exercising his surgical privileges pending the Hospital's investigation of this matter. By letter dated October 7, 2009, the physician advised the Hospital that he resigned from the Hospital effective October 16, 2009. Accordingly, the Hospital took no further action regarding the physician's privileges or employment. However, the Hospital's quality assurance review of this matter indicates departures by the physician from standard of care with regard to the laparoscopic appendectomy that he performed on October 2, 2009.

AR 0002 [ECF No. 19-1 (Sealed)].

Dr. Doe contends that he was unaware of the Adverse Action Report until June 2010, when a prospective employer cited it as the reason for declining to meet with him. AR 0017 [ECF No. 19-1 (Sealed)]; AR 0018 [ECF No. 19-1 (Sealed)]; First Am. Compl. ¶¶ 83-86 [ECF No. 23]; Pls.' Statement of Undisputed Material Facts Pursuant to Local R. 7(h) ¶ 13 [ECF No. 45-2 (Sealed)]. Upon discovering the report, Dr. Doe contacted the Hospital and requested that it retract the report because it was factually inaccurate. AR 0008 [ECF No. 19-1 (Sealed)]; AR 0013 [ECF No. 19-1 (Sealed)]. Dr. Doe also submitted a Subject Statement to the National Practitioner Data Bank and placed the Adverse Action Report in a disputed status "challenging both the factual accuracy of the report and whether the report was submitted in accordance with

the [National Practitioner Data Bank's] reporting requirements." First Am. Compl. ¶ 89 [ECF No. 23]; *see also* AR 0018-27 [ECF No. 19-1 (Sealed)].

When the Hospital refused to revise or void the Adverse Action Report, Dr. Doe submitted a letter to the National Practitioner Data Bank requesting that the Secretary of the Department of Health and Human Services review and remove the report. First Am. Compl. ¶ 91 [ECF No. 23]; AR 0007-17 [ECF No. 19-1 (Sealed)]. On June 25, 2012, Judy Rodgers, Senior Advisor for the Division of Practitioner Data Banks at the Department of Health and Human Services, issued a Secretarial Review Decision denying Dr. Doe's request and stating that the Secretary found that "[t]here is no basis on which to conclude that the Report should not have been filed in the NPDB or that it is not accurate, complete, timely or relevant." AR 0268-73 [ECF No. 19-6 (Sealed)].

One month later, on July 25, 2012, the plaintiffs filed this lawsuit claiming that the defendants' acceptance, maintenance, and disclosure of the disputed Adverse Action Report in the National Practitioner Data Bank "has for the last two and one half years caused all prospective employers in the United States to reject plaintiff physician's applications for employment and medical staff privileges." First Am. Compl. ¶ 4 [ECF No. 23]. The plaintiffs advanced six causes of action alleging that (1) the defendants' actions with respect to the Adverse Action Report were unlawful and should be set aside in accordance with the Administrative Procedure Act (the "APA"), (2) the Health Care Quality Improvement Act and the implementing regulations that apply to the National Practitioner Data Bank violate the Due Process Clause both facially and (3) as applied by the defendants, (4) the Secretary's actions violated §§ 522a(g)(1)(A) and (C) of the Privacy Act, (5) the defendants' interpretation and

application of the Health Care Quality Improvement Act and the implementing regulations constitute an unconstitutional Bill of Attainder, and (6) the defendants' interpretation and application of the Health Care Quality Improvement Act and the implementing regulations violate the Eighth Amendment's prohibition on cruel and unusual punishments. *Id.* ¶¶ 102-84. In lieu of an answer, the defendants moved to dismiss the entirety of the First Amended Complaint or, alternatively, for summary judgment. Mem. In Support of Defs.' Mot. to Dismiss or, Alternatively, for Summ. J. 2-3 [ECF No. 33 (Sealed)]. The plaintiffs countered with a Cross-Motion for Summary Judgment [ECF No. 45 (Sealed)] and also filed a Motion for Leave to Supplement the Record of Continuing Constitutional Deprivation [ECF No. 58], which was opposed by the defendants.

DISCUSSION

A. Whether the Agency's Actions Regarding the Adverse Action Report were Arbitrary, Capricious, an Abuse of Discretion or Unlawful

The plaintiffs' first cause of action invokes the APA and alleges that the defendants' actions with regard to the Adverse Action Report should be set aside because (1) there was no "investigation" by the Hospital, (2) Dr. Doe's resignation was obtained by fraud and therefore not "voluntary," (3) NPDB Guidebook Rule F-8 is overly broad, overly inclusive, and contrary to the purposes of the Health Care Quality Improvement Act, (4) the Adverse Action Report was untimely because it was not filed within 30 days of the adverse action as required by 45 C.F.R. § 60.5(d), and (5) the Hospital's quality assurance review was not a reportable event because it did not result in the suspension of Dr. Doe's privileges given that he had already resigned. First. Am. Compl. ¶¶ 102-125. The government moved to dismiss this cause of action on the grounds that the Secretary's review is limited to a determination about whether the report accurately

describes the actions the Hospital took and the reasons for those actions, the scope of the Secretary's review does not involve an evaluation of the merits of the Hospital's findings, the administrative record reflects that there was an ongoing investigation at the time Dr. Doe surrendered his surgical privileges and resigned, any errors in the record evidence supplied by the Hospital were typographical and do not indicate fraud or that an investigation never occurred, the 30-day reporting deadline is not a legal bar to an otherwise valid adverse report, and there is no requirement that a physician know that an investigation is occurring before a voluntary suspension becomes reportable and, furthermore, to adopt such a requirement would be burdensome for the Secretary. Mem. In Support of Defs.' Mot. to Dismiss or, Alternatively, for Summ. J. 11-21 [ECF No. 33 (Sealed)].

The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. When exercising judicial review, "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 5 U.S.C. § 706(2)(A).

It is well established that, when confronted with an APA case, "[t]he district court sits as an appellate tribunal in such a case, and the question whether [the defendants] acted in an arbitrary and capricious manner is a legal one which the district court can resolve on the agency record—regardless of whether it is presented in the context of a motion for judgment on the pleadings or in a motion for summary judgment (or in any other Rule 12 motion under the Federal Rules of Civil Procedure)." *University Med. Ctr. of S. Nevada v. Shalala*, 173 F.3d 438,

441 n.3 (D.C. Cir. 1999). Moreover, the court's determination about whether the defendants' actions were arbitrary and capricious is based on the evidence that was provided to the agency and the court's "concern is not whether the [defendants] might have reached a different decision had [they] considered additional evidence, but only whether the decision [they] did reach, based on the evidence that was before [them], was unreasonable." *Conax Florida Corp. v. United States*, 824 F.2d 1124, 1128 (D.C. Cir. 1987).

The Court is mindful that "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

1. Whether it was arbitrary and capricious for the Secretary to determine that the Hospital was conducting an investigation when Dr. Doe suspended his surgical privileges

When a hospital accepts a physician's surrender of clinical privileges while the physician is the subject of a pending investigation relating to possible incompetence or improper conduct the hospital must report that event to the National Practitioner Data Bank. 42 U.S.C. § 11134(b); 45 C.F.R. § 60.12. The Adverse Action Report submitted by the Hospital in this case was classified as a "voluntary surrender of clinical privilege(s), while under, or to avoid, investigation relating to professional competence or conduct." AR 0002 [ECF No. 19-1 (Sealed)] (capitalization formatting omitted). Although the plaintiffs concede that surrendering clinical privileges while under investigation is a reportable event, First Am. Compl. ¶ 57, they

nonetheless challenge the defendants' actions with respect to the Adverse Action Report on the ground that there was no evidence that an investigation was occurring either before or at the time Dr. Doe surrendered his surgical privileges and resigned, *id.* ¶¶ 105-107. The Secretary concluded otherwise and found that an investigation commenced on October 5, 2009, as demonstrated by several documents contained in the Administrative Record. AR 0256 [ECF No. 19-6 (Sealed)].

The term "investigation" is not defined in either the Health Care Quality Improvement Act or the regulations that implement it. *Doe v. Leavitt*, 552 F.3d 75, 79-80 (1st Cir. 2009) ("[T]he secretary has not exercised [the] rulemaking authority to set forth [her] interpretation of the word 'investigation.' Instead, the Secretary's interpretation must be gleaned from (i) an agency manual, the NPDB Guidebook . . . and (ii) the Secretary's decision in this case."); *Simpkins v. Shalala*, 999 F. Supp. 106, 115 (D.D.C. 1998) ("Neither the statute nor the regulations promulgated in furtherance of the HCQI Act define an investigation."). The 2001 version of the NPDB Guidebook that was in effect at the time of the challenged Secretarial Review also did not define the term "investigation," although it gave the following examples of types of evidence that might demonstrate that an investigation was occurring:[10]

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[10] During oral arguments counsel for the defendants acknowledged that the NPDB Guidebook contains "an explanation of how the agency looks at an investigation or what . . . goes into there being an investigation" but does not offer "a definition in sort of a nice one-sentence kind of way." Hr'g Tr. 11:10-13:18, Oct. 24, 2013 [ECF No. 57].

As an aside, the recently revised 2015 version of the NPDB Guidebook, *see supra* n.3, contains a more fulsome explanation about how the Department of Health and Human Services interprets the term "investigation." U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RESOURCES & SERVS. ADMIN., NPDB GUIDEBOOK E-34 (2015), *available at* http://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf. The 2015 NPDB Guidebook announces that "NPDB interprets the word 'investigation' expansively" and that "[i]t may look

> A health care entity that submits an AAR based on surrender or restriction of a physician's . . . privileges while under investigation should have contemporaneous evidence of an ongoing investigation at the time of surrender . . . . The reporting entity should be able to produce evidence that an investigation was initiated prior to the surrender of clinical privileges by a practitioner. Examples of acceptable evidence may include minutes or excerpts from committee meetings, orders from hospital officials directing an investigation, and notices to practitioners of an investigation.

NPDB GUIDEBOOK E-19. The 2001 NPDB Guidebook further stated that an investigation "must be carried out by the health care entity, not an individual on the staff," "must be focused on the practitioner in question," "must concern the professional competence and/or professional conduct of the practitioner in question," and "a routine or general review of a particular practitioner is not an investigation." *Id.*

The Court's consideration begins with the accepted principle that "[t]he views of agencies charged with implementing a statute are entitled to deference." *Bragdon v. Abbott*, 524 U.S. 624, 626 (1998). With respect to the interpretation of "investigation" found in the NPDB

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at a health care entity's bylaws and other documents for assistance in determining whether an investigation has started or is ongoing, but it retains the ultimate authority to determine whether an investigation exists." *Id.* The 2015 NPDB Guidebook also states that:

> A routine, formal peer review process under which a health care entity evaluates, against clearly defined measures, the privilege-specific competence of all practitioners is not considered an investigation for the purposes of reporting to the NPDB. However, if a formal, targeted process is used when issues related to a specific practitioner's professional competence or conduct are identified, this is considered an investigation for the purposes of reporting to the NPDB.

Id. In addition, the 2015 NPDB Guidebook states that "the term 'investigation' is not controlled by how that term may be defined in a health care entity's bylaws or policies and procedures." *Id.* E-34-35. Because the Court applies the 2001 version of the NPDB Guidebook, which was in effect at the time the events at issue took place, the Adverse Action Report was filed, and the Secretarial Review Decision was issued, the additional interpretations of the term "investigation" found in the 2015 NPDB Guidebook have not been considered and the Court takes no position about whether these additional interpretations are consistent with prior interpretations.

Guidebook, the plaintiffs maintain that the Guidebook is not entitled to the deference announced in *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984), but they offer no further suggestion about the level of deference that they argue should be applied, if any. Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 41 [ECF No. 45 (Sealed)]. The defendants do not contest that *Chevron* deference is not applicable, Defs.' Combined Reply Br. 30 [ECF No. 48], and they concede that the NPDB Guidebook "do[es] not have the force of law," but they argue that the NPDB Guidebook's interpretation of the term "investigation" is entitled to "substantial deference," Mem. In Support of Defs.' Mot. to Dimiss 12 [ECF No. 33 (Sealed)], which is a reference to the deference that applies to an agencies' interpretation of its own regulations, *see, e.g.*, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87 (1995).

Determining the appropriate level of deference to apply to agency interpretations in certain scenarios can be puzzling, to say the least. The general rule is that, when a statute is silent about an issue a court will defer to an agency's interpretation contained in a regulation if it is reasonable, based on a permissible construction of the statute, involves a statute the agency administers, and the regulations were promulgated pursuant to notice and comment so they have the force of law. *Chevron*, 467 U.S. at 842-43. When the agency's interpretation is derived from a source other than regulations that have the force of law, however, the landscape of legal principles that apply becomes somewhat tangled. In *Christensen v. Harris County*, 529 U.S. 576 (2012), the Supreme Court cautioned that interpretations contained in "policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law – do not warrant *Chevron*-style deference," albeit such interpretations might be "entitled to respect under [its] decision in *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) . . . ." 529 U.S. at 587 (internal

quotation marks and parallel citation omitted). Under *Skidmore*, the deference owed to an agency interpretation that does not have the force of law "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." 323 U.S. at 140. "The Supreme Court later clarified, however, that 'the fact that [an] Agency . . . [reaches] its interpretation through means less formal than 'notice and comment' rulemaking, *see* 5 U.S.C.A § 553 (West 2014), does not automatically deprive that interpretation of the judicial deference otherwise its due." *Fox v. Clinton*, 684 F.3d 67, 77 (D.C. Cir. 2012) (quoting *Barnhart v. Walton*, 535 U.S. 212, 221 (2002)). "Rather, 'the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time [may] indicate that *Chevron* provides the appropriate legal lens through which to view the legality of [a disputed] Agency interpretation' of its authorizing statute." *Id.* (quoting *Barnhart*, 535 U.S. at 222). So the legal pronouncements have, in essence, helpfully advised courts that *Chevron* deference does not apply to agency interpretations that lack the force of law -- except when it does apply. Additionally, apart from these legal standards, an agency's interpretation of its own regulations (versus a statute), is also entitled to a measure of deference, which the Supreme Court has described as "substantial." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

Which leads the Court to point out the puzzle in this case. The defendants appear to treat the NPDB Guidebook interpretation of the term "investigation" as though it is the agency's interpretation of its own regulation. Defs.' Combined Reply In Support of Mot. to Dismiss 30

[ECF No. 48] ("[A]s subregulatory guidance, the Guidebook should be accorded substantial deference."). But the regulations' use of the term "investigation" simply carries over the language of the statute, and nothing more. *Compare* 45 C.F.R. § 60.12(a)(1)(ii)(A), *with* 42 U.S.C. § 11133(a)(1)(B)(i). As a result, with respect to the term "investigation," it seems to the Court that the NPDB Guidebook interpretation technically constitutes an interpretation of the statue and not an interpretation of the regulation. Thus, it is the Court's view that the NPDB Guidebook interpretation of "investigation" would fall under the rubric of *Skidmore*-style deference, which is what two federal courts of appeals appear to think as well, although neither expressly so held. *Leal*, 620 F.3d at 1282-83 (citing *Christensen*, 529 U.S. at 587, as "explaining that interpretations contained in enforcement guidelines get *Skidmore* deference"); *Doe*, 552 F.3d at 79-80 (finding that the NPDB Guidebook does not qualify for *Chevron* deference but indicating that it might qualify for a lesser degree of deference pursuant to *Skidmore*). A resolution about the question of deference is unnecessary in this particular circumstance, though, because the Court concludes that "the level of deference is not determinative here; whether viewed through the prism of *Chevron* or the less forgiving prism of *Skidmore*, the Secretary's interpretation of the word 'investigation' withstands scrutiny." *Id.* at 80. Furthermore, the Court is not convinced that the 2001 NPDB Guidebook actually defines the term "investigation" in any event.

Although the 2001 NPDB Guidebook provides examples of the types of evidence that might suggest that an investigation occurred, and presents generalized guidelines about who must conduct the investigation, who it must be about and what it must be about, it does not appear to the Court that the Guidebook actually sets forth an interpretative definition of what

actions taken by a health care entity would, in fact, constitute an "investigation" -- given that the possibilities vary from the simple act of obtaining medical records to the formalized conduct of adversarial-type review proceedings, and there might be many stages in between from fact gathering to deliberations to formal resolution, with numerous individuals involved from nursing staff to executive officials. The Secretarial Review Decision also does not define the term "investigation" and, instead, simply identifies the documents that the Secretary deems to "demonstrate" the start of an investigation. AR 0256 [ECF No. 19-6 (Sealed)]. Consequently, it appears to the Court that neither the 2001 NPDB Guidebook nor the Secretarial Review Decision offer an interpretive definition of the term "investigation" that warrants the Court wading into the legal morass of determining what deference to apply to that interpretation. *See Doe*, 552 F.3d at 79-80 (noting that "the level of deference owing to informal agency interpretations" such as the NPDB Guidebook and the Secretary's decisions "is freighted with uncertainty" and poses "an interesting legal conundrum").[11]

When a statute does not define a term, the Court "must presume that Congress intended to give the term its ordinary meaning." *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1176 (D.C. Cir. 2003). The term "investigation" is ordinarily understood to mean a systematic examination. Merriam-Webster, http://www.merriam-webster.com/dictionary/investigation (last visited May 8, 2015). Applying this common meaning of the term "investigation," the Court will consider whether the Secretarial Review Decision reasonably

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[11] In *Leavitt*, the United States Court of Appeals for the First Circuit considered when an "investigation" has concluded for the purpose of determining whether a challenged investigation was ongoing, 552 F.3d at 78-79, whereas here the Court is confronted with the question of when an "investigation" has begun.

concludes that the Hospital was conducting a systematic examination of Dr. Doe's conduct before or at the time he surrendered his surgical privileges and resigned.

The Secretarial Review Decision states that the Secretary "review[ed] the information available and the record presented to this office," AR 0254 [ECF No. 19-6 (Sealed)], and found that there was an investigation occurring at the time Dr. Doe surrendered his privileges and resigned, AR 0256 [ECF No. 19-6 (Sealed)]. The Secretarial Review Decision notes that the following documents lend support to the finding that an investigation was underway at the time Dr. Doe voluntarily surrendered his privileges and resigned:

> [T]he [Hospital's] meeting notes dated October 5, 2009 demonstrate the initial stage of the investigation, as indicated by the Quality Management (QM) Coordinator's handwritten note after a meeting with the Hospital's VPMA, Corporate Compliance Officer, Director of QM, and Medical Staff Coordinator. The notes state that "Dr. [Doe] voluntarily has agreed not to take any new surgical patients and pts currently on his service will be reassigned until investigation complete ..." (Exhibit 6). Furthermore, the Root Cause Report submitted on November 3, 2009 confirms that you were under investigation at the time of your resignation. The Report states "On 10/5 the surgeon voluntarily suspended his surgical privileges pe[n]ding completion of the [Hospital's] investigation. On 10/07/2009, prior to the completion of the investigation and the meeting of the RCA Committee he submitted his resignation from the Medical Staff effective 10/16/2009" (Exhibit 15). It is clear from the documentation provided by PBMC that the review went beyond a routine or general review of your cases.

AR 0256 [ECF No. 19-6 (Sealed)]. The Court evaluated each of these documents, which consist of exhibits attached to a letter that that Hospital submitted as part of the adversarial Secretarial review process. *See* AR 0101-31 [ECF No. 19-3 (Sealed)].

With respect to the question of when the Hospital's investigation began, the Secretarial Review Decision states "the [Hospital's] meeting notes dated October 5, 2009 demonstrate the initial stage of the investigation, as indicated by the Quality Management (QM) Coordinator's handwritten note after a meeting with the Hospital's VPMA, Corporate Compliance Officer,

Director of QM, and Medical Staff Coordinator." AR 0256 [ECF No. 19-6 (Sealed)]. The cited meeting notes state that, on October 5, 2009, the medical chart was copied, the patient was released, and the Vice President of Medical Affairs and other Hospital officials met at noon to discuss the case. AR 0105 [ECF No. 19-3 (Sealed)]. The notes also state that the Vice President of Medical Affairs planned to meet later that day with the physician who assisted Dr. Doe during the surgery and then with Dr. Doe. AR 0105 [ECF No. 19-3 (Sealed)]. The Secretarial Review Decision's quotation of part of the notes indicating that Dr. Doe voluntarily suspended his surgical privileges accurately reflects what is stated in the notes. AR 0105 [ECF No. 19-3 (Sealed)], 0256 [ECF No. 19-6 (Sealed)]. The notes also state that the gross pathology report was received, a report was submitted to NYPORTS, and a physician and another individual were asked to form an "RCA team," AR 0105 [ECF No. 19-3 (Sealed)], which the record evidence and legal briefs indicate refers to a Root Cause Analysis given that a contemporaneous email from The Joint Commission stated that a Root Cause Analysis and Action Plan regarding the incident would be due in November, AR 0111 [ECF No. 19-3 (Sealed)]; Pls.' Reply Mem. In Support of Cross-Motion for Summ. J. 18 [ECF No. 56 (Sealed)] (indicating that "Root Cause Analysis" is abbreviated as "RCA").

Taken as a whole, these coincident notes reflect that, on October 5, 2009, Hospital officials[12] embarked on a systematic examination of Dr. Doe's conduct relating to the surgical incident by gathering the necessary documentation, conferring with the relevant Hospital executives, meeting with the physicians who were involved, reporting the incident to the state

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[12] The notes state that four Hospital executives attended the meeting, which demonstrates that the actions were taken by the Hospital as an entity versus an individual.

health department, and organizing a team to conduct a Root Cause Analysis. These activities on the part of the Hospital strike the Court as fundamental characteristics of an "investigation," at least as that term is commonly understood, so it was reasonable for the Secretary to conclude that they demonstrated the beginning of an investigation by the Hospital. That the Hospital viewed itself as conducting an investigation is corroborated by the following contemporaneous documents: the QM Coordinator's notes, AR 0105 [ECF No. 19-3 (Sealed)] (stating "Dr [Doe] voluntarily has agreed to not take any new surgical patients and pts currently on his service will be reassigned until investigation complete"); an October 5, 2009 memorandum memorializing a meeting of the Vice President for Medical Affairs, Quality Management, and the Medical Staff Coordinator, AR 0106 [ECF No. 19-3 (Sealed)] (stating "[i]t was reported that a meeting took place this morning" and "[a]t this meeting, Dr. [Doe's] privileges were suspended while the case in question is undergoing investigation'); the submitted NYPORTS Short Form, AR 0107-08 [ECF No. 19-3 (Sealed)] (stating "[t]he physician has been placed on suspension pending completion of the investigation"); and the Sentinel Event Self-Report submitted to the Joint Commission, AR 0109 [ECF No. 19-3 (Sealed)] (stating "[t]he physician has been placed on suspension pending completion of the investigation").

The plaintiffs take issue with the Secretary's reliance on the cited documents and argue that such reliance was arbitrary and capricious because "the Secretary ruled only on Hospital created, misdated documents and did not explain or consider the contrary evidence from Dr. Doe including that he never received the By-Laws or any other written notice of investigation 'to the practitioner.'" Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 44-45 [ECF No. 45 (Sealed)]. In particular, the plaintiffs contend that the type of evidence submitted by the hospital failed to

comply with the NPDB Guidebook requirements, several documents were forged or otherwise not bona fide because they contained incorrect dates or parroted the same language found in the NYPORTS Short Form Report and Sentinel Even Self-Report, there was no evidence that the Hospital's Credentials Committee requested in writing that an investigation be commenced, there was no documentation of an October meeting of the Root Cause Analysis Committee, and the plaintiffs submitted evidence that individuals identified as being in attendance at the Root Cause Analysis Committee meeting were not there. Pls.' Reply Mem. In Support of Cross-Motion for Summ. J. 17-21. Upon review of the administrative record, however, the plaintiffs' allegations simply are not well founded or supported.

First, the plaintiffs misconstrue the 2001 NPDB Guidebook as mandating that the Hospital submit minutes of committee meetings, orders from hospital officials, and notices to Dr. Doe in order to prove that an investigation was taking place. First Am. Compl. ¶ 71 [ECF No. 23]; Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 16-17 [ECF No. 56 (Sealed)]. The NPDB Guidebook contains no such command. The only source the plaintiffs cite for this premise is a provision that states "[e]xamples of acceptable evidence may include minutes or excerpts from committee meetings, orders from hospital officials directing an investigation, and notices to practitioners of an investigation."[13] Pls.' Reply Mem. In Support of Cross-Motion for Summ. J. 16 [ECF No. 56 (Sealed)] (citing NPDB GUIDEBOOK E-19). The terms of this provision make clear that the identified evidence serves only as expressed "examples" of what a hospital may submit, not as the sole requirements regarding what a hospital must submit. The use of the term "may" renders the examples permissive and not exclusive. Consequently, there

[13] NPDB GUIDEBOOK E-19.

simply is no basis to assert that it was unreasonable or irrational for the Secretary to consider other types of evidence in the Administrative Record. In fact, given that the provision identifies only permissive examples, an argument could be made that it would have been unreasonable for the Secretary to limit her consideration to only those cited examples while excluding other types of contemporaneous evidence.

Turning to the plaintiffs' allegation that several documents were forged or otherwise not bona fide because they contained incorrect dates or simply echoed the same language found in the NYPORTS Short Form Report and Sentinel Even Self-Report, the Court finds that the Secretary reasonably relied on the challenged documents. The plaintiffs called into question the minutes of a Medical Staff Performance Improvement Committee meeting because it was dated September 2009 and not October 2009, as well as a memorandum memorializing a review meeting that was dated "Monday, October 6, 2009" when, in fact, October 6, 2009, fell on a Tuesday. Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 18 [ECF No. 56 (Sealed)]; First Am. Compl. ¶ 63. The Hospital noted that the two date discrepancies were typographical errors. AR 0084 n.1, 0085 n.3 [ECF No. 19-2 (Sealed)]. The plaintiffs' indictment of these documents as fakes involving "back-dating"[14] -- and their refusal to accept that the date errors might actually be mere typographical errors -- is surprising given that Dr. Doe himself submitted a document that suffered from the very same infirmity. With respect to a letter he wrote to the American Board of Thoracic Surgery, which he characterized as a "significant" piece of evidence during the Secretarial review process, he noted:

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[14] Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 20 [ECF No. 56 (Sealed)] (arguing that the Secretary "never acknowledged or explained these critical inconsistencies, back-dating and unsigned and 'redacted' documents").

> Although this letter was written late on October 5, 2009, it mistakenly bears the date October 6, 2009. While I drafted the letter to Dr. Baumgartner on October 5, I did not mail it until October 6. Prior to mailing it the next morning, I simply changed the date on the letter from "5" to "6" without thoroughly proofreading the letter again. I neglected to change the word "today" to "yesterday." This gives the impression that I learned of the ABTS' final decision on October 6, but it actually happened the day before.

AR 0157 n.1 [ECF No. 19-4 (Sealed)]. In light of the plaintiffs own guilt in submitting evidence with a typographical date error, the plaintiffs' criticism of the Hospital's documents certainly call to mind the proverb that he who lives in a glass house should not throw stones. Because there was no other evidence in the administrative record to buttress the plaintiffs' allegations that the defendants' typographical errors should be attributed to document fabrication, it was not unreasonable for the Secretary --who was confronted by documents from both parties that contained typographical date errors -- to accept the parties' explanations for the errors and otherwise rely on the documents. It would be arbitrary for the Secretary to apply a double standard whereby typographical errors in the Hospital's documents would be deemed to be an indication of fabrication whereas similar errors in Dr. Doe's documents would be overlooked as mere mistakes.

The Court also is not troubled by the fact that the minutes of the Medical Staff Performance Improvement Committee meeting were redacted and the discussion is described using language that is identical to the Summary of Occurrence on the NYPORTS Short Form. Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 18 [ECF No. 56 (Sealed)]. As far as the Court can tell, the only thing of any consequence that was redacted in the document was the identity of Hospital employees, but a review of the administrative record reveals that this was a consistent practice for all documents submitted by the Hospital during the Secretarial review

process. *See, e.g.*, AR 0101, 0103, 0104, 0109, 0115 [ECF No. 19-3 (Sealed)]. In addition, although the "Discussion" section of the minutes contain a description that is a verbatim copy of what is documented in the NYPORTS Short Form, the "Action" section of the minutes, which state that "[t]he physician voluntarily removed himself from surgery pending completion of the investigation" is not identical, so it is not clear what, if anything, can be inferred from this. Moreover, even if, as the plaintiffs allege, the minutes were created by simply copying the information contained in the NYPORTS Short Form, that does not, ipso facto, mean that no meeting actually took place. It could simply mean that the Hospital took a short cut in terms of documenting the details of the discussion that took place. There was no basis for the Secretary to conclude, based solely on similarities between the descriptions contained in the meeting minutes and the NYPORTS Short Form, that no meeting actually occurred.

The plaintiffs also complain that the Secretary improperly relied on documents that contained hearsay. Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 19 [ECF No. 56 (Sealed)]. This is a perplexing position for the plaintiffs to take because Dr. Doe's own submissions to the Secretary contained hearsay. *See, e.g.*, AR 0233 [ECF No. 19-5 (Sealed)] (stating that "Dr. [Richard] Rubenstein has advised Dr. [Doe] that he (Dr. Rubenstein) was not aware that [an October RCA Committee] meeting was being held"). Regardless, "it has long been settled that the technical rules for the exclusion of evidence applicable in jury trials do not apply to proceedings before federal administrative agencies in the absence of a statutory requirement that such rules are to be observed." *Opp Cotton Mills v. Administrator of Wage & Hour Div. of Dep't of Labor*, 312 U.S. 126, 155 (1941). Accordingly, "[c]ourts, including the

D.C. Circuit, have held that hearsay evidence can be considered as part of the administrative record." *Kadi v. Geithner*, 42 F. Supp. 3d 1, 12 (D.D.C. 2012).

The plaintiffs question the reasonableness of the Secretary's reliance on hospital documents stating that an investigation was pending because they contend that Dr. Doe's "Oct. 5, 2009 letter of resignation," *see* AR 0110, serves as contrary evidence that "reflects no 'pending investigation' or 'reassignment' of his cases, just that he would not take new ones because he would be leaving for the Tennessee fellowship." Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 20 [ECF No. 56 (Sealed)]; First Am. Compl. ¶ 60 [ECF No. 23]. As an initial observation, the Court finds itself compelled to point out that, just as Dr. Doe's October 5, 2009 letter does not state that an investigation was pending, it also does not state that Dr. Doe would be leaving for the Tennessee fellowship. AR 0110 [ECF No. 19-3 (Sealed)]. The plaintiffs' characterization of the letter as "contrary" evidence also is unavailing. To reiterate, the letter at issue stated:

> I will not operate at [the Hospital] for the next two weeks effective October 5, 2009 through October 19, 2009, or until mutually agreed upon. I will however, finish the follow-up care on patients that I am currently involved with on the clinical floors without performing any surgery.

AR 0110 [ECF No. 19-3 (Sealed)]. This quotation represents the entire body of the letter, which by its terms states that Dr. Doe is temporarily surrendering his surgical privileges for two weeks or until mutually agreed upon. There is nothing in this letter to suggest that it contemplated a permanent departure in the nature of a "resignation" and, again, it is silent about the reason for the surrender of privileges. The Court also finds it odd that the plaintiffs characterize this letter as a "resignation" in anticipation of Dr. Doe leaving the Hospital to complete a fellowship in Tennessee when it is unambiguously temporary and the plaintiffs claim, on the one hand, that it

was drafted by the Vice President of Medical Affairs[15] while also claiming, on the other hand, that Dr. Doe drafted it.[16] Regardless, upon analysis, the October 5, 2009 letter in which Dr. Doe voluntarily surrendered his surgical privileges for two weeks does not actually contradict or refute any of the matters contained in the documents the Secretary cited as support for the Secretarial Review Decision. The letter's silence with respect to whether an investigation was occurring renders it essentially irrelevant to that point. The Court also is not vexed by the Secretary's failure to address in the Secretarial Review Decision every allegation, including this one, raised by Dr. Doe. It is well established in this Circuit that an agency's decision need not "repeat every contention of the parties, especially where the argument accepted is mutually exclusive of the others and the basis for its acceptance is made clear." *Puerto Rico Mar. Shipping Auth. v. Federal Mar. Comm'n*, 678 F.2d 327, 352 (D.C. Cir. 1982).

The plaintiffs also attempt to undermine the Secretarial Review Decision by arguing that there was no evidence that the actions taken by the Hospital were consonant with the Hospital's internal bylaws setting forth how or when an investigation would be conducted and there was no formal request for an investigation by the Hospital's Credentials Committee. Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 44-45 [ECF No. 45 (Sealed)]; Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 17 [ECF No. 56 (Sealed)]; First Am. Compl. ¶ 107 [ECF No. 23]; First Am. Compl. ¶¶ 59, 69 [ECF No. 23]. Nowhere, though, does the Health Care Quality

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15 Pls.' Statement of Undisputed Material Facts Pursuant to Local R. 7(h) ¶ 9 [ECF No. 45-2 (Sealed)] (stating that the October 5, 2009 letter "was actually drafted by [the Vice President of Medical Affaris]").

16 Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 10 [ECF No. 56 (Sealed)] (stating that "Dr. Doe went to [the Vice President of Medical Affairs'] office on October 7, 2009 with an unsigned resignation letter . . .").

Improvement Act, the Department of Health and Human Services regulations implementing the Act, or the NPDB Guidebook state that, to qualify as an "investigation" for the purpose of the mandatory reporting requirements, the Hospital's actions must be taken in accordance with its own internal bylaws or policies. The reportable event is based on an "investigation" as that term is contemplated by the statute, not as contemplated by a health care entity's individualized and internal governing documents. To hold otherwise would result in ad hoc reporting and reporting inconsistencies across the multitude of health care entities throughout the nation. "The federal judiciary and the agency to which the interpretive task has been entrusted have independent responsibilities for fashioning a global definition, and a hospital cannot frustrate that definition through its bylaws." *Doe*, 552 F.3d at 85.

The plaintiffs additionally question the occurrence of an October 2009 meeting of the Root Cause Analysis Committee because there is no evidence in the administrative record that this meeting occurred other than the statements by the Hospital's counsel in a filing submitted during the Secretarial review process. Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 18 [ECF No. 56 (Sealed)]. First, the Court notes that this meeting was not cited in the Secretarial Review Decision. In addition, the occurrence of this meeting would not be dispositive of the determination that an investigation was ongoing because there was other evidence in the administrative record that demonstrated that the Hospital's investigation continued at least into November 2009. *See* AR 0114, 0115, 0118-30 [ECF No. 19-3 (Sealed)].

The plaintiffs also take exception with the Hospital's statement that the Root Cause Analysis Committee met in October and the participants consisted of a number of Hospital executives, including the Attending Gynecology Oncology Surgeon and Attending

General/Thoracic Surgeon. Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 18 [ECF No. 56 (Sealed)]; AR 0085 [ECF No. 19-2 (Sealed)]; First Am. Compl. ¶ 58 [ECF No. 23]. According to the plaintiffs, "documentary evidence in the AR proved that neither the Attending Gynecology Oncology Surgeon, Dr. [Hannah] Ortiz, nor the Attending General/Thoracic Surgeon, Dr. [Richard] Rubenstein attended or even knew of an October 14, 2009 meeting as alleged at AR 0085." *Id.* The documentary evidence cited by the plaintiffs consists of a letter from Dr. Rubenstein that makes no reference at all to any Root Cause Analysis Committee meetings, AR 0196-97 [ECF No. 19-4 (Sealed)], the submissions by Dr. Doe, AR 0222, 0233 [ECF No. 19-5 (Sealed)], and a letter from Dr. Ortiz that states only that she does "not recall being present at any Root Cause Analysis Committee meeting," although she did remember discussing the surgical incident with the Vice President of Medical Affairs, AR 0240 [ECF No. 19-5 (Sealed)]. The Hospital asserts, however, that another general/thoracic surgeon -- other than Dr. Rubenstein -- served on the Root Cause Analysis Committee and the Committee "received, and reasonably relied, on statements from Dr. Ortiz regarding the appropriateness of seeking a gynecological consultation under the circumstances presented during the surgery in question." AR 0291 [ECF No. 32-1 (Sealed)]. There is nothing in the administrative record that contradicts these last two points and the Root Cause Report that was filed by the Hospital on November 3, 2009 states that an intraoperative gynecological consultation should have been obtained, which is consistent with Dr. Ortiz's letter stating the same. AR 0116 [ECF No. 19-3 (Sealed)]; AR 0240 [ECF No. 19-5 (Sealed)]. Accordingly, although there might be a factual dispute about whether Dr. Ortiz attended an October 2009 Root Cause Analysis Committee meeting, there is no dispute that she was consulted about the surgical incident by a member of

the committee, AR 0233 [ECF No. 19-5 (Sealed)] (identifying the Vice President of Medical Affairs as a committee member). The fact that she might not have attended the Root Cause Analysis Committee meeting, alone, is an insufficient basis for the Secretary to conclude that the meeting was "non-existent" so the Adverse Action Report must be stricken, *see* Pls.'s Reply Mem. In Support of Cross-Mot. for Summ. J. 18 [ECF No. 56 (Sealed)].

In sum, the administrative record supports the Secretary's finding that the Hospital launched an investigation of Dr. Doe's conduct relating to the surgical incident on October 5, 2009, the same day he was told he was fired but then reinstated, the same day he temporarily surrendered his surgical privileges for two weeks, and two days before he submitted a letter of resignation.[17] The Secretary stated that she reviewed the relevant data, which consisted of the "information available and the record presented to this office." AR 0254 [ECF No. 19-6

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[17] The plaintiffs' admissions that Dr. Doe was fired during an early meeting with Hospital executives on October 5, 2009, belie their argument that the Hospital was not reviewing Dr. Doe's professional conduct on that date. AR 0203 [ECF No. 19-5 (Sealed)] (letter from Dr. Doe's girlfriend stating that "[Dr. Doe] called me on my cell phone that morning and told me that he had just met with [the Vice President of Medical Affairs] and he had been fired from his position at the hospital as a result of this specific case"); AR 0009 [ECF No. 19-1 (Sealed)] (arguing that "the purported investigation conducted by [the Hospital] relating to the October 2, 2009 procedure was not an inquiry into my professional competence or conduct, but rather a routine and general review of a very complicated case involving an emergency situation . . ."); AR 0143 [ECF No. 19-3 (Sealed)] (stating that the Vice President of Medical Affairs "told the plaintiff that he was fired"); First Am. Compl. ¶¶ 61 [ECF No. 23] (asserting that the NYPORTS short form report submitted by the Hospital "was to report an incident under state law, and was not an 'investigation' of the physician"). According to the Hospital:

> [T]he Hospital commenced an investigation into what transpired during the surgery at issue and how [Dr. Doe] inadvertently removed a section of a 14 year old patient's Fallopian tube. Included in this investigation was whether [Dr. Doe] exercised the appropriate standard of care and whether he was professionally competent to continue performing such surgeries at the Hospital. Accordingly, [Dr. Doe's] competence was under investigation prior to his resignation.

AR 0284 [ECF No. 32-1 (Sealed)].

(Sealed)]. The referenced information and record consisted of numerous adversarial filings setting forth, in detail, both the Hospital's and Dr. Doe's respective positions and arguments about the events reported in the Adverse Action Report and included documentary evidence that both parties asserted supported and corroborated their arguments. The Secretary's finding that an investigation was commenced on October 5, 2009, was rationally connected to the facts found, which showed that the Hospital had gathered the relevant documents, conferred with executive officials about the surgical incident and the course of action the Hospital would take, met with the physicians who were involved, reported the incident to the state health department and The Joint Commission, and formed a team to conduct a root cause analysis. All of these activities are the trappings of an investigation as that term is commonly understood, so the Secretary's conclusion was rationally conceived, regardless of whether viewed with deference.

2. Whether it was arbitrary and capricious for the Secretary to conclude that Dr. Doe's suspension of privileges was "voluntary" in light of his allegation of fraud

In the Subject Statement disputing the Adverse Action Report, and throughout the Secretarial Review proceedings, Dr. Doe challenged the accuracy of the report on the ground that it falsely stated that he had resigned "while under investigation" notwithstanding his contention that the Hospital's Vice President of Medical Affairs assured Dr. Doe that there was no such investigation underway at the time Dr. Doe submitted his resignation. AR 0003, 0009 [ECF No. 19-1 (Sealed)], AR 0154, 0157, 0161-66, 0173 [ECF No. 19-4 (Sealed)], AR 0232 [ECF No. 19-5 (Sealed)]. Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 43-44 [ECF No. 45 (Sealed)]; Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. 7-10 [ECF No. 56 (Sealed)]. The Hospital concedes only that the Vice President of Medical Affairs told "Dr. [Doe] on October 5, 2009 that if he agreed to voluntarily refrain from exercising his privileges, no suspension would be

imposed and thus no report (other than an incident report) would have to be made at that time." AR 0285 [ECF No. 32-1 (Sealed)] (emphasis in original). The Secretarial Review Decision acknowledges this dispute by stating "[y]ou dispute the report claiming: 1. There was no investigation at the time of your resignation, which you confirmed with the PBMC." AR 0255 [ECF No. 19-6 (Sealed)] (emphasis added). The decision resolves the dispute by concluding that the documentary evidence in the Administrative Record demonstrated that an investigation was, in fact, taking place at the time Dr. Doe resigned. AR 0256 [ECF No. 19-6 (Sealed)]. However, in a subsequent paragraph addressing Dr. Doe's other claims that the Adverse Action Report was submitted without his knowledge, maliciously, in bad faith and without due process, AR 0255 [ECF No. 19-6 (Sealed)] (identifying the dispute claims), the Secretary stated that "a voluntary resignation while under investigation is reportable to the NPDB regardless of whether you were misinformed as to the investigation's existence and regardless of whether or not you were aware of the ongoing investigation at the time you resigned," AR 0257 [ECF No. 19-6 (Sealed)].

In the plaintiffs' First Amended Complaint they recast the dispute about whether Dr. Doe was "under investigation" into an allegation that Dr. Doe's resignation was not "voluntary" because it was induced by fraud. First Am. Compl. ¶¶ 108-09 [ECF No. 23]. According to this new theory, the plaintiffs assert that the Adverse Action Classification Code documented in the Adverse Action Report is inaccurate because it states "voluntary surrender of clinical privilege(s), or to avoid, investigation relating to professional competence or conduct," AR 0002 [ECF No. 19-1 (Sealed)] (capitalization formatting omitted emphasis added). Based on their new formulation of the argument Dr. Doe raised during the Secretarial review process, the plaintiffs declare that the "defendants should have concluded that plaintiff did not 'voluntarily

resign' for purposes of the statute and the AAR should not have been accepted or should have been voided." First Am. Compl. ¶ 108.

The Health Care Quality Improvement Act and the regulations establishing the National Practitioner Data Bank state that a health care entity must report the acceptance of a physician's "surrender" of clinical privileges while the physician is the subject of an investigation relating to possible incompetence or improper professional conduct. 42 U.S.C.A. § 11133(a)(1)(B); 45 C.F.R. § 60.12(a)(1)(ii). Neither the statute nor the regulations define or qualify the term "surrender" in any way or require that the surrender occur with knowledge of the investigation. One meaning of the term "surrender" is to "yield to the power, control, or possession of another upon compulsion or demand." Merriam-Webster, http://www.merriam-webster.com/dictionary/surrender (last visited May 25, 2015). Consequently, Congress's use of the term "surrender" arguably intimates that it intended the statute to apply to any relinquishment of clinical privileges, whether voluntary or compelled, in which case Dr. Doe's resignation was reportable even if it was not, in fact, "voluntary."[18]

In some respects this point might seem unjust. But the Health Care Quality Improvement Act clearly manifests a policy that favors strict reporting in the event of a resignation during an investigation to ensure patients are protected and to prevent physicians from skirting peer review. The Secretary's interpretation that a resignation while under investigation is reportable whether

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[18] The Court therefore questions why Adverse Action Classification Code number 1635 includes the term "voluntary." The regulations refer to "voluntary surrender" only in the context of licensing or certification. 45 C.F.R. §§ 60.3, 60.9(a)(3), 60.10(a)(3), 60.12(a)(2). Because there is no statutory or regulatory basis for using the term "voluntary" with respect to a surrender of clinical privileges while under investigation, it strikes the Court that the term should be removed from the descriptive language for Adverse Action Classification Code number 1635.

or not a physician knew about the investigation furthers this policy and avoids reporting loopholes that would make it easier for incompetent physicians to dodge (via surrender or resignation) the peer review that Congress expressly found could remedy the occurrence of malpractice and improve the quality of medical care. *See* 42 U.S.C. § 11111. Given the nature and purpose of the National Practitioner Data Bank, and the congressional intent and findings expressed in the statute that authorized it, when the countervailing interests of protecting patients and protecting physicians cannot be reconciled, the structure and purpose of the statute suggests that the course to be followed is the one that protects patients, assuming that course to be otherwise lawful. So it is not unreasonable for the Secretary to interpret the statute as imposing a strict reporting requirement in the sense that the physician's motivations for surrendering clinical privileges and knowledge of the ongoing investigation do not bear on whether the surrender while under investigation must be reported. The relevant concern is that the surrender or resignation while under investigation curtails the effective professional peer review that Congress viewed as paramount to remedy the problems the statute was intended to address.

The defendants raise a fair point that, absent a strict reporting requirement, a physician could cause harm to a patient and then promptly resign before a hospital had the opportunity to put the physician on notice that an investigation was underway. Mem. In Support of Defs.' Mot. to Dismiss or, Alternatively, for Summ. J. 17 [ECF No. 33 (Sealed)]. The instant case, though, also could be construed as exemplifying a different reporting loophole.

Although the plaintiffs maintain that Dr. Doe was fraudulently induced to resign, the administrative record contains evidence suggesting a mistake on the Hospital's part about whether Dr. Doe was under an "investigation" for the purpose of reporting to the National

Practitioner Data Bank. Assuming, for the sake of argument, that it is true that Dr. Doe was told he was not under investigation, it is possible that the Vice President for Medical Affairs made that representation because it was the Vice President of Medical Affairs' belief that the investigation the Hospital commenced was for the purpose of conducting a root cause analysis consistent with the Hospital's immediate report to the New York Department of Health and not for the purpose of reporting to the National Practitioner Data Bank. Dr. Doe concedes that the Vice President of Medical Affairs alerted him that the surgical event was being reported to the New York Department of Health and that such a report would have obligated the Hospital to conduct an investigation, albeit Dr. Doe contends that the investigation would have been of the "incident" and not of his professional competence, AR 0168 [ECF No. 19-4 (Sealed)] (stating that "[m]y attorneys have explained to me that the statute and regulations go on to state that the hospital must conduct an investigation (described on NYPORTS website as a root cause analysis) of any of the listed incidents within thirty days of obtaining knowledge of any information which reasonably appears to show that such an incident has occurred . . .") (emphasis omitted). The possibility that the Hospital was operating under the mistaken belief that there was no investigation underway for the purpose of reporting to the National Practitioner Data Bank might also explain the Vice President of Medical Affairs' later statement that he did not know that a National Practitioner Data Bank report would be the "final step," AR 0162, 0166 [ECF No. 19-4 (Sealed)]; AR 0206 [ECF No. 19-5 (Sealed)]. Or, less innocently, it is also possible that the Hospital had an interest in avoiding a report to the National Practitioner Data Bank and believed, erroneously, that as long as officials did not designate an investigation as being for the purpose of reporting to the National Practitioner Data Bank, then no such report

would be required. At some later time, though, the Hospital obviously must have realized that it was required to report Dr. Doe's resignation, perhaps while trying to figure out whether the quality assurance review results had to be reported.

Speculation aside, though, the point is that a requirement that physicians have knowledge of an investigation in order for a resignation to be reportable would provide an opportunity for both physicians and hospitals to game the statute, whether guilelessly or intentionally, and avoid reporting. Both hospitals and physicians might make mistakes about whether their actions are causing a reportable event with respect to a surrender of privileges and they might later discover that the event should have been reported. Or hospitals and physicians might be ignorant, rightly or wrongly, of all the nuances of the National Practitioner Data Bank's regulations and rules but later learn, whether from legal counsel or otherwise, that their activities constituted an investigation for the purpose of the National Practitioner Data Bank even though a report to the Data Bank was never foreseen as an objective of the investigation. In any of these circumstances, a requirement that the physician have knowledge of an investigation would mean that no reporting would occur, thereby frustrating the very purposes of the statute. 42 U.S.C. § 11101.

In the final analysis, the relevant consideration for the purpose of the reporting requirement under the statute is whether a physician was being investigated and whether that investigation "related" to possible incompetence or improper professional conduct at the time a surrender of clinical privileges was accepted. If so, it is reasonable for the agency to interpret the statute as mandating that hospitals report the surrender of clinical privileges regardless of whether the surrender was voluntary or not, regardless of whether the physician knew about the

investigation or not, and regardless of whether a hospital anticipated that an investigation would result in a report to the National Practitioner Data Bank.

That being said, the question of whether Dr. Doe's surrender via resignation was reportable, even if induced or without knowledge of an investigation, is a different inquiry from the question of whether the Adverse Action Report's description of the surrender is accurate. Although the Secretary considered the resignation to be reportable, the Secretary never expressly addressed Dr. Doe's allegation that, because the resignation allegedly was procured by fraud, the Adverse Action Classification Code identified in the Adverse Action Report inaccurately stated that the surrender was "voluntary." Pls.' Reply Mem. In Support of Cross-Motion for Summ. J. 7 [ECF No. 56 (Sealed)]. Indeed, the standards cited by the Secretary in the Secretarial Review Decision apply only to reportability and not to the Secretary's consideration of accuracy. AR 0257 [ECF No. 19-6 (Sealed)] (stating that, e.g., "a voluntary resignation while under investigation is reportable," "[y]ou officially resigned before the final closing of PBMC's review(s) and that is a reportable event," and "[t]he fact that you had to work in an unethical environment has no bearing on PBMC's legal responsibility to report your voluntary surrender"). The Court expresses some concern that, in this respect, the Secretarial Review Decision abrogated the responsibility to review the accuracy of the Adverse Action Report by addressing only whether the resignation was reportable to the exclusion of whether it was accurately described. On this particular issue, the Secretarial Review Decision almost treats reportability as determinative of accuracy, which simply is not a reasonable approach.

The Court is not, however, sanguine about the plaintiffs' suggestion that the issue should be framed as requiring the Secretary "to determine whether Dr. Doe's resignation was

'voluntary' or whether in any event . . . it was fraudulently obtained." *Id.* To the contrary, the Secretary reasonably stated that the scope of her review is not so broad. AR 0257 [ECF No. 19-6 (Sealed)]. The regulations provide that the Secretary "will . . . review the accuracy of the reported information" although that review "will not consider the merits or appropriateness of the action or the due process that the subject received." 45 C.F.R. § 60.21(c)(1). Chapter F of the NPDB Guidebook likewise states that "[t]he Secretary reviews disputed reports only for accuracy of factual information and to ensure that the information was required to be reported." NPDB GUIDEBOOK F-3. These regulatory and NPDB Guidebook interpretations of the limited scope of Secretarial Review are in harmony with the Health Care Quality Improvement Act, which mandates that the Secretary "by regulation, provide for . . . procedures in the case of disputed accuracy of the information." 42 U.S.C.A. § 11136(2). Thus, the statute limits the Secretary's regulatory authority to providing procedures to dispute the accuracy of the reported information but nowhere does the statute authorize, or even contemplate, that the Secretary will actually adjudicate the underlying merits of the events, professional review actions, activities, findings, or determinations. The point of the statute is to restrict the ability of incompetent physicians to move from state to state without disclosing previously damaging or incompetent performance and it was Congress's view that this nationwide problem could be remedied by effective professional peer review that would be conducted by health care entities -- not the agency. 42 U.S.C.A. § 11101.

The Court agrees with the defendants that the Eleventh Circuit's decision in *Leal v. Secretary, U.S. Department of Health & Human Services*, which is cited by the Court several times herein, persuasively sets forth the scope of the Secretary's review for accuracy. In *Leal*,

the United States Court of Appeals for the Eleventh Circuit considered a physician's claim that it was arbitrary and capricious for the Secretary to conclude that an Adverse Action Report was accurate in the absence of corroborating evidence to prove the reported conduct. 620 F.3d at 1283-84. The plaintiff in *Leal* was a surgeon who, upon being told that his access to an operating room would be delayed, became enraged, damaged property, verbally abused hospital staff, and otherwise "pitched a fit." *Id.* at 1281 (internal quotation marks omitted). The plaintiff appealed the district court's judgment denying the physician's APA action and argued that an Adverse Action Report could only be deemed accurate if the administrative record included witness statements to substantiate the reported misconduct because, "[w]ithout that requirement . . . a hospital could unfairly 'blacklist' a physician by filing a report in the Data Bank based on conduct that never occurred." *Id.* at 1283. So similar concerns about fabrication or fraud on the part of hospitals were raised by the plaintiff in *Leal*.

On review, the Eleventh Circuit in *Leal* admonished that "[b]ecause information in the Data Bank is intended only to fully notify the requesting hospital of disciplinary action against a physician and the charges on which that action was based, the Secretary's review of information in the Data Bank is limited in scope." *Id.* at 1284. As the Eleventh Circuit reasoned:

> The review process does not provide a physician with a procedure for challenging the reporting hospital's adverse action. Nor does it provide a physician with a procedure for challenging the allegations about the conduct that led to the action that is reported. The Secretary reviews a report for factual accuracy deciding only if the report accurately describes the adverse action that was taken against the physician and the reporting hospital's explanation for the action, which is the hospital's statement of what the physician did wrong. The Secretary does not act as a factfinder deciding whether incidents listed in the report actually occurred or as an appellate body deciding whether there was sufficient evidence for the reporting hospital to conclude that those actions did occur.

Id. (internal citations omitted). With regard to the argument that a hospital might abuse the National Practitioner Data Bank reporting process to further a fraud that harms a physician's career, the Eleventh Circuit reflected that a hospital requesting a report is "free to ignore information in the Data Bank for purposes of making its hiring decision or to investigate it," "a physician who is the subject of a report can add a statement to the report giving his side of the story," and "the Data Bank is not designed to provide protection to physicians at all costs, including the cost of not protecting future patients from problematic physicians." *Id.* at 1285.

Even accepting that the scope of the Secretary's review for accuracy is limited, however, it is not the case that the Secretary can ignore actual evidence of fraud when considering whether an Adverse Action Report is accurate. Under the APA, the Secretarial Review Decision must be supported by substantial evidence. 5 U.S.C. § 706(2)(E). "Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolidated Edison Co. of New York v. N.L.R.B.*, 305 U.S. 197, 229 (1938). The D.C. Circuit has observed that:

> In applying the substantial evidence test, we have recognized that an agency decision "may be supported by substantial evidence even though a plausible alternative interpretation of the evidence would support a contrary view." *Robinson v. Nat'l Transp. Safety Bd.*, 28 F.3d 210, 215 (D.C. Cir. 1994) (internal quotation marks omitted). Our function is to determine "whether the agency . . . could fairly and reasonably find the facts that it did." *Id.* (internal quotation marks omitted). However, the court "may not find substantial evidence 'merely on the basis of evidence which in and of itself justified [the agency's decision], without taking into account contradictory evidence or evidence from which conflicting inferences could be drawn.'" *Lakeland Bus Lines, Inc. v. NLRB*, 347 F.3d 955, 962 (D.C. Cir. 2003) (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487, 71 S.Ct. 456, 95 L.Ed. 456 (1951)).

Morall v. DEA, 412 F.3d 165, 176 (D.C. Cir. 2005). If the Administrative Record contained evidence that a reasonable mind might accept as adequate to support the conclusion that Dr.

Doe's resignation was obtained by fraud, then the plaintiffs might have a meritorious claim that the Secretarial Review Decision failed to properly consider this evidence or set forth the Secretary's rationale for rejecting it. The problem here is that Dr. Doe never alleged during the Secretarial review process that his resignation was not "voluntary" because it was procured by fraud and, moreover, the Administrative Record is devoid of evidence sufficient to establish the elements of such a claim.

The NPDB Guidebook states that a physician "must . . . [s]tate clearly and briefly in writing which facts are in dispute and what the subject believes are the facts." NPDB GUIDEBOOK F-3. During the Secretarial review process, Dr. Doe identified the following facts as being in dispute:

> (i) [T]he surgical procedure, a laparoscopic appendectomy, that I performed on a female patient ("Patient J.J.") on October 2, 2009, (ii) the reason why I left Peconic, (iii) what is described by Peconic as the pendency of an investigation arising from that surgical procedure, and Peconic's attempt to link my resignation to that investigation, and (iv) Peconic's statement that its quality assurance review 'indicates departures by the physician from [the] standard of care with regard to the laparoscopic appendectomy."

AR 0152 [ECF No. 19-4 (Sealed)]. Dr. Doe's argument that he relied on the Vice President of Medical Affairs' false representation was proffered only to counter the question of whether an investigation was, in fact, underway when Dr. Doe resigned, which is identified as disputed fact number (iii). Cultivating this argument, Dr. Doe sought to distinguish his case from those in which a physician resigned without knowing that an investigation was pending by stating "I was not simply unaware of an investigation -- I was affirmatively told by [the Hospital's] senior medical officer that there was no such investigation, that there would not be an investigation, and that except for the filing of a routine form with the Department of Health, nothing would be

reported to any regulatory agency."[19] AR 0163 [ECF No. 19-4 (Sealed)]. As presented, though, this argument falls short of an allegation of fraud because "[t]he essential elements of a D.C. common-law fraud claim are '(1) a false representation (2) made in reference to a material fact, (3) with knowledge of its falsity, (4) with the intent to deceive, and (5) an action that is taken in reliance upon the representation.'" *In re APA Assessment Fee Litigation*, 766 F.3d 39, 55 (D.C. Cir. 2014). The Administrative Record lacks any evidence to suggest that, when the Vice President of Medical Affairs told Dr. Doe that no investigation was underway, he did so knowing the statement to be false and with the intent to deceive Dr. Doe.[20] Importantly, Dr. Doe's own admission during the Secretarial review process that "[t]his letter is not the place to question the motives of [the Hospital] acting through its Vice President of Medical Affairs, in communicating to me information that, I learned later, was false" served as a concession that deceit, and therefore fraud, was not being advanced as an argument during the Secretarial review proceeding. AR 0162 [ECF No. 19-4 (Sealed)].

In addition, as best the Court can tell, Dr. Doe never used the word "fraud" in any of the legal arguments he presented during the Secretarial review process or in the Subject Statement he originally submitted to place the Adverse Action Report in dispute. He also never actually

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19 The only "evidence" to support this assertion of fact is found in Dr. Doe's own unsworn statements contained in legal arguments, as well as unsworn hearsay statements by two third parties who were simply repeating what Dr. Doe had told them. AR 0161, 0200, 0203 [ECF No. 19-4 (Sealed)].

20 To the contrary, as mentioned *supra*, during the Secretarial review process Dr. Doe reported that, during a telephone call with the Vice President of Medical Affairs that occurred after the Adverse Action Report was filed, the Vice President of Medical Affairs stated "I did not know that [submission of an Adverse Action Report] would be the final step." AR 0166 [ECF No. 19-4 (Sealed)]. This statement arguably calls into question the elements of a knowing falsehood and intent to deceive.

argued that the Adverse Action Report's classification as a "voluntary surrender" was inaccurate. Instead, he repeatedly couched his reliance argument as implicating the accuracy of the statement that he was "under investigation" when he resigned and not as implicating whether his resignation was "voluntary" because it was induced by fraud. *See, e.g.*, AR 0152 (stating that the Adverse Action Report is inaccurate "relating to . . . what is described by [the Hospital] as the pendency of an investigation arising from that surgical procedure, and [the Hospital's] attempt to link my resignation to that investigation"), 0161 ("The reason I am in my current predicament is because [the Hospital] claims that I resigned while there was an investigation taking place. However, before I submitted that resignation, I inquired of [the Vice President of Medical Affairs] . . . if there was or would be an investigation."). As a result, the Secretary never identified the voluntariness of Dr. Doe's resignation to be in dispute or addressed fraud as a basis for Dr. Doe's claim that the Adverse Action Report was inaccurate.[21] "As a general rule, claims not presented to the agency may not be made for the first time to a reviewing court." *Omnipoint Corp. v. F.C.C.*, 78 F.3d 620, 635 (D.C. Cir. 1996). "To preserve a legal or factual argument, we

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[21] Although the Secretarial Review Decision stated that Dr. Doe disputed the Adverse Action Report by claiming that "[t]he Report to the NPDB was made without your knowledge, in bad faith, and in a malicious manner by few senior physicians who personally disliked you," AR 0255 [ECF No. 19-6 (Sealed)], this refers to Dr. Doe's Subject Statement stating "I intend to notify the NY Licensure board this action was taken in bad faith and in a malicious manner." AR 0002 [ECF No. 19-1 (Sealed)] (emphasis added). Later in that same Subject Statement Dr. Doe added that he believed the Report was "an act of vengeance against me by a few senior physicians who disliked me personally" and he indicated that two doctors "wished to harm me." AR 0003 [ECF No. 19-1 (Sealed)]. The Vice President of Medical Affairs, who allegedly told Dr. Doe that he was not under investigation, was not one of those two doctors. *Id.* (identifying Drs. 4 and 5 as seeking to harm Dr. Doe, whereas the Vice President of Medical Affairs was identified as Dr. 1). So the Secretarial Review Decisions' reference to bad faith and malice related to Dr. Doe's general assertions about the filing of the Adverse Action Report and not a specific argument that the Vice President of Medical Affairs falsely, and with the intent to deceive, told Dr. Doe that no investigation was underway when Dr. Doe resigned.

require its proponent to have given the agency a 'fair opportunity' to entertain it in the administrative forum before raising it in the judicial one." *Nuclear Energy Institute, Inc. v. EPA*, 373 F.3d 1251, 1290 (D.C. Cir. 2004).

The NPDB Guidebook states that documentation submitted to contest the accuracy of a fact "must . . . substantially contribute to a determination of the factual accuracy of the report." NPDB GUIDEBOOK F-3. Again, the only evidence Dr. Doe submitted to support his allegation of fraud consisted of his own statements and third party statements that simply reported what Dr. Doe said to the third party. When considered in light of the entire Administrative Record, the evidence submitted by Dr. Doe failed to substantially contribute to a determination that the Adverse Action Report's classification as a "voluntary surrender of clinical privileges" was inaccurate, versus merely disputed. "That the evidence in the record may also support other conclusions, even those that are inconsistent with the [Secretary's] does not prevent [the Court] from concluding that [her] decisions were rational and supported by the record." *Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130, 1160 (D.C. Cir. 1980).

3. Whether NPDB Guidebook Rule F-8 is overly broad, overly inclusive, and contrary to the purposes of the Health Care Quality Improvement Act

The plaintiffs demur to the NPDB Guidebook's statement that a physician "need not be aware of an ongoing investigation at the time of the resignation in order for the entity to report the resignation to the NPDB, since many investigations start without any formal allegation being made against the practitioner," NPDB GUIDEBOOK F-8. The NPDB Guidebook adds that "[t]he reason the practitioner gives for leaving an entity while under investigation is irrelevant to reportability of the resignation." *Id.* The plaintiffs characterize this NPDB Guidebook interpretation as overly broad and inclusive, and argue that it is constitutionally infirm because it

stigmatizes physicians and deprives them of a "fundamental" right. First Am. Compl. ¶ 110 [ECF No. 23]. As a result, the plaintiffs argue, the defendants' "adoption and application of this Guidebook Rule is arbitrary, capricious, an abuse of discretion, and not in accordance with law." *Id.* ¶ 111 [ECF No. 23].

Because the Court finds, *infra* part B, that the plaintiffs failed to establish a cognizable substantive due process claim or that the right to practice a chosen profession is a fundamental right, the Court will decline the plaintiffs' invitation to hold that the NPDB Guidebook interpretation is facially invalid. The Court has already pointed out the statutory purposes and policies that undergird the requirement for strict reporting and that render the NPDB Guidebook interpretations challenged by the plaintiffs to be reasonable.

4. Whether it was arbitrary and capricious for the Secretary to accept an untimely Adverse Action Report

During the Secretarial review process, Dr. Doe argued that the agency should have rejected the Adverse Action Report because it was untimely. The Secretary concluded, however, that "even if the [National Practitioner Data Bank] determined that [the Hospital's] report was late, it would not be a basis for voiding the report." AR 0257 [ECF No. 19-6 (Sealed)]. The Secretary's interpretation is consistent with the Health Care Quality Improvement Act's stated purpose and structure, which is to insure that a physician's prior damaging or incompetent performance is not hidden from a health care entity that might be considering granting clinical privileges to the physician. 42 U.S.C. § 11101. Because the statute imposes a significant sanction for the failure to submit a required report -- i.e., the potential loss of immunity pursuant

to 42 U.S.C. § 11111(a)[22] -- the clear message is that Congress intended to compel all reporting required by the statute, even if late. If Congress intended otherwise, it could have expressly said so in this same sanction provision or in the statutory provision that covers the "[t]iming and form" of reporting, which states only that reporting should occur "regularly (but not less often than monthly)" and delegates to the Secretary the authority to prescribe the "form and manner" of such reporting. 42 U.S.C. § 11134(a).

5. Whether it was arbitrary and capricious for the Secretary to retain the Hospital's quality assurance review comment because it was not a reportable event

The plaintiffs also protest the fact that the Adverse Action Report contains the "unreportable" statement that "the Hospital's quality assurance review of this matter indicates departures by the physician from standard of care with regard to the laparoscopic appendectomy that he performed on October 2, 2009." AR 0002 [ECF No. 19-1 (Sealed)]; Pls.' Reply Mem. In Support of Cross-Motion for Summ. J. 22-23 [ECF No. 56 (Sealed)]. This statement follows a statement that, because Dr. Doe resigned, "the Hospital took no further action regarding the physician's privileges or employment." AR 1112 [ECF No. 19-1 (Sealed)]. The Secretary did not address this argument in the Secretarial Review Decision, most likely because Dr. Doe raised it so obliquely in his submissions during the Secretarial review process that it might not have seemed apparent.

In Dr. Doe's April 19, 2011, submission to the Secretary he generally argued that the investigation by the Hospital was so flawed that it should be disregarded. He did, however, specifically question the Root Cause Report and the basis for its conclusion that he violated the

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22 42 U.S.C. § 11133(c)(1).

standard of care. AR 0170-0172 [ECF No. 19-4 (Sealed)]. At the conclusion of that argument, he stated that the "review of the Patient J.J. case was severely flawed" and "was not even the type of report that should have served as the predicate for an Adverse Action Report to the Data Bank . . . ." AR 0172 [ECF No. 19-4 (Sealed)].

The Health Care Quality Improvement Act states that "[t]he information to be reported under this subsection is -- (A) the name of the physician or practitioner involved, (B) a description of the acts or omissions or other reasons for the action or, if known, for the surrender, and (C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate." 42 U.S.C. § 11133(a)(3). The regulations require additional identifying information about the physician, the "action taken, date the action was taken, and effective date of the action, and" other information the Secretary requires after notice and comment. 45 C.F.R. § 60.12(a)(3). The Court notes that both the statute and the regulations omit language that would typically indicate that these enumerated categories are not intended to be exclusive, however, such as by stating that the information to be reported "may include" the cited categories. So it does appear that the argument could be made that the categories of information to be reported are exclusive, in which case information that does not fall within the enumerated categories could be deemed unreportable.

The Court is unable to assess the merit of the plaintiffs' contention, however, because the Secretary did not consider it. Given that this argument was raised by Dr. Doe during the Secretarial review process, AR 0172 [ECF No. 19-4 (Sealed)], and he is not an attorney, the Court will give him the benefit of the doubt and remand to the Secretary to consider whether the statement that "the Hospital's quality assurance review of this matter indicates departures by the

physician from standard of care with regard to the laparoscopic appendectomy that he performed on October 2, 2009" is reportable. AR 0002 [ECF No. 19-1 (Sealed)].

B. Whether the Plaintiffs Established Due Process Violations

The plaintiffs' second and third causes of action, which are not models of clarity, allege that the right to practice a chosen profession is a fundamental right that is violated by the defendants' interpretation and application of the Health Care Quality Improvement Act. First Am. Compl. ¶¶ 127-130. The plaintiffs also claim that, absent procedural safeguards to contest the accuracy of the facts alleged in the Adverse Action Report, the defendants' acceptance, maintenance and dissemination of the report excludes Dr. Doe from the right to employment in his chosen profession and thereby subjects him to a stigma-plus "disability." *Id.* ¶ 128. The plaintiffs take particular issue with the example dispute described in the NPDB Guidebook that indicates that a physician's resignation while under investigation is reportable even when the physician is unaware of the investigation. *Id.* ¶¶ 131-134; NPDB GUIDEBOOK F-8. The plaintiffs also take exception to what they assert is a lack of due process to determine whether facts in an Adverse Action Report are true. First Am. Compl. ¶¶ 135-139 [ECF No. 23]. Although not entirely apparent in either the First Amended Complaint or the plaintiffs' legal briefs, the plaintiffs have launched attacks on both the facial constitutionality of the Health Care Quality Improvement Act as well as the constitutionality of the statute, regulations and NPDB Guidebook as they were applied to Dr. Doe. *Id.* ¶¶ 128, 133, 134, 136, 138, 139, 156.

1. General legal standards that apply to due process challenges

The Supreme Court "has held that the Due Process Clause protects individuals against two types of government action . . . [s]o-called 'substantive due process' prevents the

government from engaging in conduct that 'shocks the conscience,' or interferes with rights 'implicit in the concept of ordered liberty.'" *United States v. Salerno*, 481 U.S. 739, 746 (1987) (internal citations omitted). "When government action depriving a person of life, liberty, or property survives substantive due process scrutiny, it must still be implemented in a fair manner." *Id.* "This requirement has traditionally been referred to as 'procedural' due process." *Id.*

With respect to as-applied versus facial challenges, "the distinction between facial and as-applied challenges . . . goes to the breadth of the remedy employed by the Court, not what must be pleaded in a complaint." *Citizens United v. FEC*, 558 U.S. 310, 331 (2010). "The substantive rule of law is the same for both challenges." *Edwards v. District of Columbia*, 755 F.3d 996, 1001 (D.C. Cir. 2014). The Supreme Court has emphasized, however, that "[f]acial challenges are disfavored" because, among other reasons, "facial challenges threaten to short circuit the democratic process by preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution." *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 450 (2008). Consequently, "[a] facial challenge to a legislative Act is . . . the most difficult to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *Salerno*, 481 U.S. at 745.

2. Whether the right to practice a chosen profession is a fundamental right that triggers strict scrutiny

The Fifth Amendment states that "[n]o person shall . . . be deprived of life, liberty, or property, without due process of law." U.S. Const. Amend. V. The "threshold requirement of a due process claim" is "that the government has interfered with a cognizable liberty or property

interest." *Hettinga v. United States*, 677 F.3d 471, 478-80 (D.C. Cir. 2012) (per curiam). "The Supreme Court has held that the right to hold specific private employment and to follow a chosen profession free from unreasonable governmental interference comes within the 'liberty and property' concepts of the Fifth Amendment, 'property' being the employment, and 'liberty' being the chosen profession." *Fitzgerald v. Hampton*, 467 F.2d 755, 760-61 (D.C. Cir. 1972).

The plaintiffs claim that the right to practice a chosen profession is a "fundamental right under the United States Constitution." First Am. Compl. ¶ 127. If the plaintiffs are correct, the Due Process Clause "provides heightened protection against government interference with certain fundamental rights and liberty interests." *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). "Unless legislation infringes a fundamental right," though, "judicial scrutiny under the substantive due process doctrine is highly deferential." *Empresa Cubana Exportadora de Alimentos y Productos Varios v. United States*, 638 F.3d 794, 800 (D.C. Cir. 2011). So the first question for the Court is whether the right to practice a chosen profession is a fundamental right.

The plaintiffs cite several historical Supreme Court cases they believe establish that the right to practice a profession is a "fundamental" right that is subject to strict scrutiny. The plaintiffs first seize on Justice Bradley's concurring opinion in *Butchers' Union Co. v. Crescent City Co.*, 111 U.S. 746, 762 (1884), which states that "[t]he right to follow any of the common occupations of life is an *inalienable* right." But that case involved questions of the legality of state constitutional and New Orleans ordinances that repealed the exclusive right to maintain slaughterhouses pursuant to the legislature's and municipality's police powers and did not involve a due process challenge. Justice Bradley's quoted comment was offered in the context of analyzing the issue as one of monopolization.

In the second case cited by the plaintiffs, *Dent v. West Virginia*, 129 U.S. 114 (1889), the Supreme Court upheld a requirement that a person be licensed to practice medicine. Although the Supreme Court acknowledged that "[i]t is undoubtedly the right of every citizen of the United States to follow any lawful calling, business, or profession he may choose," 129 U.S. at 121, the Supreme Court went on to state, significantly with respect to the instant case, that "there is no . . . arbitrary deprivation of such right where its exercise is not permitted because of a failure to comply with conditions imposed by the state for the protection of society," *id.* at 122. The Supreme Court in *Dent* stated that the right to pursue a profession cannot be deprived "arbitrarily," making clear that no heightened or strict scrutiny was applied. 129 U.S. at 121.

In the last case cited by the plaintiffs for their assertion that the right to pursue one's chosen profession is a "fundamental" right subject to strict scrutiny, *Schware v. Board of Examiners*, 353 U.S. 232 (1957), the question was whether the appellant, who was denied the right to take the bar examination based on his prior membership in the Communist Party and arrest record for union activities, was deprived of a license to practice law in violation of the Due Process Clause. 353 U.S. at 238. On review, the Supreme Court emphasized that "[a] State cannot exclude a person from the practice of law or from any other occupation in a manner or for reasons that contravene the Due Process or Equal Protection Clause . . . ." *Id.* at 239. The Supreme Court went on to note, however, that a State can require "high standards of qualification" but "any qualification must have a rational connection with the applicant's fitness or capacity to practice law" and no person can be excluded "when there is no basis for [a] finding that he fails to meet these standards, or when their action is invidiously discriminatory." *Id.*

None of these cases support the plaintiffs' argument that the right to practice one's chosen profession is a fundamental right subject to strict scrutiny. To the contrary, the review applied in these cases is properly characterized as rational basis review.

The Supreme Court has very narrowly construed the rights that qualify as "fundamental" and stated that "in addition to the specific freedoms protected by the Bill of Rights, the 'liberty' specially protected by the Due Process Clause includes the rights to marry; to have children; to direct the education and upbringing of one's children; to marital privacy; to use contraception; to bodily integrity, and to abortion." *Washington v. Glucksberg* 521 U.S. 702, 720 (1997) (Rehnquist, J.). In addition, the Supreme Court has "also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment." *Id.* The right to pursue one's chosen occupation, however, has never been recognized as "fundamental" in federal jurisprudence, so the Court would be creating a new rule of law if it chose to adopt a heightened standard of review for such cases, which would be counter to the general principle that "the [Supreme] Court has always been reluctant to expand the concept of substantive due process because guideposts for responsible decisionmaking in this unchartered area are scarce and open-ended," *Collins v. City of Harker Heights*, 503 U.S. 115, 125 (1992). "By extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action." *Washington*, 521 U.S. at 720. The Supreme Court therefore cautions that the "utmost care" must be exercised "whenever we are asked to break new ground in this field." *Id.* (quoting *Collins*, 503 U.S. at 125).

Furthermore, at least one federal circuit has concluded that "[b]ecause [the Health Care Quality Improvement Act] does not burden any fundamental right or draw distinctions based on any suspect criteria, it is subject only to rational basis review." *Freilich v. Upper Chesapeake Health, Inc.*, 313 F.3d 205, 211 (4th Cir. 2002). Plus, numerous federal circuit courts have concluded that the right to engage in a chosen profession is not a fundamental right that triggers heightened scrutiny under the Equal Protection Clause,[23] so the Court will resist the plaintiffs' attempt to craft a new constitutional rule that declares the right to engage in a chosen profession to be a fundamental right under the Due Process Clause.

It also is notable that, for more than a century, the Supreme Court has recognized that "[n]o one has a right to practice medicine without having the necessary qualifications of learning and skill," *Dent*, 129 U.S. at 122. Although the Supreme Court has suggested that a person cannot be excluded from an occupation like medicine in a manner or for reasons that contravene the Due Process Clause, it is permissible for the government to "require high standards of qualification" for a profession if the standards have a rational connection to the person's fitness or capacity to practice the profession. *Schware*, 353 U.S. 232 at 239. If such standards "are appropriate to the calling or profession, and attainable by reasonable study or application, no objection to their validity can be raised because of their stringency or difficulty." *Dent*, 129 U.S.

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[23] *Lupert v. California*, 761 F.2d 1325, 1327 n.2 (9th Cir. 1985) ("There is no basis in law for the argument that the right to pursue one's chosen profession is a fundamental right for the purpose of invoking strict scrutiny under the Equal Protection Clause."); *Whittle v. United States*, 7 F.3d 1259, 1262 (6th Cir. 1993) (same); *Hawkins v. Moss*, 503 F.2d 1171, 1177 n.11 (4th Cir. 1974) (declining to apply strict scrutiny analysis to the right to pursue a chosen profession); *Green v. Waterford Bd. of Educ.*, 473 F.2d 629, 632 (2d Cir. 1973) (applying rational basis review despite the plaintiff's assertion that the case involved the "fundamental" right to work in one's chosen profession).

at 122. So there is a long history of jurisprudence that recognizes that the right to practice medicine is qualified by standards of skill. The National Practitioner Data Bank serves to ensure that peer review actions that call into question whether an individual physician meets those standards of skill are disclosed to health care entities that are considering extending clinical privileges to that physician.

As the entirety of this discussion demonstrates, there is no legal basis for the plaintiffs' assertion that the right to practice a chosen profession is a "fundamental" right. The fact that a right is acknowledged to be a liberty covered by the Due Process Clause does not automatically render that right "fundamental" such that any statutory regulation of that right must be subjected to the highest constitutional scrutiny.

3. Whether the Health Care Quality Improvement Act is rationally related to a legitimate government interest and therefore facially valid

Because the Health Care Quality Improvement Act does not infringe on a fundamental right, "judicial scrutiny under the substantive due process doctrine is highly deferential." *Empresa Cubana Exporadora de Alimento y Productos Varios*, 638 F.3d at 800. According to the highly deferential standard of review, the Court "ask[s] only whether the legislation is rationally related to a legitimate government interest." *Id.* Pursuant to this standard, the plaintiffs "ha[ve] a claim only if [they] can show that there is no rational relationship between [the Health Care Quality Improvement Act] and some legitimate governmental purpose." *Gordon v. Holder*, 721 F.3d 638, 656 (D.C. Cir. 2013). As the D.C. Circuit has explained:

> This burden "to negative every conceivable basis which might support" the law is especially difficult to meet. Rational basis review "is not a license for courts to judge the wisdom, fairness, or logic of legislative choices." Courts must uphold legislation "[e]ven if the classification involved . . . is to some extent both underinclusive and overinclusive . . . ." In the ordinary case, "a law will be

> sustained if it can be said to advance a legitimate government interest, even if the law seems unwise or works to the disadvantage of a particular group, or if the rationale for it seems tenuous."

Id. (internal citations omitted). Additionally, "[i]t is irrelevant whether the reasons given actually motivated the legislature; rather, the question is whether some rational basis exists upon which the legislature could have based the challenged law." *Goodpaster v. Indianapolis*, 736 F.3d 1060, 1071 (7th Cir. 2013).

In *Freilich v. Upper Chesapeake Health, Inc.*, the Fourth Circuit applied rational-basis review to a physician's claim that the Health Care Quality Improvement Act violated the Fifth Amendment because it authorized and encouraged a hospital to act irresponsibly in matters of credentialing, reappointment, and wrongful denial of privileges. 313 F.3d at 211. Passing on the question of whether the Act was rationally related to a legitimate governmental purpose, the Fourth Circuit determined that:

> The legitimacy of Congress's purpose in enacting the HCQIA is beyond question. Prior to enacting the HCQIA, Congress found that "[t]he increasing occurrence of medical malpractice and the need to improve the quality of medical care ... [had] become nationwide problems," especially in light of "the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance." 42 U.S.C. § 11101. The problem, however, could be remedied through effective professional peer review combined with a national reporting system that made information about adverse professional actions against physicians more widely available. However, Congress also believed that "[t]he threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourage[d] physicians from participating in effective professional peer review." Id. Congress therefore enacted the HCQIA in order to "facilitate the frank exchange of information among professionals conducting peer review inquiries without the fear of reprisals in civil lawsuits. The statute attempts to balance the chilling effect of litigation on peer review with concerns for protecting physicians improperly subjected to disciplinary action." *Bryan v. James E. Holmes Regional Med. Ctr.*, 33 F.3d 1318, 1322 (11th Cir.1994).

Id. at 211-12. For these same reasons, which are clearly supported by the Congressional findings that preamble the Health Care Quality Improvement Act, 42 U.S.C. § 11101, the Court finds that the statute is rationally related to a legitimate government interest.

In addition to challenging the statute generally, the plaintiffs also assert that an NPDB Guidebook interpretation violates substantive due process. The questioned interpretation states that "the practitioner need not be aware of an ongoing investigation at the time of the resignation in order for the entity to report the resignation to the NPDB, since many investigations start without any formal allegation being made against the practitioner." NPDB GUIDEBOOK F-8. The NPDB Guidebook also states that "[t]he reason the practitioner gives for leaving an entity while under investigation is irrelevant to reportability of the resignation." *Id.* According to the defendants, requiring knowledge of an investigation as a prerequisite to reporting would "impermissibly widen the scope of Secretarial Review beyond what was authorized by Congress" and "requiring physician knowledge of an investigation runs counter to the central purposes of the NPDB and would create a large reporting loophole." Mem. In Support of Defs.' Mot. to Dismiss or, Alternatively, for Summ. J. 17 [ECF No. 33 (Sealed)]. The defendants also note that the agency is not equipped to conduct the type of investigation that would be necessary to determine a physician's knowledge about an investigation and such an investigation would unduly burden the agency, be difficult to prove, and would be contrary to the goals and objectives of the statute. *Id.* at 17-18.

The Court finds the NPDB Guidebook interpretation to be rationally related to the Health Care Quality Improvement Act's goals and objectives, which the Court has already determined serves a legitimate government interest. As already discussed, *supra* part A(2), the statute's

language, structure and purpose evinces a clear policy that favors strict reporting, there are valid considerations that substantiate that policy, and the NPDB Guidebook interpretation is consistent with that policy and with the overall statutory scheme.

4. Whether the Health Care Quality Improvement Act violates substantive due process by subjecting Dr. Doe to a so-called "stigma-plus"

In addition to the foregoing claims, the plaintiffs' second cause of action also advances a claim that the defendants applied the Health Care Quality Improvement Act to Dr. Doe in such a way that it "effects, without due process, a tangible change in plaintiff physician's and similarly reported physicians' status, disqualifying and foreclosing them from significant employment opportunities, impairing their ability to obtain clinical privileges, and imposes a stigma-plus disability that forecloses their freedom to take advantage of other employment opportunities." First Am. Compl. ¶ 128. To support this cause of action the plaintiffs rely on a line of Supreme Court cases that establish the so-called "stigma-plus" theory, namely *Wisconsin v. Constantineau*, 400 U.S. 433, 437 (1971), *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972), *Paul v. Davis*, 424 U.S. 693 (1976), and *Siegert v. Gilley*, 500 U.S. 226 (1991). Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 12-15 [ECF No. 43]. The stigma-plus theory stands for the proposition that certain government actions (stigmas) that cause a change in the plaintiffs' status under the law (plus) and preclude a plaintiff from being able to secure future employment opportunities may be actionable under the Fifth Amendment. The D.C. Circuit has interpreted this line of cases to hold that "a government action that potentially constrains future employment opportunities must involve a tangible change in status to be actionable under the due process clause." *Kartseva v. Dep't of State*, 37 F.3d 1524, 1527 (D.C. Cir. 1994). "If a government

action does constitute an adjudication of status under law, the underlying factual and legal determinations are subject to due process protections." *Id.*

To be clear, the D.C. Circuit recognizes two categories of "plus" claims that emanate from the Supreme Court's decision in *Roth. O'Donnell v. Barry*, 148 F.3d 1126, 1139-40 (D.C. Cir. 1998). The first is a "reputation-plus" claim, "in which the plaintiff points to the conjunction of official defamation and adverse employment action," and the second is a "stigma-plus" claim, which "turns on the combination of an adverse employment action and a stigma or other disability that foreclosed [the plaintiff's] freedom to take advantage of other employment opportunities." *Id.* at 1140 (internal quotation marks omitted). Although it is not clear whether the plaintiffs are asserting the reputation-plus theory, the stigma-plus category, or both, the Court need not concern itself with this question because the plaintiff is unable to prevail under either category.

To succeed on a reputation-plus claim a plaintiff must demonstrate a defamation "that is 'accompanied by a discharge from government employment or at least a demotion in rank and pay.'" *Id.* (quoting *Mosrie v. Barry*, 718 F.2d 1151, 1161 (D.C. Cir. 1998)). "Although the conceptual basis for reputation-plus claims is not fully clear, it presumably rests on the fact that official criticism will carry much more weight if the person criticized is at the same time demoted or fired." *Id.* In this case, Dr. Doe was never employed by the government, and the Adverse Action Report did not accompany Dr. Doe's termination of his employment with the Hospital, so the essential elements of a reputation-plus cause of action are lacking.

Under the stigma-plus theory, the plaintiffs must demonstrate "the combination of an adverse employment action and 'a stigma or other disability that foreclosed [the plaintiff's]

freedom to take advantage of other employment opportunities.'" *Id.* (quoting *Roth*, 408 U.S. at 573). The stigma-plus theory "does not depend on official speech, but on a continuing stigma or disability arising from official action." *Id.*

"As the [Supreme] Court made clear in *Siegert v. Gilley*, 500 U.S. 226, 111 S.Ct. 1789, 114 L.Ed.2d 277 (1991), a showing of reputational harm alone cannot suffice to demonstrate that a liberty interest has been infringed" for the purpose of establishing a stigma-plus cause of action. *Id.* at 1141. "Thus, a plaintiff who . . . seeks to make out a claim of interference with the right to follow a chosen trade or profession that is based exclusively on reputational harm must show that the harm occurred in conjunction with, or flowed from, some tangible change in status." *Id.* The D.C. Circuit has "described two ways that a litigant alleging government interference with his future employment prospects may demonstrate the tangible change in status required to prove constitutional injury[:]"

> In *Kartseva v. Department of State*, 37 F.3d 1524 (D.C.Cir.1994), we held that "if [the government's] action formally or automatically excludes [the plaintiff] from work on some category of future [government] contracts or from other government employment opportunities, that action . . . implicates a liberty interest." *Id.* at 1528. Alternatively, the plaintiff may demonstrate that the government's action precludes him—whether formally or informally—from such a broad range of opportunities that it "interferes with [his] constitutionally protected 'right to follow a chosen trade or profession.'" In other words, government action precluding a litigant from future employment opportunities will infringe upon his constitutionally protected liberty interests only when that preclusion is either sufficiently formal or sufficiently broad.

Id. (internal citation omitted). The plaintiffs appear to be proceeding under both the "formal or automatic exclusion" and the "broad range preclusion" theories. Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 15-16 [ECF No. 45 (Sealed)].

The stigma alleged in the plaintiffs' First Amended Complaint appears to be that an Adverse Action Report citing a resignation while under investigation "brands resigning physicians as 'incompetent' and makes them unemployable." First Am. Compl. ¶¶ 133 (quote), 140. In this Circuit, however, the publication of reasons for an employment termination that involve unsatisfactory job performance "does not carry with it the sort of opprobrium sufficient to constitute a deprivation of liberty." *Harrison v. Bowen*, 815 F.2d 1505, 1518 (D.C. Cir. 1987). According to the D.C. Circuit:

> [W]e must discriminate between a dismissal "for dishonesty, for having committed a serious felony, for manifest racism, for serious mental illness, or for lack of 'intellectual ability, as distinguished from [ ] performance . . . .'" The former characteristics imply an inherent or at least a persistent personal condition, which both the general public and a potential future employer are likely to want to avoid. Inadequate job performance, in contrast, suggests a situational rather than an intrinsic difficulty; as part of one's biography it invites inquiry, not prejudgment.

Id. Thus, "a plaintiff is not deprived of his liberty interest when the employer has alleged merely improper or inadequate performance, incompetence, neglect of duty or malfeasance." *Ludwig v. Bd. of Trustees of Ferris State Univ.*, 123 F.3d 404, 410 (6th Cir. 1997). The Court sees no fundamental difference between a governmental publication that states the reasons for an employment termination and the defendants' acceptance, maintenance and disclosure of the Adverse Action Report in this case.

As a general proposition, an Adverse Action Report is intended to document a situational event related to job performance that "invites inquiry, not prejudgment" by the hospitals to which the reports are disclosed. Specific to the case at hand, the Adverse Action Report documents matters related exclusively to Dr. Doe's job performance, namely a resignation while under an investigation related to competence or professional conduct in the performance of the

surgery during which a patient's Fallopian tube was inadvertently removed. An Adverse Action Report that documents a resignation while under investigation related to job performance frankly is less onerous than one that documents a dismissal. It therefore follows that if a publication of a dismissal as a result of job performance does not result in a deprivation of liberty then it surely is the case that a publication of a resignation while merely under investigation for job performance likewise does not result in a deprivation of liberty. The plaintiffs have, therefore, failed to establish stigma via an injury to a constitutionally-protected interest. *Hutchinson v. C.I.A.*, 393 F.3d 226, 231 (D.C. Cir. 2005).

Even if, contrary to Circuit law, Dr. Doe could establish that an Adverse Action Report in the National Practitioner Data Bank qualified as a stigma for the purpose of the substantive due process analysis, the fact of the matter is that the collection, retention and dissemination of an Adverse Action Report does not in any way amount to a government act that formally or automatically excludes the plaintiffs from future employment opportunities. Like the letter at issue in *Siegert*, 500 U.S. at 234, the Adverse Action Report was not collected and retained by the government incident to any change in legal status. Dr. Doe resigned from the Hospital before the Adverse Action Report was collected and retained by the government, and the report, in and of itself, neither formally nor automatically excludes Dr. Doe from any employment.

Indeed, neither the Health Care Quality Improvement Act nor its implementing regulations mandate that health care entities do anything with the information contained in an Adverse Action Report other than apprise themselves of a physician's prior disciplinary history while conducting a credentials review. This point merits emphasis. As the NPDB Guidebook explains:

> NPDB information is an important supplement to a comprehensive and careful review of a practitioner's professional credentials. The NPDB is intended to augment, not replace, traditional forms of credentials review. As a nationwide flagging system, it provides another resource to assist State licensing boards, hospitals, and other health care entities in conducting extensive, independent investigations of the qualifications of the health care practitioner they seek to license or hire, or to whom they wish to grant clinical privileges.
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> The information in the NPDB should serve only to alert State licensing authorities and health care entities that there may be a problem with a particular practitioner's professional competence or conduct. NPDB information should be considered together with other relevant data in evaluating a practitioner's credentials (e.g., evidence of current competence through continuous quality improvement studies, peer recommendations, health status, verification of training and experience, and relationships with patients and colleagues).

NPDB GUIDEBOOK A-3. Thus, the information in the National Practitioner Data Bank is intended only to add to a health care entities' "extensive, independent investigation[]" of the qualifications of a physician they intend to hire. *Id.* As stated, the reported information is not intended to "replace . . . traditional forms of credentials review" or otherwise be treated by hospitals as an automatic employment bar. *Id.* "[T]he official purpose of the report is to disclose information, not to reprimand." *Rochling v. Dep't of Veterans Affairs*, 725 F.3d 927, 932 (8th Cir. 2013).

Assuming, again, that the plaintiffs could establish that an Adverse Action Report in the National Practitioner Data Bank causes a cognizable stigma, which the Court has concluded they cannot, the only theory that remains available to the plaintiffs provides relief if "the agency took informal action against [Dr. Doe] so broad that it infringed upon his right to follow a chosen trade or profession[,]" *Taylor*, 56 F.3d at 1506 (internal quotation marks omitted). "The standard [the plaintiffs] must meet in this regard—showing that the government has seriously affected, if

not destroyed, [the plaintiffs'] ability to obtain employment in [his] field—is high: the [defendant's] misconduct must substantially reduce the value of his human capital, as it would if his skills were highly specialized and rendered largely unmarketable as a result of the agency's acts." *Id.* at 1506-07.

Dr. Doe's skills are undoubtedly specialized and the plaintiffs' First Amended Complaint generally avers that his skills have been rendered largely unmarketable as a result of the agency's disclosure of the Adverse Action Report. First Am. Compl. ¶¶ 99-100, 128-129, 133, 139, 141-148, 151-155. And the agency's disclosure of Adverse Action Reports contained in the National Practitioner Data Bank could be deemed to be broad informal action because all health care entities considering extending clinical privileges to a physician are required to query the Data Bank, 42 U.S.C. § 11135(a).

But the plaintiffs cannot prevail on the broad-action theory because the alleged harm – an inability to obtain employment – is not the result of a "tangible change of status vis-à-vis the government." *Doe v. U.S. Dep't of Justice*, 753 F.2d 1092, 1108-09 (D.C. Cir. 1985). By way of relevant example, the email that Dr. Doe received from an official at Reston Hospital Center states:

> I am sorry to have to tell you that we won't be able to meet with you on June 7th. A report from the National Practitioner Data Bank shows a "Voluntary Surrender of Clinical Privilege(s), While Under, or to Avoid, Investigation Relating to Professional Competence or Conduct" for an event that occurred in October, 2009. A resignation under these circumstances would preclude your being credentialed at Reston Hospital Center.

AR 0017 [ECF No. 19-1 (Sealed)]. As expressed, the reason the official canceled the meeting with Dr. Doe was because the "circumstances" of his resignation "would preclude your being credentialed at Reston Hospital Center." *Id.* It was the reported conduct -- not the mere

existence of the report -- that prevented Dr. Doe from being employed by Reston Hospital Center. An email Dr. Doe received in 2013 from the Manager of Medical Staff Services at North Fulton Hospital in Georgia similarly states that "[r]elinquishment of privileges while under investigation, whether voluntary or involuntary, does not meet North Fulton Hospital's medical staff criteria." Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. Ex. A [ECF No. 56 (Sealed)]. Notably, the Manager at North Fulton Hospital further stated that "I understand your circumstances so if you can provide a copy of the original letter from the University of Tennessee accepting you into the fellowship program and your certificate of completion, it can be taken into re-consideration and an exception may be made." *Id.* (emphasis in original).

As these two examples demonstrate, although the plaintiffs characterize the existence of the Adverse Action Report as being the basis for Dr. Doe's employment difficulties and, therefore, the change in his status (employable to unemployable),[24] the evidence in the record reflects that it is the hospitals' reactions to the reported conduct (resignation while being investigated) that has caused the change in his status. The harm in this case, therefore, is the result of private hospitals responding to information contained in the National Practitioner Data Bank and not the result of government action that changed Dr. Doe's status.[25] "The reaction of

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[24] Pls.' Opp'n to Defs.' Mot. to Dismiss 15 n.16 [ECF No. 45 (Sealed)] (stating that "hospitals have told Dr. Doe expressly that his employment applications were rejected because of the AAR maintained and released by the Government . . .").

[25] For this reason the plaintiffs' citation to *McGinnis v. District of Columbia*, ___ F. Supp. 3d ___, 2014 WL 4243542, at *6 (D.D.C. 2014), is inapposite. Pls.' Mem. of Law In Support of Mot. for Preliminary Injunction 19 [ECF No. 62-1]. In *McGinnis*, the plaintiff was terminated from government employment and the court's analysis was premised on the principle that "[t]he stigma theory "provides a remedy where the terminating employer imposes upon the discharged employee a stigma or other disability that foreclosed the plaintiff's freedom to take advantage of

others to unfavorable publicity about a person is not . . . a change in legal status imposed by the government officials who generated the publicity." *Mosrie*, 718 F.2d at 1162. "When a specified harm is predicated on voluntary third-party behavior, it cannot serve as a 'plus' factor" to establish a stigma-plus substantive due process claim." *URI Student Senate v. Town of Narragansett*, 631 F.3d 1, 11 (1st Cir. 2011). The hospitals' decisions to hire or not hire Dr. Doe are totally independent of the governmental act of collecting, maintaining and disclosing Adverse Action Reports contained in the National Practitioner Data Bank. Even though hospitals are required to query the National Practitioner Data Bank, 42 U.S.C. § 11135(a), what they choose to do with that information is entirely a product of their own free will. "Even if catalyzed by government action, harms at the hands of [third] parties cannot serve as 'plus' factors . . . ." *URI Student Senate*, 707 F. Supp. 2d 282, 298 (D.R.I. 2010).

5. Whether the Health Care Quality Improvement Act deprives Dr. Doe of property without due-process procedural protections

The plaintiffs allege that the defendants' actions violate procedural due process by failing to provide an opportunity to challenge the accuracy of an Adverse Action Report's facts before or after it has been accepted, failing to provide prior notice to a physician before a report is submitted, and failing to make a determination about whether the Hospital's due process was adequate. First Am. Compl. ¶¶ 129, 130, 134, 135, 136, 159, 160. A two-stage analysis applies to allegations that the government has deprived a person of life, liberty or property without due process of law. *Ingraham v. Wright*, 430 U.S. 651, 672 (1977). The Court "must first ask

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other employment opportunities." *Id.* (emphasis added) (quoting *McCormick v. District of Columbia*, 752 F.3d 980, 988 (D.C. Cir. 2014).

whether the asserted individual interests are encompassed within the [Fifth Amendment's][26] protection of 'life, liberty or property'; if protected interests are implicated, [the Court] then must decide what procedures constitute 'due process of law.'" *Id.* "A cognizable liberty or property interest is essential because process is not an end in itself. Its constitutional purpose is to protect a substantive interest to which the individual has a legitimate claim of entitlement." *Roberts v. United States*, 741 F.3d 152, 161 (D.C. Cir. 2014) (internal quotation marks, citations and formatting omitted).

Although the plaintiffs' First Amended Complaint repeatedly refers to "constitutionally-protected rights," the only rights claimed in the document are an asserted liberty and property interest in the right to practice one's chosen profession, *see* First Am. Compl. ¶¶ 127, 128, 139, 149, 156. As far as the liberty interest in the right to practice one's chosen profession is concerned, "[o]ne simply cannot have been denied his liberty to pursue a particular occupation when he admittedly continues to hold a job . . . in that very occupation." *Abcarian v. McDonald*, 617 F.3d 931, 942 (7th Cir. 2010); *accord Roberts*, 741 F.3d at 162 (finding that liberty interests in employment and the freedom to practice a chosen profession "are not implicated" when the plaintiff remains employed in that profession). Whereas the plaintiffs claimed at the outset of the litigation that Dr. Doe was unable to secure employment as a physician anywhere in the United States because of the Adverse Action Report, First Am. Compl. ¶ 154, he is now employed at a hospital in the United States and has been so employed since early 2013. Pls.' Opp'n to Defs.' Mot. to Dismiss 18 n.19 [ECF No. 45 (Sealed)]. Moreover, at least one potential employer,

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[26] The quotation states "Fourteenth Amendment" and the D.C. Circuit has stated that "[t]he procedural due process protections under the Fifth Amendment and Fourteenth Amendments are the same . . . ." *English v. District of Columbia*, 717 F.3d 968, 972 (D.C. Cir. 2013).

North Fulton Hospital, discussed *supra* part 4, indicated a willingness to reconsider whether Dr. Doe's resignation while under investigation precluded his ability to obtain privileges if he submitted additional specified documentation, Pls.' Reply Mem. In Support of Cross-Mot. for Summ. J. Ex. A [ECF No. 56 (Sealed)].

More to the point, though, and as already explained, the plaintiffs cannot show that Dr. Doe's asserted liberty interest was deprived by government action. Dr. Doe's inability to obtain hospital privileges is the result of private, third-party hospitals' responses to the Adverse Action Report. It is the Court's view that hospitals are treating Adverse Action Reports inconsistently with the spirit of the Health Care Quality Improvement Act if they are deeming such a report to be an automatic bar to employment in lieu of conducting the "extensive, independent investigation[]" of a physician's qualifications that is anticipated by the policies underlying the National Practitioner Data Bank, *see* NPDB GUIDEBOOK A-3. Setting this point aside, though, the fact of the matter is that the defendants' collection, retention and disclosure of Adverse Action Reports, particularly when hospitals are not required in any way at all to act on those reports, simply does not constitute a federal action that prevents Dr. Doe from pursuing his profession. As the Supreme Court has made clear, "[t]he most familiar office of [the Due Process] Clause is to provide a guarantee of fair procedure in connection with any deprivation of life, liberty, or property by a State." *Collins*, 503 U.S. at 125 (emphasis added). An Adverse Action Report does not deprive Dr. Doe of employment. Private hospitals are depriving Dr. Doe of employment by using the reports in a way that is contrary to what was contemplated by Congress. "Unless there has been a 'deprivation' by 'state action,' the question of what process is required and whether any provided could be adequate in the particular factual context is

irrelevant." *Stone v. University of Maryland Medical System Corp.*, 855 F.2d 167, 172 (4th Cir. 1988). "This absence of state action is fatal to [the plaintiffs'] constitutional claim." *Shirvinski v. U.S. Coast Guard*, 673 F.3d 308, 317 (4th Cir. 2012).

Regarding the plaintiffs claim to a property interest in the right to practice a chosen profession, "[p]roperty interests are not created by the Constitution; rather, 'they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law-rules or understandings that secure certain benefits and that support claims of entitlement to those benefits.'" *Ciambriello v. County of Nassau*, 292 F.3d 307, 313 (2d Cir. 2002) (quoting *Roth*, 408 U.S. at 577). Furthermore, "[t]o have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it . . . [h]e must have a legitimate claim of entitlement to it." *Roth*, 408 U.S. at 577. Because the plaintiffs omitted to identify any law, rule or understanding that secures benefits or privileges to Dr. Doe and entitles him to those benefits to a degree sufficient to constitute a property right protected by the Constitution, the Court finds that no property right has been adequately pled in the First Amended Complaint. The plaintiffs' First Amended Complaint makes a passing reference to property rights in a professional license to practice medicine and to have clinical and hospital staff privileges, First Am. Compl. ¶¶ 128, 146, but the plaintiffs never allege that Dr. Doe's license has been affected (versus his ability to use his license) or the basis for asserting a property right in clinical and hospital staff privileges that he surrendered by resigning. Again, too, any harm to Dr. Doe's license or clinical privileges is the result of actions taken by private hospitals in response to Dr. Doe's resignation while under investigation and not the product of the government's collection, retention and disclosure of Adverse Action Reports.

Even if the plaintiffs could make out a claim that a liberty or property right has been implicated, the Court finds that the Health Care Quality Improvement Act and the dispute procedures provided by the agency's regulations afford adequate due process for the plaintiffs to challenge an Adverse Action Report. "Beyond the basic requirements of notice and an opportunity to be heard, the precise requirements of procedural due process are flexible." *English v. District of Columbia*, 717 F.3d 968, 972 (D.C. Cir. 2013). When a plaintiff contests a stigmatizing report about the circumstances of an employee's termination, the Supreme Court has noted that the due process remedy "is 'an opportunity to refute the charge.'" *Codd v. Velger*, 429 U.S. 624, 627 (1977) (per curiam) (quoting *Roth*, 408 U.S. at 573).

As a preliminary point, the Court is impelled to emphasize that Congress intended that procedural due process regarding the merits of a hospital's actions involving a physician remain the purview of the professional peer review process conducted by health care entities and hospitals. 42 U.S.C. §§ 11111, 11112. That this is so is made clear by the structure of the statute and the plaintiffs' own citation to the legislative history of the Health Care Quality Improvement Act. *See* Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 39 [ECF No. 45 (Sealed)]. The plaintiffs quote a House of Representatives Report and argue that "Congress intended that the HCQIA allow 'physicians [to] receive fair and unbiased review to protect their reputations and medical practices.'" *Id.* (quoting H.R. Rep. 99-903 at *11 (1986)). This is true; however, the quoted language is found in the section discussing the Committee on Energy and Commerce's views about what ultimately was codified as 42 U.S.C. § 11112, setting forth standards for professional review actions. So the Committee's comments about ensuring fair and unbiased review relates to the procedures the statute establishes to encourage hospitals to provide

procedural due process when engaging in professional review actions. Dr. Doe was unable to avail himself of those due process protections because he resigned.

Aside from the procedural due process the Health Care Quality Improvement Act promotes during professional peer review, the Department of Health and Human Services regulations, in conjunction with the NPDB Guidebook, also set forth three procedures to refute an Adverse Action Report by disputing its accuracy. First, a physician must dispute the report with the hospital. To do this, the physician must request that the Secretary enter the report into "disputed status," which triggers the agency to notify queriers, the reporting entity and the physician that the report has been disputed. 45 C.F.R. § 60.21(b)(1)-(2); NPDB GUIDEBOOK F-1. The physician must then "attempt to enter into discussion with the reporting entity to resolve the dispute." 45 C.F.R. § 60.21(b)(3).

Second, if the hospital does not revise the reported information or respond within 60 days, the physician may request that the Secretary review the report for accuracy. 45 C.F.R. § 60.21(b)(3). To commence Secretarial review, the physician must submit a request asking the Secretary to review the report for accuracy and include "appropriate materials that support the [physician's] position." 45 C.F.R. § 60.21(c)(1). "The Secretary will only review the accuracy of the reported information, and will not consider the merits or appropriateness of the action or the due process that the subject received." *Id.* The Secretary will then take various actions with respect to the Adverse Action Report depending on whether she concludes that the information is accurate and reportable, inaccurate, the issues are outside the scope of the agency's review, or the adverse action was not reportable. *Id.*

A third procedure permits a physician to add a statement to the Adverse Action Report. 45 C.F.R. § 60.21(b)(3). A physician "may add a statement to the report at any time." NPDB GUIDEBOOK F-1. The statement may be provided directly by the physician or via a designated representative. 45 C.F.R. § 60.21(b)(3).

The plaintiffs in this case took advantage of all three dispute procedures. Dr. Doe requested that the Adverse Action Report be placed into disputed status, attempted to resolve the dispute with the Hospital, and then requested that the Secretary review the report for accuracy. Dr. Doe was represented by legal counsel during the Secretarial review process, which was conducted as an adversarial proceeding during which both parties submitted, via counsel, lengthy arguments to support their respective positions and respond to the other party's contentions. Both parties also submitted documentary evidence to support their respective arguments. The record reflects that the Secretary reviewed "the information available and the record presented to this office" to arrive at the conclusions stated in the Secretarial Review Decision. AR 0254 [ECF No. 19-6 (Sealed)]. The Secretary also provided Dr. Doe a second opportunity to submit a statement to append to the Adverse Action Report and replace his prior statement. AR 0258 [ECF No. 19-6 (Sealed)]. The Adverse Action Report now reflects both the Hospital's and Dr. Doe's accounts of events, so any hospital viewing the report will have both sides of the story. The Court finds that this panoply of procedures provided adequate opportunity to refute the Adverse Action Report by challenging its accuracy.

C. Whether the Defendants Violated the Privacy Act

In addition to the APA and due process claims, the plaintiffs also assert a cause of action seeking to void the Adverse Action Report pursuant to sections 552a(g)(1)(A) and 552a(g)(1)(C) of the Privacy Act. First Am. Compl. ¶ 168. Together, sections 552a(g)(1)(A) and 552a(g)(1)(C) provide that:

> Whenever any agency . . . makes a determination under subsection (d)(3) of this section not to amend an individual's record in accordance with his request, or fails to make such review in conformity with that subsection. . . [or] fails to maintain any record concerning any individual with such accuracy, relevance, timeliness, and completeness as is necessary to assure fairness in any determination relating to the qualifications, character, rights, or opportunities of, or benefits to the individual that may be made on the basis of such record, and consequently a determination is made which is adverse to the individual . . . the individual may bring a civil action against the agency, and the district courts of the United States shall have jurisdiction in the matters under the provisions of this subsection.

5 U.S.C. §§ 552a(g)(1)(A), 552a(g)(1)(C). According to the plaintiffs, the defendants violated section 552a(g)(1)(A) by issuing the Secretarial Review Decision without amending the Adverse Action Report, First Am. Compl. ¶ 172, and the defendants violated section 552a(g)(1)(C) by maintaining and releasing the report without ensuring its accuracy, timeliness and completeness, and by accepting the Hospital's documentary evidence "even though it included on its face fabricated, backdated, not contemporaneous and false information," *id.* ¶ 168.

Addressing the last challenge first, the plaintiffs cannot state a claim under section 552a(g)(1)(C) of the Privacy Act because "[c]entral to a cause of action under subsection (g)(1)(C) is the existence of an adverse agency determination resulting from inaccurate agency records." *Chambers v. U.S. Dep't of Interior*, 568 F.3d 998, 1007 (D.C. Cir. 2009) (emphasis added). The only adverse agency "determination" at issue is the Secretarial Review Decision and the alleged inaccurate agency record is the Adverse Action Report. Even if the Adverse

Action Report is inaccurate, though, the Secretarial Review Decision did not "result from" that report. The basis for the Secretarial Review Decision was the Administrative Record, which consisted of extra-agency documents submitted by the Hospital and Dr. Doe. Logically, the Adverse Action Report could not be the basis for the Secretarial Review Decision because the whole point of the Secretary's review was to determine whether that report was accurate. The plaintiffs point to no inaccurate agency document that was the basis for the adverse Secretarial Review Decision.

To the extent the plaintiffs are asserting that the defendants' acts of maintaining and releasing the Adverse Action Report constitute an "adverse agency determination," the Court is not so persuaded. An adverse determination "is defined as a decision 'resulting in the denial of a right, benefit, entitlement, or employment by an agency which the individual could reasonably have been expected to have been given if the record had not been deficient.'" *Dick v. Holder*, ___ F. Supp. 3d ___, 2014 WL 4450531, at *11 (D.D.C. 2014) (quoting *Lee v. Geren*, 480 F. Supp. 2d 198, 210 (D.D.C. 2007)). The maintenance and release of Adverse Action Reports do not result in the denial of a right, benefit, entitlement or employment to which the plaintiffs could reasonably be expected to have been given under the circumstances. The only agency "decision" that arguably meets this definition is the Secretarial Review Decision, but, again, the plaintiffs have not identified any inaccurate agency report that the Secretary relied on to reach that decision.

Because the Court is remanding to the Secretary for a determination about the reportability of the Adverse Action Report's statement that "the Hospital's quality assurance review of this matter indicates departures by the physician from standard of care with regard to

the laparoscopic appendectomy that he performed on October 2, 2009," the Court will deny the defendants' request to dismiss the plaintiffs' contention that section 552a(g)(1)(A) of the Privacy Act was violated by the Secretary's alleged failure to amend the Adverse Action Report.

D. Whether the Health Care Quality Improvement Act is an Unlawful Bill of Attainder

Article I, section 9 of the Constitution provides that "[n]o Bill of Attainder . . . shall be passed." U.S. Const. art. I, § 9, cl. 3. "As the Supreme Court explained in *United States v. Brown*, 381 U.S. 437 (1965), the Clause was intended to serve as 'a general safeguard against legislative exercise of the judicial function, or more simply – trial by legislature.'" *Foretich v. U.S.*, 351 F.3d 1198, 1216 (D.C. Cir. 2003). "Today, the prohibition against bills of attainder prevents any legislative acts, no matter what their form, that apply either to named individuals or to easily ascertainable members of a group in such a way as to inflict punishment on them without a judicial trial." *BellSouth Corp. v. F.C.C.*, 162 F.3d 678, 683 (D.C. Cir. 1998) (Edwards, J.). Importantly, "only the clearest proof [can] suffice to establish the unconstitutionality of a statute on such a ground." *Communist Party of U.S. v. Subversive Activities Control Board*, 367 U.S.1, 83 (1961).

"A law is an impermissible bill of attainder 'if it (1) applies with specificity, and (2) imposes punishment.'" *Emory v. United Air Lines, Inc.*, 720 F.3d 915, 923 (D.C. Cir. 2013) (Brown, J.) (quoting *Foretich*, 351 F.3d at 1218. "Both specificity and punishment must be shown before a law is condemned as a bill of attainder." *Foretich*, 351 F.3d at 1217 (quotation marks omitted). "[T]he principal touchstone of a bill of attainder," however, "is punishment." *Id.* To determine whether a statute imposes punishment, the "Supreme Court has instructed that a court should pursue a three-part inquiry" that asks "(1) whether the challenged statute falls

within the historical meaning of legislative punishment; (2) whether the statute, viewed in terms of the type and severity of burdens imposed, reasonably can be said to further nonpunitive legislative purposes; and (3) whether the legislative record evinces a congressional intent to punish." *Foretich*, 351 F.3d at 1218 (quotation marks omitted). "[T]he second factor -- the so-called functional test -- invariably appears to be the most important of the three." *Id.* "Indeed, compelling proof on this score may be determinative." *Id.*

The Health Care Quality Improvement Act "imposes none of the burdens historically associated with punishment," *Selective Service System v. Minnesota Public Interest Research Group*, 468 U.S. 841, 852 (1984). With the exception of sanctions imposed for a health care entity's failure to comply with reporting requirements governed by the Act, *see* 42 U.S.C. §§ 11131(c), 11133(c), the Act prescribes no punishments or penalties, either expressly or impliedly, and in no way compels health care entities to treat Adverse Action Reports in any particular manner, such as by denying employment. In addition, on its face, the Act advances nonpunitive legislative goals, which are discussed *supra* part B(3) and elsewhere in this decision. Because the Health Care Quality Improvement Act does not inflict punishment of any sort sufficient to be deemed a bill of attainder, the Court will dismiss this cause of action for failure to state a claim for relief.

E. Whether the Health Care Quality Improvement Act Violates the Eighth Amendment

Although the Supreme Court has never definitively addressed the question of whether the Eighth Amendment generally, or the Cruel and Unusual Punishments Clause specifically, applies in civil cases, existing precedent has limited the amendment's application to criminal cases. On a prior occasion the Supreme Court noted that "our concerns in applying the Eighth Amendment

have been with criminal process and with direct actions initiated by government to inflict punishment." *Browning-Ferris Industries of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 259 (1989). "Given that the Amendment is addressed to bail, fines, and punishments, our cases long have understood it to apply primarily, and perhaps exclusively, to criminal prosecutions and punishments." *Id.* at 262. "Bail, fines, and punishment traditionally have been associated with the criminal process, and by subjecting the three to parallel limitations the text of the Amendment suggests an intention to limit the power of those entrusted with the criminal-law function of government." *Id.* at 263.

Although the Supreme Court "left open in *Ingraham* [*v. Wright*, 430 U.S. 651 (1977)] the possibility that the Cruel and Unusual Punishments Clause might find application in some civil cases," *id.* at 263 n.3, the Court cautioned that such applicability would inure only if the punishment at issue was "sufficiently analogous to criminal punishments in the circumstances in which they are administered to justify application of the Eighth Amendment," *Ingraham*, 430 U.S. at 669 n.37. This is not such a case. The Health Care Quality Improvement Act and the National Practitioner Data Bank contain only two provisions that could be considered punitive, one of which provides for a civil money penalty for the failure to report medical malpractice payments, 42 U.S.C. § 11131(c), and the other imposes a sanction for noncompliance with the reporting requirements for professional review actions, *id.* § 11133(c). Otherwise, both the statute and the regulations that implement it provide for the collection and limited dissemination of reports about hospital actions in which the government generally has no involvement and the government commands no requirement to act on the reports. The statute and regulations

therefore lack any analogy to criminal punishments sufficient to warrant extending the scope of the Eighth Amendment to apply to this civil case.

CONCLUSION

The Court has given this case careful and lengthy consideration to arrive at the conclusions contained herein. Although the Court shares the plaintiffs' concern that Adverse Action Reports are being misused by health care entities, the Court cannot conclude that the Health Care Quality Improvement Act, at least as challenged by the plaintiffs in the First Amended Complaint, is the source of that problem. Congress had an undeniably rational reason for enacting the statute and the National Practitioner Databank furthers the statutory intent.

Accordingly, for the reasons set forth in this opinion, the Court will grant in part and deny in part the Motion to Dismiss or, Alternatively, for Summary Judgment [ECF No. 26] that was filed by the defendants and deny the Cross-Motion for Summary Judgment [ECF No. 45 (Sealed)] that was filed by the plaintiffs. Specifically, the Court will grant the defendants' motion for summary judgment with respect to the plaintiffs' First Cause of Action to Set Aside Report as Arbitrary, Capricious, Abuse of Discretion and not in Accordance with Law, with the exception of the question of whether the statement that "the Hospital's quality assurance review of this matter indicates departures by the physician from standard of care with regard to the laparoscopic appendectomy that he performed on October 2, 2009" is reportable. The Court will deny the defendants' motion for summary judgment with respect to that question and remand to the Secretary of the Department of Health and Human Services for further proceedings consistent with this opinion. Because the plaintiffs' Second, Third, Fifth and Sixth Causes of Action fail to state claims for relief, the Court will grant the defendants' motion to dismiss those

claims. As for the Fourth Cause of Action for Defendants' Violation of the Federal Privacy Act, the Court concludes that the plaintiffs have failed to state a claim for relief with respect to section 552a(g)(1)(C) of the Privacy Act, so dismissal will be granted for that claim. In light of the remand to the Secretary to resolve the reportability issue, though, the Court will deny the motion to dismiss the section 552a(g)(1)(A) claim. The plaintiffs' Cross-Motion for Summary Judgment will be denied in its entirety and this case will be stayed pending the Secretary's action on remand.

June 17, 2015

Thomas F. Hogan

THOMAS F. HOGAN
SENIOR UNITED STATES DISTRICT JUDGE